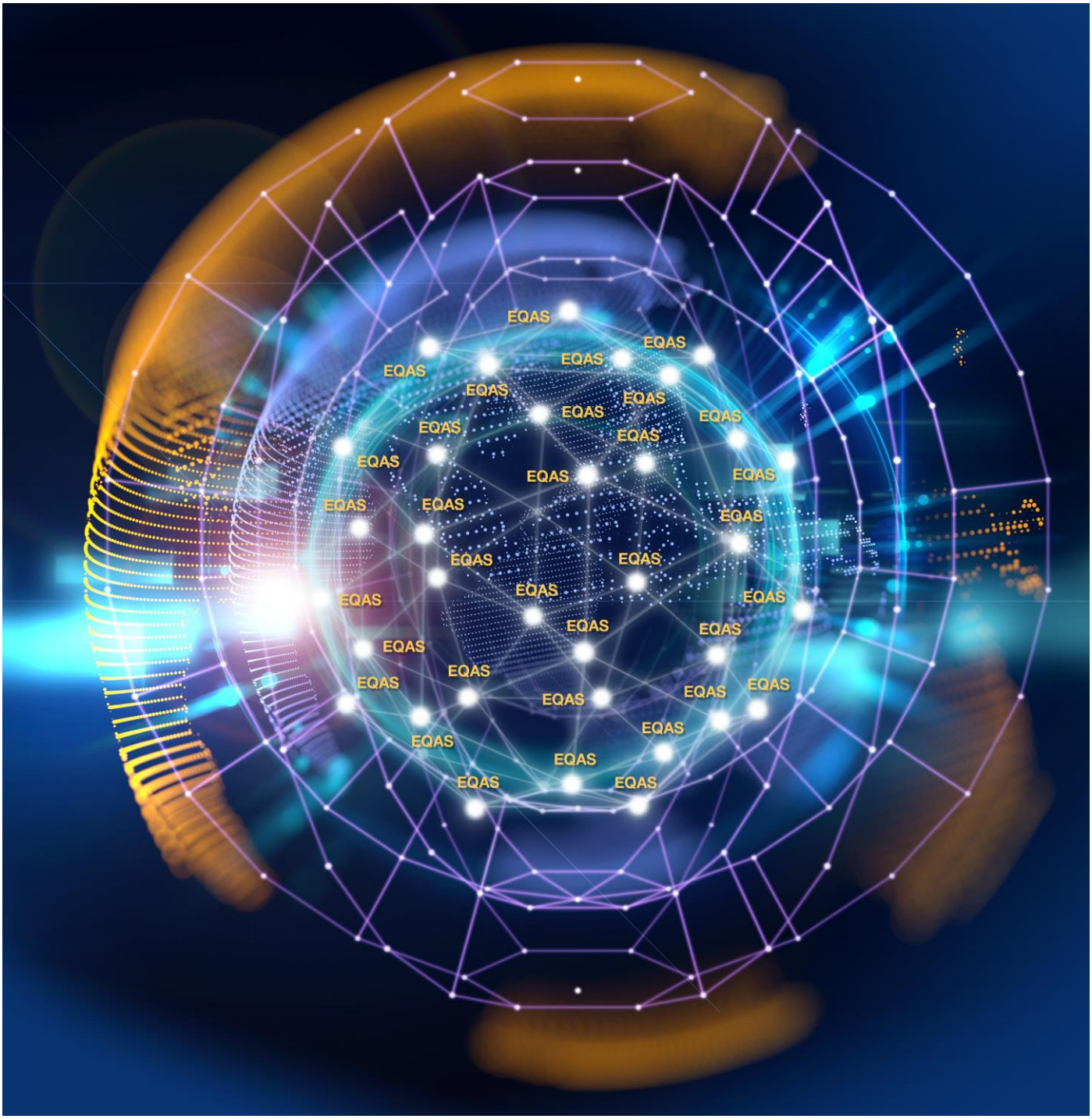
External Quality Assurance Services

EQAS Program User Guide

V6.0



Visit bio-rad.com/eqas for more information.

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chapter 1

Introduction and Overview

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Welcome to the EQAS Program

Welcome to the Bio-Rad External Quality Assurance Services (EQAS) Program. We are pleased you have selected us as your laboratory's trusted provider of external quality assessment. We know that you value participating in a fully accredited program such as ours, as it ensures the high quality of product and services you receive. The Bio-Rad EQAS Program is open to all types of laboratories worldwide that desire to assess the performance of their test systems with peers on an international scale. Your EQAS reports will provide you with valuable feedback on the quality improvement processes you have implemented in your laboratory. We are proud to join you in your effort to continually meet the needs of those you serve, by generating and reporting high quality test results.

This User Guide provides information to help you achieve the full benefit of the Bio-Rad EQAS Program. Please review the information in this guide along with the information contained in the insert of each specimen package you receive. As the worldwide leading provider of quality solutions for the clinical laboratory, Bio-Rad is pleased to partner with your laboratory through the EQAS Program to meet your regulatory requirements and advance the quality of patient care. If you require assistance in interpreting your performance in EQAS, need additional information on the EQAS Program, or have general questions on improving quality in your laboratory, Bio-Rad can offer expert assistance and advice.
Please contact your local Bio-Rad representative or email us directly at eqas_support@bio-rad.com. We are happy to have the opportunity to serve you.

Introduction

External quality assessment (EQA) programs, such as Bio-Rad EQAS, are accepted around the world æsvaluable tools for laboratories to assess the performance of their test systems. Participant results from blind samples (unknown analyte concentration) are compared objectively to other laboratories using the same methodologies, instruments, and reagents. When used with daily quality control (QC) procedures, Bio-Rad EQAS Programs give laboratories additional confidence in their reported patient test results.

All Bio-Rad EQAS Programs are developed and maintained under a compliant and comprehensive quality management system. The EQAS Programs are independently accredited, providing participants with confidence and assurance of high-quality programs supported by human based samples of measured stability and homogeneity. EQAS Online and EQAS Mobile should be used to submit your laboratory's EQAS results. In most cases a single shipment is made of all samples required in a program cycle. Program cycles extend for a predefined period of one year with samples typically tested every month. Your laboratory receives a report for each sample that provides you with an individual performance analysis of your submitted results. For quantitative programs, statistical processes from ISO 13528, "Statistical methods for use in proficiency testing by interlaboratory comparisons," are used to calculate a robust estimate of the consensus mean and standard deviation, which are used to assess acceptable performance. The twelve samples comprising one cycle are typically replicates from four unique batches. At the end of each quantitative program cycle, each participating laboratory is provided a report that summarizes overall performance in the cycle and provides statistics for each batch. Your individual laboratory performance over the entire cycle is then compared to other laboratories in the program in terms of bias for all analytes reported. By submitting a required amount of acceptable data throughout a program cycle, your laboratory can earn a Certificate of Achievement, awarded at the end of a cycle

Aims

The Bio-Rad EQAS Program aims to provide:

- An easy to use and comprehensive external quality assessment service that meets the needs of participants.
- Professional technical advice and information.
- Clear statistical reports in a consistent and timely manner.
- High quality, human based samples.
- Detailed method differentiation.
- Samples with varied analyte levels to cover the areas of clinical significance.
- Method performance analyses for method evaluations.
- Efficient and reliable customer support.
- Specialized electronic reports for common interest groups.
- Accredited programs to provide participants confidence in quality assurance.
- A commitment to impartiality, with proactive measures to ensure consistent adherence.

Objective

External quality assessment (EQA) programs have been used by laboratories for over half a century to maintain and demonstrate analytical quality. The object of EQA is to improve and maintain analytical interlaboratory agreement. As patients and clinicians move from one area or hospital to another, it is important that there is good analytical agreement between laboratories. Your laboratory can help ensure this by participating in external quality assessment and taking appropriate actions when your results do not meet acceptable performance.

Bio-Rad EQAS Programs are accredited, unbiased, international EQA schemes with participants in over 118 countries. It is our objective to assist laboratories worldwide to achieve high standards and confidence in the results they produce for the clinicians and patients they serve. The need for quality and confidence in analytical performance is paramount as an aid in the diagnosis of medical conditions. Additionally, national regulations and international standards applicable to the clinical laboratory require participation in an EQA scheme from a recognized provider, such as Bio-Rad.

Bio-Rad Quality Policy

Bio-Rad Laboratories is a company with a global network of operations that support the complete life-cycle of innovative products and solutions for the life science research and clinical diagnostic markets. Bio-Rad is committed to:

- Developing, manufacturing, and supplying high-quality products and services that advance scientific discovery and improve global healthcare.
- Fostering long-lasting customer relationships based on understanding and meeting their requirements, responding to feedback, and providing exceptional support.
- Conducting business ethically while complying with applicable industry, statutory, and regulatory requirements.
- Implementing risk-based process approaches that sustain effective global business operations with internal and external partners.
- Dedicating adequate resources including competent employees, infrastructure, and work environments needed to meet our organization's objectives.
- Monitoring, continually improving, and maintaining effectiveness of the Quality Management System.

The Quality Policy is integral to our success as a strategic market leader and partner to our customers. We achieve this policy through application of Bio-Rad's Guiding Principles and Core Values: Innovation, Involvement, Independence, and Integrity.

EQAS Program Details

Bio-Rad EQAS offers comprehensive external quality assessment programs for clinical chemistry (serum and urine), ethanol/ammonia, lipids, therapeutic drug monitoring, immunoassay, immunology, hematology, coagulation, cardiac assessment, hemoglobin, blood gas, infectious disease, and blood bank testing. The product insert provides a complete list of the current analytes/parameters associated with each EQAS Program. Program information is also easily accessible on our website at www.bio-rad.com/eqas.

EQAS Programs Available

- EQAS Blood Gas Program
  A monthly program for reporting routine blood gas, electrolytes, glucose, lactate, and magnesium.
- EQAS Blood Typing Program
  A comprehensive program for clinical lab, blood bank and transfusion center testing.
- EQAS Cardiac Markers Program
  A monthly comprehensive cardiac assessment program.
- EQAS Clinical Chemistry (Monthly) Program
  A monthly serum chemistry program with general chemistries and thyroid tests.

- EQAS Coagulation Program
  A monthly program for reporting basic coagulation parameters.
- EQAS Ethanol/Ammonia Program
  A monthly program for reporting ethanol and ammonia.
- EQAS Hematology Program
  A monthly program for basic hematology parameters.
- EQAS Hemoglobin Program
  A monthly program for Hemoglobin A1c and A2.
- EQAS HIV/Hepatitis Program
  A comprehensive monthly program suitable for serological testing used to detect key HIV and Hepatitis viral antibodies and antigens.
- EQAS Immunoassay (Monthly) Program
  A comprehensive monthly program covering the most commonly tested immunoassay analytes including endocrinology, thyroid function, oncology, and therapeutic drugs.
- EQAS Lipids Program
  A monthly program for reporting routine analytes for lipids analysis.
- EQAS Serum Proteins Program
  A monthly program for serum proteins.
- EQAS Specialty Immunoassay Program
  A monthly program for specialty immunoassay analyte measurements, including Procalcitonin, Active Vitamin B_{12}, Interleukin-6, and Fructosamine.
- EQAS Syphilis/Chagas Program
  A monthly program suitable for serological tests detecting *treponemal*, *non-treponemal* and *Trypanosoma cruzi* antibodies.
- EQAS Therapeutic Drug Monitoring Program
  A monthly program for therapeutic drugs in human serum.
- EQAS ToRCH/EBV/MuMz Program
  A comprehensive monthly program suitable for serological tests used to detect pediatric diseases and congenital infections.
- EQAS Urinalysis Program
  A monthly program for manual and automated dipstick analysis.
- EQAS Urine Chemistry Program
  A comprehensive, matrix-appropriate, monthly program for basic and specialty urine chemistry analytes.

EQAS Services Provided

In addition to the regular services provided through the EQAS Program, Bio-Rad offers all participants value added services. A Method Summary Report is available at the end of most program cycles. Laboratories find this report helpful in evaluating methods under consideration for future use.

The leader of a common interest group can receive a special Subgroup Report for the regular monitoring of individual laboratory performance. Evaluations against alternative acceptable performance limits can be monitored through monthly Quality Specification Reports.

Bio-Rad can assist oversight bodies with the monitoring of laboratories under their guidance. Participants that require assistance in interpreting their EQAS reports or in troubleshooting their performance can request professional assistance from our staff of experts. Also available from Bio-Rad are educational materials regarding quality control practices and laboratory accreditation to ISO 15189. Contact your local Bio-Rad office or representative for additional information.

Participation as a Subgroup

Laboratories with a common interest may elect to participate as a subgroup. An elected subgroup leader is identified and can either be a participating laboratory or a member of an independent oversight body.
The subgroup leader receives an electronic Subgroup or Quality Specification Subgroup Report for each program sample. These reports provide a summary of individual laboratory results against Bio-Rad and/or an alternate selection of quality specifications for all members in the subgroup. The reports are provided as a Microsoft® Excel® spreadsheet allowing for the easy transfer of information to a database for long term storage and performance monitoring. The reports are available to the subgroup leader on the Bio-Rad QCNet website (www.QCNet.com).

- Note: A laboratory can only be added to the subgroup with the authorization of that laboratory. It is assumed that such authorization is valid until specifically canceled. Contact your local Bio-Rad office or representative for more information about how to set up a subgroup or to add or remove a laboratory from a subgroup.

Terms and Conditions

Terms and conditions for the purchase of any EQAS Program are provided locally. Contact the Bio-Rad office or the representative nearest you for information. If you do not know a local representative, please, contact Bio-Rad through the corporate website at www.bio-rad.com.

Customer Complaint Procedure

If there is a concern with any aspect of your participation in the EQAS Program, you are encouraged to contact your local Bio-Rad office or representative so that immediate action can be taken. For concerns related to the program, results submitted, EQAS reports, EQAS Online, EQAS Mobile, or Certificates (Registration, Participation, or Achievement), you can contact your local Bio-Rad representative or email eqas_support@bio-rad.com. See Chapter 2, “EQAS Contact Information” for more information.

Customer Appeal Procedure

To appeal decisions or actions you believe to be unsatisfactory, you must submit your appeal in writing, providing clear details of the decision you are appealing and the reasons behind your dissatisfaction. Appeals must be submitted by contacting your local Bio-Rad representative, and should include:

- Your contact details.
- Lab number.
- A summary of the original decision or action being appealed.
- Reasons for the appeal, supported by relevant documentation or evidence.

Upon receiving the appeal, you will be informed of the next steps and the expected timeline for resolution. We will review the appeal, considering all relevant documentation or evidence. Based on the review, a decision will be made regarding the appeal. You will be informed of the outcome, which may include:

- Upholding the original decision.
- Revising the decision based on new information.
- Offering an alternative solution, if applicable.

The decision and rationale will be clearly explained to you in writing.

Replacement Policy

Bio-Rad offers a replacement sample in instances where there was damage or any other identified deficiency to the package. Replacements are also available if you make an error in reconstitution or handling of samples (subject to available inventory). Contact your local Bio-Rad office or representative to request replacement.

Customer Satisfaction Survey

Bio-Rad EQAS participants are invited to appraise the programs and services offered through a regular survey of customer satisfaction. Using this survey, Bio-Rad is continually assessing the program's quality and information delivery to determine if the needs of participants are being met. Bio-Rad works to provide services and programs that customers value. Among these offerings are forums and workshops, and the email address eqas_support@bio-rad.com is available for customers to send input on the programs, services, and support received. We look forward to hearing from you.

Confidentiality

Bio-Rad maintains a high respect for participant confidentiality. This includes confidentiality of participation, results, and outcomes. To protect the identity of a participant, each laboratory is identified by a unique laboratory code known only to Bio-Rad and the participant. Participants in a common subgroup agree to have their information shared with the identified subgroup leader. Bio-Rad EQAS will not release participant details without prior written consent of the participant, unless required to do so by regulation.

For UK laboratories, confidentiality of individual participant's results and performance data is maintained in accordance with the Joint Working Group for Quality Assurance Conditions of Participation.

EQAS Performance Criteria

Quantitative Programs

Individual laboratory performance is displayed in each laboratory specific Sample Report. Acceptable performance in this global program is identified as falling within 2 Z-score from your comparator mean. Results outside ± 2 Z-score are highlighted in the “Exceptions” section of the Sample Report. Care should be taken when evaluating your comparison at the Method or Mode/All Results comparator, as your instrument/reagent can have a bias from others included in a “grouped” comparator. Ensure that results highlighted as exceptions are investigated and the reason for each deviation determined. Please see “Sample Report (Quantitative)” on page 30 and “Exceptions” on page 48 for details about exceptions. Results outside ± 3.0 Z-score are also noted in the “Exceptions” section of the Sample Report. These results require your immediate attention for determination of root cause with corrective measures implemented where appropriate.

Your laboratory may follow local or national guidance with respect to acceptable performance in an EQA program. Examine your reports carefully in cases where local guidance differs from that stated above, as additional follow up action may be necessary.

Qualitative Programs

Individual laboratory performance is displayed in each laboratory specific Sample Report. Acceptable performance in this global program is identified as reporting Within Consensus from your comparator; when 4 or more response options are possible, immediately adjacent to the consensus group is also considered acceptable. (See Chapter 5, “EQAS Reports” for detailed information on Consensus calculations.) Unacceptable results are highlighted in the “Exceptions” section of the Sample Report. Make sure that results highlighted as exceptions are investigated and the reason for the deviation is determined. (See “Sample Report (Qualitative)” on page 46 and “Exceptions” on page 48 for more information.) Results outside Consensus, or results considered unacceptable, require immediate attention for determination of the root cause. Use reference values, if available, to evaluate the results.

In instances of No Consensus, with no available reference or expected response, you are encouraged to compare your results to other instrument responses displayed in the right-hand column of the analyte report.

Your laboratory may follow local or national guidance with respect to acceptable performance in an EQA program. Examine your reports carefully in cases where local guidance differs from that stated above, as additional follow up action may be necessary.

Responsibilities of EQAS Participants

- Allow sufficient time for delivery of the specimen package by placing your order approximately ten weeks prior to the start of a cycle.
- Inspect the specimen package on receipt and store it according to instructions in the package insert. Contact Bio-Rad immediately if there is a deficiency identified in the specimen package or with individual samples.
- Ensure accuracy of all your test configurations (analyte, method, instrument/kit, reagent, and unit) through EQAS Online or EQAS Mobile. If your configurations are incorrect, your data will be placed in the wrong peer groups, which will cause an incorrect comparison of your results. Please refer to the *EQAS Online User Guide* for more information on configuring your tests: http://www.qcnet.com/Portals/0/PDFs/EQAS%20Online%20User%20Guide.pdf
- Handle and test the EQAS specimen as you would a routine patient sample following the normal procedures used in your laboratory. This is the only way an objective comparison of your result can be made.
- Submit results for each specimen prior to the Sample Due Date. Late data will be processed but will be flagged as late in your reports.
- Fully review each EQAS report to ensure the results reflected are as you submitted them. Errors are made during the submission process from time to time. Submit any corrections to a sample result before the next sample close or before the cycle close.
- Thoroughly review your Sample Report to identify opportunities to improve performance, especially those results shown in the “Exceptions” section.
- Review the “EQAS News” section on all reports received and routinely check for any program-specific messages in the EQAS Online “Home” screen. Bio-Rad uses these as tools to communicate upcoming deadlines, changes, and other important or useful information. Please ensure that your email address associated with EQAS Online remains current to receive similar information quickly and easily. Please refer to the *EQAS Online User Guide* for instructions. Link to User Guide: http://www.qcnet.com/Portals/0/PDFs/EQAS%20Online%20User%20Guide.pdf
- Implement and assess the effectiveness of any corrective measure taken in response to poor performance.
- Communicate any EQAS related problems or difficulties to your local Bio-Rad office or representative. Bio-Rad personnel are trained to assist you for problems such as configuration issues, performance concerns, reports not being received, etc. Please note that the EQAS Programs have definitive and required deadlines for external quality assessment or proficiency testing. If there is a problem, avoid delay in contacting Bio-Rad. A delay could prevent your laboratory from receiving the full benefits of the program.

Conditions for Publication

Bio-Rad believes it is in the best interests of participants that the general publication of information derived from the EQAS Program should be subject to reasonable control. Participants agree to comply with the Bio-Rad Conditions of Publication set out below.

Staff of a participating laboratory agrees to maintain in strict confidence and not to publish or otherwise disclose to any third party any information supplied to them by Bio-Rad without first obtaining the consent in writing of the EQAS organizers. This restriction applies to all publications, including commercial and promotional literature.

It is understood that:

a) Such consent is not required for disclosure in confidence to colleagues with whom they are working for their personal scientific interest.

b) Bio-Rad will not use information gained by the operation of the EQAS Program for any purpose other than the compilation of confidential reports for participants, the provision of assay values for batches of material, or the publication of pooled data of general scientific interest, except for subgroup and/or accreditation reports.

Program Accreditation

Program Accreditation

The Bio-Rad EQAS Programs are accredited to help meet the regulatory needs of today's clinical laboratories. Accreditation is a process by which an organization's activities and processes are recognized for guaranteed high quality. It involves an external audit by an independent and recognized body to an appropriate standard. By declaring a defined standard of practice and having it independently confirmed, accredited programs, such as Bio-Rad EQAS, attain a hallmark of performance that reassures their participants of the program's competence as a provider, and in the high quality of products and services offered.

The American Association for Laboratory Accreditation (A2LA)

Bio-Rad EQAS Programs are fully accredited by the American Association for Laboratory Accreditation (A2LA), a non-profit, non-governmental public service, membership society. A2LA is governed by a Board of Directors and obtains technical guidance from a number of technical committees. A2LA inspectors are trained assessors who are technical experts in their fields. Accreditation decisions are made by the Accreditation Council.

The Bio-Rad EQAS Program is accredited to the recognized International Standard ISO/IEC 17043:2010 Conformity assessment-General requirements for proficiency testing. Additional information on the accrediting body, A2LA, can be found on their website at www.a2la.org.

Monitoring of Laboratories

National Quality Assurance Advisory Panel (UK Labs)

The National Quality Assurance Advisory Panel (NQAAP) retains responsibility for monitoring performance of UK participants in the public and private sectors that perform medical testing for the detection, diagnosis or management of disease in humans.

The Bio-Rad EQAS policy for implementing the NQAAP guidance is to follow a series of steps designed to assist laboratories in effectively addressing performance issues. A consultation procedure is initiated when necessary.

Laboratory performance is assessed by:

a) The consistent and timely return of results. Data must be submitted for a minimum of 75% of samples within a cycle (9 of 12). Laboratories are expected to submit results by the Sample Due Date. Exceptions may be made where assays are carried out for clinical trials and regular reporting is not applicable.

b) Satisfactory analysis, as judged from the data. Results that fall consistently outside ± 2 Z-score from the comparator mean, or that are outside the consensus, usually indicate an analysis problem. The consultation procedure will be initiated for any laboratory submitting three results that are outside ± 2 Z-score, or that are outside the consensus, in any four consecutive samples. Discretion is used in assessing results where the mean of comparison contains results from more than one method.

Non-analytical errors (for example, transcription errors), amended results, and inconsistent results (such as several different analytes outside ± 2 Z-score or consensus at each sample) are also monitored.
The consultation procedure is used where the frequency or clinical consequences of such results gives reason for concern.

After all avenues of consultation have been exhausted and there is no apparent improvement of performance, such performance issues are referred to the Bio-Rad EQAS Steering Committee and then, as a last resort, to the NQAAP. Information concerning the actions and procedures of the NQAAP in relation to laboratories referred, is available from the NQAAP.

Additional details are available from Bio-Rad on request.

Monitoring of Non-UK Laboratories

Bio-Rad EQAS can provide special reports to laboratory oversight and accrediting bodies to aid in their auditing of laboratory services. In countries where participation and performance in this scheme can be used for laboratory accreditation purposes, Bio-Rad will provide all relevant information to participating laboratories and divulge laboratory results to the accrediting body. Contact Bio-Rad for more information.

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EQAS Contact Information

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Customer Support

The EQAS Customer Support staff provides advice, information, and assistance with troubleshooting your EQAS results. The trained staff members are fully capable to assist you in all aspects of our external quality assessment program.

Use the contact information in this section if you have questions, comments, or concerns regarding any aspect of your EQAS Programs.

Important: Make sure you include your EQAS lab number on all correspondence to Bio-Rad.

Telephone:	1-800-854-6737 (U.S. and Canada only), Option #1
Hours of direct coverage:	6:00 AM – 5:00 PM (Pacific Time)
Email:	eqas_support@bio-rad.com For enrollment, data analysis, report interpretation and troubleshooting, mode assignment, EQAS Online, EQAS Mobile, certificates, subgroups, monitoring of laboratories, and manufacturer assistance.
For customers outside of the United States, contact your local Bio-Rad office or representative.	

Orders and Order Inquiries

Contact your local Bio-Rad office or representative to order your EQAS Program or for any questions about the status of your order. If you are unable to contact your local Bio-Rad representative directly, submit your inquiry through email to eqas_support@bio-rad.com.

EQAS Online

Bio-Rad offers an EQAS Online reporting option that allows you to submit and maintain test configurations and results. Visit www.QCNet.com, contact your local Bio-Rad representative, or send an email to eqas_support@bio-rad.com for more information.

EQAS Mobile

The EQAS Online reporting option is also available on most smartphones for quantitative programs. Please follow the EQAS Online setup procedure on www.QCNet.com before accessing the mobile application.

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Getting Started

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Overview

Bio-Rad EQAS Programs run in twelve-month cycles. Each cycle typically consists of twelve numbered samples. For convenience, all samples for the entire cycle are provided at the same time. The twelve samples comprising a cycle are derived as replicates from four unique batches.

- Note: The liquid hematology and blood typing samples are provided in multiple shipments of three samples each.

Samples are tested every month. Registered results received at Bio-Rad by 20.00 Greenwich Mean Time (GMT) on the Sample Due Date are included in the statistical analysis. All submitted quantitative program results for an analyte are grouped according to comparators (peer, method, and mode/all results) and a robust statistical analysis based on ISO 13528 is performed. Qualitative program results are determined to be either within or acceptable, outside, or show no consensus. Consensus is reached when at least 80% of comparator responses are the same.

- Note: Three blood typing samples are tested every four months for a total of 9 samples per year-long cycle.

Within three to five working days of statistical analysis, a laboratory-specific performance report is generated for each participant. These reports are easy to interpret and include graphical representations of your performance. Reports are available electronically through the secure Bio-Rad www.QCNet.com website. Should you require paper copies, please contact your Bio-Rad representative.

At the end of each quantitative program cycle, a detailed End-of-Cycle Report is generated for each participant. This report consists of batched peer group statistics (with the exception of the EQAS Hematology Program), linear regression analyses, and an assessment of bias (Z-score) for each analyte reported on. Each participant is given a national and international ranking based on their overall performance.

A Certificate of Achievement is provided to those participants who successfully complete the program cycle with a minimum of 9 reported samples within ± 3.0 Z-score or are considered acceptable for at least one analyte. Additionally, a Certificate of Acceptable Performance is provided with each End of Cycle report listing all analytes which passed the program criteria.

Order Your EQAS Program

Contact your local Bio-Rad office or representative to order any of the Bio-Rad EQAS Programs. Your Bio-Rad representative will provide you with program and pricing information, a listing of the available analytes, catalog numbers, and cycle schedules. Terms and conditions for your order will be provided by your local Bio-Rad office or representative.

Orders should be submitted approximately ten weeks prior to the start of a new program cycle. Orders placed after this are accepted but are subject to inventory availability. If you enroll in an ongoing program cycle, you are encouraged to test and submit results for all samples that have passed their specific Sample Due Dates.

EQAS Enrollment

Your laboratory must enroll to begin participation in an EQAS Program. Your local Bio-Rad office or representative will provide you with an Order Form and issue you a unique laboratory number.

If you are an existing Bio-Rad EQAS participant and want to add a new program, you can access an Order Form on-line at http://www.qcnet.com/Portals/0/PDFs/EQAS_order_form_EN.pdf and enroll with your Bio-Rad laboratory number.

Order Form

Complete each section of the Order Form. See the following pages for more information.

- Report Preferences (this page)
- EQAS Program Selection (this page)
- Laboratory Contact Information (page 18)
- Primary Contact Information (page 18)
- Subgroup Information (if applicable; page 19)

1 Report Preferences

- Select your language preference for your EQAS reports.

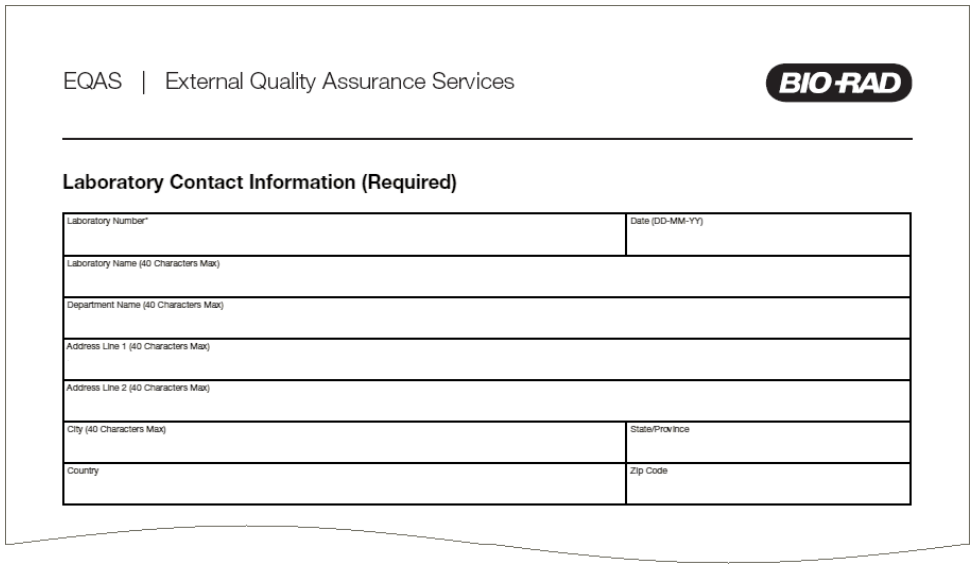
2 EQAS Program Selection

Select one or more EQAS Programs. You are encouraged to enroll in all programs applicable to meet your annual EQA requirements.

3 Laboratory Contact Information

> Note: The fields in this section are restricted to 40 characters, including spaces between words.

- Complete all information in this section.
- Enter your laboratory number, if known. If you are a new customer and have not received your laboratory number from your local Bio-Rad representative, please leave this blank. Bio-Rad will assign you a specific laboratory number on receipt of the completed Order Form.



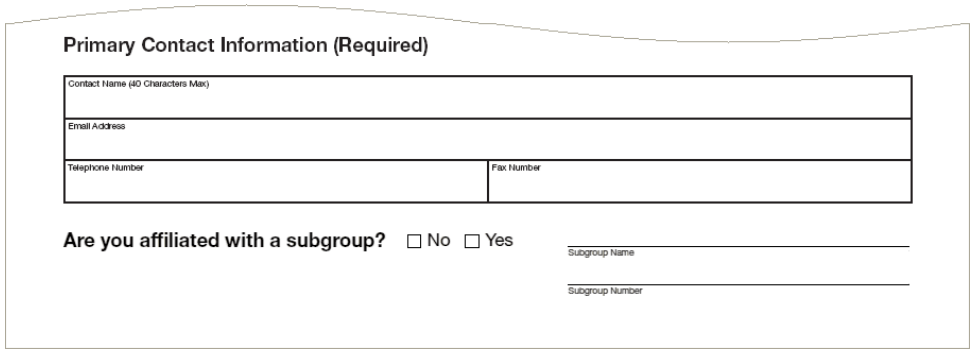
EQAS | External Quality Assurance Services

Laboratory Contact Information (Required)

Laboratory Number*	Date (DD-MM-YY)
Laboratory Name (40 Characters Max)	
Department Name (40 Characters Max)	
Address Line 1 (40 Characters Max)	
Address Line 2 (40 Characters Max)	
City (40 Characters Max)	State/Province
Country	Zip Code

4 Primary Contact Information

Enter the contact information for the person who will be responsible for managing the selected EQAS Program. You can have a different contact person for the same lab number in a different EQAS Program, but not for the same program. For example, if your laboratory number is 123456 and you are enrolled in both the Clinical Chemistry and the Hemoglobin programs, you can have a different person manage each program. Make sure you complete the contact information for one EQAS Program only if multiple programs will not be managed by the same person.



Primary Contact Information (Required)

Contact Name (40 Characters Max)	
Email Address	
Telephone Number	Fax Number

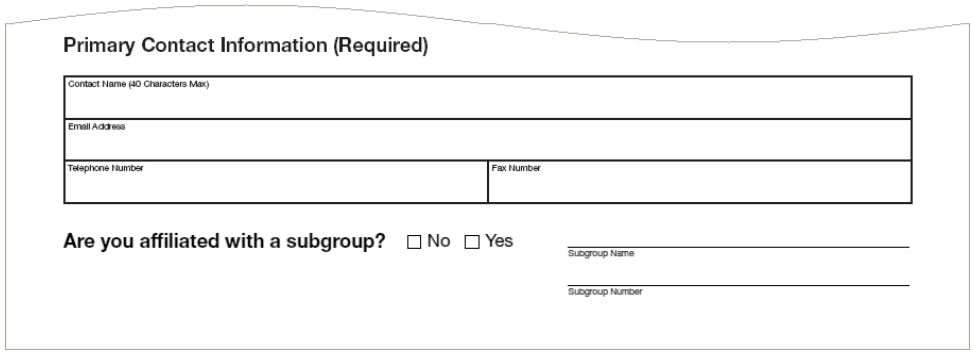
Are you affiliated with a subgroup? ☐ No ☐ Yes

Subgroup Name

Subgroup Number

5 Subgroup Information (if applicable)

If your laboratory is affiliated with a subgroup, select the “Yes” check box and provide the subgroup name and number (if known). By indicating your participation in a subgroup you agree to have your individual laboratory’s performance shared with the designated leader of the subgroup.



Primary Contact Information (Required)

Contact Name (40 Characters Max)	
Email Address	
Telephone Number	Fax Number

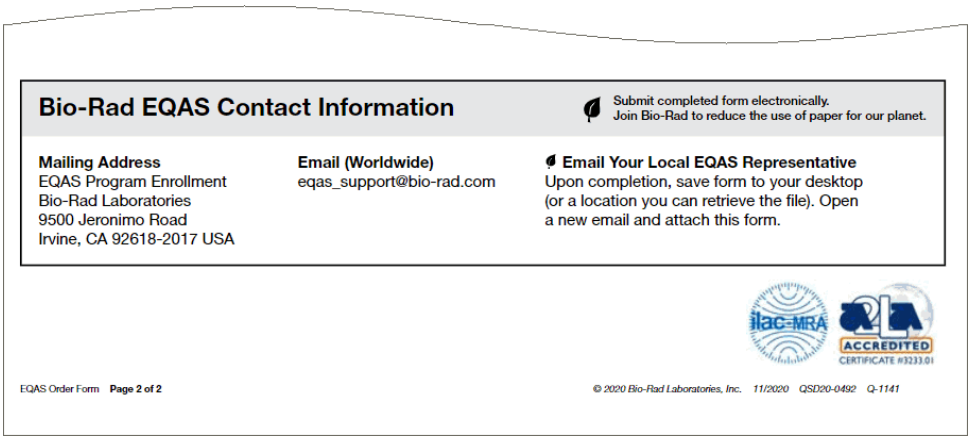
Are you affiliated with a subgroup? ☐ No ☐ Yes

Subgroup Name

Subgroup Number

Send the Order Form to Bio-Rad

After you complete the Order Form, return it to Bio-Rad for processing. Instructions for returning the form are included on the last page of the form.



Bio-Rad EQAS Contact Information

Submit completed form electronically.
Join Bio-Rad to reduce the use of paper for our planet.

Mailing Address
EQAS Program Enrollment
Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, CA 92618-2017 USA

Email (Worldwide)
eqas_support@bio-rad.com

Email Your Local EQAS Representative
Upon completion, save form to your desktop (or a location you can retrieve the file). Open a new email and attach this form.

ilac-MRA A2LA ACCREDITED CERTIFICATE #3233.01

EQAS Order Form **Page 2 of 2**

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Lab Number

New participants are assigned a laboratory specific number when they enroll in a Bio-Rad EQAS Program. Your lab number is used for all EQAS Programs your laboratory registers for and will be retained through successive cycles. Your lab number is printed on your EQAS reports and your Certificate of Achievement.

A single EQAS lab number allows you to report on multiple instruments within a program, even for the same analyte. However, if your laboratory wants to report a test (analyte or parameter) on the same instrument (make and model), Bio-Rad must issue a separate lab number to you. Contact your local Bio-Rad office or representative for assistance.

> ⚠ Important: Make sure you include your EQAS lab number on all correspondence to Bio-Rad.

Specimen Package

> ⚠ Important: Make sure you read the package insert included in the specimen package. The package insert includes information on the proper storage, handling, and reconstitution (if applicable) of the samples, and describes any limitations in the time you may perform selected tests.

You will receive a specimen package for each program cycle you enroll in and submit an order for. The specimen package contains all the samples to be tested in one EQAS cycle. The specimen package consists of the following items:

- Twelve (12) vials of freeze-dried serum, urine, or human whole blood (see notes below).
- Preparation of select samples are subcontracted to qualified suppliers. The specimen package, sample vial, and package insert will be clearly marked with Mfd. For where applicable.
- Each vial is labeled with a specific sample number (1–12).
- Each vial is labeled with the sample due date, cycle number, and lot number.

Notes: The specimen packages for one cycle of the EQAS Hematology Program will be sent to you in multiple (four) shipments. Each shipment contains three liquid samples.

The specimen packages for one cycle of EQAS Blood Typing Program will be sent to you in multiple (three) shipments. Each shipment contains three liquid test samples and one donor sample for cross-matching.

Verify the Contents of the Specimen Package

Make sure you inspect the specimen package upon receipt to ensure it is complete and undamaged. The vials are clearly identified by Sample Number. There should be one numbered vial for each cycle sample. Inspect the vials for any damage that may have occurred during their transport. Inspect samples associated with the Hematology and Blood Typing Programs for gross hemolysis. Notify your local Bio-Rad office or representative if you have any concern about the specimen package. Replacements will be provided, subject to inventory availability.

Assaying the Samples

> ⚠ Important: If Lyophilized, the sample should be reconstituted according to the instructions in the package insert. Make sure to note any limitations in analyte stability. After reconstitution, handle samples according to the insert instructions and test as you would test a patient sample.

- Handle high, out-of range samples in accordance with established laboratory procedures when a sample result exceeds the linear range of the method.
- Do not report results that are the mean of several assays, unless this is your routine procedure for patient samples.
- Use the same criteria used for a patient result to determine if the EQAS Program sample result is acceptable for reporting. This is the only way a true assessment of your laboratory's performance can be made.

chapter 4

Submit Your EQAS Results

In This Chapter

Overview....22
Unreportable Results (UR) Codes....23
Valid Configurations....24
Sample Due Date....25
Late and Amended Results....26
Send Your Results....26
Certificate of Achievement....27

Overview

You can submit your EQAS results using either of the following methods:

- EQAS Online
- EQAS Mobile

Unreportable Results (UR) Codes

Unreportable Result (UR) Codes show the possible reasons why data cannot be submitted. Unreportable results cannot be compared and will not be included in the calculations. The use of an unreportable code indicates that you attempted to test the sample, but were unable to submit a valid result. These codes can help Bio-Rad EQAS to modify analyte targets appropriately in subsequent cycles.

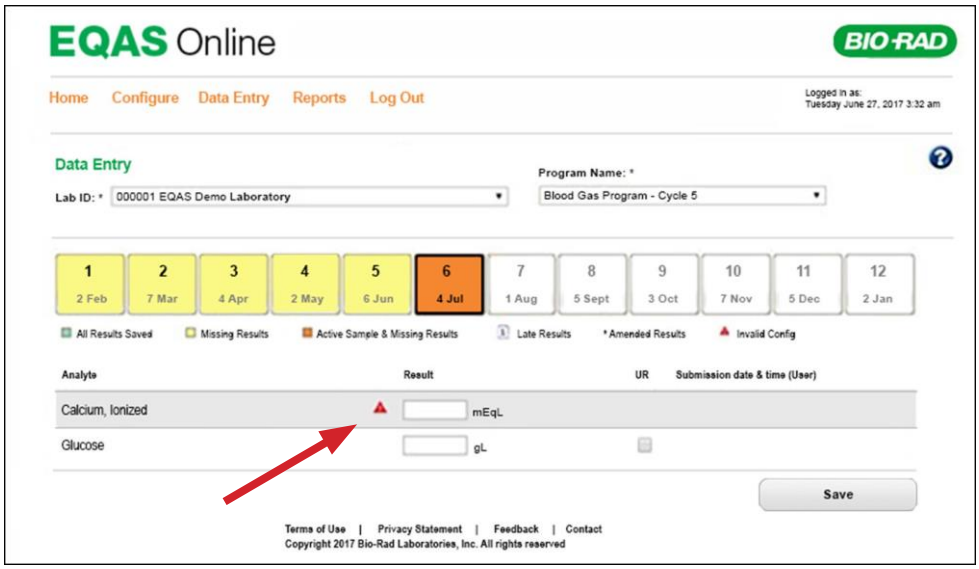
Unreportable Results Codes / Descriptions
Less than Detection Limit
Greater than Assay Range
Result of Zero
Instrument Flag
Turbid Sample/Compromised Sample
Insufficient Sample Volume
Other
Analyte Not Tested (Blood Typing)
Instrument Unavailable
Unable to Identify, Would Refer

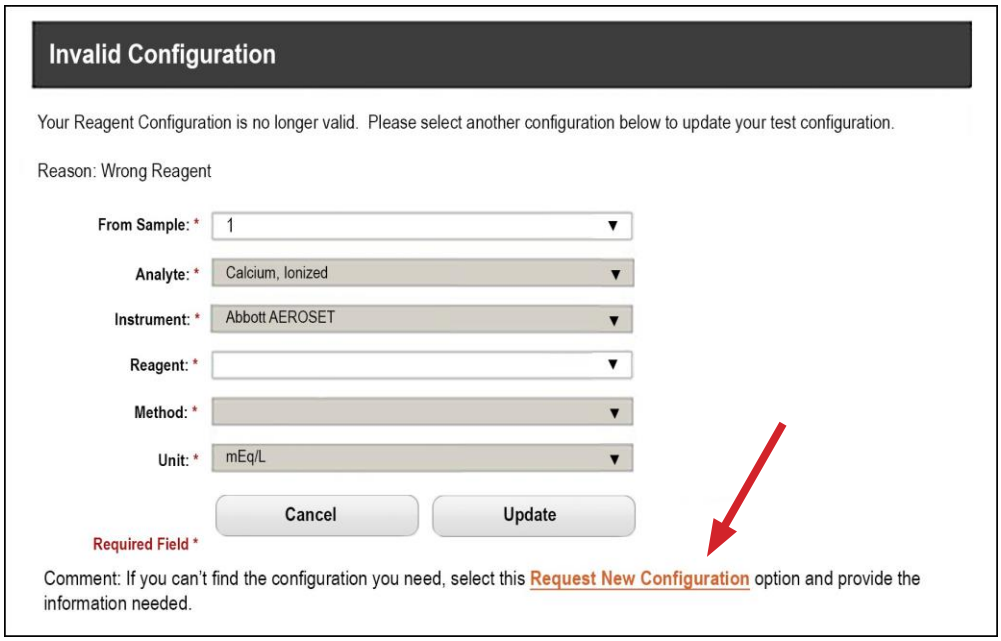
Valid Configurations

Test configurations are routinely monitored to assure continued validity. This effort is aimed at continuously improving comparator groups and sample report statistical information.

Labs with invalid test configurations will be alerted to make corrections before further submitting results.

In case your configuration is not available in the EQAS database, click on the **Request New Configuration** link and provide necessary documentation. Allow up to 15 working days for completion of the request. You will be notified by email once the configuration has been validated and added to your test setup.





Sample Due Date

The Sample Due Date is the latest date by which your sample results must arrive at Bio-Rad EQAS, by 20.00 Greenwich Mean Time. Results must be submitted prior to this date and time for them to be included in the statistical analysis of the sample. Every effort should be made to submit your results on time. Late data will be accepted and processed, but will be flagged as late on your EQAS reports and penalties will be applied in your end-of-cycle ranking calculation. If you registered for a test and no result is submitted for that test, it will be flagged as missing (No Result) in your report. Under no circumstances will results be accepted after the close of a program cycle. Results cannot be accepted for a sample that has exceeded its expiration date. The expiration date can be found on the specimen package insert.

You can find the Sample Due Date in the following locations:

- EQAS Online Software / EQAS Mobile Software
- Sample Vial Label
- Product Insert (included in the Specimen Package)
- EQAS / Unity Calendar (electronic form on www.QCNet.com)

Late and Amended Results

Late Results

Results received after the Sample Due Date are considered late and will be noted with the symbol in your EQAS reports. The reason for a missed and subsequent late submission may be made in the Comment section of your EQAS report.

Send late results as soon as possible using EQAS Online or EQAS Mobile.

Late results (as flagged in your EQAS reports) will be penalized in the calculation of your end-of-cycle rankings. The penalty applied for submitting late results is not as severe as that associated with amended results.

Amended Results

An amendment to a result previously submitted in a current cycle will be made at your request. Amended results are noted with an * (asterisk) on your EQAS reports when they are received after the Sample Due Date.

Make sure to note the reason for the amendment in the Comment section of your EQAS report. If correction to a submitted result is made on Bio-Rad's behalf (as in a data entry error), the result will be corrected, and an amended result flag will not appear on your EQAS report for that result.

Send amendments as soon as possible via EQAS Online or EQAS Mobile. Amended results (as flagged in your EQAS reports) will be penalized in the calculation of your end-of-cycle rankings. The penalty applied for submitting amended results is more severe than that associated with late results.

Send Your Results

You can send results in either of the following ways:

- EQAS Online
  Bio-Rad offers an EQAS Online reporting option that allows you to submit test configurations and results. Visit www.QCNet.com, contact your local Bio-Rad representative, or send an email to eqas_support@bio-rad.com for more information.
- EQAS Mobile
  The EQAS Mobile reporting option is also available on most smartphones. Please follow the EQAS Online setup procedure on www.QCNet.com before accessing the mobile application.

Certificate of Achievement

Bio-Rad provides a Certificate of Achievement at the end of each completed EQAS cycle. Certificates are made available electronically under the Reports section of EQAS Online. You can print and display this certificate in your facility as evidence of program participation for the purpose of laboratory accreditation. Your laboratory must submit a sufficient amount of valid data over a program cycle to qualify for the Certificate of Achievement.

The information in the “Lab Name” and “Department” in the Lab Setup and Program Setup pages in EQAS Online will be printed on your Certificate of Achievement. Please make sure this information is correct and appears as you would like printed on the Certificate of Achievement. If any information needs to be changed, update the Lab/Department information in EQAS Online.

How to Qualify for a Certificate

You must meet the following criteria within a given EQAS Program to qualify for a Certificate of Achievement:

- You submit results for at least 9 of the 12 samples.
- Quantitative
  For a given analyte in those 9 samples, your performance was found to be within ± 3.0 Z-score based on the level of your comparator for each of those samples.
- Qualitative
  For a given analyte in those 9 samples, your performance was found to be Within Consensus or considered Acceptable. When No consensus was reached the sample will also be seen as accepted.

> Note: For the Blood Typing Program (Qualitative), labs must submit results for at least 6 of the 9 samples. For a given analyte in those 6 samples, results must be within consensus based on the comparator for each of those samples.

chapter 5

EQAS Reports

In This Chapter

Overview....28
Sample Report (Quantitative)....30
Sample Report (Qualitative)....46
Quality Specification Report (Quantitative)....69
Quality Specification Subgroup Report (Quantitative)....73
End-of-Cycle Report (Quantitative)....75
Method Summary Report (Quantitative)....90
Subgroup Report (Quantitative)....92
Subgroup Report (Qualitative)....94

Overview

Each registered participant receives one Sample Report for each sample in the cycle and one End-of-Cycle Report. These reports are specific to your laboratory and provide you with information on how your laboratory performed in comparison to others participating in the program cycle.

The Method Summary Report is generated at the end of each cycle. This report is optional and does not contain information specific to your laboratory. The Method Summary Report contains method performance statistics for instruments in use during the cycle by participating laboratories.

The Subgroup Report is another optional report that can be provided electronically to the leader of a subgroup. The Subgroup Report provides a list of all laboratories in the subgroup and their individual performance for each EQAS Program sample.

Reports are posted on www.QCNet.com within three to five business days of a sample close. Accessing reports on-line allows you to assess your laboratory's performance, investigate any deficiencies in a timely manner, and be environmentally responsible.

Sample Report (Quantitative and Qualitative Programs)

The Sample Report is easy to read and understand. It provides concise information about your laboratory's performance in the form of histograms, Z-score, and consensus trend charts. This report provides an instant indication of the performance of all reported analytes for a particular sample. A separate page is provided for each analyte. You can review performance comparison with peer groups by statistics or graphically with the histograms, Levey-Jennings charts and Yundt Plots. The last section of this report provides a summary of all data submitted to date within a cycle. A Certificate of Registration is provided as the final page of your Sample 1 Report. See "Sample Report (Quantitative)" on page 30 and "Sample Report (Qualitative)" on page 46 for more information.

Quality Specification Report (Quantitative Programs Only)

With the Quality Specification Report, a laboratory may assess their EQA test performance based on the quality specification of their choice. Performance in this report is based on the percent deviation of the reported test result. This value-added report is only available through EQAS Online. A laboratory may generate their EQAS Quality Specification Report for each sample reported on. It does not replace the EQAS Sample Report.

Bio-Rad offers a number of analytical performance criteria to choose from for the EQAS Quality Specification Report, such as: Biological Variation (BV), CLIA, RiliBAK, IQMH, GOST (Russia), RCPA, and more. Contact Bio-Rad if additional specifications are needed. See "Quality Specification Report (Quantitative)" on page 69 for more information.

Quality Specification Subgroup Report (Quantitative Programs Only)

Subgroup leaders can generate a single report (in Excel spreadsheet format for easy sorting) and view performance of all their labs based on Bio-Rad EQAS and alternative scientific or regulatory quality specifications. This report does not replace the monthly EQAS Sample Report.

End-of-Cycle Report (Quantitative Programs Only)

At the end of each cycle an overall assessment of your laboratory's performance for each analyte is given in terms of bias among participating laboratories. A Regression Line Analysis shows bias at different concentrations. Your laboratory's results are ranked nationally and internationally, and a Certificate of Acceptable Performance is provided on the final page. The End-of-Cycle Report is typically generated about 2 weeks after sample 12 data analysis to allow for late submission and amendments. See "End-of-Cycle Report (Quantitative)" on page 75 for more information.

Method Summary Report (Quantitative Programs Only)

The Method Summary Report provides a summary of individual method performance (not laboratory performance) among participating laboratories. The Method Summary Report is helpful to evaluate method/instrument performance. The Method Summary Report is an optional report generated at the end of a program cycle. See “Method Summary Report (Quantitative)” on page 90 for more information.

Subgroup Report (Quantitative and Qualitative Programs)

The Subgroup Report is provided only to a designated subgroup leader and is in a Microsoft® Excel® spreadsheet format. The report is provided electronically (posted on www.QCNet.com) with each sample close in a program. All individual laboratories in the subgroup are included along with their performance for each registered analyte in the sample. See “Subgroup Report (Quantitative)” on page 92 and “Subgroup Report (Qualitative)” on page 94 for more information.

Sample Report (Quantitative)

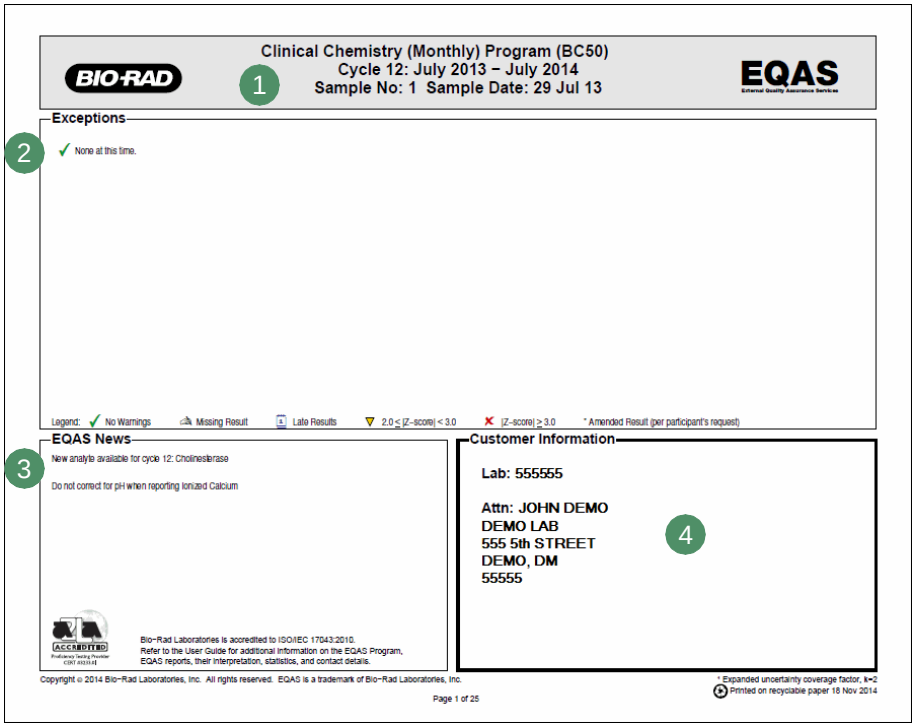
The Quantitative Sample Report provides clear and concise information about your laboratory performance in the form of histograms, Levey-Jennings charts, and Yundt Plots. This report is provided for each program sample and provides an easy to read summary and statistical comparison of your laboratory’s results for each analyte that has valid method registrations on file.

The Sample Report consists of the following main parts:

- Coversheet
- Configuration Report
- Sample Summary Report
- Analyte Report(s)
- Data on File Report
- Certificate of Registration (with Sample 1 Report only)

Sample Report (Quantitative): Coversheet

The first page of the Sample Report is the coversheet.



1 Header

This section shows the following information:

- EQAS Program name
- Cycle number and cycle dates
- Sample number
- Sample due date

2 Exceptions

This section provides a quick overview of any results that may require additional attention due to performance or to information that is needed for proper submission. The legend located below the Exceptions describes the symbols used in this section and elsewhere in the report.

Legend	
✓	No warnings
	Missing result A result is considered missing when a test registration is on file with Bio-Rad EQAS but no result was submitted for the sample.
	Late results
▼	2.0 ≤ |Z-score| < 3.0 Your absolute sample Z-score was greater than or equal to 2.0 and less than 3.0
✕	|Z-score| ≥ 3.0 Your absolute sample Z-score was greater than or equal to 3.0.
*	Amended result (per participant's request)
J::I	Non-robust determination of mean and SD Indicates that the robust statistical process could not be used.

3 EQAS News

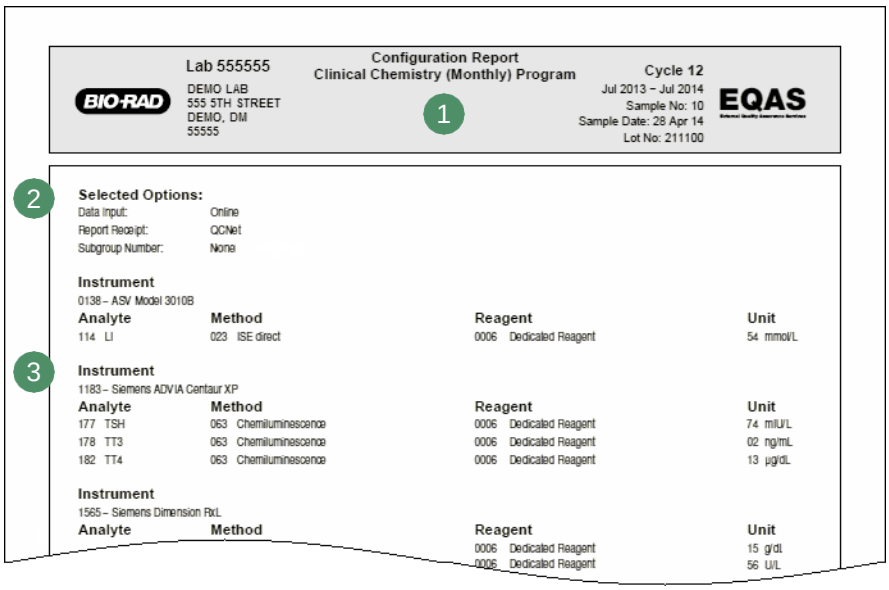
This section provides information, reminders, and news about the EQAS Program.

4 Customer Information

This section shows your Bio-Rad EQAS lab number and your laboratory's contact information.

Sample Report (Quantitative): Configuration Report

The second section of the Sample Report is the Configuration Report.



Lab 555555
DEMO LAB
555 5TH STREET
DEMO, DM
55555

Configuration Report
Clinical Chemistry (Monthly) Program

Cycle 12
Jul 2013 – Jul 2014
Sample No: 10
Sample Date: 28 Apr 14
Lot No: 211100

Selected Options:
Data Input: Online
Report Receipt: QCNet
Subgroup Number: None

Instrument
0138 – ASV Model 3010B

Analyte	Method	Reagent	Unit
114 LI	023 ISE direct	0006 Dedicated Reagent	54 mmol/L

Instrument
1183 – Siemens ADVIA Centaur XP

Analyte	Method	Reagent	Unit
177 TSH	063 Chemiluminescence	0006 Dedicated Reagent	74 mIU/L
178 TT3	063 Chemiluminescence	0006 Dedicated Reagent	02 ng/mL
182 TT4	063 Chemiluminescence	0006 Dedicated Reagent	13 µg/dL

Instrument
1565 – Siemens Dimension RxL

Analyte	Method	Reagent	Unit
		0006 Dedicated Reagent	15 g/dL
		0006 Dedicated Reagent	56 U/L

1 Header

This section shows the following information:

- Laboratory information
- Report name
- EQAS Program name
- Cycle number and cycle dates
- Sample number and sample due date
- Lot number (Cycle)

2 Selected Options

This section shows the following items associated with your laboratory:

- Data Input
  The method by which Bio-Rad received your results for the sample.
- Report Receipt
  Your reports will be available through QCNet, unless otherwise requested through your local Bio-Rad representative.
- Subgroup Number (if applicable)
  If there is no subgroup association, it is noted as “None.”

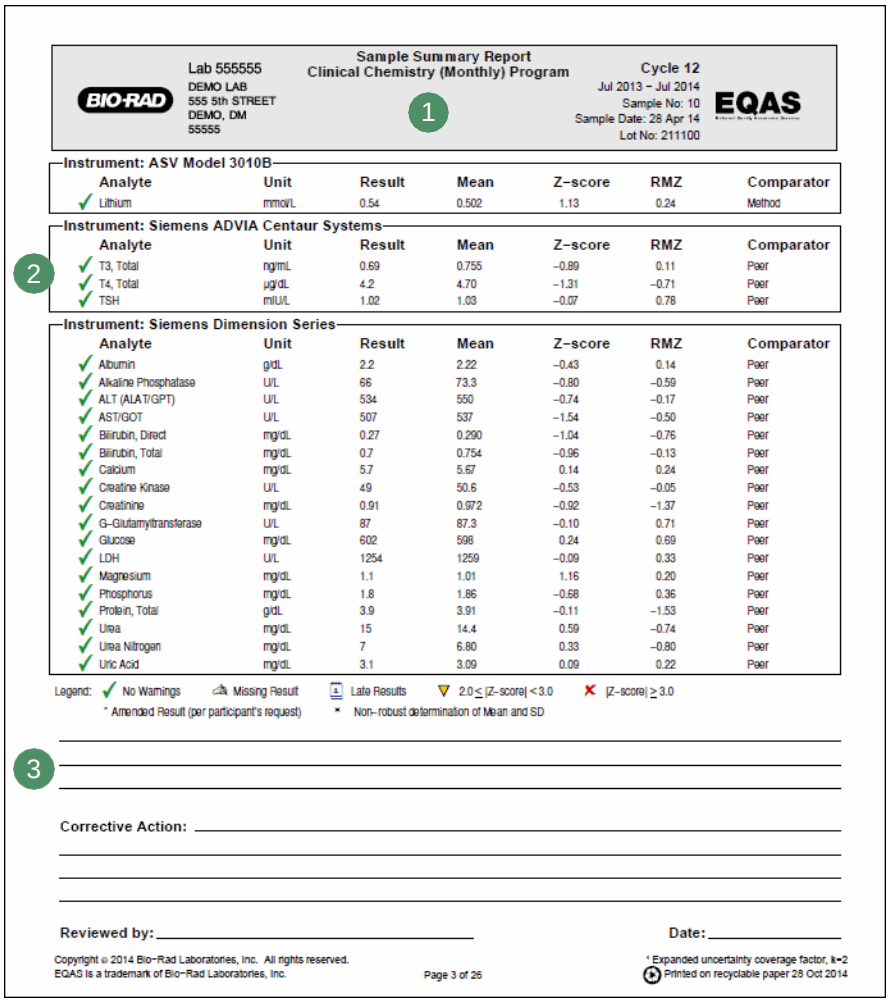
3 Instrument Configurations

This section shows a summary of your laboratory's registered analytes and the test configurations (instrument, method, reagent, and unit) applicable at the time of the sample close. The configurations are grouped alphabetically by instrument.

- Note: This section provides an easy way to review your laboratory's test configurations. The instrument code and description are shown with the codes and descriptions for analytes (abbreviations), methods, reagents, and units. It is important to verify that this information is correct when troubleshooting your results as incorrect configurations may lead to inaccurate peer groups and poor performance assessments.

Sample Report (Quantitative): Sample Summary Report

The third section of the Sample Report is the Sample Summary Report. The Sample Summary Report shows a summary of performance for all results reported and registered for a particular sample. The report is arranged alphabetically by instrument. The registered analytes are grouped by instrument.



Lab 555555
DEMO LAB
555 5th STREET
DEMO, DM
55555

Sample Summary Report
Clinical Chemistry (Monthly) Program

Cycle 12
Jul 2013 – Jul 2014
Sample No: 10
Sample Date: 28 Apr 14
Lot No: 211100

Instrument: ASV Model 3010B

Analyte	Unit	Result	Mean	Z-score	RMZ	Comparator
✓ Lithium	mmol/L	0.54	0.502	1.13	0.24	Method

Instrument: Siemens ADVIA Centaur Systems

Analyte	Unit	Result	Mean	Z-score	RMZ	Comparator
✓ T3, Total	ng/mL	0.69	0.755	−0.89	0.11	Peer
✓ T4, Total	µg/dL	4.2	4.70	−1.31	−0.71	Peer
✓ TSH	mIU/L	1.02	1.03	−0.07	0.78	Peer

Instrument: Siemens Dimension Series

Analyte	Unit	Result	Mean	Z-score	RMZ	Comparator
✓ Albumin	g/dL	2.2	2.22	−0.43	0.14	Peer
✓ Alkaline Phosphatase	U/L	66	73.3	−0.80	−0.59	Peer
✓ ALT (ALAT/GPT)	U/L	534	550	−0.74	−0.17	Peer
✓ AST/GOT	U/L	507	537	−1.54	−0.50	Peer
✓ Bilirubin, Direct	mg/dL	0.27	0.290	−1.04	−0.76	Peer
✓ Bilirubin, Total	mg/dL	0.7	0.754	−0.96	−0.13	Peer
✓ Calcium	mg/dL	5.7	5.67	0.14	0.24	Peer
✓ Creatine Kinase	U/L	49	50.6	−0.53	−0.05	Peer
✓ Creatinine	mg/dL	0.91	0.972	−0.92	−1.37	Peer
✓ G-Glutamyltransferase	U/L	87	87.3	−0.10	0.71	Peer
✓ Glucose	mg/dL	602	598	0.24	0.69	Peer
✓ LDH	U/L	1254	1259	−0.09	0.33	Peer
✓ Magnesium	mg/dL	1.1	1.01	1.16	0.20	Peer
✓ Phosphorus	mg/dL	1.8	1.86	−0.68	0.36	Peer
✓ Protein, Total	g/dL	3.9	3.91	−0.11	−1.53	Peer
✓ Urea	mg/dL	15	14.4	0.59	−0.74	Peer
✓ Urea Nitrogen	mg/dL	7	6.80	0.33	−0.80	Peer
✓ Uric Acid	mg/dL	3.1	3.09	0.09	0.22	Peer

Legend: ✓ No Warnings Missing Result Late Results 2.0 ≤ |Z-score| < 3.0 ✗ |Z-score| ≥ 3.0
* Amended Result (per participant's request) * Non-robust determination of Mean and SD

Corrective Action:

Reviewed by: Date:

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EQAS is a trademark of Bio-Rad Laboratories, Inc.
Page 3 of 26
* Expanded uncertainty coverage factor, k=2
Printed on recyclable paper 28 Oct 2014

1 Header

This section shows the following information:

- Laboratory information
- Report name
- EQAS Program name
- Cycle number and cycle dates
- Sample number and sample due date
- Lot number (Cycle)

2 Summary of Data

This report provides a summary of performance for all results reported and registered for a particular sample. The report is sorted alphabetically by instrument.

The registered analytes are grouped by instrument. The first column shows a symbol for any exception. Use the legend at the bottom of the page for assistance with the symbols.
See “Exceptions” on page 32 for more information.

For each analyte with its corresponding unit, the report shows the result submitted, the comparator mean, your laboratory’s Z-score, Running Mean Z-score (RMZ), and the comparator. Use the following guidelines to interpret your performance for a test.

| Z-score |	Interpretation
0.0	Perfect comparison with consensus group.
≤ 2.0	Acceptable.
2.01 - 2.99	Warning. Investigation of the test system is recommended.
≥ 3.0	Unacceptable performance. Remedial action usually required.

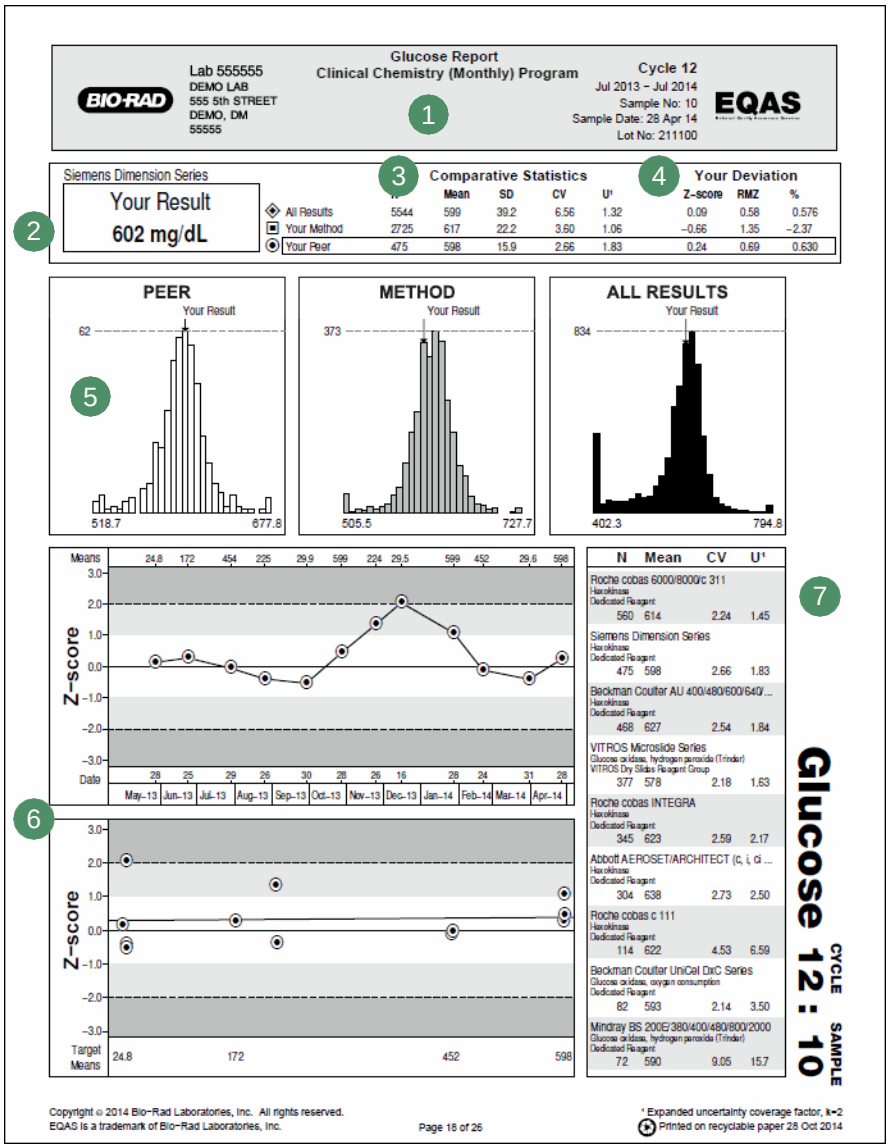
- RMZ
  The mean of the Z-scores over the last six samples for a given analyte.
- Comparator
  Indicates if the analyte was compared to Peer, Method, All Results, or Mode.

3 Problem Classifications

This section provides an area for the reviewer to add comments such as problem classification, corrective action, the reviewer’s name, and date of the review. Maintaining this type of information can be helpful in responding to external audits by providing objective evidence of the review and any actions taken.

Sample Report (Quantitative): Analyte Report

The fourth section of the Sample Report consists of the individual Analyte Reports. A separate page is provided for each registered analyte. Analytes that do not have a method registration on file are not included in the report.



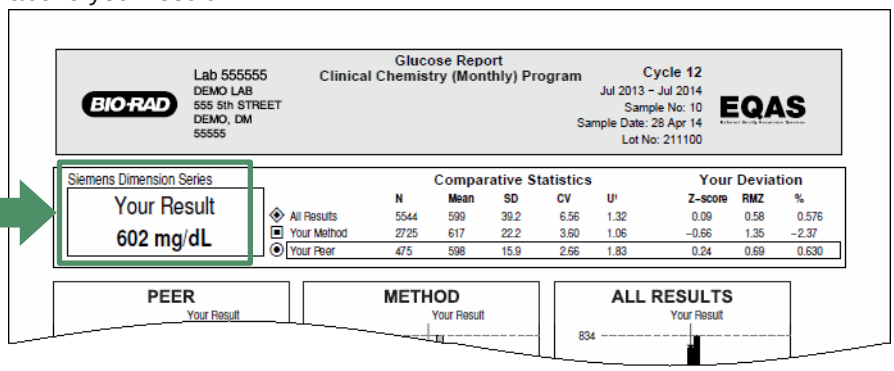
1 Header

This section shows the following information:

- Laboratory information
- Report name
- EQAS Program name
- Cycle number and cycle dates
- Sample number and sample due date
- Lot number (Cycle)

2 Your Result

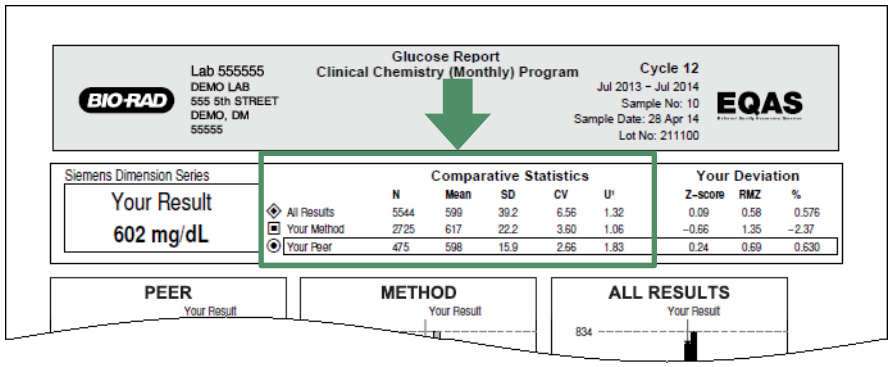
Your result is shown in the top left corner. A dash is shown in the “Your Result” section if a result for a registered test was not received or was unreportable. The unit of measure associated with your result determines the units for other Mean and Standard Deviation values displayed in the report. The peer group your result was compared against is shown above your result.



3 Comparative Statistics

This section shows the number of results received (N), robust estimates of the Mean and standard deviation (SD), the coefficient of variation (CV), and expanded uncertainty (U) of the mean. The data shown represents your comparative statistics for Peer, Method, and All Results or Mode, if applicable.

The comparator for your laboratory is shown by a boxed outline.



There are three levels of comparison. Ideally, your laboratory is compared to Your Peer, which is other laboratories using the same analyte, method, instrument, and reagent combination as yours. However, for a comparison to be made at the peer level there must be a minimum of 9 reported results for that test.

The next level of your result comparison is dependent on the data distribution, as uni-modal or multi-modal. A Mode is a collection of peer or method groups that yield a similar result. It may include various instruments and reagents for that test. If less than 9 results are received

for Your Peer, your comparison is Your Method for a uni-modal distribution or Your Mode for a multi-modal distribution of data. Your Method is other laboratories using the same analyte and method combinations for that test. However, for a comparison to be made at the method level there must be a minimum of 9 reported results for that uni-modal test. Finally, if there are less than 9 results received in the method you are compared to “All Results.” All Results is comprised of all laboratories using the same analyte as yours and will include other methods, instruments and reagent combinations for that test.

Uni-modal Distributions (All Results)

Symbol	Comparator	Description
◈	All Results	If fewer than 9 data points in your method group.
▣	Your Method	If fewer than 9 data points in your peer group and at least 9 data points in your method group.
◉	Your Peer	If there are at least 9 data points in your peer group.

Multi-modal Distributions

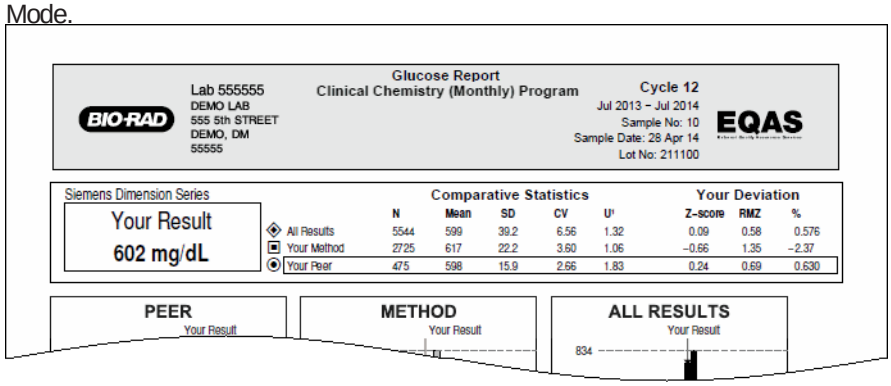
If reported results have a multi-modal distribution of data, results for a registered test are separated into different Modes.

Symbol	Comparator	Description
◈	Your Mode	If fewer than 9 data points in your peer group.
◉	Your Peer	If there are at least 9 data points in your peer group.

The comparative statistics for Your Method are provided for informational purposes only. As a given methodology may cross multiple modes, the variability observed at this comparator may be considerable.

4 Your Deviation

Shows the Z-score, RMZ, and the % (Deviation) from your Peer, Method, and All Results or Mode.



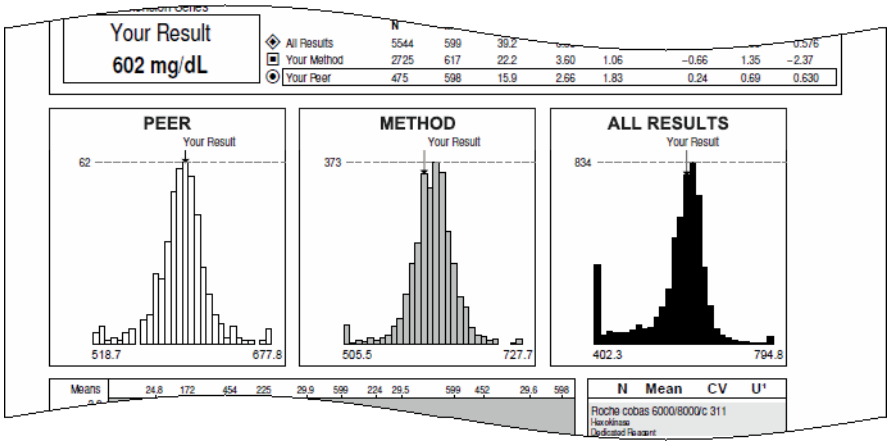
Note: See Chapter 8, “Statistics and Algorithms Used in EQAS Reports” and Chapter 10, “Glossary” for more information about the comparative statistics.

5 Histograms

This section shows three histograms:

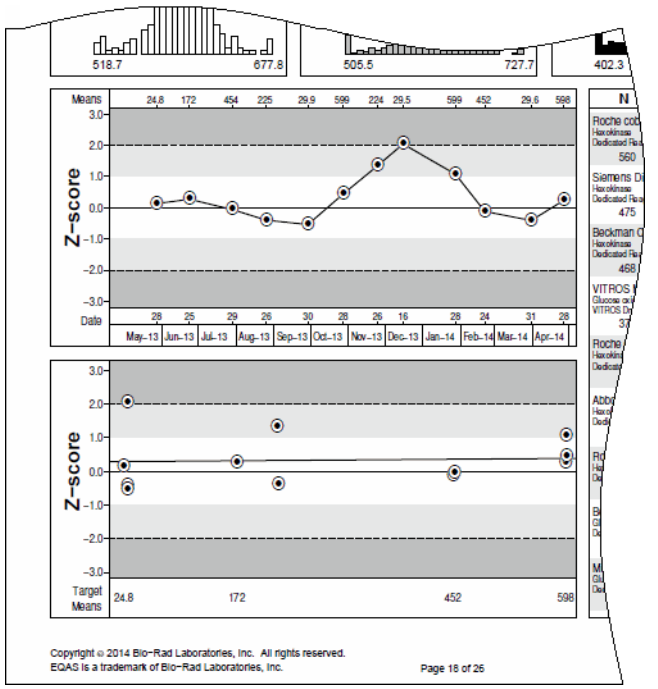
- Peer
- Method
- Mode or All Results

Each histogram shows the distribution of the results received for the sample. The number of participants in the tallest bar in each histogram is shown on the top left of the graph at the start of the horizontal line. Your Result is shown with an arrow in each comparator histogram. Arrows are not shown for late or amended results. The histograms show the lowest and highest reported values on the X-axis with a maximum of 5 SD. All lower or higher values are compressed into this 5 SD limit.



6 Z-score Trend Charts

Two charts plot your Z-score performance for each program sample. The Levey-Jennings Chart and Yundt Plot provide a visual representation of how well a test is working. Each chart shows a
-3 to +3 Z-score range. The optimal result is at the central zero line. Both charts show the last 12 samples and can be across two cycles. Any change to a specific test configuration only shows the data points for the updated configuration.



Levey-Jennings Chart

-1 to +1 Z-score (white)

-2 to +2 Z-score (light gray)

-3 to +3 Z-score (dark gray)

Yundt Plot

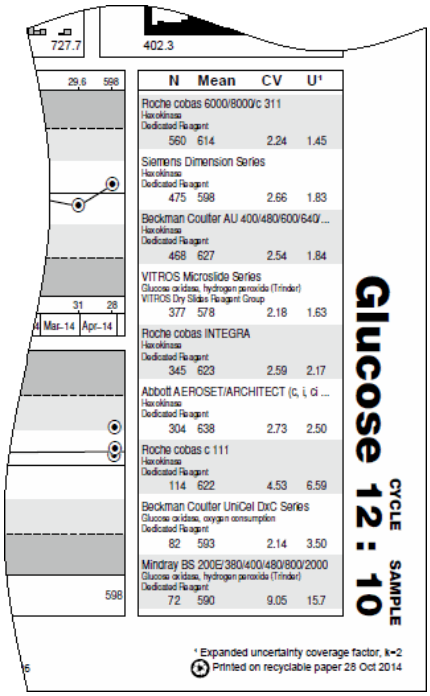
- Levey-Jennings Chart
  Sample dates are displayed along the bottom of this chart. The comparator mean for each sample date appears along the top of the chart. Your laboratory's comparator Z-score is plotted for each reported sample. The symbols for your Z-score indicate the comparator for a given sample. Z-score plots are connected for consecutive samples and disconnected if a result is missing. The Levey-Jennings Chart starts new with a change in your laboratory's test configuration.
- Yundt Plot
  The Yundt Plot shows your samples Z-scores, arranged by concentration of the reported samples along the bottom of the chart. A line of best fit is shown allowing for a determination of test bias by concentration of the samples analyzed.

7 Summary of Most Reported Peer Groups

This table shows the following statistics for 9 peer groups with the highest participation:

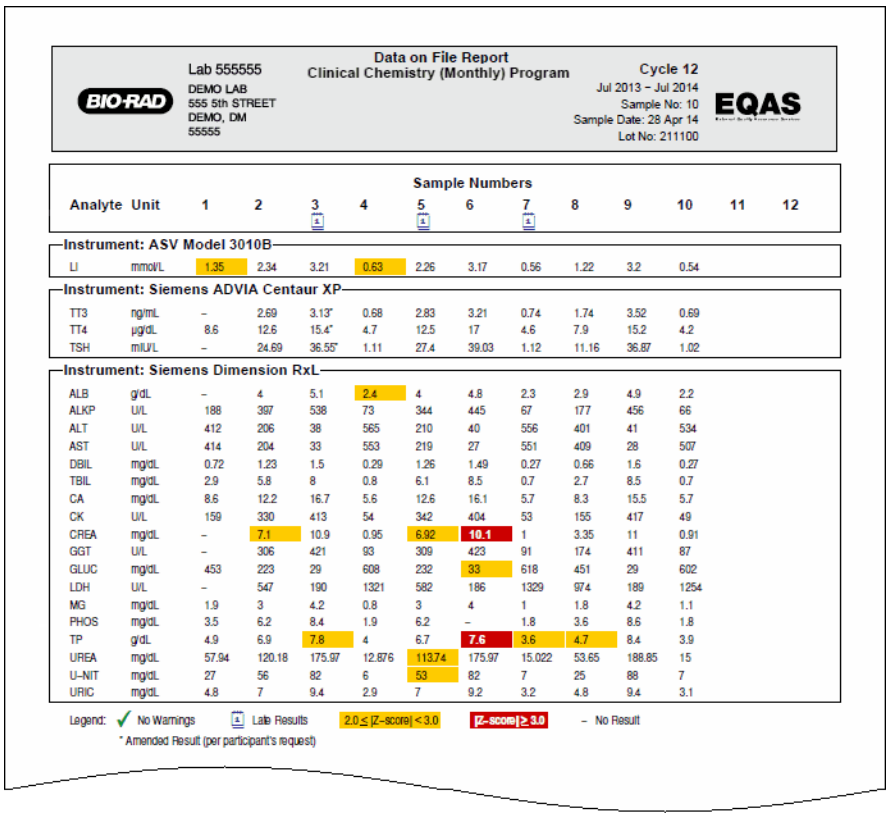
- Number of results received (N)
- Mean
- CV
- Expanded uncertainty (U)

The statistics shown are a result of grouping the results based on instrument, method, and reagent combination. If more than one reagent is associated with an instrument (dedicated and an alternate), it is possible for each to be shown if they are both highly reported on.



Sample Report (Quantitative): Data on File Report

The last section of the Sample Report is the Data on File Report. This report provides a summary of all results received to date within a cycle and is sorted alphabetically by instrument.



BIO-RAD

Lab 555555
DEMO LAB
555 5th STREET
DEMO, DM
55555

Data on File Report
Clinical Chemistry (Monthly) Program

Cycle 12
Jul 2013 – Jul 2014
Sample No: 10
Sample Date: 28 Apr 14
Lot No: 211100

EQAS

Analyte	Unit	Sample Numbers 1	2	3	4	5	6	7	8	9	10	11	12
Instrument: ASV Model 3010B													
LI	mmol/L	1.35	2.34	3.21	0.63	2.26	3.17	0.56	1.22	3.2	0.54		
Instrument: Siemens ADVIA Centaur XP													
TT3	ng/mL	–	2.69	3.13*	0.68	2.83	3.21	0.74	1.74	3.52	0.69		
TT4	µg/dL	8.6	12.6	15.4*	4.7	12.5	17	4.6	7.9	15.2	4.2		
TSH	mIU/L	–	24.69	36.55*	1.11	27.4	39.03	1.12	11.16	36.87	1.02		
Instrument: Siemens Dimension RxL													
ALB	g/dL	–	4	5.1	2.4	4	4.8	2.3	2.9	4.9	2.2		
ALKP	U/L	188	397	538	73	344	445	67	177	456	66		
ALT	U/L	412	206	38	565	210	40	556	401	41	534		
AST	U/L	414	204	33	553	219	27	551	409	28	507		
DBIL	mg/dL	0.72	1.23	1.5	0.29	1.26	1.49	0.27	0.66	1.6	0.27		
TBIL	mg/dL	2.9	5.8	8	0.8	6.1	8.5	0.7	2.7	8.5	0.7		
CA	mg/dL	8.6	12.2	16.7	5.6	12.6	16.1	5.7	8.3	15.5	5.7		
CK	U/L	159	330	413	54	342	404	53	155	417	49		
CREA	mg/dL	–	7.1	10.9	0.95	6.92	10.1	1	3.35	11	0.91		
GGT	U/L	–	306	421	93	309	423	91	174	411	87		
GLUC	mg/dL	453	223	29	608	232	33	618	451	29	602		
LDH	U/L	–	547	190	1321	582	186	1329	974	189	1254		
MG	mg/dL	1.9	3	4.2	0.8	3	4	1	1.8	4.2	1.1		
PHOS	mg/dL	3.5	6.2	8.4	1.9	6.2	–	1.8	3.6	8.6	1.8		
TP	g/dL	4.9	6.9	7.8	4	6.7	7.6	3.6	4.7	8.4	3.9		
UREA	mg/dL	57.94	120.18	175.97	12.876	113.74	175.97	15.022	53.65	188.85	15		
U-NIT	mg/dL	27	56	82	6	53	82	7	25	88	7		
URIC	mg/dL	4.8	7	9.4	2.9	7	9.2	3.2	4.8	9.4	3.1		

Legend: ✓ No Warnings Late Results 2.0 ≤ |Z-score| < 3.0 |Z-score| ≥ 3.0 – No Result
* Amended Result (per participant's request)

1 Header

This section shows the following information:

- Laboratory information
- Report name
- EQAS Program name
- Cycle number and cycle dates
- Sample number and sample due date
- Lot number (Cycle)

2 Sample Numbers

The results for each sample are shown in the column below the appropriate number.
A late symbol located below the sample number indicates that all results for that sample were
received after the close of the sample.

3 Results

This section shows all the sample results received up to the current sample. The results are shown by analyte and grouped by the instruments that you have registered. There are no calculated statistics in this report, only the results received in the cycle. Each sample is in a separate column and sample exceptions are indicated per the legend.

4 Legend

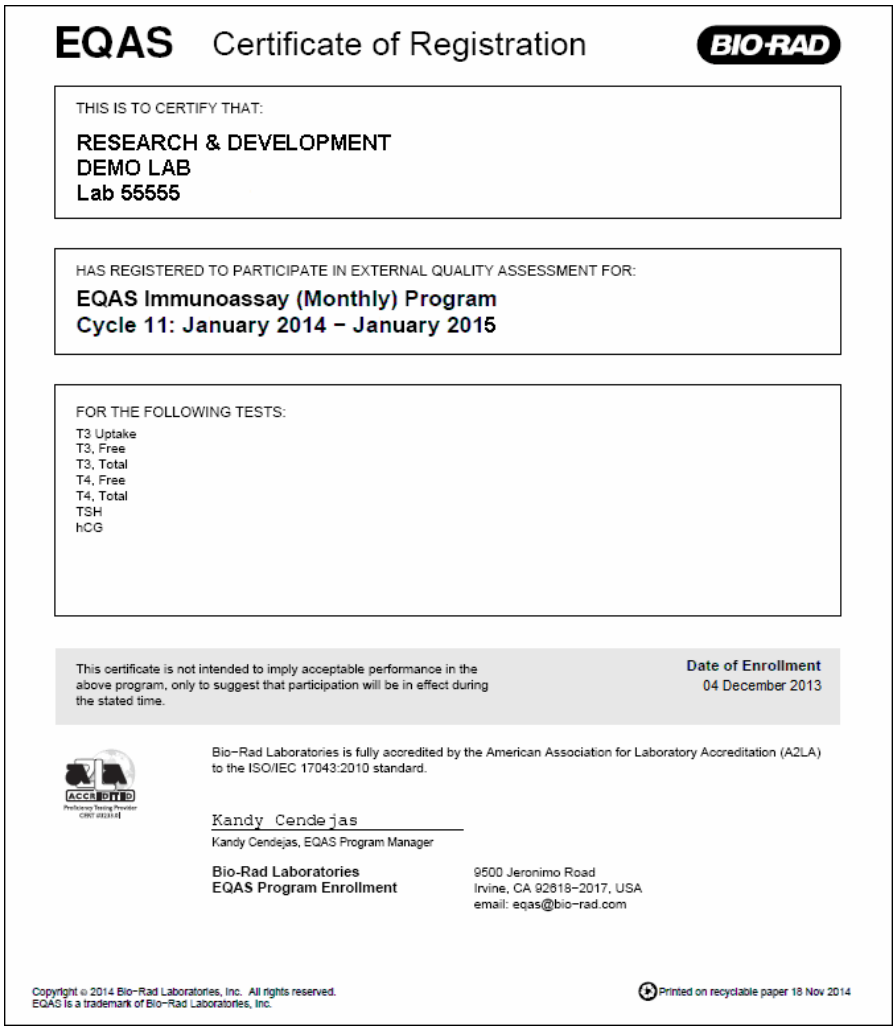
The legend at the lower part of the page describes the exception symbols and highlighted results.

Legend	
✓	No warnings All sample results for an analyte have been evaluated without any exceptions.
	Late results The result was received after the sample close date.
	2.0 ≤ |Z-score| < 3.0 Your absolute sample Z-score was greater than or equal to 2.0 and less than 3.0.
	|Z-score| ≥ 3.0 Your absolute sample Z-score was greater than or equal to 3.0.
–	No result No result or an Unreportable Result Code was received for a particular sample prior to the cycle close date.
*	Amended result (per participant's request) The result was edited by the EQAS participant after the sample close date.
J	Non-robust determination of mean and SD Indicates that the robust statistical process could not be used.

Sample Report (Quantitative): Certificate of Registration

The Certificate of Registration is for use by your laboratory as an official record that you have registered for and intend to participate in an EQAS Program for one cycle. The Certificate of Registration contains the Laboratory/Hospital Name and Department and the program and cycle information. It also shows all registered tests at the onset of the program cycle.

A Certificate of Registration is provided with your Sample 1 Report. If no tests have been configured for sample #1, then no certificate can be issued.



EQAS Certificate of Registration **BIO-RAD**

THIS IS TO CERTIFY THAT:

RESEARCH & DEVELOPMENT
DEMO LAB
Lab 55555

HAS REGISTERED TO PARTICIPATE IN EXTERNAL QUALITY ASSESSMENT FOR:

EQAS Immunoassay (Monthly) Program
Cycle 11: January 2014 – January 2015

FOR THE FOLLOWING TESTS:

T3 Uptake
T3, Free
T3, Total
T4, Free
T4, Total
TSH
hCG

This certificate is not intended to imply acceptable performance in the above program, only to suggest that participation will be in effect during the stated time.

Date of Enrollment
04 December 2013

Bio−Rad Laboratories is fully accredited by the American Association for Laboratory Accreditation (A2LA) to the ISO/IEC 17043:2010 standard.

Kandy Cendejas
Kandy Cendejas, EQAS Program Manager

Bio-Rad Laboratories
EQAS Program Enrollment

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email: eqas@bio−rad.com

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Printed on recyclable paper 18 Nov 2014

Sample Report (Qualitative)

The Qualitative Sample Report provides clear and concise information about your laboratory performance for qualitative tests in the form of histograms and modified Levey-Jennings charts. This report is provided for each sample and provides an easy to read summary and comparison of your laboratory's results.

There are two different Qualitative Sample Reports available:

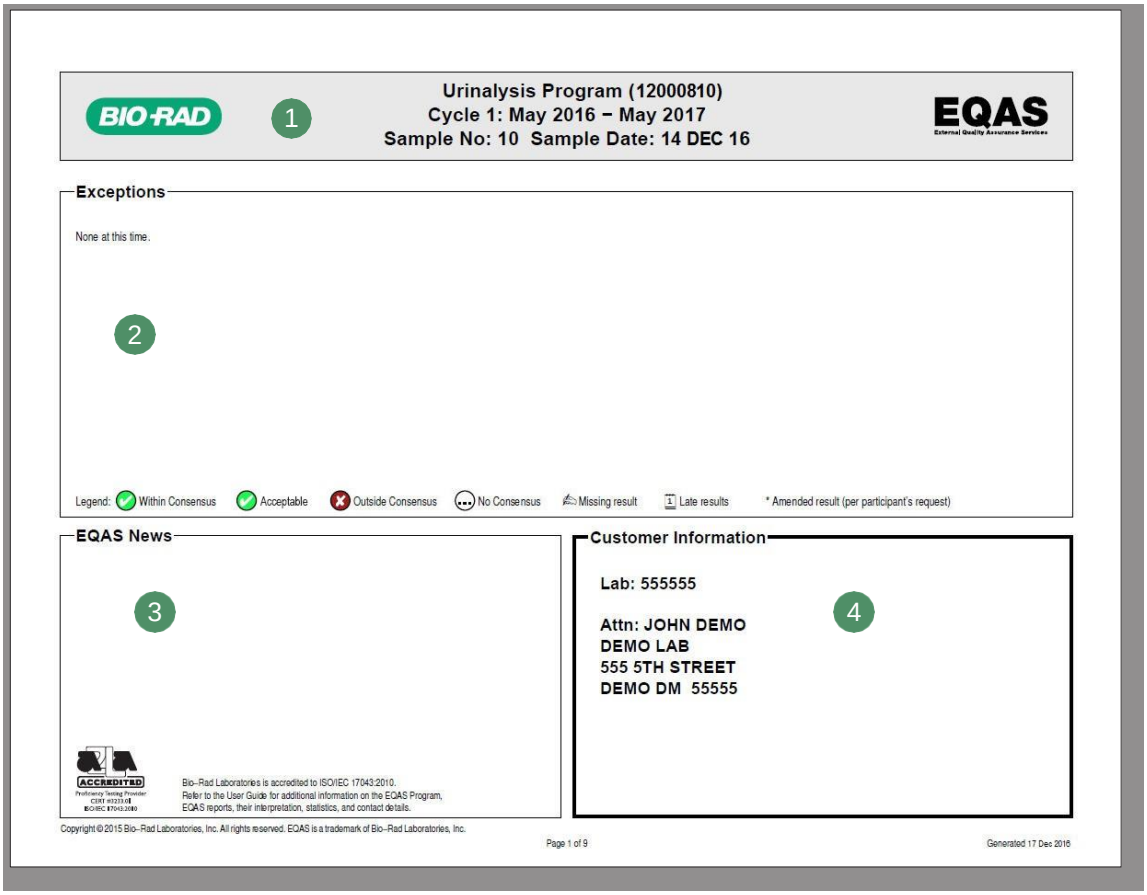
- Peer Qualitative Sample Report
  This report is used for EQAS Urinalysis and the infectious disease programs. It compares your laboratory's results to those of the peer group. The peer group consists of all labs that perform the test with the same instrument, method, and reagent as your lab.
- Peer-Method-All Results Qualitative Sample Result Report
  This report is used for the Blood Typing program. It compares your laboratory's results to those of your three comparators: the Peer, Method, and All Results groups.

Both Qualitative Sample Reports consist of the following main parts:

- Coversheet
- Configuration Report
- Sample Summary Report
- Analyte Report(s)
- Data on File Report
- Certificate of Registration (with Sample 1 Report Only)

Sample Report (Qualitative): Coversheet

The first page of the Qualitative Sample Report is the coversheet.



1 Header

This section shows the following information:

- EQAS Program name
- Cycle number and cycle dates
- Sample number
- Sample due date

2 Exceptions

This section provides a quick overview of any results that may require additional attention due to performance or information that is needed for proper submission. The legend located below the Exceptions describes the symbols used in this section and elsewhere in the report.

Legend	
	Within Consensus Your lab reported a result that is within consensus of at least 80% of your comparator group. This result would reflect a passing score.
	Acceptable Your lab reported a result that is immediately adjacent to the consensus bar for an analyte that has a minimum of 4 possible responses to choose from.
	Outside Consensus Your lab reported a result that is either outside consensus (≥ 80% of your comparator group), or is not considered acceptable. This result would reflect a failing score.
	No Consensus Your comparator group was inconclusive and did not reach an 80% consensus, or your comparator group consists of less than five results. This result would reflect an inconclusive score.
	Missing result A result is considered missing when a test registration is on file with Bio-Rad EQAS but no result was submitted for the sample.
	Late results
*	Amended result (per participant's request)

3 EQAS News

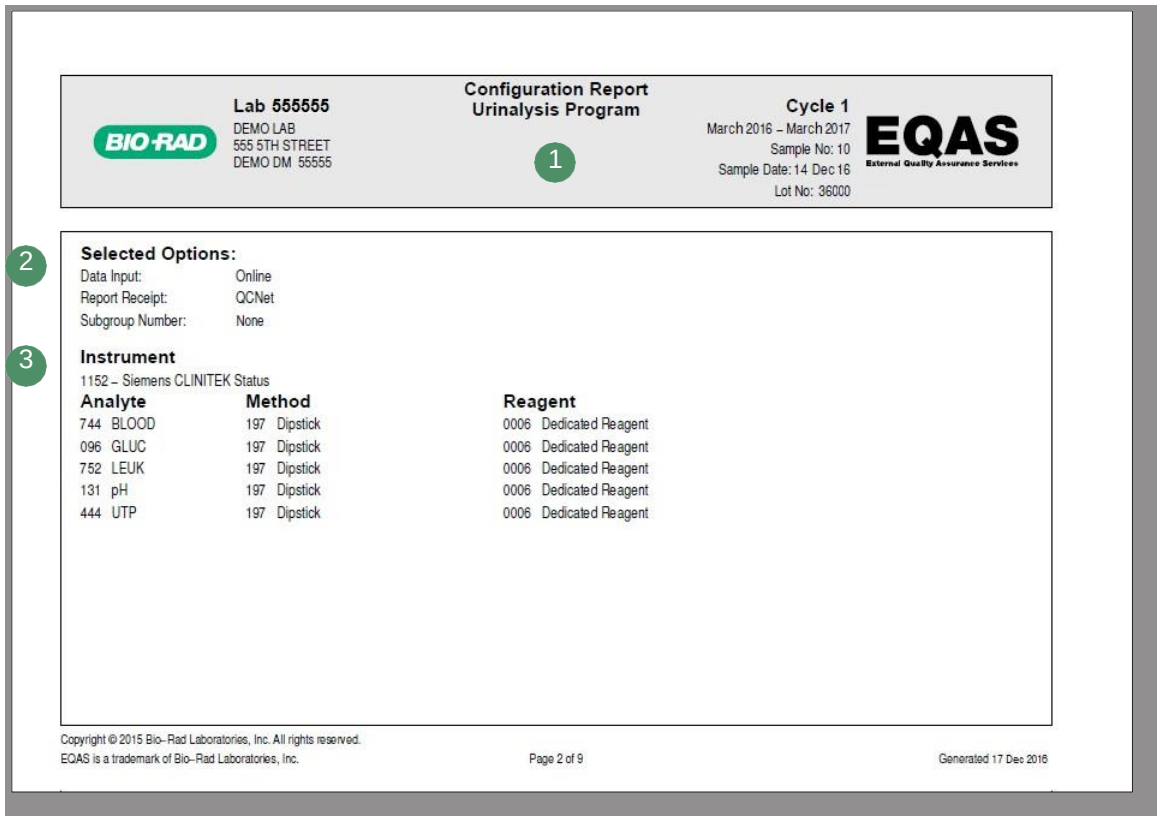
This section provides information, reminders, and news about the EQAS Program.

4 Customer Information

This section shows your Bio-Rad EQAS lab number and your laboratory's contact information.

Sample Report (Qualitative): Configuration Report

The second section of the Sample Report is the Configuration Report.



Lab 555555
DEMO LAB
555 5TH STREET
DEMO DM 55555

Configuration Report
Urinalysis Program

Cycle 1
March 2016 – March 2017
Sample No: 10
Sample Date: 14 Dec 16
Lot No: 36000

EQAS
External Quality Assurance Services

Selected Options:
Data Input: Online
Report Receipt: QCNet
Subgroup Number: None

Instrument
1152 – Siemens CLINITEK Status

Analyte	Method	Reagent
744 BLOOD	197 Dipstick	0006 Dedicated Reagent
096 GLUC	197 Dipstick	0006 Dedicated Reagent
752 LEUK	197 Dipstick	0006 Dedicated Reagent
131 pH	197 Dipstick	0006 Dedicated Reagent
444 UTP	197 Dipstick	0006 Dedicated Reagent

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Page 2 of 9
Generated 17 Dec 2016

1 Header

This section shows the following information:

- Laboratory information
- Report name
- EQAS Program name
- Cycle number and cycle dates
- Sample number and sample due date
- Lot number (Cycle)

2 Selected Options

This section shows the following items associated with your laboratory:

- Data Input
  The method by which Bio-Rad received your results for the sample.
- Report Receipt
  Your reports will be available through QCNet, unless otherwise requested through your local Bio-Rad representative.

- Subgroup Number (if applicable)
  If there is no subgroup association, it is noted as “None.”

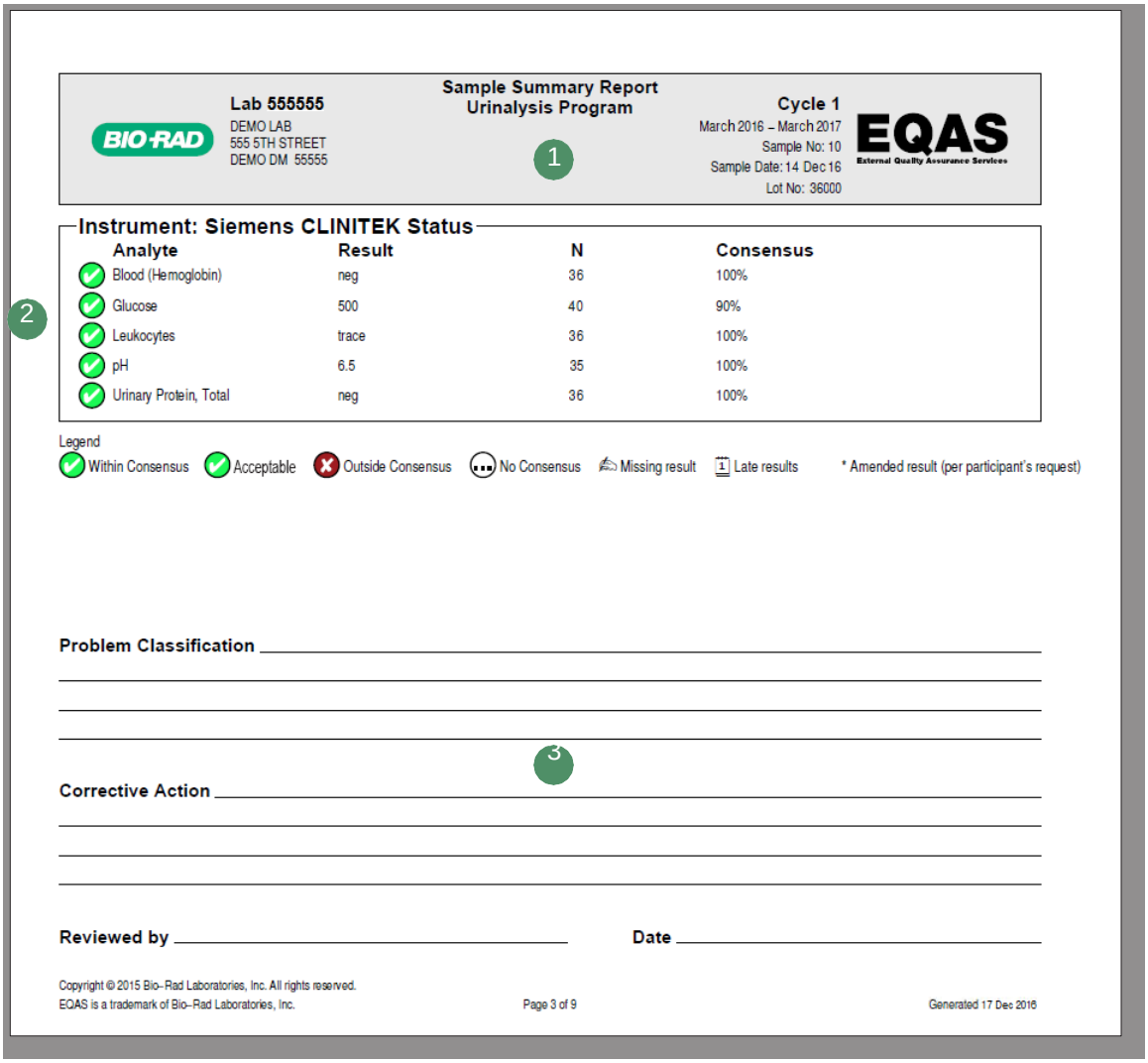
3 Instrument Configurations

This section shows a summary of your laboratory’s registered analytes and the test configurations (instrument, method, and reagent) applicable at the time of the sample close. The configurations are grouped alphabetically by instrument. Notice that no unit is listed as all qualitative programs use the same unit configuration (qualitative).

Note: This section provides an easy way to review your laboratory’s test configurations. The instrument code and description is shown with the codes and descriptions for analytes (abbreviations), methods, and reagents. It is important to verify that this information is correct when troubleshooting your results.

Sample Report (Qualitative): Sample Summary Report

The third section of the Qualitative Sample Report is the Sample Summary Report. The Sample Summary Report shows a summary of performance for all results reported and registered for a particular sample. The report is arranged alphabetically by tiered (grouped) instruments and analytes.



Lab 555555
DEMO LAB
555 5TH STREET
DEMO DM 55555

Sample Summary Report
Urinalysis Program

1

Cycle 1
March 2016 – March 2017
Sample No: 10
Sample Date: 14 Dec 16
Lot No: 36000

EQAS
External Quality Assurance Services

Instrument: Siemens CLINITEK Status

Analyte	Result	N	Consensus
Blood (Hemoglobin)	neg	36	100%
Glucose	500	40	90%
Leukocytes	trace	36	100%
pH	6.5	35	100%
Urinary Protein, Total	neg	36	100%

2

Legend
Within Consensus Acceptable Outside Consensus No Consensus Missing result Late results * Amended result (per participant's request)

Problem Classification _____

3

Corrective Action _____

Reviewed by _____ Date _____

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Page 3 of 9

Generated 17 Dec 2016

1 Header

This section shows the following information:

- Laboratory information
- Report name
- EQAS Program name
- Cycle number and cycle dates
- Sample number and sample due date
- Lot number (Cycle)

2 Summary of Data

This report provides a summary of performance for all results reported and registered for a particular sample. The report is sorted alphabetically by instrument and analyte.

The registered analytes are arranged by tiered (grouped) instruments. The first column shows a symbol for the qualitative evaluation. Use the legend at the bottom of the page for assistance with the symbols.

Legend	
	Within Consensus Your lab reported a result that is within consensus of at least 80% of your comparator group. This result would reflect a passing score.
	Acceptable Your lab reported a result that is immediately adjacent to the consensus bar for an analyte that has a minimum of 4 possible responses to choose from.
	Outside Consensus Your lab reported a result that is either outside consensus (≥ 80% of your comparator group), or is not considered acceptable. This result would reflect a failing score.
	No Consensus Your comparator group was inconclusive and did not reach an 80% consensus, or your comparator group consists of less than five results. This result would reflect an inconclusive score.
	Missing result A result is considered missing when a test registration is on file with Bio-Rad EQAS but no result was submitted for the sample.
	Late results
*	Amended result (per participant's request)

3 Problem Classification / Corrective Action

This section provides an area for the reviewer to add comments such as problem classification, corrective action, the reviewer's name, and date of the review. Maintaining this type of information can be helpful in responding to external audits by providing objective evidence of the review and any actions taken. This can be done electronically in the provided file (remember to save the file to your computer hard drive after adding comments) or written down on the printed report.

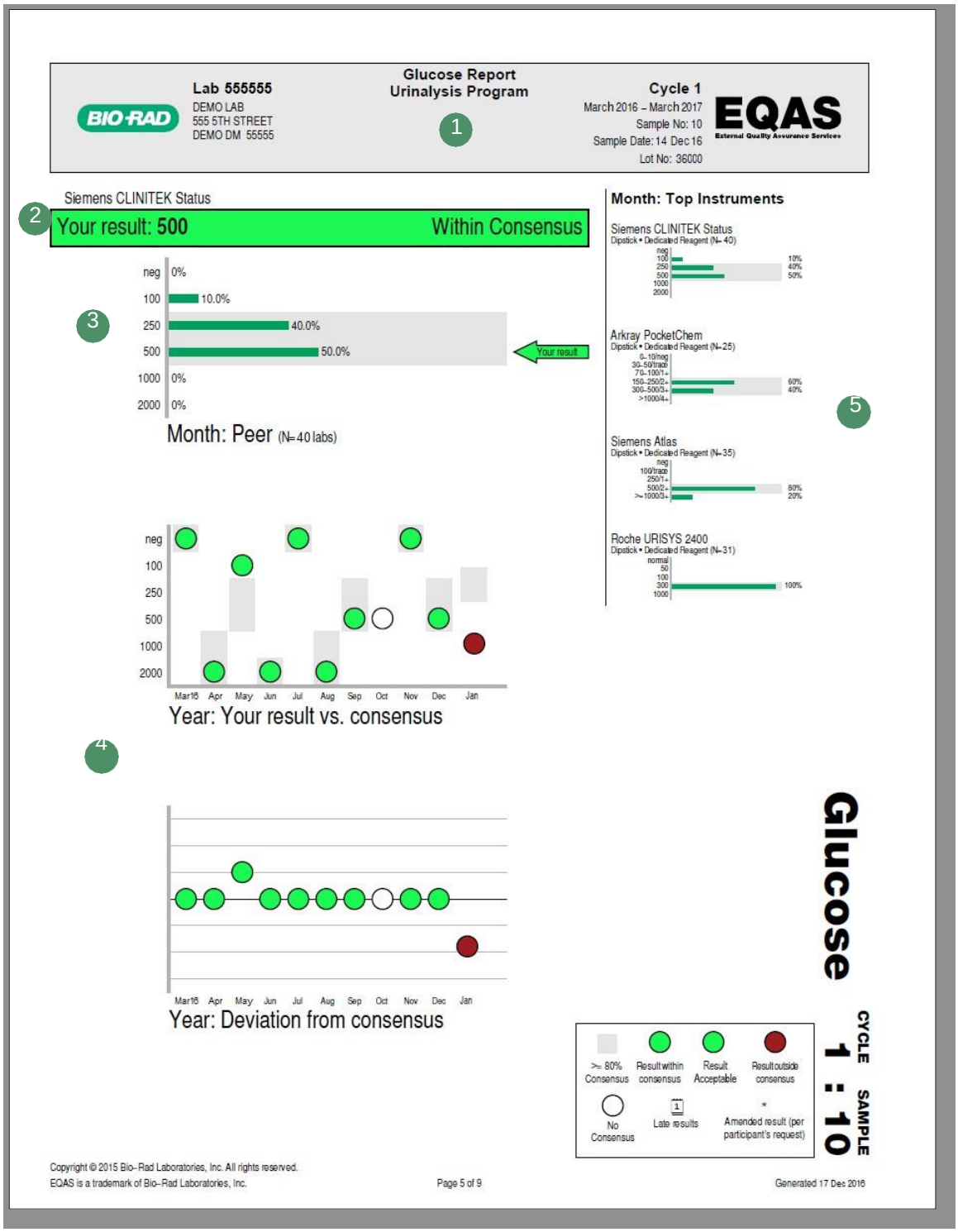
Sample Report (Qualitative): Analyte Report

The fourth section of the Qualitative Sample Report consists of the individual Analyte Reports. A separate page is provided for each registered analyte.

There are two different Analyte Reports available.

- Peer Qualitative Sample Report
  This report is used for EQAS Urinalysis and the infectious disease programs. It compares your laboratory's results to those of the peer group. The peer group consists of all labs that perform the test with the same instrument, method, and reagent as your lab.
- Peer-Method-All Results Qualitative Sample Result Report
  This report is used for the Blood Typing program. It compares your laboratory's results to those of your three comparators: the Peer, Method, and All Results groups.

Peer Qualitative Sample Report: Analyte Report



1 Header

This section shows the following information:

- Laboratory information
- Report name
- EQAS Program name
- Cycle number and cycle dates
- Sample number and sample due date
- Lot number (Cycle)

2 Your result

Your result is shown in the top left outlined box. If you reported a unreportable result, then “Unreportable” is shown here. The peer group your result was compared against is shown above the “Your result” box.

If your result was late, a late flag ( ) is shown in front of your result. If you amended your result or updated your test configuration after the sample close date, an amended flag (*) is shown at the right of your result.

Your analyte evaluation is shown at the right side of the “Your result” box and indicates how your result compared to the peer group. The “Your result” box also appears in the same color as your evaluation flag.

Legend	
	Within Consensus Your lab reported a result that is within consensus of at least 80% of your comparator group. This result would reflect a passing score.
	Acceptable Your lab reported a result that is immediately adjacent to the consensus bar for an analyte that has a minimum of 4 possible responses to choose from.
	Outside Consensus Your lab reported a result that is either outside consensus (≥ 80% of your comparator group), or is not considered acceptable. This result would reflect a failing score.
	No Consensus Your comparator group was inconclusive and did not reach an 80% consensus, or your comparator group consists of less than five results. This result would reflect an inconclusive score.
	Late results
*	Amended result (per participant’s request)

How is consensus calculated?

Bio-Rad uses the following formula to evaluate qualitative peer group consensus:

- Peer group consensus is reached if at least 80% or more of the reported results have the same response(s).
- Consensus can only be reached if 5 or more results are reported.
- Consensus can be reached with multiple responses, but only responses that are adjacent to each other (if a tie is reached when calculating consensus, then the lowest response will be selected).
- Consensus can never span across all responses.

Consensus Algorithm

1. Consensus starts with the response reporting the highest number of results.
2. If this response represents less then 80%, then the adjacent responses are evaluated and the response with the highest number of results is selected to be added to the consensus.
3. If this new consensus represents less then 80%, then the responses adjacent to this new consensus are evaluated and the response with the highest number of results is selected to be added to the consensus.
4. This process keeps repeating until 80% of results are reached or until all responses are reached which would result in No Consensus.

Examples:

Responses	Number of reported results	%	
Response 1	19	95	Consensus
Response 2	1	5	
Response 3	0	0	
Response 4	0	0	

Responses	Number of reported results	%	
Response 1	10	50	Consensus
Response 2	9	45	Consensus
Response 3	1	5	
Response 4	0	0	

Examples (continued)

Responses	Number of reported results	%	
Response 1	10	50	Consensus
Response 2	1	5	Consensus
Response 3	9	45	Consensus
Response 4	0	0	

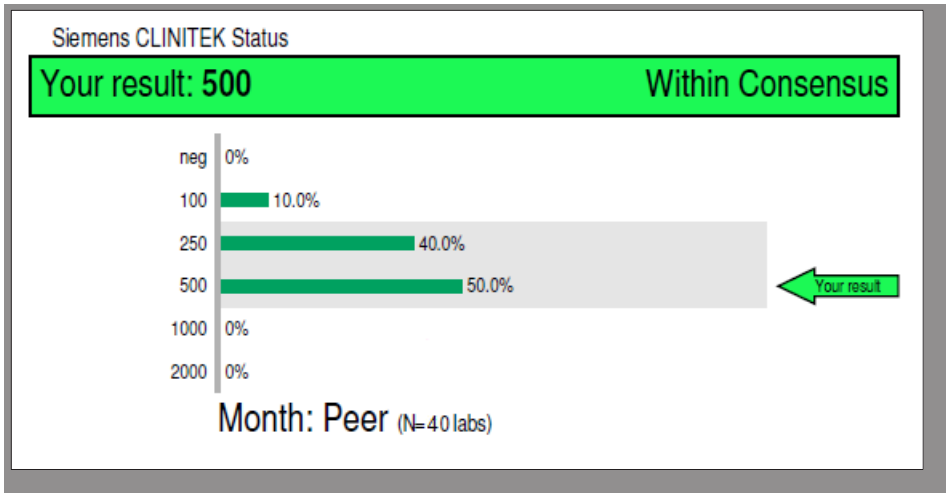
Responses	Number of reported results	%	
Response 1	3	100	
Response 2	0	0	No Consensus (N<5)
Response 3	0	0	
Response 4	0	0	

3 Peer Histogram

The peer (horizontal) histogram shows all possible responses on the left side. The green bar indicates the number of results reported for each response and is expressed as a percentage. The consensus is calculated and highlighted in grey. Your Result is shown with an arrow on the right side of the histogram.

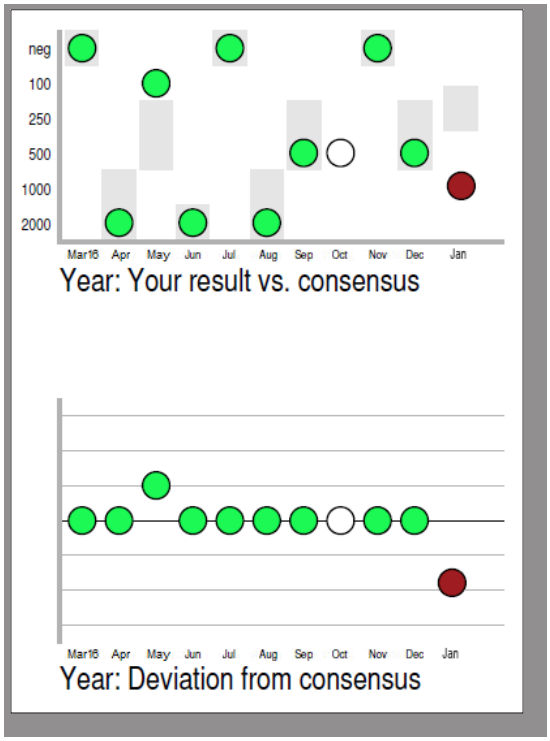
- If your result is within consensus, the arrow is colored in green.
- For analytes with a minimum of 4 possible responses, if your result is immediately adjacent to the consensus bar, the arrow is colored in green and considered acceptable.
- If your result is outside of consensus, or not acceptable, the arrow is colored in red.
- If no consensus was reached (or N <5), the arrow is not colored.

The legend below the histogram shows the Peer and the number of results received for this sample (N). If a reference value is available, it is shown below the Month: Peer legend.



4 Evaluation Trend Charts

Two charts will plot your performance for each sample. The charts show the last 12 samples and can span across cycles. Both charts provide a visual representation of test performance.



- Your Result vs. Consensus chart

  Sample dates are displayed along the bottom of this chart. The responses appear on the left side of this chart. Each sample result is represented as a colored circle placed at the
  corresponding response. A grey squared area represents the consensus responses found for each sample. The sample result circle will be colored using the color scheme as shown below. White or non-colored circles indicate Non Consensus samples or samples with less than 5 results in the peer group. The color scheme is helpful to identify any trends or systematic errors during the last 12 samples.

> = 80% Consensus	Result within consensus	Result Acceptable	Result outside consensus	No Consensus

- Deviation from Consensus chart:

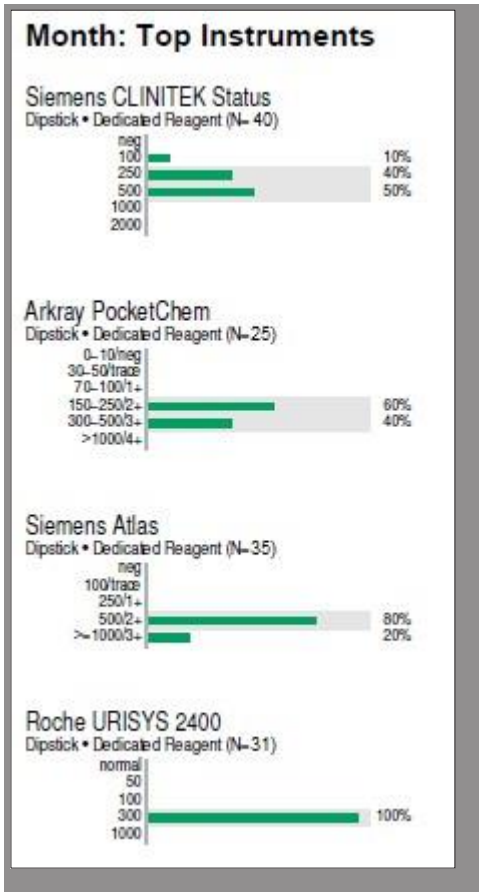
  Sample dates are displayed at the bottom of the chart. The laboratory's performance is plotted against the normalized consensus. The middle bold lines represent the consensus; the lines above or below the consensus line represent a single deviation above or below the consensus.

  Results within consensus will all be plotted on the middle consensus line. Results outside of consensus will be shown on the corresponding deviation lines.

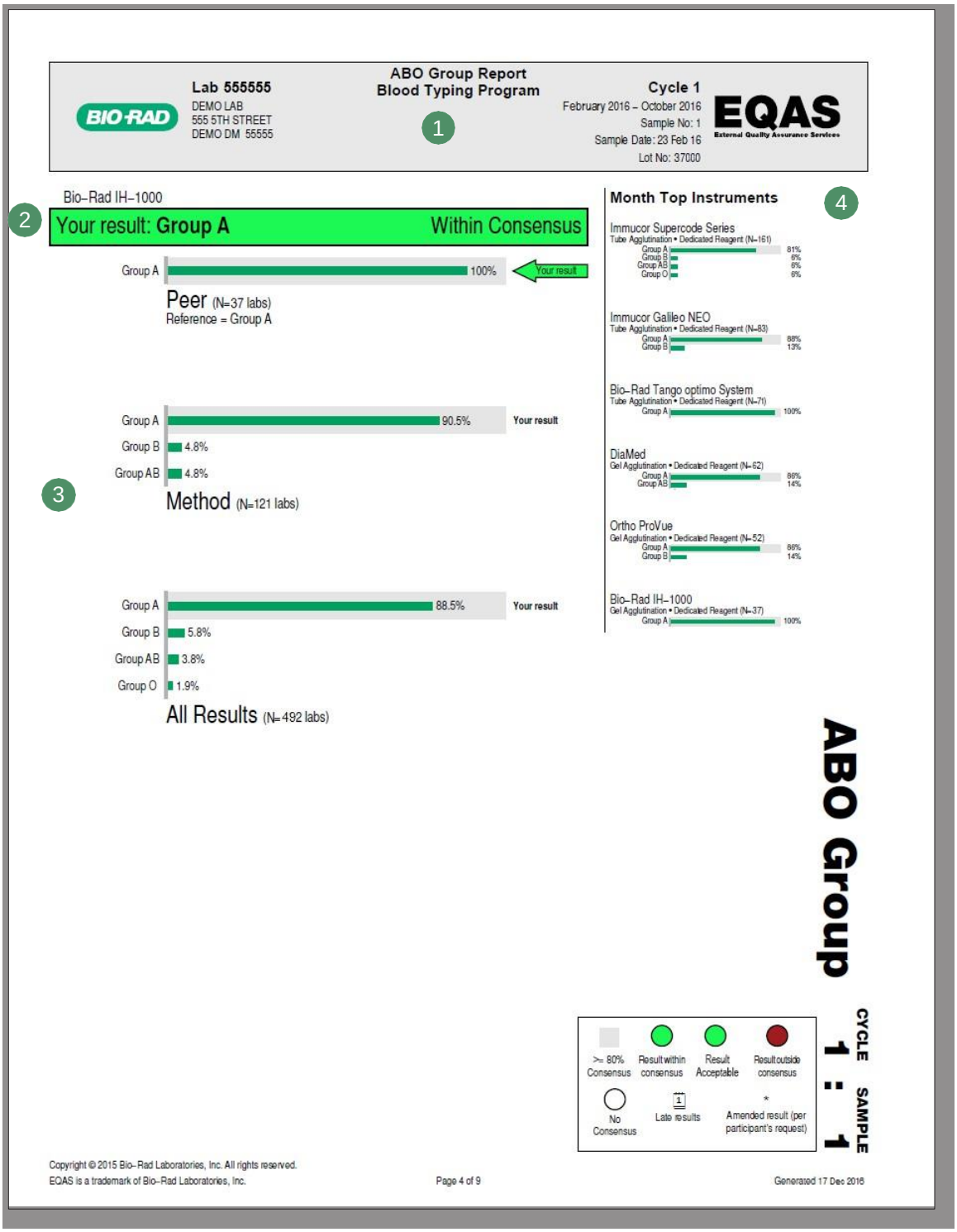
  When no consensus was reached or less than 5 results received, the circle will be displayed on the middle consensus line. The sample result circle will be colored using the color scheme as shown in the legend on the previous page. The color scheme is helpful to detect systematic errors across the different responses of the test.

5 Summary of Most Reported Peer Groups

This table shows a small peer histogram for up to 9 peer groups with the highest participation. The peer histogram shows the instrument, method, reagent name, and number of reported results (N).



Peer-Method-All Results Qualitative Sample Report: Analyte Report



1 Header

This section shows the following information:

- Laboratory information
- Report name
- EQAS Program name
- Cycle number and cycle dates
- Sample number and sample due date
- Lot number (Cycle)

2 Your Result

Your result is shown in the top left outlined box. If you reported a unreportable result then “Unreportable” will be displayed here. The peer group your result is part of is shown above the “Your result” box.

If your result was late, a late flag ( ) is shown in front of your result. If you amended your result or updated your test configuration after the sample close date an amended flag (*) will be displayed at the right of your result.

Your analyte evaluation is displayed at the right side of the “Your result” box and will indicate how your result compared to the peer group. The “Your result” box will also be displaying the same color as your evaluation flag.

Legend	
	Within Consensus
	Acceptable
	Outside Consensus
	No Consensus

How is consensus calculated?

Bio-Rad uses the following formula to evaluate qualitative Peer-Method-All Results consensus:

- Comparator group consensus is reached if at least 80% or more of the reported results have the same response.
- Consensus can only be reached if 5 or more results are reported.

▸ Note: Consensus can never span across multiple responses.

Examples:

Responses	Number of reported results	%	Consensus?
Response 1	19	95	Consensus
Response 2	1	5	
Response 3	0	0	
Response 4	0	0	

Responses	Number of reported results	%	
Response 1	10	50	No Consensus
Response 2	9	45	
Response 3	1	5	
Response 4	0	0	

Responses	Number of reported results	%	
Response 1	10	50	No Consensus
Response 2	1	5	
Response 3	9	45	
Response 4	0	0	

Responses	Number of reported results	%	
Response 1	3	100	No Consensus (N<5)
Response 2	0	0	
Response 3	0	0	
Response 4	0	0	

There are three levels of comparison. Ideally, your laboratory is compared to Your Peer, which is other laboratories using the same analyte, method, instrument, and reagent combination as yours. However, for a comparison to be made at the peer level there must be a minimum of 5 reported results for that test.

The next level of your result comparison is made at the Method level. The Method are all other laboratories using the same analyte and method as yours. However, for a comparison to be made at method level there must be a minimum of 5 reported results for that test.

If less than 5 results are received for both Peer and Method your laboratory will be compared to All Results. All Results is comprised of all laboratories using the same analyte as yours and will include other methods, instruments and reagent combinations for that test.

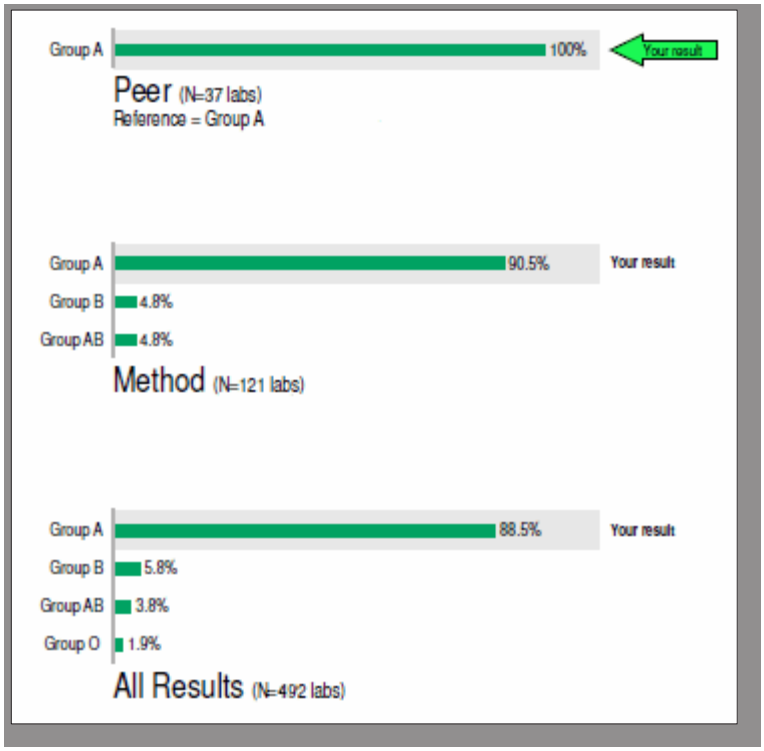
3 Comparator Histograms

The Peer-Method-All Results Qualitative Report consists of 3 comparator histograms. The Peer histogram on top followed by the Method histogram and finally the All Results histogram at the bottom of the page.

The comparator (horizontal) histogram displays only the reported responses on the left side. The green bar indicates the number of results reported for each response expressed as percentage. The consensus is calculated and highlighted in grey. Your Result is shown with an arrow on the right side of the histogram. If Your Result is Within Consensus the arrow will be colored in green, if your results is outside of consensus the arrow will be colored in red and if no consensus was reached (or N <5) the arrow will not be colored. The arrow indicates the comparator level your laboratory is compared against. If Your result is listed without arrow it is just displayed for your information but not used as primary evaluation.

The legend below the histogram will display the comparator name and the number of results received for this sample (N).

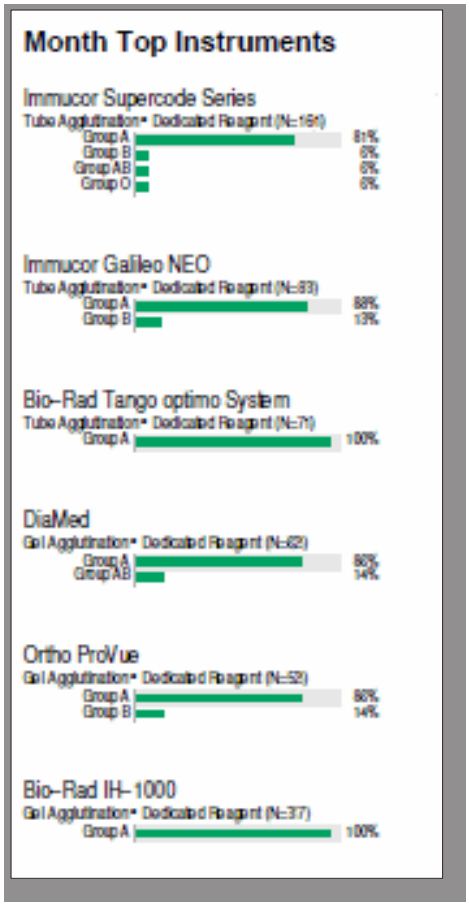
If a reference value is available it will be displayed below the Peer legend.



- Important note: Responses for which no results have been received (N=0) will not be listed in the histograms. The responses for the Peer-Method-All Results qualitative reports are listed sorted from highest percentage to lowest (with a maximum of 8 responses displayed). If more than 8 responses are received the lowest reported responses will be grouped together as “Other.”

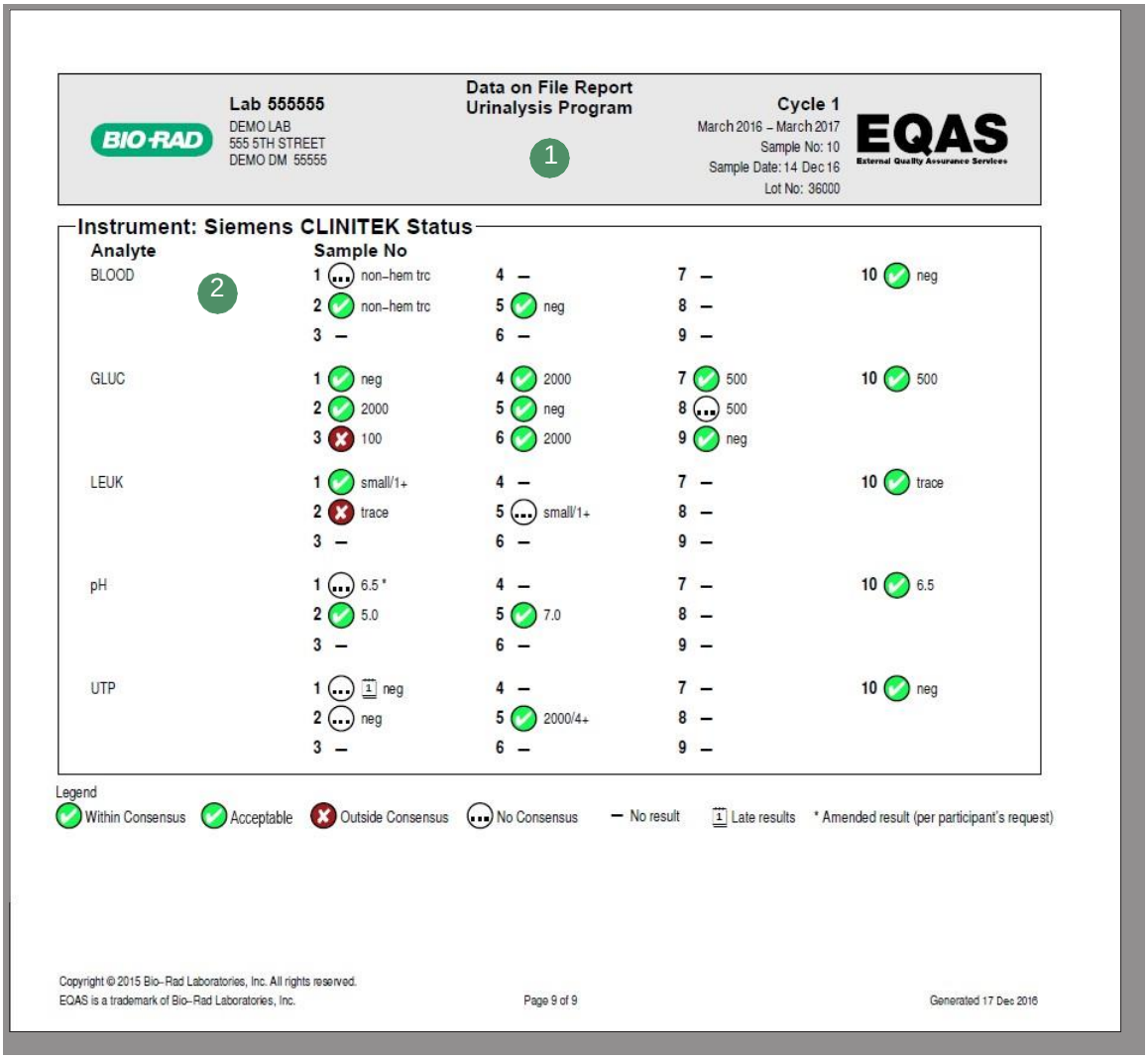
4 Summary of Most Reported Peer Groups

This table shows a small peer histogram for up to 9 peer groups with the highest participation. The peer histogram displays the instrument, method and reagent name and number of reported results (N).



Sample Report (Qualitative): Data on File Report

The last section of the Qualitative Sample Report is the Data on File Report. This report provides a summary of all results received to date within a cycle and is sorted alphabetically by instrument.



BIO-RAD

Lab 555555
DEMO LAB
555 5TH STREET
DEMO DM 55555

Data on File Report
Urinalysis Program

1

Cycle 1
March 2016 – March 2017
Sample No: 10
Sample Date: 14 Dec 16
Lot No: 36000

EQAS
External Quality Assurance Services

Instrument: Siemens CLINITEK Status

Analyte	Sample No									
BLOOD	1	non–hem trc	4	–	7	–	10	neg		
2	2	non–hem trc	5	neg	8	–				
	3	–	6	–	9	–				
GLUC	1	neg	4	2000	7	500	10	500		
	2	2000	5	neg	8	500				
	3	100	6	2000	9	neg				
LEUK	1	small/1+	4	–	7	–	10	trace		
	2	trace	5	small/1+	8	–				
	3	–	6	–	9	–				
pH	1	6.5 *	4	–	7	–	10	6.5		
	2	5.0	5	7.0	8	–				
	3	–	6	–	9	–				
UTP	1	1 neg	4	–	7	–	10	neg		
	2	neg	5	2000/4+	8	–				
	3	–	6	–	9	–				

Legend
Within Consensus · Acceptable · Outside Consensus · No Consensus · – No result · 1 Late results · * Amended result (per participant's request)

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Page 9 of 9

Generated 17 Dec 2016

1 Header

This section shows the following information:

- Laboratory information
- Report name
- EQAS Program name
- Cycle number and cycle dates
- Sample number and sample due date
- Lot number (Cycle)

2 Analyte Details

Analytes are grouped by tiered (grouped) instrument. The sample numbers to date are displayed and sorted in groups of three. Your result is shown next to the corresponding sample number with display of the evaluation flag. When your result is late, a late flag ( ) will be displayed in front of your result. If you amended your result or updated your test configuration after the sample close date an amended flag (*) will be displayed at the right of your result.

3 Legend

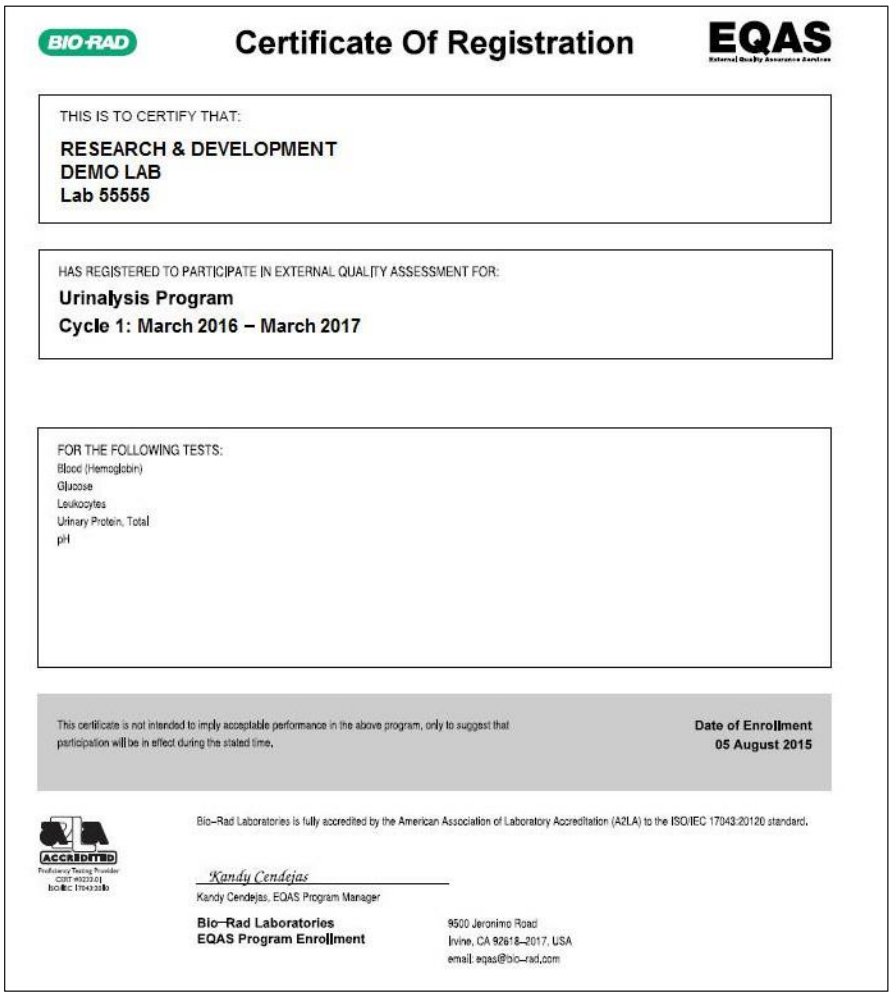
The legend at the lower part of the page describes the symbols.

Legend	
	Within Consensus Your lab reported a result that is within consensus of at least 80% of your comparator group. This result would reflect a passing score.
	Acceptable Your lab reported a result that is immediately adjacent to the consensus bar for an analyte that has a minimum of 4 possible responses to choose from.
	Outside Consensus Your lab reported a result that is either outside consensus (≥ 80% of your comparator group), or is not considered acceptable. This result would reflect a failing score.
	No Consensus Your comparator group was inconclusive and did not reach an 80% consensus, or your comparator group consists of less than five results. This result would reflect an inconclusive score.
–	No result No result or an Unreportable Result (UR) was received for a particular sample prior to the cycle close date.
	Late results
*	Amended result (per participant's request)

Sample Report (Qualitative): Certificate of Registration

The Certificate of Registration is for use by your laboratory as an official record that you have registered for and intend to participate in an EQAS Program for one cycle. The Certificate of Registration contains the Laboratory/Hospital Name and Department and the program and cycle information. It also shows all registered tests at the onset of the program cycle.

A Certificate of Registration is provided with your Sample 1 Report. If no tests have been configured for sample #1, then no certificate can be issued.



BIO-RAD

Certificate Of Registration

EQAS

THIS IS TO CERTIFY THAT:

RESEARCH & DEVELOPMENT
DEMO LAB
Lab 55555

HAS REGISTERED TO PARTICIPATE IN EXTERNAL QUALITY ASSESSMENT FOR:

Urinalysis Program
Cycle 1: March 2016 – March 2017

FOR THE FOLLOWING TESTS:
Blood (Hemoglobin)
Glucose
Leukocytes
Urinary Protein, Total
pH

This certificate is not intended to imply acceptable performance in the above program, only to suggest that participation will be in effect during the stated time.

Date of Enrollment
05 August 2015

ACCREDITED

Bio–Rad Laboratories is fully accredited by the American Association of Laboratory Accreditation (A2LA) to the ISO/IEC 17043:20120 standard.

Kandy Cendejas
Kandy Cendejas, EQAS Program Manager

Bio–Rad Laboratories
EQAS Program Enrollment

9500 Jeronimo Road
Irvine, CA 92618–2017, USA
email: eqas@bio–rad.com

Quality Specification Report (Quantitative)

Note: The Quality Specification Report is only available through EQAS Online. This report does not replace the EQAS Program Sample Report or End-Of-Cycle Report.

The Quality Specification Report offers laboratories an additional evaluation of results for their EQAS program based on local regulatory or scientific specifications.

In the new Quality Specification Report, a laboratory may assess their EQA test performance based on the quality specification of their choice. Performance in this report is based on the percent deviation of the reported test result. A laboratory may generate their Quality Specification Report for each sample reported on.

Bio-Rad offers the following specifications for the report:

- RiLiBÄK
- CLIA
- CLIA 2024
- RCPA
- Biological Variation or BV (minimum, desirable and optimum)
- GOST (Russia)
- IQMH (Canada)
- WS/T (China)
- NCCL EQA (China)
- TEa (Turkey)
- SEKK
- COBJwDL (Poland)
- IPH (Belgium)
- EMC (Spain)
- BCQ 2024
- BC DAP

If your region or country has regulatory or scientific specifications that are freely available to use, please contact eqas_support@bio-rad.com to have them added.

Create a Quality Specification Report

1 Log on to your EQAS Online account.

2 Point to Reports and click My EQAS Reports.

3 Select the Lab ID (lab number), Program Name, and Cycle from the respective lists.

4 Select the Quality Specification Report from the Report Type list.

5 Select the Sample and Specification from the respective lists.

- Note: You can only select one specification at a time for a sample. If you want to view multiple specifications for the same sample, you must create different reports and print or save each report.

The report is generated on the EQAS Online page.

Interpret the Quality Specification Report

All Quality Specification Reports are based on the same evaluation process. The percentage deviation (also shown in the statistical Sample Report) is calculated for each analyte.

Calculate the percentage deviation (%):

$$\% = \frac{\text{Your Result - Comparator Mean}}{\text{Comparator Mean}} \times 100$$

The comparator selection is based on the same process as the Sample Report and is shown in the report.

Uni-modal Distributions (All Results)

Symbol	Comparator	Description
◈	All Results	If fewer than 9 data points in your method group.
▣	Your Method	If fewer than 9 data points in your peer group and at least 9 data points in your method group.
◉	Your Peer	If there are at least 9 data points in your peer group.

Multi-modal Distributions

If reported results have a multi-modal distribution of data, results for a registered test are separated into different Modes.

Symbol	Comparator	Description
▣	Your Mode	If fewer than 9 data points in your peer group.
◉	Your Peer	If there are at least 9 data points in your peer group.

The Quality Specification is displayed as percentage.

- When your (absolute) percentage deviation is less than the specification, the symbol ✓ is displayed to the left of the analyte name. (See “Example: Percentage Specification” on page 71 below.)
- If your (absolute) percentage deviation is greater than the specification, the symbol X is displayed to the left of the analyte name. (See “Example: Failed Analyte” on page 72.)

Quality Specifications may be presented in a guidance document as absolute values or even Standard Deviations, but the Quality Specification Report will always calculate the percentage value of this specification (based on the comparator mean) and display it accordingly.

When a Quality Specification is not available, a – (dash) is displayed in the specification field. (See “Example: No Quality Specification Available” on page 72.)

Quality Specification Report Examples

Example: Percentage Specification

Analyte: Albumin

CLIA Criteria for acceptable performance: ± 10%

Roche MODULAR

	Analyte	Unit	Result	Mean	Comparator	Deviation	CLIA
✓	Albumin	g/L	24	24.6	Peer	-2.49%	10%

Example: Absolute Specification Based on Concentration

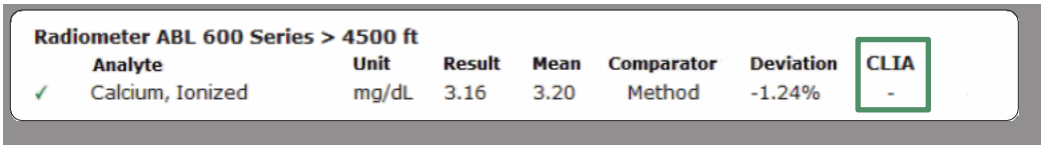
Analyte: Albumin

RCPA Criteria for acceptable performance: +/- 2.0 g/L for values up to 33 g/L

Roche MODULAR

	Analyte	Unit	Result	Mean	Comparator	Deviation	RCPA
✓	Albumin	g/L	24	24.6	Peer	-2.49%	8.13%

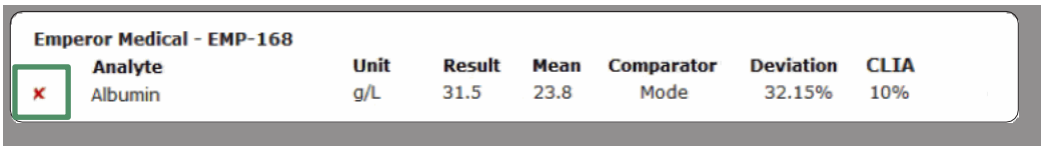
Example: No Quality Specification Available



Radiometer ABL 600 Series > 4500 ft

	Analyte	Unit	Result	Mean	Comparator	Deviation	CLIA
✓	Calcium, Ionized	mg/dL	3.16	3.20	Method	-1.24%	-

Example: Failed Analyte

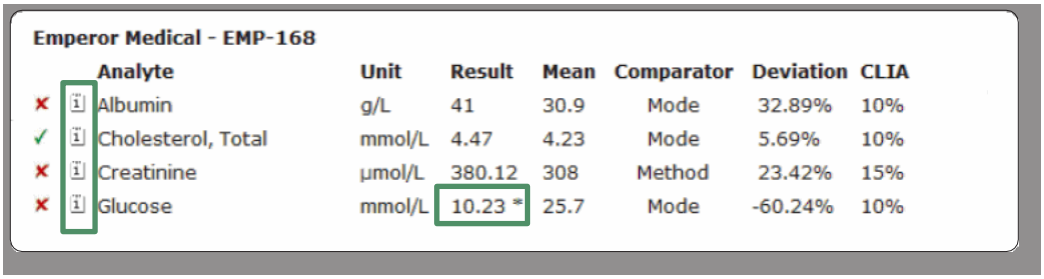


Emperor Medical - EMP-168

	Analyte	Unit	Result	Mean	Comparator	Deviation	CLIA
✘	Albumin	g/L	31.5	23.8	Mode	32.15%	10%

Example: Late and Amended Flags for Results

Late and amended (*) flags are shown for results.



Emperor Medical - EMP-168

		Analyte	Unit	Result	Mean	Comparator	Deviation	CLIA
✘	i	Albumin	g/L	41	30.9	Mode	32.89%	10%
✓	i	Cholesterol, Total	mmol/L	4.47	4.23	Mode	5.69%	10%
✘	i	Creatinine	µmol/L	380.12	308	Method	23.42%	15%
✘	i	Glucose	mmol/L	10.23 *	25.7	Mode	-60.24%	10%

Quality Specification Subgroup Report (Quantitative)

This report combines elements of the Subgroup Report (page 94) together with performance evaluations against select Quality Specifications (page 69). Subgroup leaders may use this report to view performance of their labs in a single Excel worksheet.

- Note: This report does not replace the EQAS Program Sample Report or End-of-Cycle Report.

How to Access Quality Specification Subgroup Reports

1 Navigate to the EQAS Reports page in EQAS Online and select the Quality Specification Subgroup Report from the drop down menu.

2 Select the desired specification and wait for the report to download (the report will download in a new page which can be closed again after download).

3 The Excel file may be saved locally.

Quality Specification Subgroup Report Example

The report initially shows the default Subgroup report header, which displays the program, cycle, and sample details. The Quality Specification Subgroup Report opens up as the first report from the left and displays the lab number, lab name, and all test configuration fields (analyte, instrument, method, reagent, and unit), followed by the Quality Specification fields (result, mean, comparator, % deviation, and the selected Quality Specification). Failed tests are highlighted in red.

D36 | Rayto RT-9200

Bio-Rad Laboratories

Clinical Chemistry (Monthly) Program

Cycle: 12 Sample: 12 Sample Date: 02 March 2018

Quality Specification Subgroup Report

Lab	Lab Name	Analyte	Instrument	Method	Reagent	Unit	Result	Mean	Comparator	% Deviation	BV Desirable	Result
250539	Lab 1	Chloride	Medica EasyLyte/Expand	ISE direct	Dedicated Reagent	mmol/L	101	105.97	Peer	-4.69%	1.47%	101
250539	Lab 1	Cholesterol, Total	Awareness Technology Stat Fax 3300	Cholesterol oxidase, esterase, peroxidas	Chema Diagnostica	mmol/L	5.8	6.79	Peer	-14.58%	9.01%	5.8
250539	Lab 1	Creatinine	Awareness Technology Stat Fax 3300	Alkaline picrate-kinetic rate blanked	Biochemical Diagnostics	µmol/L	477.36	632.43	Method	-24.52%	8.87%	477.36
250539	Lab 1	Glucose	Awareness Technology Stat Fax 3300	Glucose oxidase, hydrogen peroxide (Tri	Biochemical Diagnostics	mmol/L	12.4	11.98	Peer	3.49%	6.96%	12.4
250539	Lab 1	Potassium	Medica EasyLyte/Expand	ISE direct	Dedicated Reagent	mmol/L	4.24	4.44	Peer	-4.50%	5.61%	4.24
250539	Lab 1	Sodium	Medica EasyLyte/Expand	ISE direct	Dedicated Reagent	mmol/L	147.4	145.93	Peer	1.01%	0.73%	147.4
250539	Lab 1	Urea Nitrogen	Awareness Technology Stat Fax 3300	Urease, UV	Chema Diagnostica	mmol/L	16.5	21.72	Peer	-24.05%	-	16.5
250539	Lab 1	Uric Acid	Awareness Technology Stat Fax 3300	Uricase, colorimetric	Chema Diagnostica	mmol/L	0.39	0.41	Peer	-4.60%	11.97%	0.39
250723	Lab 2	Cholesterol, Total	Cormay Accent 200	Cholesterol oxidase, esterase, peroxidas	P.Z. CORMAY	mmol/L	5.88	6.88	Mode	-14.53%	9.01%	5.88
250723	Lab 2	Creatinine	Cormay Accent 200	Alkaline picrate-kinetic	P.Z. CORMAY	µmol/L	533.05	618.43	Method	-13.81%	8.87%	533.05
250723	Lab 2	Glucose	Cormay Accent 200	Glucose oxidase, hydrogen peroxide (Tri	P.Z. CORMAY	mmol/L	12.13	12.32	Method	-1.55%	6.96%	12.13
250723	Lab 2	Urea Nitrogen	Cormay Accent 200	Urease, UV	P.Z. CORMAY	mmol/L	19.06	20.95	Method	-9.02%	-	19.06
250723	Lab 2	Uric Acid	Cormay Accent 200	Uricase, colorimetric	P.Z. CORMAY	mmol/L	0.45	0.42	Method	7.06%	11.97%	0.45
425882	Lab 3	Albumin	Roche cobas c 311	Bromcresol Green (BCG)	Dedicated Reagent	g/L	42.9	42.93	Peer	-0.06%	4.07%	42.9
425882	Lab 3	Chloride	Roche cobas c 311	ISE indirect	Dedicated Reagent	mmol/L	96.7	96.29	Peer	0.42%	1.47%	96.7
425882	Lab 3	Cholesterol, Total	Roche cobas c 311	Cholesterol oxidase, esterase, peroxidas	Dedicated Reagent	mmol/L	7.12	6.83	Peer	4.27%	9.01%	7.12
425882	Lab 3	Creatinine	Roche cobas c 311	Alkaline picrate-kinetic rate blanked,IFC	Dedicated Reagent	µmol/L	652	649.94	Peer	0.32%	8.87%	652
425882	Lab 3	Glucose	Roche cobas c 311	Hexokinase	Dedicated Reagent	mmol/L	12.69	12.33	Peer	2.93%	6.96%	12.69
425882	Lab 3	Potassium	Roche cobas c 311	ISE indirect	Dedicated Reagent	mmol/L	4.61	4.59	Peer	0.40%	5.61%	4.61
425882	Lab 3	Protein, Total	Roche cobas c 311	Biuret, no serum blank, end point	Dedicated Reagent	g/L	67.7	65.97	Peer	2.62%	3.63%	67.7
425882	Lab 3	Sodium	Roche cobas c 311	ISE indirect	Dedicated Reagent	mmol/L	148	147.30	Peer	0.48%	0.73%	148
425882	Lab 3	Urea	Roche cobas c 311	Urease, UV	Dedicated Reagent	mmol/L	20.88	20.53	Peer	1.70%	15.55%	20.88
425882	Lab 3	Uric Acid	Roche cobas c 311	Uricase, colorimetric	Dedicated Reagent	µmol/L	434.4	416.75	Peer	4.23%	11.97%	434.4

The regular Subgroup Report appears in the right hand columns, where red rows indicate either missing results or results that fall outside 2.0 |Z-score|.

Subgroup

Result	Submitted Unit	Converted Result	Converted Unit	Comparator	Comparator Z-score	RMZ	Peer N	Peer Mean	Peer SD	Peer CV	Peer Uncertainty	Method N	Method Mean	Method SD	Method CV	Method Uncertain
101	mmol/L	101.000	mEq/L	Peer	-1.570	0.070	322	105.97	3.17	2.99	0.44	1546	103.79	3.78	3.64	0.24
5.8	mmol/L	224.285	mg/dL	Peer	-1.170	-0.430	18	262.57	32.78	12.48	19.31	5298	264.20	12.93	4.90	0.44
477.36	µmol/L	5.400	mg/dL	Method	-4.070	-1.320	1	5.40	0.00	0.00	0.00	232	7.15	0.43	6.02	0.07
12.4	mmol/L	223.423	mg/dL	Peer	0.370	0.425	10	215.90	20.15	9.33	15.93	2620	222.01	13.36	6.02	0.65
4.24	mmol/L	4.240	mEq/L	Peer	-1.560	0.382	397	4.44	0.13	2.88	0.02	1927	4.56	0.16	3.53	0.01
147.4	mmol/L	147.400	mEq/L	Peer	0.430	1.033	400	145.93	3.44	2.36	0.43	1928	147.47	3.47	2.35	0.20
16.5	mmol/L	46.218	mg/dL	Peer	-1.090	0.430	9	60.85	13.40	22.02	11.17	1754	58.68	3.64	6.21	0.22
0.39	mmol/L	6.610	mg/dL	Peer	-0.550	0.150	15	6.93	0.58	8.33	0.37	4624	7.12	0.40	5.57	0.01
5.88	mmol/L	227.378	mg/dL	Mode	-3.460	-2.565	3	255.09	29.26	11.47	42.23	5298	264.20	12.93	4.90	0.44
533.05	µmol/L	6.030	mg/dL	Method	-1.270	-0.870	2	5.71	0.51	8.99	0.91	2239	7.00	0.76	10.86	0.04
12.13	mmol/L	218.559	mg/dL	Method	-0.260	-0.973	3	219.32	1.01	0.46	1.46	2620	222.01	13.36	6.02	0.65
19.06	mmol/L	53.389	mg/dL	Method	-1.450	-1.627	2	46.11	11.68	25.33	20.65	1754	58.68	3.64	6.21	0.22
0.45	mmol/L	7.627	mg/dL	Method	1.270	0.790	3	7.45	0.30	4.01	0.22	4624	7.12	0.40	5.57	0.01
42.9	g/L	4.290	g/dL	Peer	-0.020	-0.142	467	4.29	0.11	2.62	0.01	2960	4.20	0.20	4.82	0.01
96.7	mmol/L	96.700	mEq/L	Peer	0.200	-0.045	443	96.29	2.02	2.10	0.24	2175	99.74	2.86	2.87	0.15
7.12	mmol/L	275.329	mg/dL	Peer	1.920	0.565	544	264.06	5.87	2.22	0.63	5298	264.20	12.93	4.90	0.44
652	µmol/L	7.376	mg/dL	Peer	0.100	0.163	219	7.35	0.23	3.11	0.04	398	7.39	0.30	4.03	0.04
12.69	mmol/L	228.649	mg/dL	Peer	1.250	0.062	571	222.14	5.23	2.35	0.55	2833	222.78	6.22	2.79	0.29
4.61	mmol/L	4.610	mEq/L	Peer	0.220	-0.158	462	4.59	0.08	1.82	0.01	2291	4.55	0.09	1.90	0.00
67.7	g/L	6.770	g/dL	Peer	1.130	0.305	43	6.60	0.15	2.32	0.06	943	6.68	0.19	2.78	0.02
148	mmol/L	148.000	mEq/L	Peer	0.330	-0.228	459	147.30	2.15	1.46	0.25	2289	146.90	2.54	1.73	0.13
20.88	mmol/L	125.783	mg/dL	Peer	0.640	0.867	482	123.68	3.28	2.65	0.37	2593	125.75	5.48	4.36	0.27
434.4	µmol/L	7.363	mg/dL	Peer	1.680	0.878	543	7.06	0.18	2.53	0.02	4624	7.12	0.40	5.57	0.01
52.2	g/L	5.220	g/dL	Mode	4.680	1.857	2	4.74	0.78	16.37	1.37	2960	4.20	0.20	4.82	0.01

Method Uncertainty	Mode N	Mode Mean	Mode SD	Mode CV	Mode Uncertainty	UR	UR Name	% Deviation	Late	Amended
0.24	3849	101.19	3.34	3.30	0.13	-	-	-4.69%	No	No
0.44	4959	265.02	11.16	4.20	0.40	-	-	-14.58%	No	No
0.07	5755	7.23	0.57	7.88	0.02	-	-	-24.52%	No	No
0.65	5798	222.36	8.84	3.98	0.29	-	-	3.49%	No	No
0.01	4340	4.55	0.12	2.74	0.00	-	-	-4.50%	No	No
0.20	4329	147.09	3.04	2.07	0.12	-	-	1.01%	No	No
0.22	2582	58.03	4.47	7.71	0.22	-	-	-24.05%	No	No
0.01	5496	7.13	0.37	5.24	0.01	-	-	-4.60%	No	No
0.44	4959	265.02	11.16	4.20	0.40	-	-	-14.53%	No	No
0.04	5755	7.23	0.57	7.88	0.02	-	-	-13.81%	No	No
0.65	5798	222.36	8.84	3.98	0.29	-	-	-1.55%	No	No
0.22	2582	58.03	4.47	7.71	0.22	-	-	-9.02%	No	No
0.01	5496	7.13	0.37	5.24	0.01	-	-	7.06%	No	No
0.01	3800	4.15	0.23	5.48	0.01	-	-	-0.06%	No	No
0.15	3849	101.19	3.34	3.30	0.13	-	-	0.42%	No	No
0.44	4959	265.02	11.16	4.20	0.40	-	-	4.27%	No	No
0.04	5755	7.23	0.57	7.88	0.02	-	-	0.32%	No	No
0.29	5798	222.36	8.84	3.98	0.29	-	-	2.93%	No	No
0.00	4340	4.55	0.12	2.74	0.00	-	-	0.40%	No	No

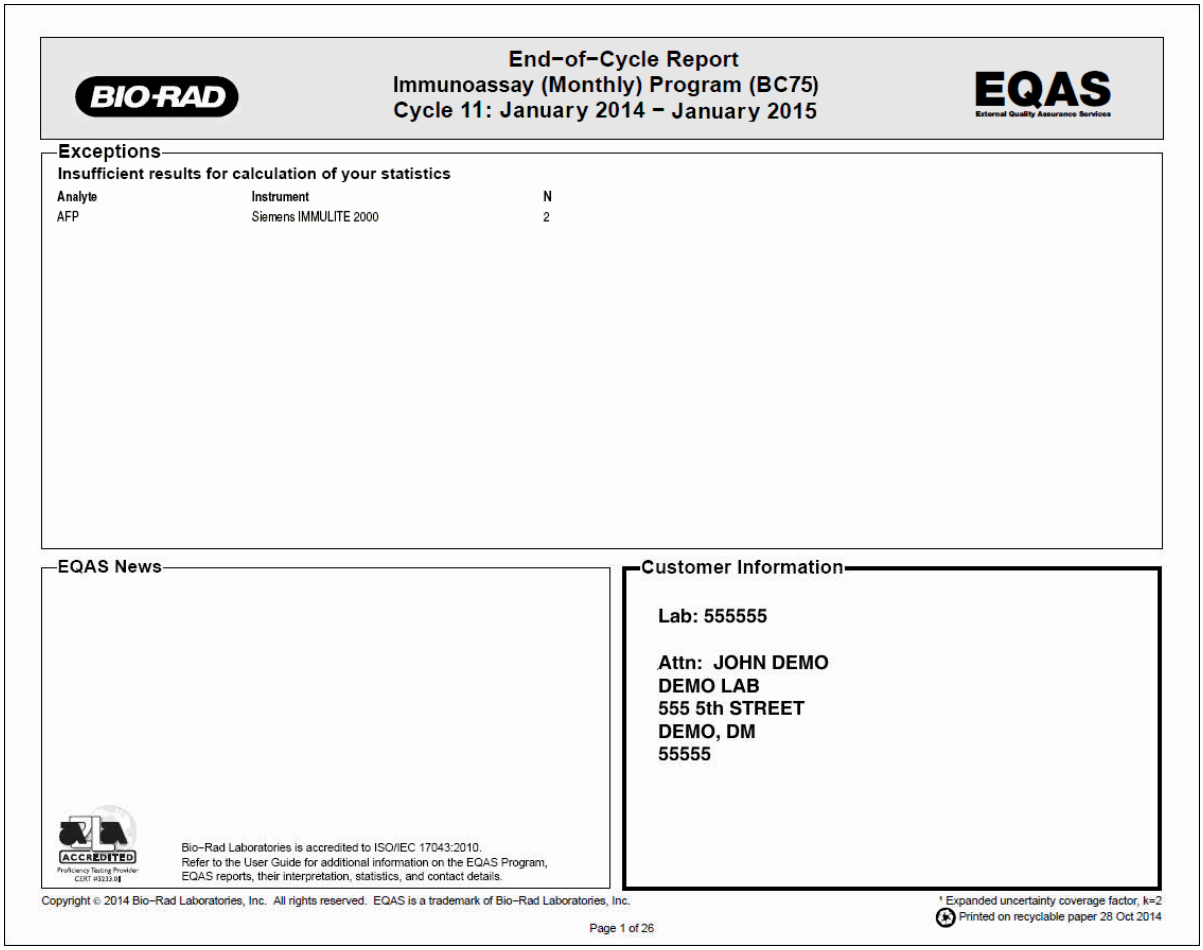
End-of-Cycle Report (Quantitative)

The End-of-Cycle Report consists of four main parts:

- Coversheet
- Cycle Data on File Report
- Analyte Summary Report
- Mean Z-score Report

End-of-Cycle Report (Quantitative): Coversheet

The first page of the End-of-Cycle Report is the Coversheet.



BIO-RAD

End-of-Cycle Report
Immunoassay (Monthly) Program (BC75)
Cycle 11: January 2014 – January 2015

EQAS
External Quality Assurance Services

Exceptions

Insufficient results for calculation of your statistics

Analyte	Instrument	N
AFP	Siemens IMMULITE 2000	2

EQAS News

ACCREDITED
Proficiency Testing Provider
CERT #3333.01

Bio-Rad Laboratories is accredited to ISO/IEC 17043:2010.
Refer to the User Guide for additional information on the EQAS Program, EQAS reports, their interpretation, statistics, and contact details.

Customer Information

Lab: 555555

Attn: JOHN DEMO
DEMO LAB
555 5th STREET
DEMO, DM
55555

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[1] Expanded uncertainty coverage factor, k=2
Printed on recyclable paper 28 Oct 2014

1 Header

This section shows the following information:

- EQAS Program name

- Cycle number and cycle dates

2 Exceptions

This section shows all analytes with fewer than 9 results reported during the cycle. Although the End-of-Cycle Report provides some statistical analysis, Bio-Rad highly recommends that each laboratory submit at least 9 results per analyte per cycle. Nine samples is also the minimum number of reported results needed to be eligible to receive a Certificate of Achievement for the cycle. (See “Certificate of Achievement” on page 27 for more information.)

3 EQAS News

This section is used to communicate specific EQAS Program related news to participants.

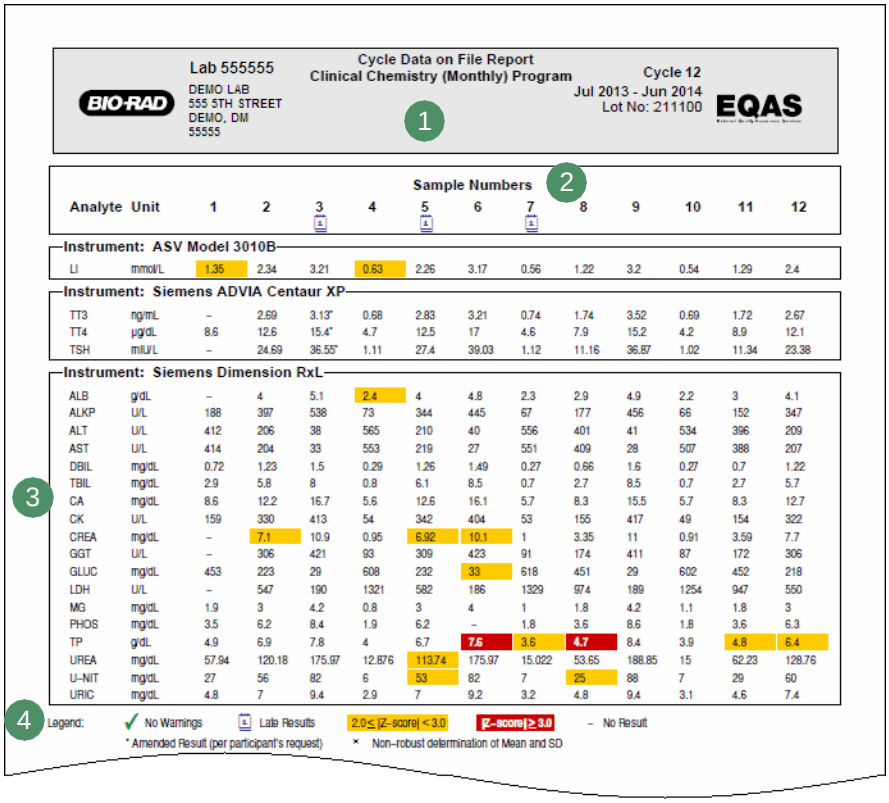
4 Customer Information

This section shows your Bio-Rad lab number and your laboratory information.

End-of-Cycle Report (Quantitative): Cycle Data on File Report

The second section of the End-of-Cycle Report is the Cycle Data on File Report.

Important: The End-of-Cycle Report shows the recalculated statistics with all participants' late and amended data included in the data set. Due to this recalculation, your evaluation may be different from the original sample statistics.



Lab 555555
DEMO LAB
555 5TH STREET
DEMO, DM
55555

Cycle Data on File Report
Clinical Chemistry (Monthly) Program

Cycle 12
Jul 2013 - Jun 2014
Lot No: 211100

Analyte	Unit	Sample 1	2	3	4	5	6	7	8	9	10	11	12
Instrument: ASV Model 3010B													
LI	mmol/L	1.35	2.34	3.21	0.63	2.26	3.17	0.56	1.22	3.2	0.54	1.29	2.4
Instrument: Siemens ADVIA Centaur XP													
TT3	ng/mL	–	2.69	3.13*	0.68	2.83	3.21	0.74	1.74	3.52	0.69	1.72	2.67
TT4	µg/dL	8.6	12.6	15.4*	4.7	12.5	17	4.6	7.9	15.2	4.2	8.9	12.1
TSH	mIU/L	–	24.69	36.55*	1.11	27.4	39.03	1.12	11.16	36.87	1.02	11.34	23.38
Instrument: Siemens Dimension RxL													
ALB	g/dL	–	4	5.1	2.4	4	4.8	2.3	2.9	4.9	2.2	3	4.1
ALKP	U/L	188	397	538	73	344	445	67	177	456	66	152	347
ALT	U/L	412	206	38	565	210	40	556	401	41	534	396	209
AST	U/L	414	204	33	553	219	27	551	409	28	507	388	207
DBIL	mg/dL	0.72	1.23	1.5	0.29	1.26	1.49	0.27	0.66	1.6	0.27	0.7	1.22
TBIL	mg/dL	2.9	5.8	8	0.8	6.1	8.5	0.7	2.7	8.5	0.7	2.7	5.7
CA	mg/dL	8.6	12.2	16.7	5.6	12.6	16.1	5.7	8.3	15.5	5.7	8.3	12.7
CK	U/L	159	330	413	54	342	404	53	155	417	49	154	322
CREA	mg/dL	–	7.1	10.9	0.95	6.92	10.1	1	3.35	11	0.91	3.59	7.7
GGT	U/L	–	306	421	93	309	423	91	174	411	87	172	306
GLUC	mg/dL	453	223	29	608	232	33	618	451	29	602	452	218
LDH	U/L	–	547	190	1321	582	186	1329	974	189	1254	947	550
MG	mg/dL	1.9	3	4.2	0.8	3	4	1	1.8	4.2	1.1	1.8	3
PHOS	mg/dL	3.5	6.2	8.4	1.9	6.2	–	1.8	3.6	8.6	1.8	3.6	6.3
TP	g/dL	4.9	6.9	7.8	4	6.7	7.6	3.6	4.7	8.4	3.9	4.8	6.4
UREA	mg/dL	57.94	120.18	175.97	12.876	113.74	175.97	15.022	53.65	188.85	15	62.23	128.76
U-NIT	mg/dL	27	56	82	6	53	82	7	25	88	7	29	60
URIC	mg/dL	4.8	7	9.4	2.9	7	9.2	3.2	4.8	9.4	3.1	4.6	7.4

Legend: ✓ No Warnings; * Late Results; 2.0≤ |Z-score| <3.0; |Z-score| ≥3.0; – No Result
* Amended Result (per participant's request); × Non-robust determination of Mean and SD

1 Header

This section shows the following information:

- Laboratory information
- Report name
- EQAS Program name
- Cycle number and cycle dates
- Lot number (Cycle)

2 Sample Numbers

The results for each sample are shown in the column below the appropriate number.
A late symbol located below the sample number indicates that all results for that sample were received after the close of the sample.

3 Results

This section is organized by instrument and appears in alphabetical order. The analytes reported on for each sample are shown with the corresponding instrument. Each analyte shows the reported unit of measure. This corresponds to the latest reported unit if multiple units have been used during the program cycle. Prior results are appropriately converted to correspond to that
which was last reported. A late symbol located next to an individual result indicates that the result was received after the close of sample.

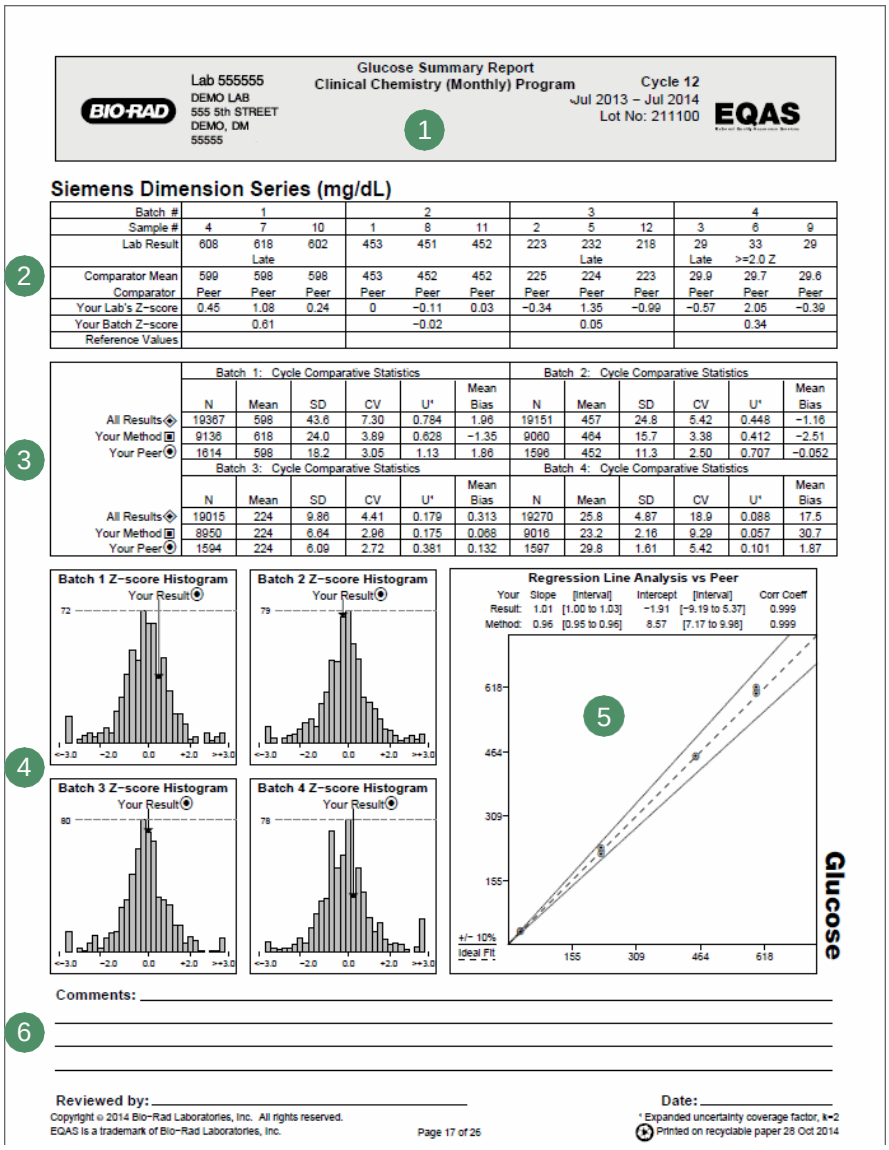
4 Legend

The legend at the lower part of the page describes the exception symbols and highlighted results.

Legend	
✓	No warnings All sample results for an analyte have been evaluated without any exceptions.
	Late results The result was received after the sample close date.
	2.0 ≤ |Z-score| < 3.0 Your absolute sample Z-score was greater than or equal to 2.0 and less than 3.0.
	|Z-score| ≥ 3.0 Your absolute sample Z-score was greater than or equal to 3.0.
–	No result No result or an Unreportable Result Code was received for a particular sample prior to the cycle close date.
*	Amended result (per participant's request) The result was edited by the EQAS participant after the sample close date.
J	Non-robust determination of mean and SD Indicates that the robust statistical process could not be used.

End-of-Cycle Report (Quantitative): Analyte Summary Report

The third section of the End-of-Cycle Report is the Analyte Summary Report. This section shows a summary of performance for all results reported and registered for a particular analyte throughout the cycle. A separate page is provided for each registered analyte/instrument combination.



Glucose Summary Report
Clinical Chemistry (Monthly) Program
Cycle 12
Jul 2013 – Jul 2014
Lot No: 211100

Lab 555555
DEMO LAB
555 5th STREET
DEMO, DM
55555

1

Siemens Dimension Series (mg/dL)

2

Batch #	1			2			3			4		
Sample #	4	7	10	1	8	11	2	5	12	3	6	9
Lab Result	608	618 Late	602	453	451	452	223	232 Late	218	29 Late	33 >=2.0 Z	29
Comparator Mean	599	598	598	453	452	452	225	224	223	29.9	29.7	29.6
Comparator	Peer	Peer	Peer	Peer	Peer	Peer	Peer	Peer	Peer	Peer	Peer	Peer
Your Lab's Z-score	0.45	1.08	0.24	0	−0.11	0.03	−0.34	1.35	−0.99	−0.57	2.05	−0.39
Your Batch Z-score		0.61			−0.02			0.05			0.34	
Reference Values												

3

	Batch 1: Cycle Comparative Statistics						Batch 2: Cycle Comparative Statistics					
	N	Mean	SD	CV	U*	Mean Bias	N	Mean	SD	CV	U*	Mean Bias
All Results	19367	598	43.6	7.30	0.784	1.96	19151	457	24.8	5.42	0.448	−1.16
Your Method	9136	618	24.0	3.89	0.628	−1.35	9060	464	15.7	3.38	0.412	−2.51
Your Peer	1614	598	18.2	3.05	1.13	1.86	1596	452	11.3	2.50	0.707	−0.052
	Batch 3: Cycle Comparative Statistics						Batch 4: Cycle Comparative Statistics					
	N	Mean	SD	CV	U*	Mean Bias	N	Mean	SD	CV	U*	Mean Bias
All Results	19015	224	9.86	4.41	0.179	0.313	19270	25.8	4.87	18.9	0.088	17.5
Your Method	8950	224	6.64	2.96	0.175	0.068	9016	23.2	2.16	9.29	0.057	30.7
Your Peer	1594	224	6.09	2.72	0.381	0.132	1597	29.8	1.61	5.42	0.101	1.87

4

Batch 1 Z−score Histogram (Your Result)
Batch 2 Z−score Histogram (Your Result)
Batch 3 Z−score Histogram (Your Result)
Batch 4 Z−score Histogram (Your Result)

Regression Line Analysis vs Peer

	Slope	[Interval]	Intercept	[Interval]	Corr Coeff
Your Result:	1.01	[1.00 to 1.03]	−1.91	[−9.19 to 5.37]	0.999
Method:	0.96	[0.95 to 0.96]	8.57	[7.17 to 9.96]	0.999

5

Glucose

6

Comments:

Reviewed by:

Date:

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* Expanded uncertainty coverage factor, k=2
Printed on recyclable paper 28 Oct 2014

1 Header

This section shows the following information:

- Laboratory information
- Report name (with analyte)
- EQAS Program name
- Cycle number and cycle dates
- Lot number (Cycle)

2 Analyte Summary

This section shows the peer group applicable to your instrument/reagent and the unit for the analyte's This section shows the peer group applicable to your instrument/reagent and the unit for the analyte's reported Lab Results, Comparator Means, and Reference Values.

- Batch #
  The samples are grouped by batch. A batch typically consists of three samples (replicates) with the same concentration.
- Sample #
  Sample numbers associated to the batch are listed in ascending order. The example above shows samples 4, 7, and 10 are the samples in Batch 1.
- Lab Result
  Sample results associated with each of the indicated sample numbers are presented. It is possible that results that were previously within acceptable limits in the Sample Report are now flagged in the End-of-Cycle Report or vice versa. Exceptions associated with the sample are shown. Since only one exception can be shown, a late exception takes precedence over other exceptions (such as ≥ 2.0 Z-score).
- Comparator Mean
  Robust mean of the comparator for the given sample is estimated. The symbol J::! appears if there was a non-robust calculation of the sample comparator mean.

- Comparator
  The comparator level for each sample is noted for your lab.

Important: This comparator can be different from that in the original Sample Report, as the End-of-Cycle Report reflects the recalculated statistics with all participants' late and amended data included in the data set. The recalculated Z-score is given for each sample result.

- Your Lab Z-score:

$$\frac{\text{Your result} - \text{Comparator mean}}{\text{Comparator SD}}$$

- Your Batch Z-score:

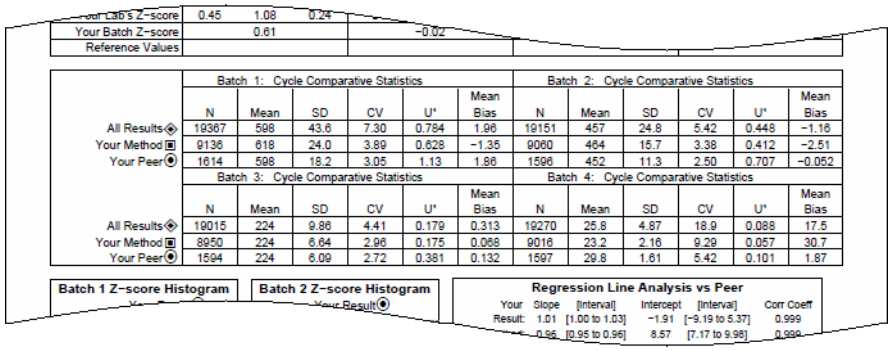
$$\frac{\text{Your mean batch result} - \text{Comparator batch mean}}{\text{Comparator batch SD}}$$

- Reference Values
  The target value for the batch result analyzed with the reference method (if available).

  Note: The reference values are provided for information only. No statistical comparisons are provided against the reference values.

  Reference Values for the EQAS Therapeutic Drug Monitoring Program are weighed in amounts of the active chemicals in the sample.

3 Cycle Comparative Statistics by Batch



Your Lab's Z-score	0.45	1.08	0.24
Your Batch Z-score	0.61		-0.02
Reference Values			

Batch 1: Cycle Comparative Statistics

	N	Mean	SD	CV	U*	Mean Bias
All Results ◈	19367	598	43.6	7.30	0.784	1.96
Your Method ▣	9136	618	24.0	3.89	0.628	-1.35
Your Peer ⦿	1614	598	18.2	3.05	1.13	1.86

Batch 2: Cycle Comparative Statistics

	N	Mean	SD	CV	U*	Mean Bias
All Results ◈	19151	457	24.8	5.42	0.448	-1.16
Your Method ▣	9060	464	15.7	3.38	0.412	-2.51
Your Peer ⦿	1596	452	11.3	2.50	0.707	-0.052

Batch 3: Cycle Comparative Statistics

	N	Mean	SD	CV	U*	Mean Bias
All Results ◈	19015	224	9.86	4.41	0.179	0.313
Your Method ▣	8950	224	6.64	2.96	0.175	0.068
Your Peer ⦿	1594	224	6.09	2.72	0.381	0.132

Batch 4: Cycle Comparative Statistics

	N	Mean	SD	CV	U*	Mean Bias
All Results ◈	19270	25.8	4.87	18.9	0.088	17.5
Your Method ▣	9016	23.2	2.16	9.29	0.057	30.7
Your Peer ⦿	1597	29.8	1.61	5.42	0.101	1.87

Batch 1 Z-score Histogram | **Batch 2 Z-score Histogram** (Your Result ⦿)

Regression Line Analysis vs Peer

	Your Result:	Slope	[Interval]	Intercept	[Interval]	Corr Coeff
		1.01	[1.00 to 1.03]	-1.91	[-9.19 to 5.37]	0.999
		0.96	[0.95 to 0.96]	8.57	[7.17 to 9.98]	0.989

The cycle comparative statistics are grouped by batch. All four batches are represented in this section. The following results appear in each column for every comparator:

All Results ◈ or Mode, Your Method ▣, and Your Peer ⦿.

If “All Results” has a multi-modal distribution of data, the results are separated into different modes and your modal data is shown (Your Mode).

- N: Number of data points in the batch.
- Mean: Robust calculation of the mean.
- SD: Robust calculation of the standard deviation.
- CV: Coefficient of variation =

$$\frac{\text{Standard deviation x 100}}{\text{Mean}}$$

- U: Expanded uncertainty of the mean =

$$\frac{\text{1.25 x Robust standard deviation}}{\text{Square root of N}} \times k$$

k is defined coverage factor of 2

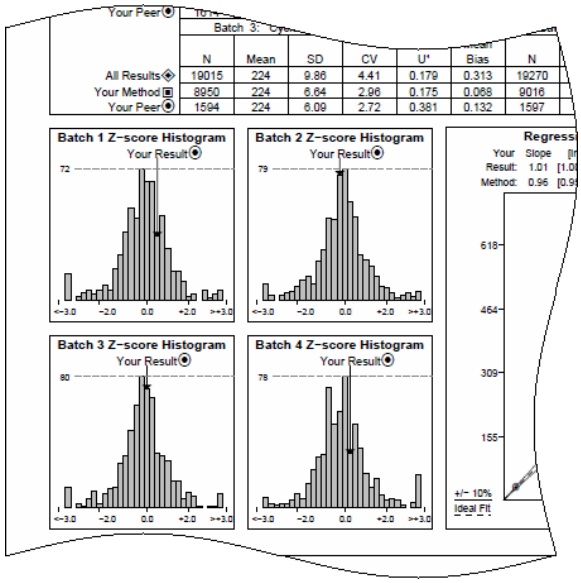
- Mean Bias: Your percentage deviation from the comparator mean =

$$\frac{\text{Your Batch Mean – Comparator Batch Mean}}{\text{Comparator Batch Mean}} \times 100$$

4 Batch Z-score Frequency Histograms

Histograms are generated for each batch. They represent all individual labs batch Z-score values for the cycle.

- This histogram can help you to detect systematic bias at different concentrations.
- The number of participants in the tallest bar in each histogram is displayed to the left of the graph at the start of the dashed horizontal line.
- Where “Your Result” falls in each Batch Z-score Histogram is shown with an arrow.
- The symbol next to “Your Result” indicates the comparator level shown in the histogram.
- The X-axis or bottom scale represents the batch Z-score value with a central 0 value and extremes of -3.0 Z-score and +3.0 Z-score. All results smaller than -3.0 or larger than 3.0 Z-score are compressed into the 3.0 limit.
- The Y-axis (vertical) scale indicates the number of reported laboratories. Only the highest distribution value is indicated on this axis to the left of the dashed line.



There are three levels of comparison. Ideally, your laboratory is compared to Your Peer, which is other laboratories using the same analyte, method, instrument, and reagent combination as yours. However, for a comparison to be made at the peer level there must be a minimum of 27 reported results for that test. If less than 27 results are received for Your Peer, your comparison is Your Method for a uni-modal distribution or Your Mode for a multi-modal distribution of data.

Your Method is other laboratories using the same analyte and method combinations for that test. However, for a comparison to be made at the method level there must be a minimum of 27

reported results for that uni-modal test. If there are less than 27 results received in the method you are compared to “All Results.” All Results is comprised of all laboratories using the same analyte as yours and will include other methods, instruments and reagent combinations for that test.

Uni-modal Distributions (All Results)

Symbol	Comparator	Description
◈	All Results	If fewer than 27 data points in your method group.
▣	Your Method	If fewer than 27 data points in your peer group and at least 27 data points in your method group.
◉	Your Peer	If there are at least 27 data points in your peer group.

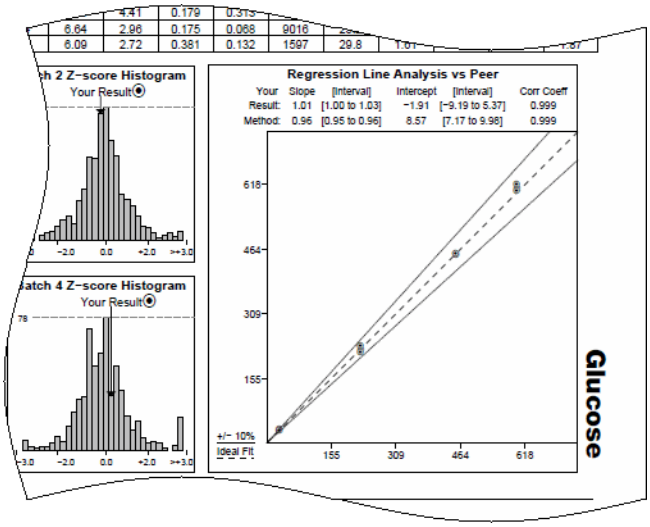
Multi-modal Distributions

If reported results have a multi-modal distribution of data, results for a registered test are separated into different Modes.

Symbol	Comparator	Description
▣	Your Mode	If fewer than 27 data points in your peer group.
◉	Your Peer	If there are at least 27 data points in your peer group.

5 Regression Line Analysis

The regression line is a graphical representation of your laboratory's measurement linearity for the selected analyte.



- The title of the Regression Line indicates the comparator level to which you are compared.

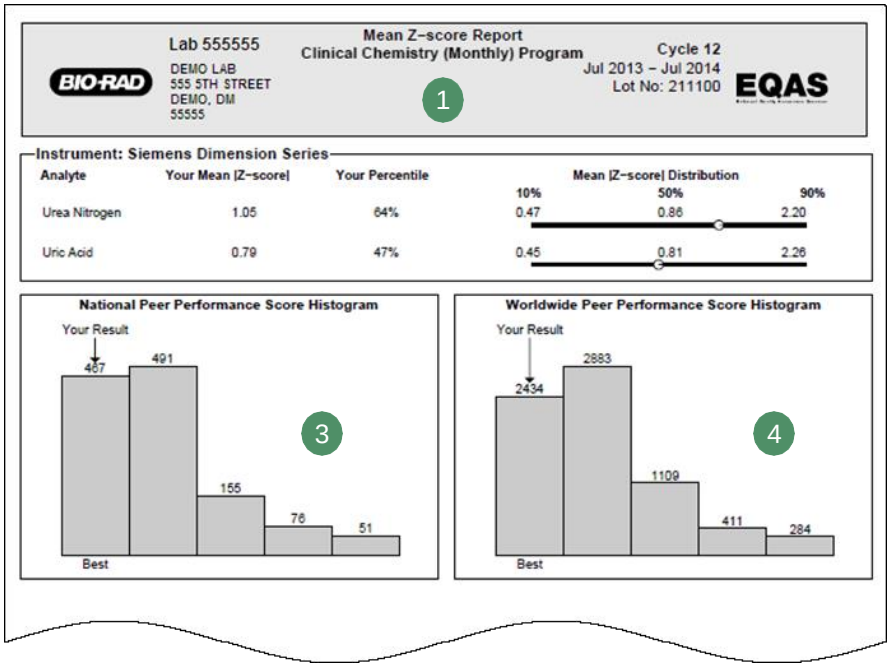
- Your individual sample results are plotted on the Y-axis (vertical) against the comparator mean values plotted on the X-axis (horizontal). Both axes are scaled to show the highest reported value and start at zero. The ideal fit line is shown as a dashed line with an ideal slope of 1. The solid lines represent a 10% deviation of the ideal fit. This provides a quick visual evaluation of the correlation between your results and the comparator results. It also helps to identify bias at a particular area of the measurement range.
- The top legend shows the Regression Line Slope, Intercept, and Correlation Coefficient for your results compared to the comparator (the comparator is shown in the chart title). 95% confidence intervals for both slope and intercept are also provided. When the lab is compared at Peer level, the Method Regression displayed is the Peer vs. the Method. If compared at Method level, the Method comparison is the Method vs. Mode. If compared at the Mode level, then the Method comparison displays the Mode vs. the Method. The Method Regression Line Slope, Intercept, and Correlation Coefficient are shown in the top legend but not in the graph.

6 Comments section

This is available on every Analyte Summary Report and can be used to note comments or evaluations. The applicable report reviewer can sign and date their assessment of the report.

End-of-Cycle Report (Quantitative): Mean Z-score Report

The final section of the End-of-Cycle Report is the Mean Z-score Report.

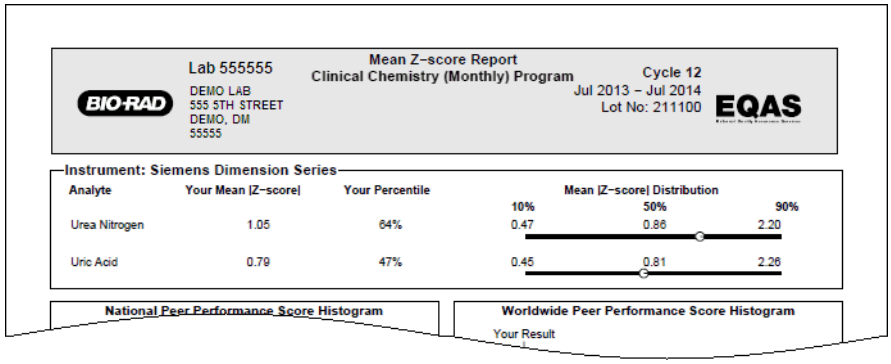


1 Header

This section shows the following information:

- Laboratory information
- Report name
- EQAS Program name
- Cycle number and cycle dates
- Lot number (Cycle)

2 Mean Z-score (summary of all analytes reported by instrument)



This section shows your registered analytes in alphabetical order by instrument with the following information:

- Analyte name
- Your Mean |Z-score|
  The mean of your reported individual sample absolute Z-score values (no negative values are displayed).
- Your Percentile
  The overall distribution for your comparator mean |Z-score| values is displayed. Your mean |Z-score| is expressed as the percentile of this distribution. A 50% percentile indicates your result is in the center of the distribution. In this case, there would be as many laboratories with a lower |Z-score| and as many laboratories with a higher |Z-score| than your laboratory.
- Mean |Z-score| Distribution
  This is a visual representation of the mean |Z-score| distribution. The 10%, 50%, and 90% |Z-score| is shown for your reference and your percentile is displayed with your comparator's symbol. The lowest percentiles represent the lowest mean |Z-score|. Therefore, a laboratory located at the left side of the distribution has a lower than average mean |Z-score|. If you are located at the right side of the distribution, your laboratory's mean |Z-score| is higher than the average mean |Z-score| (shown as the 50% percentile). A lower percentile represents better performance and less bias. If you are the only lab in the peer group, no distribution values will be displayed.

3 National Peer Performance Score Histogram

An overall laboratory performance score is calculated for each participant in the cycle. All scores for laboratories reporting in your country are grouped and a distribution of these scores is generated. The performance score is based on the overall mean Z-score, calculated across all samples and analytes. This score is affected by late and amended results. A penalty is applied for each result received late and/or amended. Amended results are more heavily penalized in the calculation of the performance score. After all penalties are applied, an individual score is normalized based on the number of individual results reported by the laboratory. Laboratories
submitting data before a sample close with no subsequent amendment after the sample close are not affected by penalties.

The distribution of overall performance scores is divided into five quintiles (20% percentile groups).

- The lowest performance score is shown on the left (best performance).
- The highest score is shown on the on the right.
- The number of laboratories contained in each quintile is shown at the top.
- Your laboratory’s performance is indicated by the “Your Result” arrow.

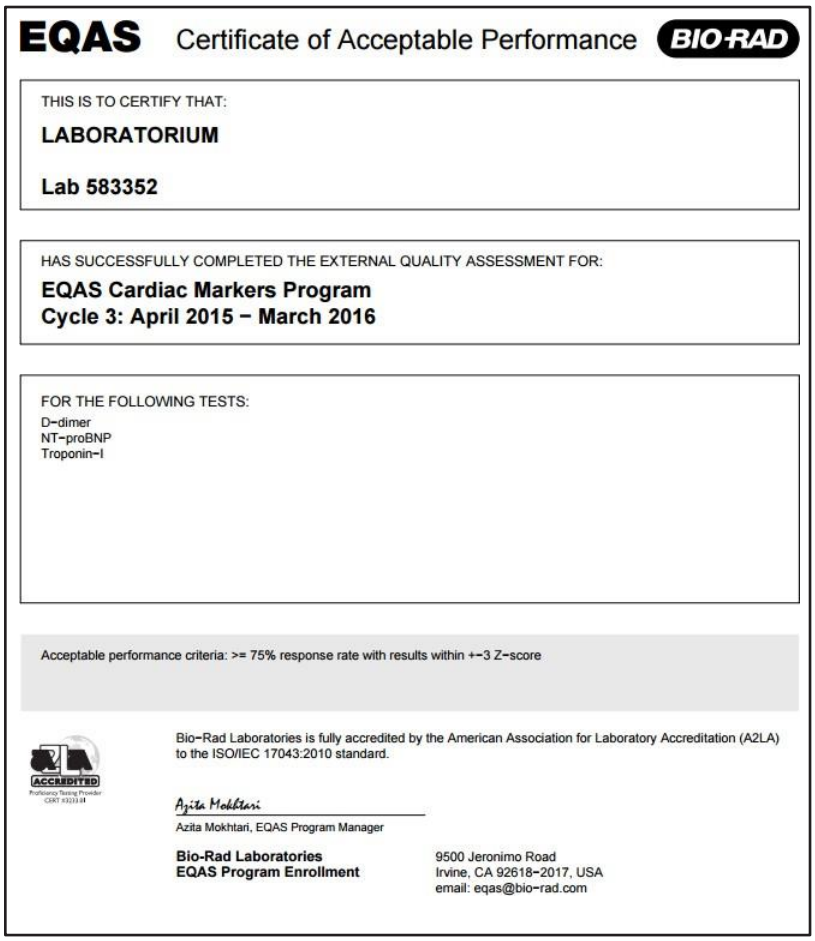
4 Worldwide Peer Performance Score Histogram

The Worldwide Performance Histogram shows all participants in the program cycle. “Your Result” shows your laboratory’s performance score compared on a worldwide basis.

End-of-Cycle Report (Quantitative): Certificate of Acceptable Performance

The final page of the End-of-Cycle Report is the Certificate of Acceptable Performance. This certificate lists all analytes that passed the acceptance criteria for the cycle.

For qualitative programs, this certificate will appear as the last page of their Sample 12 Report.



EQAS Certificate of Acceptable Performance **BIO-RAD**

THIS IS TO CERTIFY THAT:

LABORATORIUM

Lab 583352

HAS SUCCESSFULLY COMPLETED THE EXTERNAL QUALITY ASSESSMENT FOR:

EQAS Cardiac Markers Program
Cycle 3: April 2015 – March 2016

FOR THE FOLLOWING TESTS:

D-dimer
NT-proBNP
Troponin-I

Acceptable performance criteria: >= 75% response rate with results within +-3 Z-score

Bio-Rad Laboratories is fully accredited by the American Association for Laboratory Accreditation (A2LA) to the ISO/IEC 17043:2010 standard.

Azita Mokhtari

Azita Mokhtari, EQAS Program Manager

Bio-Rad Laboratories
EQAS Program Enrollment

9500 Jeronimo Road
Irvine, CA 92618-2017, USA
email: eqas@bio-rad.com

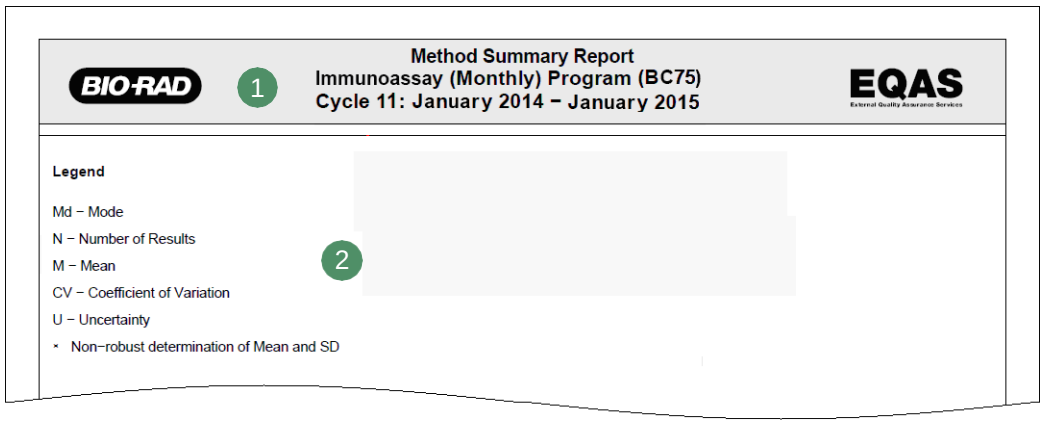
Method Summary Report (Quantitative)

The Method Summary Report provides a summary of individual peer (instrument/reagent) and method performance (not laboratory performance) among participating laboratories. You can use the information in the Method Summary Report to evaluate peer/method/instrument performance. The
Method Summary Report is available at the end of each program cycle and is available to all registered participants on www.QCNet.com.

The Method Summary Report consists of two main parts:

- Coversheet
- Analyte pages

Method Summary Report (Quantitative): Coversheet



1 Header

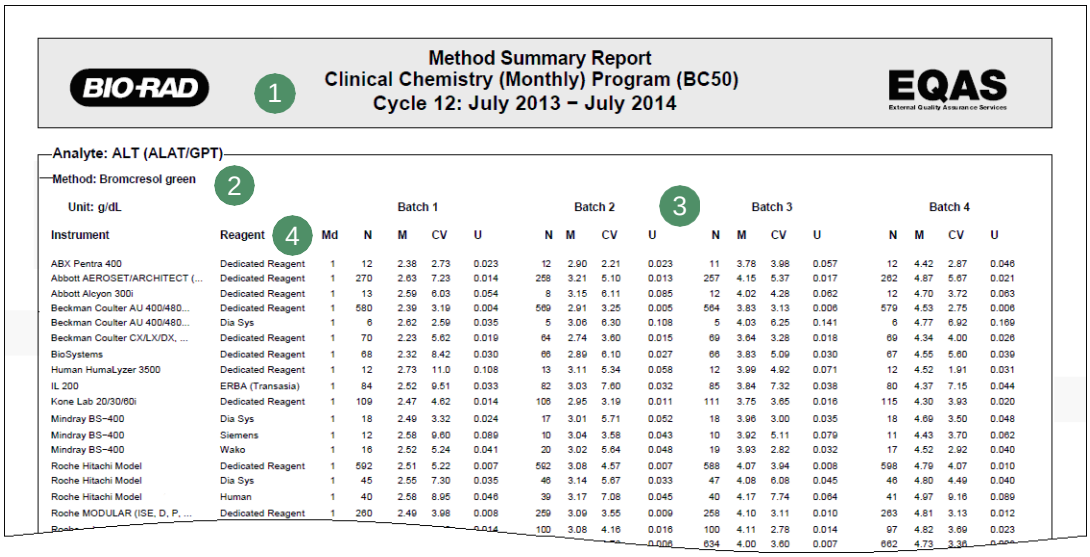
This section shows the following information:

- Report name
- EQAS Program name and catalog number
- Cycle number and cycle dates

2 Legend

This section provides descriptions of the abbreviations and symbols used on the Analyte pages.

Method Summary Report (Quantitative): Analyte Pages



Method Summary Report
Clinical Chemistry (Monthly) Program (BC50)
Cycle 12: July 2013 – July 2014

Analyte: ALT (ALAT/GPT)
Method: Bromcresol green
Unit: g/dL

Instrument	Reagent	Md	Batch 1 N	Batch 1 M	Batch 1 CV	Batch 1 U	Batch 2 N	Batch 2 M	Batch 2 CV	Batch 2 U	Batch 3 N	Batch 3 M	Batch 3 CV	Batch 3 U	Batch 4 N	Batch 4 M	Batch 4 CV	Batch 4 U
ABX Pentra 400	Dedicated Reagent	1	12	2.38	2.73	0.023	12	2.90	2.21	0.023	11	3.78	3.98	0.057	12	4.42	2.87	0.046
Abbott AEROSET/ARCHITECT (...	Dedicated Reagent	1	270	2.63	7.23	0.014	258	3.21	5.10	0.013	257	4.15	5.37	0.017	262	4.87	5.67	0.021
Abbott Alcyon 300i	Dedicated Reagent	1	13	2.59	6.03	0.054	8	3.15	6.11	0.085	12	4.02	4.28	0.062	12	4.70	3.72	0.063
Beckman Coulter AU 400/480...	Dedicated Reagent	1	580	2.39	3.19	0.004	569	2.91	3.25	0.005	564	3.83	3.13	0.006	579	4.53	2.75	0.006
Beckman Coulter AU 400/480...	Dia Sys	1	6	2.62	2.59	0.035	5	3.06	6.30	0.108	5	4.03	6.25	0.141	6	4.77	6.92	0.169
Beckman Coulter CX/LX/DX, ...	Dedicated Reagent	1	70	2.23	5.62	0.019	64	2.74	3.60	0.015	69	3.64	3.28	0.018	69	4.34	4.00	0.026
BioSystems	Dedicated Reagent	1	68	2.32	8.42	0.030	66	2.89	6.10	0.027	66	3.83	5.09	0.030	67	4.55	5.60	0.039
Human HumaLyzer 3500	Dedicated Reagent	1	12	2.73	11.0	0.108	13	3.11	5.34	0.058	12	3.99	4.92	0.071	12	4.52	1.91	0.031
IL 200	ERBA (Transasia)	1	84	2.52	9.51	0.033	82	3.03	7.60	0.032	85	3.84	7.32	0.038	80	4.37	7.15	0.044
Kone Lab 20/30/60i	Dedicated Reagent	1	109	2.47	4.62	0.014	108	2.95	3.19	0.011	111	3.75	3.65	0.016	115	4.30	3.93	0.020
Mindray BS-400	Dia Sys	1	18	2.49	3.32	0.024	17	3.01	5.71	0.052	18	3.96	3.00	0.035	18	4.69	3.50	0.048
Mindray BS-400	Siemens	1	12	2.58	9.60	0.089	10	3.04	3.58	0.043	10	3.92	5.11	0.079	11	4.43	3.70	0.062
Mindray BS-400	Wako	1	16	2.52	5.24	0.041	20	3.02	5.64	0.048	19	3.93	2.82	0.032	17	4.52	2.92	0.040
Roche Hitachi Model	Dedicated Reagent	1	592	2.51	5.22	0.007	592	3.08	4.57	0.007	588	4.07	3.94	0.008	598	4.79	4.07	0.010
Roche Hitachi Model	Dia Sys	1	45	2.55	7.30	0.035	46	3.14	5.67	0.033	47	4.08	6.08	0.045	46	4.80	4.49	0.040
Roche Hitachi Model	Human	1	40	2.58	8.95	0.046	39	3.17	7.08	0.045	40	4.17	7.74	0.064	41	4.97	9.16	0.089
Roche MODULAR (ISE, D, P, ...	Dedicated Reagent	1	260	2.49	3.98	0.008	259	3.09	3.55	0.009	258	4.10	3.11	0.010	263	4.81	3.13	0.012
[illegible]						0.014	100	3.08	4.16	0.016	100	4.11	2.78	0.014	97	4.82	3.89	0.023
										0.006	634	4.00	3.60	0.007	662	4.73	3.36	

1. Header

   This section shows the following information:

   - Report name
   - EQAS Program name and catalog number
   - Cycle number and cycle dates

2. Analytes

   - Appear in alphabetical order.
   - Methods applicable to each analyte are shown in alphabetical order.
   - The most commonly reported unit for the analyte.
   - Instruments are listed in alphabetical order for each analyte/method combination.

3. Batch

   Results are grouped by batch.

4 Column heading

Identifies the type of result in each column.

Md – Mode
N – Number of results
M – Mean
CV – Coefficient of variation
U – Uncertainty

Subgroup Report (Quantitative)

Note: The Subgroup Report is optional. Contact EQAS Customer Support or your local Bio-Rad representative to set up a subgroup for an EQAS Program. See “Customer Support” on page 13 for contact information.

The Subgroup Report shows performance for each participating laboratory in a collective or common interest group. The Subgroup Report is available at the close of each program sample. The report is provided only in Microsoft® Excel® format to a designated subgroup leader.

Important: The Subgroup Report is available only on www.QCNet.com. Therefore, the subgroup leader must have Internet access.

The subgroup leader identifies the participants in the subgroup. Participants in a subgroup provide their approval for releasing results to the designated subgroup leader. If local or national regulations require the release of laboratory results to an oversight body or organization, the Subgroup Report can also be used for that purpose.

The Microsoft® Excel® format of the report is a powerful advantage. All normal spreadsheet capabilities are available. Each spreadsheet can be imported to a compatible database for long-term trending of individual laboratories. The Subgroup Report is especially useful for large groups or affiliated laboratories, but can also be used when identical instruments are present in an individual laboratory.

There are two templates provided with the Subgroup Report:

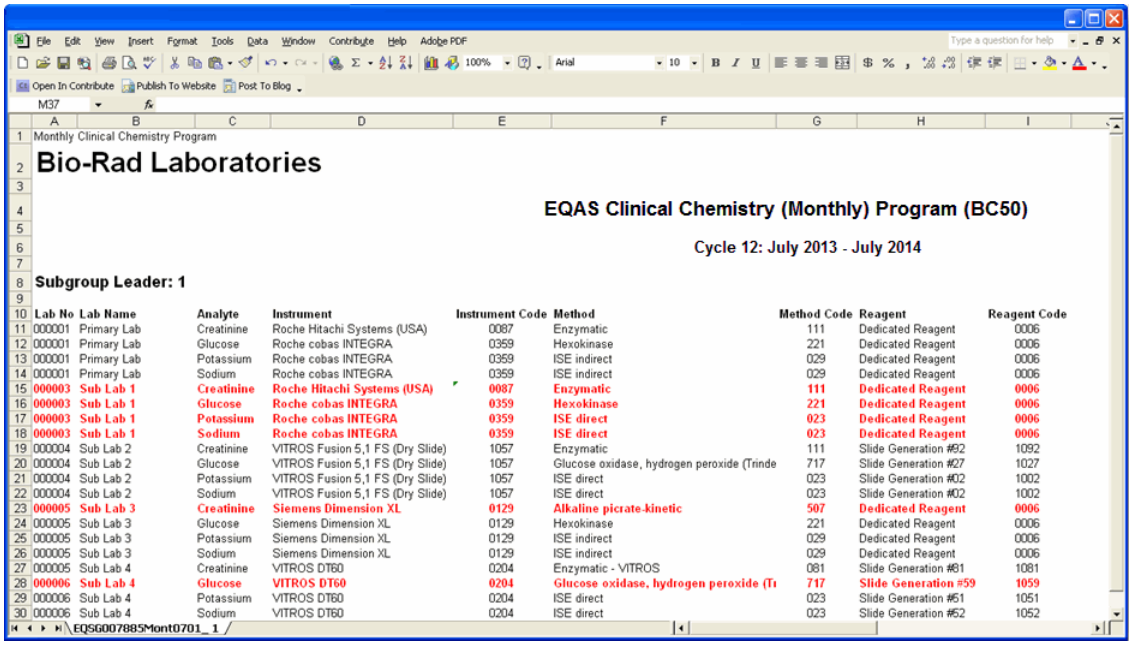
- Template 1
  Includes all statistical comparative information generated for each laboratory in the subgroup, in converted units.
- Template 2
  Includes all statistical comparative information generated for each laboratory in the subgroup, in reported units.

The Subgroup Report as a spreadsheet contains laboratory numbers in ascending order.

- All laboratory numbers belonging to a subgroup are listed.
- Laboratories that did not submit a result for a given sample are noted in the spreadsheet as a dash (-) in the Result Value column. The entire row is highlighted in bold red text.
- Rows that have a Comparator Z-score greater than or equal to 2.0 |Z-score| appear in bold red text. The level of comparison associated with the Z-score is given.

Template 1

This template includes all possible categories reported on. It includes a header with the Program Name and Catalog Number, Cycle Number, Sample Number and Sample Date. The data columns start
from the left and include: Lab Number, Lab Name, Analyte name, Instrument name, Instrument Code, Method name, Method Code, Reagent name and Reagent Code, Result Value and the unit submitted, a Converted Result and associated unit (for an easy comparison of values within the subgroup), Comparator level, Comparator Z-score, Comparator RMZ, Peer N, Peer Mean, Peer SD, Peer CV, Peer U, Method N, Method Mean, Method SD, Method CV, Method U, Mode N, Mode Mean, Mode SD, Mode CV, Mode U and any Unreportable Results (UR) Codes submitted. Results outside acceptable limits (> 2.0 |Z-score|) or missing results are highlighted in bold red text.



Monthly Clinical Chemistry Program

Bio-Rad Laboratories

EQAS Clinical Chemistry (Monthly) Program (BC50)

Cycle 12: July 2013 - July 2014

Subgroup Leader: 1

Lab No	Lab Name	Analyte	Instrument	Instrument Code	Method	Method Code	Reagent	Reagent Code
000001	Primary Lab	Creatinine	Roche Hitachi Systems (USA)	0087	Enzymatic	111	Dedicated Reagent	0006
000001	Primary Lab	Glucose	Roche cobas INTEGRA	0359	Hexokinase	221	Dedicated Reagent	0006
000001	Primary Lab	Potassium	Roche cobas INTEGRA	0359	ISE indirect	029	Dedicated Reagent	0006
000001	Primary Lab	Sodium	Roche cobas INTEGRA	0359	ISE indirect	029	Dedicated Reagent	0006
000003	**Sub Lab 1**	**Creatinine**	**Roche Hitachi Systems (USA)**	**0087**	**Enzymatic**	**111**	**Dedicated Reagent**	**0006**
000003	**Sub Lab 1**	**Glucose**	**Roche cobas INTEGRA**	**0359**	**Hexokinase**	**221**	**Dedicated Reagent**	**0006**
000003	**Sub Lab 1**	**Potassium**	**Roche cobas INTEGRA**	**0359**	**ISE direct**	**023**	**Dedicated Reagent**	**0006**
000003	**Sub Lab 1**	**Sodium**	**Roche cobas INTEGRA**	**0359**	**ISE direct**	**023**	**Dedicated Reagent**	**0006**
000004	Sub Lab 2	Creatinine	VITROS Fusion 5,1 FS (Dry Slide)	1057	Enzymatic	111	Slide Generation #92	1092
000004	Sub Lab 2	Glucose	VITROS Fusion 5,1 FS (Dry Slide)	1057	Glucose oxidase, hydrogen peroxide (Trinde	717	Slide Generation #27	1027
000004	Sub Lab 2	Potassium	VITROS Fusion 5,1 FS (Dry Slide)	1057	ISE direct	023	Slide Generation #02	1002
000004	Sub Lab 2	Sodium	VITROS Fusion 5,1 FS (Dry Slide)	1057	ISE direct	023	Slide Generation #02	1002
000005	**Sub Lab 3**	**Creatinine**	**Siemens Dimension XL**	**0129**	**Alkaline picrate-kinetic**	**507**	**Dedicated Reagent**	**0006**
000005	Sub Lab 3	Glucose	Siemens Dimension XL	0129	Hexokinase	221	Dedicated Reagent	0006
000005	Sub Lab 3	Potassium	Siemens Dimension XL	0129	ISE indirect	029	Dedicated Reagent	0006
000005	Sub Lab 3	Sodium	Siemens Dimension XL	0129	ISE indirect	029	Dedicated Reagent	0006
000005	Sub Lab 4	Creatinine	VITROS DT60	0204	Enzymatic - VITROS	081	Slide Generation #81	1081
000006	**Sub Lab 4**	**Glucose**	**VITROS DT60**	**0204**	**Glucose oxidase, hydrogen peroxide (Tı**	**717**	**Slide Generation #59**	**1059**
000006	Sub Lab 4	Potassium	VITROS DT60	0204	ISE direct	023	Slide Generation #51	1051
000006	Sub Lab 4	Sodium	VITROS DT60	0204	ISE direct	023	Slide Generation #52	1052

Template 2

This template includes all possible categories reported on. It includes a header with the Program Name and Catalog Number, Cycle Number, Sample Number and Sample Date. The data columns start
from the left and include: Lab Number, Lab Name, Analyte name, Instrument name, Instrument Code, Method name, Method Code, Reagent name and Reagent Code, Result Value and the unit submitted, a Converted Result and associated unit (for an easy comparison of values within the subgroup),

Comparator level, Comparator Z-score, Comparator RMZ, Peer N, Peer Mean, Peer SD, Peer CV, Peer U, Method N, Method Mean, Method SD, Method CV, Method U, Mode N, Mode Mean, Mode SD, Mode CV, Mode U and any Unreportable Results (UR) Codes submitted. Results outside acceptable limits (> 2.0 |Z-score|) or missing results are highlighted in bold red text. All statistical comparative information is expressed in reported units.

Subgroup Report (Qualitative)

Note: The Subgroup report is optional. Contact EQAS Customer Support or your local Bio-Rad representative to set up a subgroup for an EQAS Program. See “Customer Support” on page 13 for contact information.

The Subgroup Report shows performance for each participating laboratory in a collective or common interest group. The Subgroup Report is available at the close of each sample. The report is provided only in Microsoft Excel format to a designated subgroup leader.

The Subgroup leader identifies the participants in the subgroup. Participants in a subgroup provide their approval for releasing results to the designated subgroup leader. If local or national regulations require the release of laboratory results to an oversight body or organization, the Subgroup Report can also be used for that purpose. The Microsoft Excel format of the report is a powerful advantage. All normal spreadsheet capabilities are available. The Subgroup Report is especially useful for large groups or affiliated laboratories, but can also be used when identical instruments are present in an individual laboratory.

- The Subgroup Report as a spreadsheet contains laboratory numbers in ascending order and all numbers belonging to that subgroup are listed.
- Laboratories that did not submit a result for a given sample are noted in the spreadsheet as a dash (-) in the Submitted Response column. The entire row is highlighted in bold red text.
- Rows that have an evaluation outside of consensus appear in bold red text.
- Laboratories that submitted an Unreportable code will have that code number displayed in the Unreportable column and the entire row will be highlighted in bold red text.
- The Subgroup report includes a header with the Program Name and Catalogue Number, Cycle number, Sample Number, Sample date and Subgroup leader Laboratory number. The data columns starts from the left and include: Lab Number, Lab Name, Analyte name, Instrument name,
  Instrument code, Method name, Method code, Reagent name, Reagent code, Submitted response, Comparator, N, Evaluation (Within Consensus, Outside Consensus or No Consensus), Response 1 (name), % Response 1, Response 2 (name), % Response 2, …

chapter 6

How to Interpret Quantitative EQAS Reports

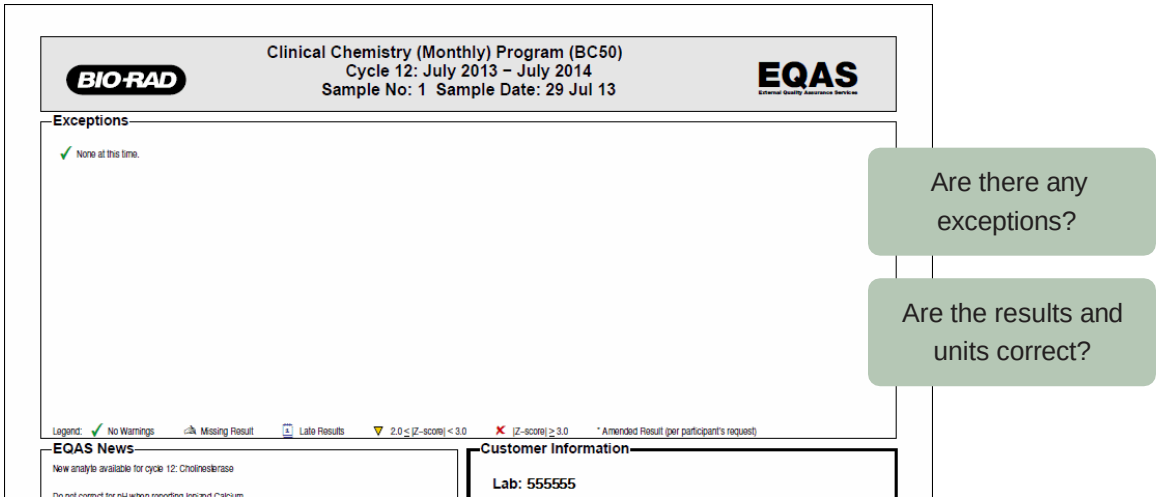
In This Chapter

How to Interpret the Sample Report 95
How to Interpret the End-of-Cycle Report 101
How to Use the Method Summary Report 104
How to Use the Subgroup Report 104
How to Use the Quality Specification Subgroup Report 104

How to Interpret the Sample Report

Review the Coversheet

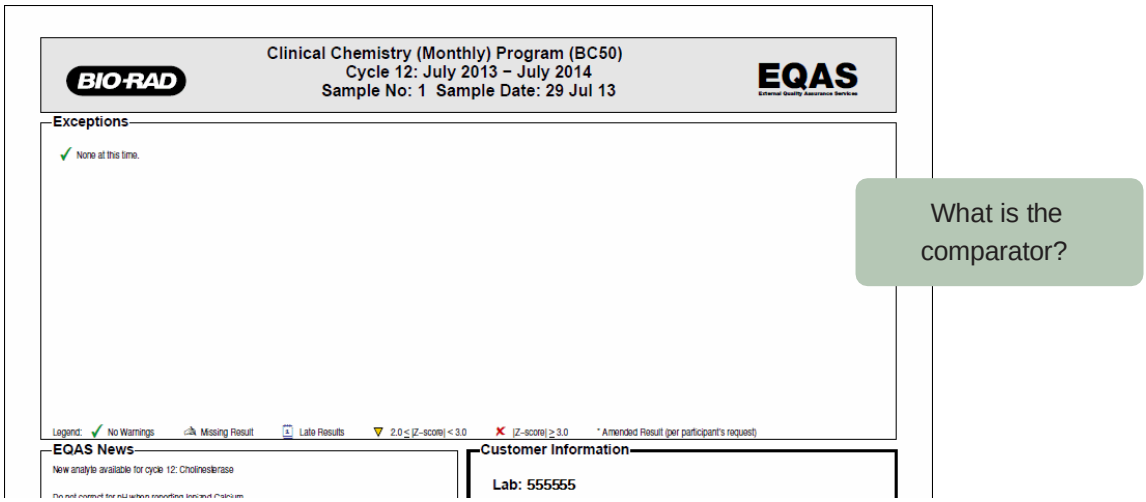
- Identify any exceptions.
- Make sure the reported results and units accurately reflect your instrument configuration and that no transcription errors occurred. Transcription errors are the most commonly reported errors.



- Look at your result's comparator. The ideal comparator is your Peer, then Method, and finally All Results or Mode. However, in cases where multiple modes exist for an analyte, your comparison

will be made at either the Peer or Mode level. Method comparisons will still be displayed for your information.

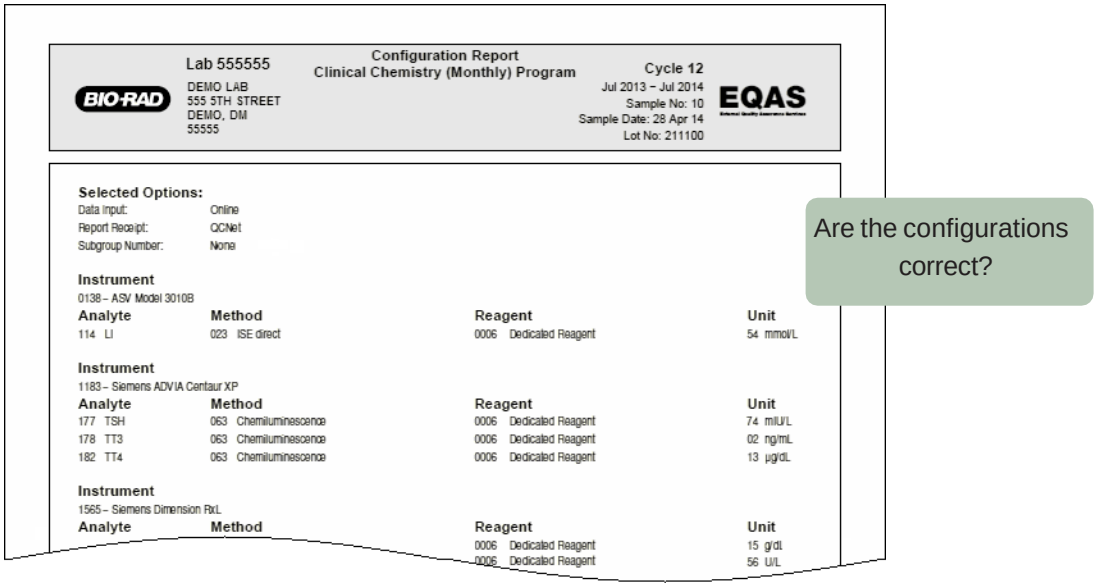
- Comparison at the Method or All Results or Mode level can reflect non-instrument specific differences.



Review the Configuration Report

Make sure the following configuration is correct for each analyte. This is especially important when you first submit results after you make changes to your configurations.

- Instrument
- Method
- Reagent
- Unit

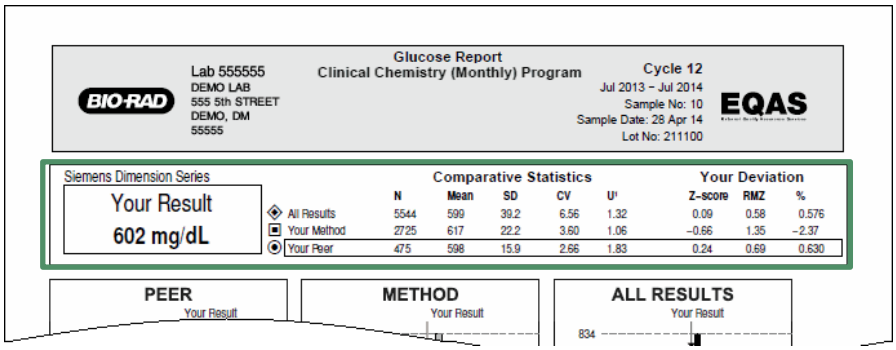


Review the Sample Summary Report

Verify that your reported units and results reflect your instrument results and that no transcription error occurred.

Review the Analyte Report

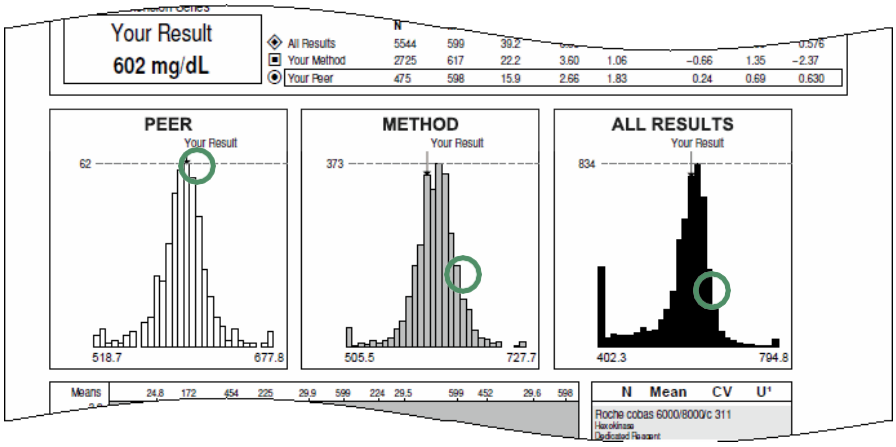
- Review the individual Analyte Reports. An analyte for which no method registration was submitted will not be included in the report.
- Review the Comparative Statistics section.
- If less than 9 results are received for your peer group, your comparison will be either to Your Method (for analytes with a single mode) or to Your Mode (for analytes with multiple modes).



- Your peer group is shown above “Your Result.”
- Consider the following in your review:
- Are there a significant number of labs reporting (N)?
  - How close is your result to the Mean of your comparator?
  - Is the CV high?
  - Is the expanded uncertainty (U) close to zero?
  - Is the Z-score significantly different from the RMZ for this sample? If so, view the Z-score Trend Charts to detect any trends.
  - Is Your Deviation percentage (%) high?
  - Does there appear to be a bias between your comparator and that of the next comparator level, Mode (for multi-modal distributions) and Method, or All Results (for uni-modal distributions)?

Review the Histograms

Look at the arrow indicating Your Result relative to the comparator distribution. Your Result arrows are not displayed for late or amended results. You can investigate if there are differences between Peer, Method, and All Results or Mode distributions. The example below shows the laboratory reporting a slightly higher result than mean of their Peer, Method, and Mode distributions. The example laboratory has a slight positive bias for this test.



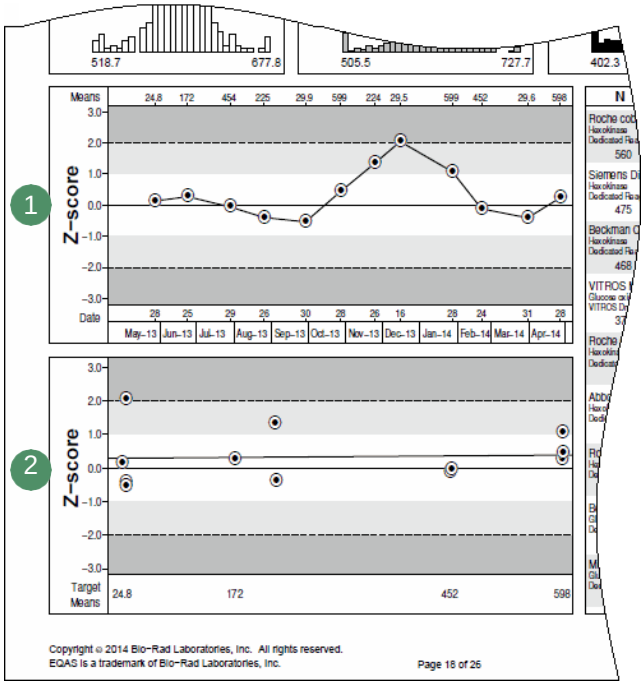
The histograms display the lowest and highest reported values along the X-axis, with a maximum of 5SD. Values outside this range will be compressed into the 5SD limit.

Review the Z-score Trend Charts

1. Use the Levey-Jennings Chart to review your laboratory's performance over time. In the example below, you can see a downward trend which indicates a negative bias trend.
2. The Yundt Plot indicates the negative trend is across all concentrations because most of the laboratory's Z-score values fall below the zero value line.

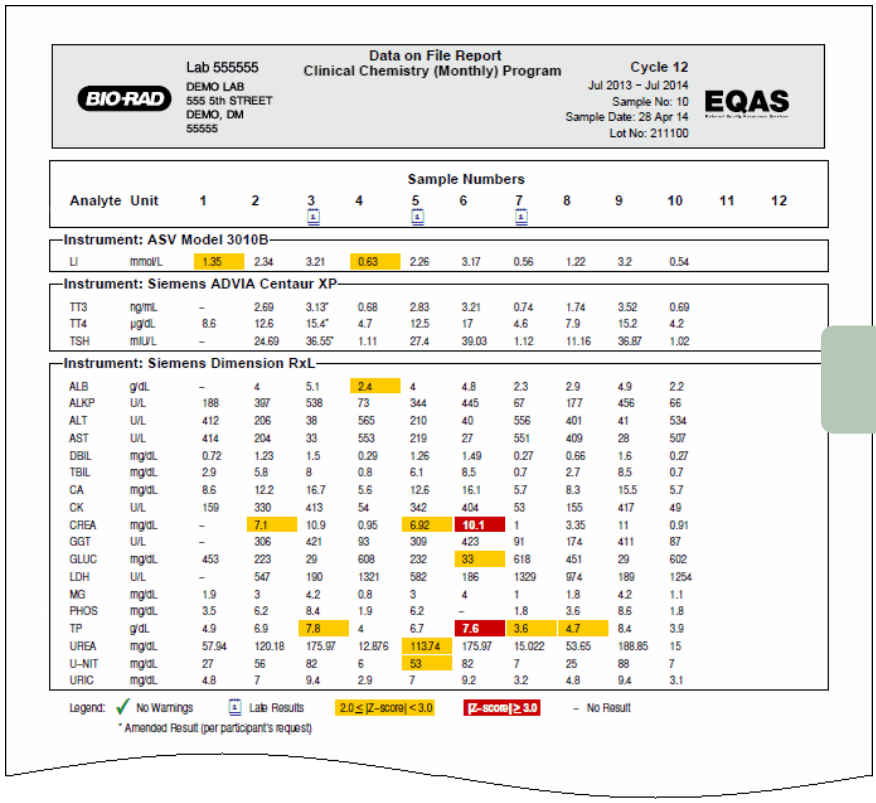
   If your results are consistently different than other laboratories, some logical questions are:

   - Is my method coded correctly?
   - Is the difference significant?
   - Do I need to investigate further?



Review the Data on File Report

- Review the Data on File Report and look for any consistent exceptions across multiple samples.
  - This could indicate a systematic problem.
  - It could also be due to incorrect configuration of the test that led to an incorrect comparison.
- Look for exceptions within one sample.
  - Are the majority of the results flagged?
  - This could indicate a problem with this specific sample (reconstitution, dilution, storage, incorrect sample analyzed).



BIO-RAD

Lab 555555
DEMO LAB
555 5th STREET
DEMO, DM
55555

Data on File Report
Clinical Chemistry (Monthly) Program

Cycle 12
Jul 2013 – Jul 2014
Sample No: 10
Sample Date: 28 Apr 14
Lot No: 211100

EQAS

Analyte	Unit	Sample Numbers 1	2	3	4	5	6	7	8	9	10	11	12
Instrument: ASV Model 3010B													
LI	mmol/L	1.35	2.34	3.21	0.63	2.26	3.17	0.56	1.22	3.2	0.54		
Instrument: Siemens ADVIA Centaur XP													
TT3	ng/mL	–	2.69	3.13*	0.68	2.83	3.21	0.74	1.74	3.52	0.69		
TT4	µg/dL	8.6	12.6	15.4*	4.7	12.5	17	4.6	7.9	15.2	4.2		
TSH	mIU/L	–	24.69	36.55*	1.11	27.4	39.03	1.12	11.16	36.87	1.02		
Instrument: Siemens Dimension RxL													
ALB	g/dL	–	4	5.1	2.4	4	4.8	2.3	2.9	4.9	2.2		
ALKP	U/L	188	397	538	73	344	445	67	177	456	66		
ALT	U/L	412	206	38	565	210	40	556	401	41	534		
AST	U/L	414	204	33	553	219	27	551	409	28	507		
DBIL	mg/dL	0.72	1.23	1.5	0.29	1.26	1.49	0.27	0.66	1.6	0.27		
TBIL	mg/dL	2.9	5.8	8	0.8	6.1	8.5	0.7	2.7	8.5	0.7		
CA	mg/dL	8.6	12.2	16.7	5.6	12.6	16.1	5.7	8.3	15.5	5.7		
CK	U/L	159	330	413	54	342	404	53	155	417	49		
CREA	mg/dL	–	7.1	10.9	0.95	6.92	10.1	1	3.35	11	0.91		
GGT	U/L	–	306	421	93	309	423	91	174	411	87		
GLUC	mg/dL	453	223	29	608	232	33	618	451	29	602		
LDH	U/L	–	547	190	1321	582	186	1329	974	189	1254		
MG	mg/dL	1.9	3	4.2	0.8	3	4	1	1.8	4.2	1.1		
PHOS	mg/dL	3.5	6.2	8.4	1.9	6.2	–	1.8	3.6	8.6	1.8		
TP	g/dL	4.9	6.9	7.8	4	6.7	7.6	3.6	4.7	8.4	3.9		
UREA	mg/dL	57.94	120.18	175.97	12.876	113.74	175.97	15.022	53.65	188.85	15		
U-NIT	mg/dL	27	56	82	6	53	82	7	25	88	7		
URIC	mg/dL	4.8	7	9.4	2.9	7	9.2	3.2	4.8	9.4	3.1		

Legend: ✓ No Warnings Late Results 2.0 ≤ |Z-score| < 3.0 |Z-score| ≥ 3.0 – No Result
* Amended Result (per participant's request)

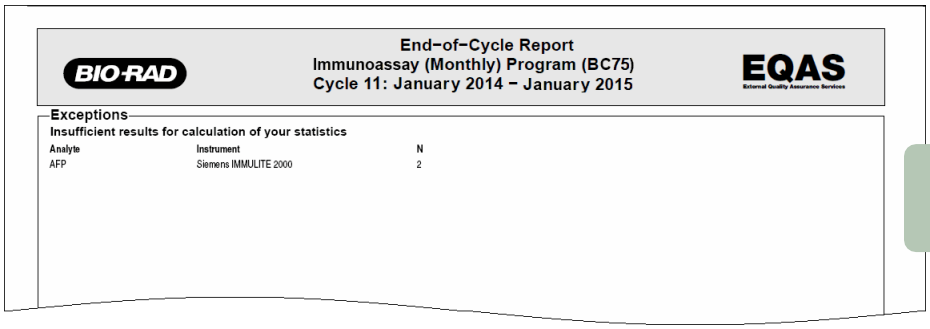
Are there any trends?

For further assistance with interpreting your results, refer to the EQAS Sample Report Flowchart and Checklist. These tools are available on the EQAS tab of the QCNet website (www.qcnet.com).

How to Interpret the End-of-Cycle Report

Review the Coversheet

The Exceptions section on the Coversheet shows analytes with fewer than 9 reported results on the same test configuration for the cycle. Although the End-of-Cycle Report provides some statistical analysis, it is highly recommended that each laboratory submit at least 9 results per analyte per cycle. Please consider this for the analytes shown when interpreting this report.



BIO-RAD

End–of–Cycle Report
Immunoassay (Monthly) Program (BC75)
Cycle 11: January 2014 – January 2015

EQAS
External Quality Assurance Services

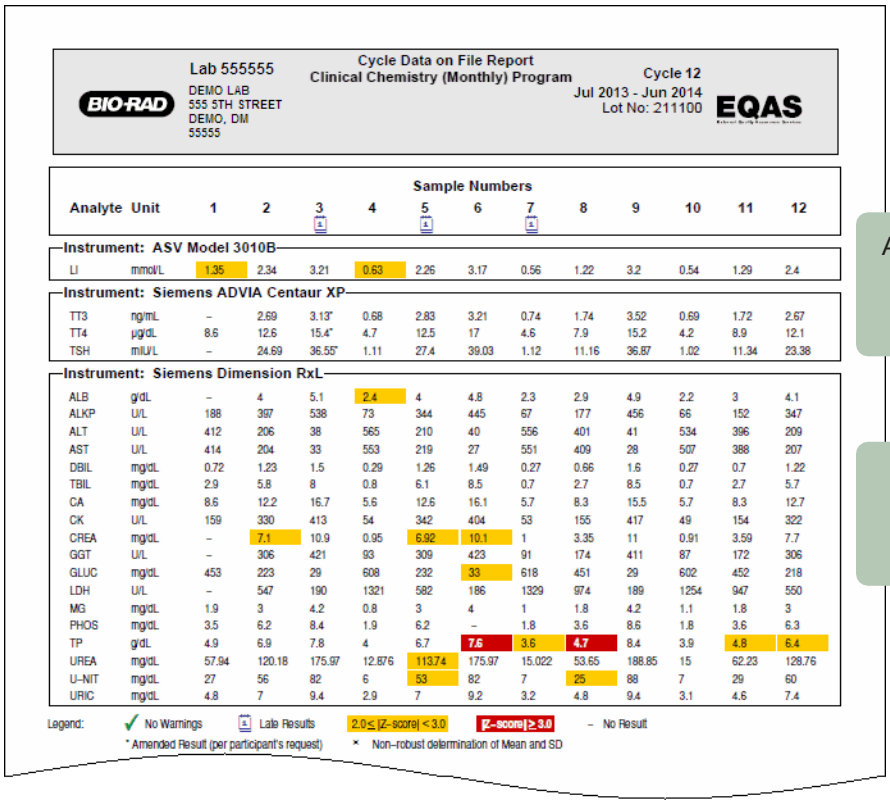
Exceptions
Insufficient results for calculation of your statistics

Analyte	Instrument	N
AFP	Siemens IMMULITE 2000	2

Are there any exceptions?

Review the Cycle Data on File Report

- The Cycle Data on File Report is similar to the Sample Report Data on File Report. However, the End-of-Cycle Report reflects the recalculated statistics with late and amended results included ıthe data set. Due to this recalculation, your evaluation might be different from your Sample Report statistics.
- Review the Cycle Data on File Report and look for any consistent exceptions across multiple samples. This could indicate a systematic problem. It could also be due to an incorrect configuration of the test.
- Look for exceptions within one sample. Are the majority of your results marked with exceptions? This could indicate a problem with this specific sample (reconstitution, dilution, storage, wrong sample). If multiple identical analytes and units are shown in this report for the same instrument, it might indicate there was a change in configuration (method, reagent) during the cycle.



Lab 555555
DEMO LAB
555 5TH STREET
DEMO, DM
55555

Cycle Data on File Report
Clinical Chemistry (Monthly) Program

Cycle 12
Jul 2013 - Jun 2014
Lot No: 211100

Analyte	Unit	Sample Numbers 1	2	3	4	5	6	7	8	9	10	11	12
Instrument: ASV Model 3010B													
LI	mmol/L	1.35	2.34	3.21	0.63	2.26	3.17	0.56	1.22	3.2	0.54	1.29	2.4
Instrument: Siemens ADVIA Centaur XP													
TT3	ng/mL	–	2.69	3.13*	0.68	2.83	3.21	0.74	1.74	3.52	0.69	1.72	2.67
TT4	µg/dL	8.6	12.6	15.4*	4.7	12.5	17	4.6	7.9	15.2	4.2	8.9	12.1
TSH	mIU/L	–	24.69	36.55*	1.11	27.4	39.03	1.12	11.16	36.87	1.02	11.34	23.38
Instrument: Siemens Dimension RxL													
ALB	g/dL	–	4	5.1	2.4	4	4.8	2.3	2.9	4.9	2.2	3	4.1
ALKP	U/L	188	397	538	73	344	445	67	177	456	66	152	347
ALT	U/L	412	206	38	565	210	40	556	401	41	534	396	209
AST	U/L	414	204	33	553	219	27	551	409	28	507	388	207
DBIL	mg/dL	0.72	1.23	1.5	0.29	1.26	1.49	0.27	0.66	1.6	0.27	0.7	1.22
TBIL	mg/dL	2.9	5.8	8	0.8	6.1	8.5	0.7	2.7	8.5	0.7	2.7	5.7
CA	mg/dL	8.6	12.2	16.7	5.6	12.6	16.1	5.7	8.3	15.5	5.7	8.3	12.7
CK	U/L	159	330	413	54	342	404	53	155	417	49	154	322
CREA	mg/dL	–	7.1	10.9	0.95	6.92	10.1	1	3.35	11	0.91	3.59	7.7
GGT	U/L	–	306	421	93	309	423	91	174	411	87	172	306
GLUC	mg/dL	453	223	29	608	232	33	618	451	29	602	452	218
LDH	U/L	–	547	190	1321	582	186	1329	974	189	1254	947	550
MG	mg/dL	1.9	3	4.2	0.8	3	4	1	1.8	4.2	1.1	1.8	3
PHOS	mg/dL	3.5	6.2	8.4	1.9	6.2	–	1.8	3.6	8.6	1.8	3.6	6.3
TP	g/dL	4.9	6.9	7.8	4	6.7	7.6	3.6	4.7	8.4	3.9	4.8	6.4
UREA	mg/dL	57.94	120.18	175.97	12.876	113.74	175.97	15.022	53.65	188.85	15	62.23	128.76
U-NIT	mg/dL	27	56	82	6	53	82	7	25	88	7	29	60
URIC	mg/dL	4.8	7	9.4	2.9	7	9.2	3.2	4.8	9.4	3.1	4.6	7.4

Legend: ✓ No Warnings; * Late Results; 2.0≤ |Z- score| < 3.0; |Z- score| ≥ 3.0; – No Result
* Amended Result (per participant's request); * Non-robust determination of Mean and SD

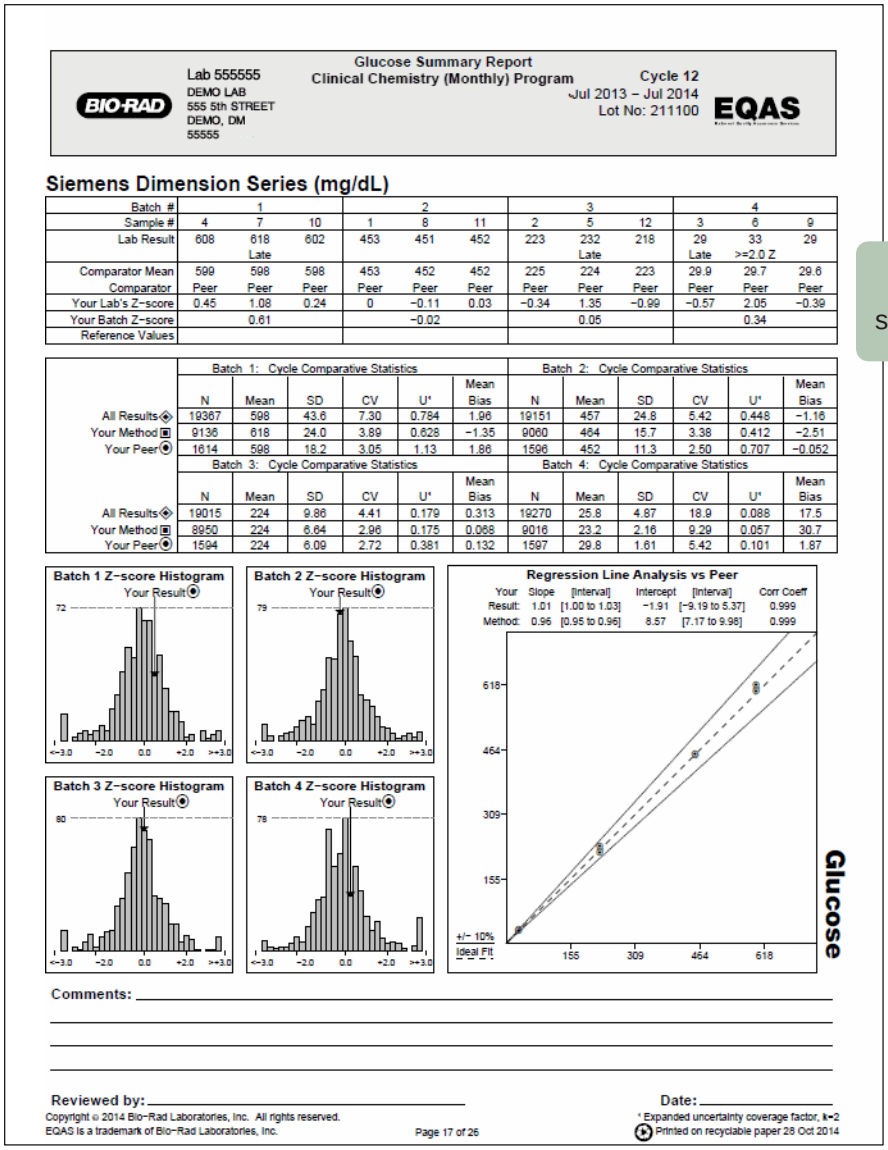
Are there consistent exceptions across multiple samples?

Are the majority of results marked with exceptions?

Review the Analyte Summary Report

The Analyte Summary Report groups your results by replicate samples (or concentrations) shown as batches. There are four batches in every cycle.

- Do the replicate samples agree?
- Are the batch statistics comparable or are there significant differences between the different batches?
- The Regression Line Analysis provides a graphical view of replicate precision and bias at different concentrations.



Glucose Summary Report
Clinical Chemistry (Monthly) Program
Cycle 12
Jul 2013 – Jul 2014
Lot No: 211100

Lab 555555
DEMO LAB
555 5th STREET
DEMO, DM
55555

Siemens Dimension Series (mg/dL)

Batch #	1			2			3			4		
Sample #	4	7	10	1	8	11	2	5	12	3	6	9
Lab Result	608	618 Late	602	453	451	452	223	232 Late	218	29 Late	33 >=2.0 Z	29
Comparator Mean	599	598	598	453	452	452	225	224	223	29.9	29.7	29.6
Comparator	Peer	Peer	Peer	Peer	Peer	Peer	Peer	Peer	Peer	Peer	Peer	Peer
Your Lab's Z-score	0.45	1.08	0.24	0	−0.11	0.03	−0.34	1.35	−0.99	−0.57	2.05	−0.39
Your Batch Z-score		0.61			−0.02			0.05			0.34	
Reference Values												

Are the batch statistics comparable?

	Batch 1: Cycle Comparative Statistics						Batch 2: Cycle Comparative Statistics					
	N	Mean	SD	CV	U*	Mean Bias	N	Mean	SD	CV	U*	Mean Bias
All Results	19367	598	43.6	7.30	0.784	1.96	19151	457	24.8	5.42	0.448	−1.16
Your Method	9136	618	24.0	3.89	0.628	−1.35	9060	464	15.7	3.38	0.412	−2.51
Your Peer	1614	598	18.2	3.05	1.13	1.86	1596	452	11.3	2.50	0.707	−0.052
	Batch 3: Cycle Comparative Statistics						Batch 4: Cycle Comparative Statistics					
	N	Mean	SD	CV	U*	Mean Bias	N	Mean	SD	CV	U*	Mean Bias
All Results	19015	224	9.86	4.41	0.179	0.313	19270	25.8	4.87	18.9	0.088	17.5
Your Method	8950	224	6.64	2.96	0.175	0.068	9016	23.2	2.16	9.29	0.057	30.7
Your Peer	1594	224	6.09	2.72	0.381	0.132	1597	29.8	1.61	5.42	0.101	1.87

Comments: _____

Reviewed by: _____ Date: _____

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* Expanded uncertainty coverage factor, k=2
Printed on recyclable paper 28 Oct 2014

How to Use the Method Summary Report

The Method Summary Report is helpful to assess how instruments using similar methodologies/reagents compare to one another and to those instruments using different methodologies/reagents. This is useful information to review if your laboratory is considering a change in the current instrument, reagent, or methodology for a test.

How to Use the Subgroup Report

You can use the Subgroup Report to assess the performance between different laboratories or between identical instruments reporting with different lab numbers within a single laboratory. All individual participant statistics are provided in the report. It is up to the subgroup leader to use this information.
You can sort the Subgroup Report by performance criteria such as Z-score which can be useful to identify laboratories requiring additional investigation of their results or follow up by the subgroup leader regarding performance.

How to Use the Quality Specification Subgroup Report

Subgroup leaders may further evaluate performance of all labs in their jurisdiction against local regulatory or scientific specifications in a single Excel report. The Quality Specification Subgroup Report provides
a snapshot of the Subgroup Report parameters along with evaluations against alternative specifications (Ex. Biological Variation (BV), CLIA, RiliBÄK, RCPA, QMP_LS, and GOST (Russia) criteria).

chapter 7

How to Interpret Qualitative EQAS Reports

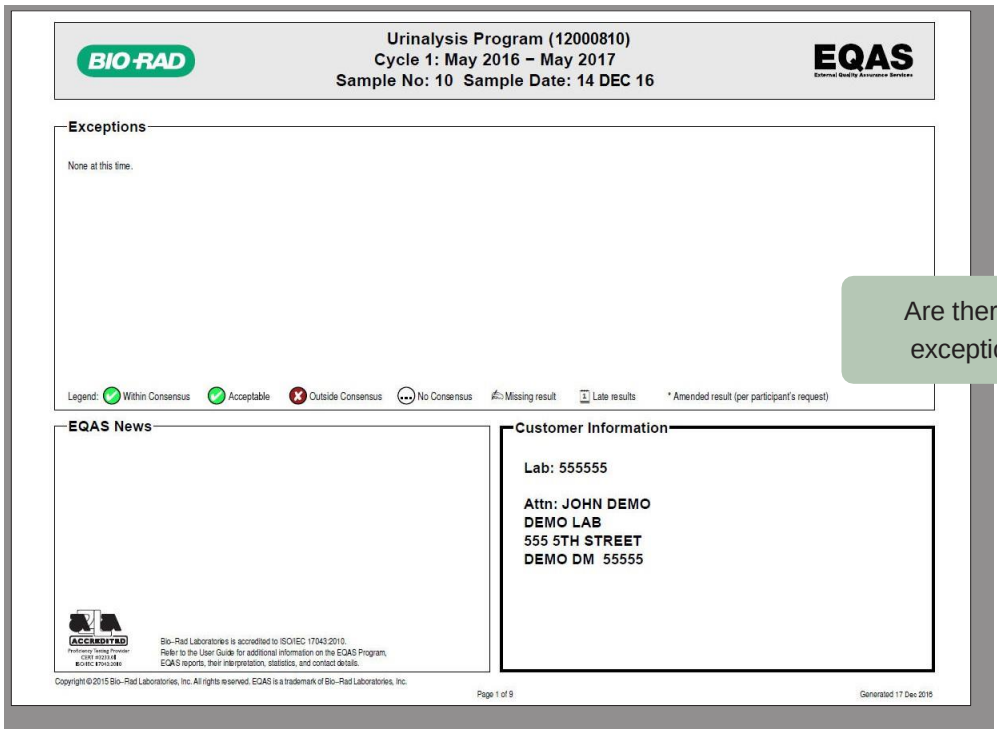
In This Chapter

How to Interpret the Peer Qualitative Sample Report.....105
How to Interpret the Peer-Method-All Results Qualitative Sample Report.....109

How to Interpret the Peer Qualitative Sample Report

Review the Coversheet

- Identify any exceptions. Are there any missing results?
- Make sure the reported results accurately reflect your instrument configuration and that no incorrect responses have been reported.

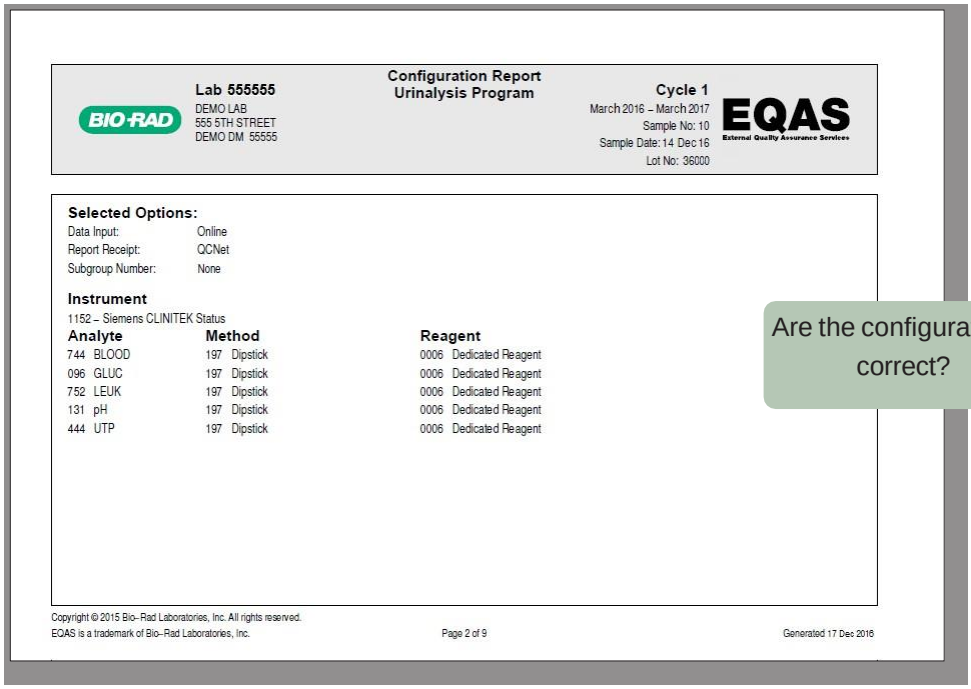


- If any results are outside consensus, please review the next report pages.

Review the Configuration Report

Make sure the following configuration is correct for each analyte. This is especially important when you first submit results after you make changes to your configurations.

- Instrument
- Method
- Reagent



Review the Sample Summary Report

This report can provide a quick overview of all your reported results. Please verify that all results reflect your instruments results and that no data entry error has occurred.

Review the Peer Qualitative Sample Report

- Review your result and evaluation, if less than 5 results are received for your peer no evaluation will be done (N <5 will be displayed in the evaluation field). Check if there is a reference value available
  (displayed below the Month: Peer legend) to compare against? If yes, how does my result compare to this reference value?
- If your result is within consensus, the result bar will be highlighted in green. Your result corresponds with 80% or more of your peer group so your performance is comparable with your peer.
- If an analyte has fewer than 4 response options and your result is outside consensus, the result bar will be highlighted in green. Your result is one pad different from the consensus group and considered acceptable.
- If an analyte has fewer than 4 response options and your result is outside consensus, the result bar will be highlighted in red. Your result does not correspond with 80% or more of your peer group and performance of the test should be investigated:
  - Is my result close to the consensus or not?
  - Is it the first time my result is outside of consensus or has this happened before?
  - If this is not the first time my result is outside consensus, is there a systematic occurrence? For example, are only the high results outside of consensus?
  - Is there a reference value available (displayed below the Month: Peer legend) to compare against? If yes, how does my result compare to this reference value?
  - How is my result compared to the top reporting instruments?
- If your peer has no consensus (less than 80% of the results are in agreement), the result bar is not highlighted. You can still proceed to investigate your performance, but please also investigate if there are any peer related performance issues:
  - Is my peer the only peer without consensus?
  - Is the peer close to consensus? What is the number of participants? There can still be value in a consensus lower but close to 80%.
  - Is this the first time there is no consensus, or does this happen regularly?
  - Is there any systematic occurrence? For example, are only the (high) positive results showing no consensus?
  - Is there a reference value available (displayed below the Month: Peer legend)? If yes, how does my peer compare to this reference value?
  - Are the top reporting instruments in consensus? And how does it compare to your peer?

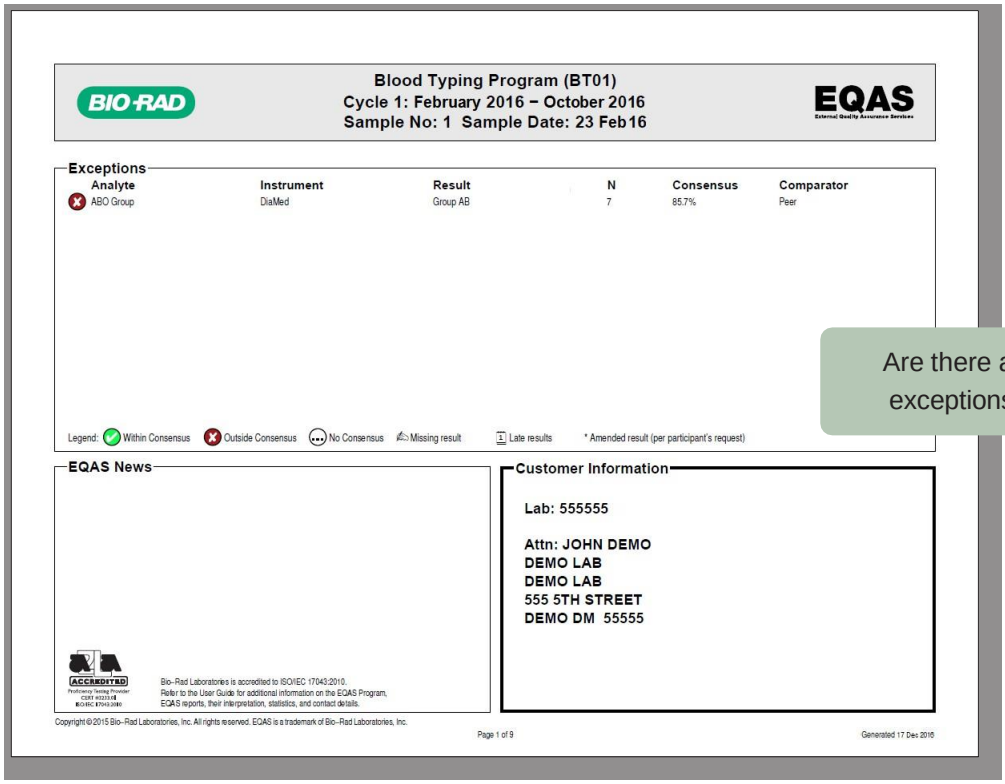
Review the Data on File Report

- Review the Data on File Report and look for any consistent exceptions across multiple samples.
  - This could indicate a systematic problem.
  - It could also be due to incorrect configuration of the test that led to an incorrect comparison.
- Look for exceptions within one sample.
  - Are the majority of the results flagged?
  - This could indicate a problem with this specific sample (reconstitution, dilution, storage, incorrect sample analyzed).

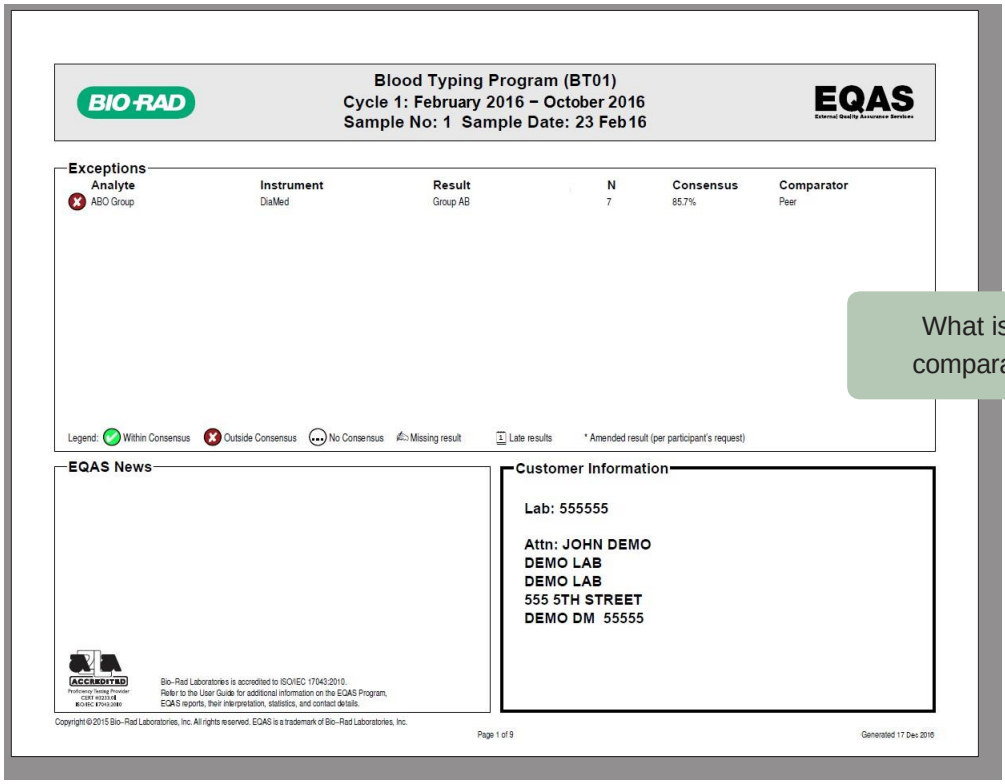
How to Interpret the Peer-Method-All Results Qualitative Sample Report

Review the Coversheet

- Identify any exceptions, are there any missing results?
- Make sure the reported results accurately reflect your instrument configuration and that no incorrect responses have been reported.
- Look at your result's comparator. The ideal comparator is your peer, then Method and finally All Results.



- Comparison at Method or All Result level can reflect non-instrument specific differences.

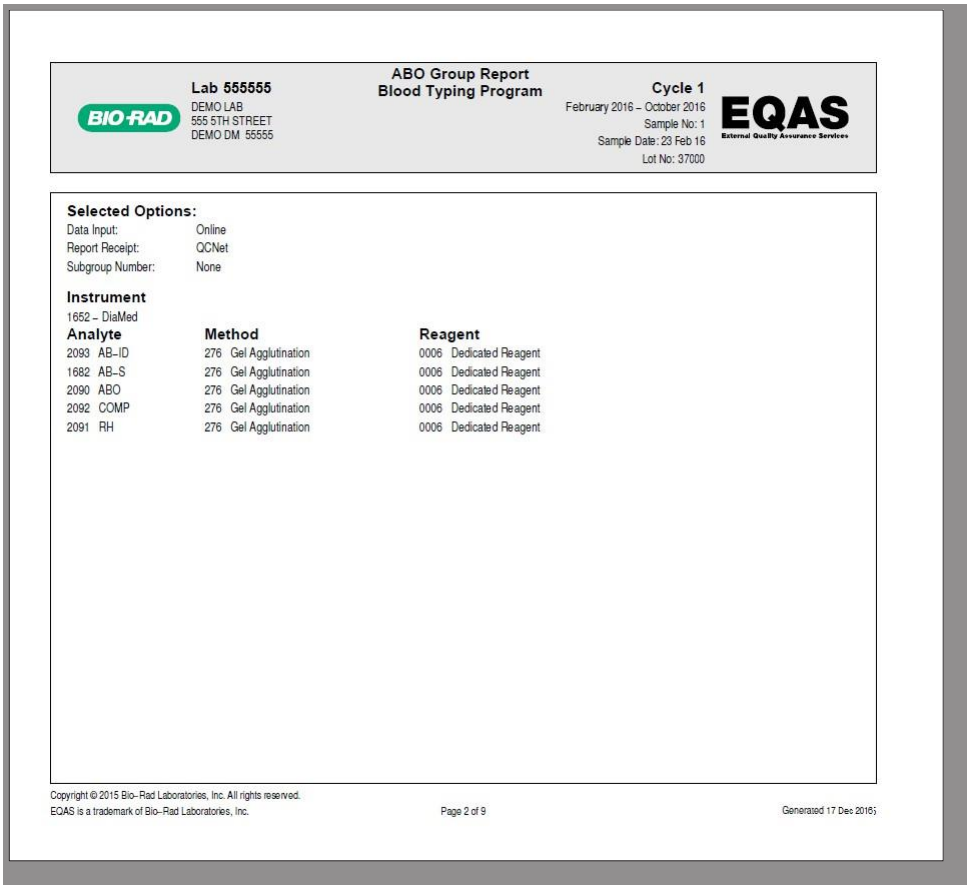


- If any results are outside consensus, please review the next report pages.

Review the Configuration Report

Make sure the following configuration is correct for each analyte. This is especially important when you submit results after you have made changes to any of the configurations.

- Instrument
- Method
- Reagent



BIO-RAD

Lab 555555
DEMO LAB
555 5TH STREET
DEMO DM 55555

ABO Group Report
Blood Typing Program

Cycle 1
February 2016 – October 2016
Sample No: 1
Sample Date: 23 Feb 16
Lot No: 37000

EQAS
External Quality Assurance Services

Selected Options:
Data Input: Online
Report Receipt: QCNet
Subgroup Number: None

Instrument
1652 – DiaMed

Analyte	Method	Reagent
2093 AB–ID	276 Gel Agglutination	0006 Dedicated Reagent
1682 AB–S	276 Gel Agglutination	0006 Dedicated Reagent
2090 ABO	276 Gel Agglutination	0006 Dedicated Reagent
2092 COMP	276 Gel Agglutination	0006 Dedicated Reagent
2091 RH	276 Gel Agglutination	0006 Dedicated Reagent

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Page 2 of 9
Generated 17 Dec 2016

Review the Sample Summary Report

This report can provide a quick overview of all your reported results. Please verify if all results reflect your instruments results and no data entry error has occurred.

Review the Peer-Method-All Results Qualitative Sample Report

- Review your result and evaluation, if less than 5 results are received for your peer, your comparison will be either your Method (if at least 5 results are received) or All Results. Notice the arrow is displayed next to the comparator group you are evaluated against!
- If your result is within consensus the result bar and your result arrow will be highlighted in green. The colored arrow indicates at which level your comparison is done (ideally this is peer, but if less than 5 results are received for the peer you will be compared against the Method. If less then 5 results are received for the Method you will be compared against All Results.) Your result corresponds with 80% or more of your peer group so your performance is comparable with your comparator group.
- If your result is outside consensus the result bar and your result arrow will be highlighted in red. Your result does not correspond with 80% or more of your comparator group and performance of the test should be investigated:
  - At what comparator level has my result been evaluated?
  - Is my result close to the consensus or not?
  - Is it the first time my result is outside of consensus or has this happened before?
  - Is there a reference value available (displayed below the Peer legend) to compare against? If yes, how does my result compare to this reference value?
  - How is my result compared to the top reporting instruments?
- If your comparator has no consensus (less than 80% of the results are in agreement) the result bar and your result arrow is not highlighted. You can still proceed to investigate your performance, but please also investigate if there are any peer related performance issues:
  - Is my comparator the only peer without consensus?
  - Is the comparator close to consensus? What is the number of participants? There can still be value in a consensus lower but close to 80%.
  - Is this the first time there is no consensus, or does this happen regularly?
  - Is there a reference value available (displayed below the Peer legend)? If yes, how does my peer compare to this reference value?
  - Are the top reporting instruments in consensus? And how does it compare to your peer?

Review the Data on File Report

- Review the data on file report and look for any consistent exceptions across multiple samples.
  - This could indicate a systematic problem
  - This could also be due to incorrect configuration of the test that led to an incorrect comparison.
- Review the data on file report and look for any consistent exceptions within a specific sample.
  - Are the majority of the results flagged?
  - This could be due to a problem with a specific sample (storage, incorrect sample analyzed, etc.)

chapter 8

Statistics and Algorithms Used in EQAS Reports

In This Chapter

Statistics Used in the Sample Report....114
Statistics Used in the End-of-Cycle Report....117
Method Summary and Subgroup Report Statistics....119

Statistics Used in the Sample Report

N
The number of results received. Defines the number of data points in the data set.

Robust Mean
The estimate of the population mean using a robust algorithm. Refer to the International Standard, ISO 13528 (2022), Annex C, Robust analysis, Algorithm A for more information.

Robust Standard Deviation (σ)
The estimate of the population standard deviation using a robust algorithm. Refer to the International Standard, ISO 13528 (2022), Annex C, Robust analysis, Algorithm A for more information.

Non-robust Mean ($\bar{x}$) and Standard Deviation (SD)

The traditional mean and SD calculation formulas. In some circumstances, the robust statistical process may not be used to evaluate the comparator statistics. In such cases “traditional” statistics are used. The use of traditional (non-robust) statistics occurs in cases where the consensus group’s standard deviation is zero. This is encountered when 50% or more of the results submitted are of the same value.

$$x = \sum x_n / n$$

Where: Σ = sum

x_n = each value in the data set

n = the number of values in the data set

$$SD = \sqrt{\frac{\Sigma(x_n - \bar{x})^2}{n - 1}}$$

Where: SD = standard deviation

x = mean (average) of the QC values

$\Sigma(x_n - \bar{x})^2$ = the sum of the squares of differences between individual QC values and the mean

n = the number of values in the data set

Coefficient of Variation (CV)

Coefficient of variation is the relative standard deviation (that is, the standard deviation expressed as a percentage of the mean). The CV is useful because it is independent of concentration.

$$CV = (SD \div \bar{x}) \times 100$$

Where: SD = standard deviation

x = mean

Uncertainty (U)

Standard uncertainty of the assigned value is estimated. It is an indicator in the confidence of the comparator mean (assigned value). Lower values, close to zero, indicate low uncertainty. Higher values indicate greater uncertainty (or reduced confidence) in the comparator results. When the assigned value is derived as a robust mean calculated using Algorithm A, the reported U represent expanded uncertainty expressed at approximately the 95% confidence level using a coverage factor of k=2.

$$U = 1.25 \times \frac{\sigma}{\sqrt{n}} \times k$$

Where: σ = the robust standard deviation

n = the number of values in the data set

k = defined coverage factor of 2

Z-score

The Z-score is the number of comparator SD that your result differs from the comparator mean. The Z-score is a measure of your laboratory's bias relative to your comparator group. Care should be taken when your comparator is comprised of other instruments or methods.

A Z-score result may be considered:

Acceptable if	|Z-score| ≤ 2.0
Warning if	2.01 < |Z-score| < 3.0 (investigation recommended)
Unacceptable if	|Z-score| ≥ 3.0 (remedial action usually required)

$$\text{Z-score} = \frac{\text{Your Result} - \text{Comparator Mean}}{\text{Comparator SD}}$$

RMZ

Running Mean Z-score. This is the average Z-score for the last six samples for a particular analyte or parameter. This is cycle independent.

Percentage Deviation (%)

The mean bias of a laboratory's result relative to the comparator mean, expressed as a percent.

$$\% = \frac{\text{Your Result} - \text{Comparator Mean}}{\text{Comparator Mean}} \times 100$$

Histogram

The minimum and maximum values shown on the X-axis of the comparator histograms are determined by a maximum of ± 5 SD of the comparator mean. If the extreme values are lower then 5 SD, they will be used. The number of participants is shown on the Y-axis in the tallest histogram bar.

Statistics Used in the End-of-Cycle Report

End-of-Cycle statistics are presented by batches, with each batch comprised of three replicate samples tested throughout the program cycle.

- Your Lab Z-score:

$$\frac{\text{Your Result} - \text{Comparator Mean}}{\text{Comparator SD}}$$

- Your Batch Z-score:

$$\frac{\text{Your mean batch result} - \text{Comparator batch mean}}{\text{Comparator batch SD}}$$

Cycle Comparative Statistics

N, robust mean and standard deviation, Non-robust (traditional) mean and standard deviation, CV and Uare all described in “Statistics Used in the Sample Report” earlier in this chapter.

Mean bias is similar to “Your Deviation” percentage (%) in the Sample Report, however the laboratory’s batch mean replaces the lab’s sample result and the comparator batch mean replaces the mean comparator result.

$$\text{Mean bias} = \frac{(\text{Lab mean of batch} - \text{Comparator mean of batch})}{\text{Comparator mean of batch}} \times 100$$

Batch Z-score Histogram

Batches are noted as 1, 2, 3, or 4. Your laboratory’s mean Z-score for the batch is identified with a downward arrow. The X-axis denotes overall Z-scores (negative to positive) such that 95% of the laboratories are reflected. The Y-axis denotes the number of laboratories.

Regression Line Analysis

The Regression Line Chart is plotted for:

Lab result vs. Comparator mean*

After the regression line is calculated the points are plotted on the curve to illustrate the bias graphically. The lab submitted result for each sample is the Y coordinate while the comparator mean for that sample is the X coordinate. This is plotted for each sample reported by the laboratory. Confidence intervals for the slope and the intercept are calculated as well as the correlation coefficient.

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* Where methods are multi-modal, the Mode mean vs. Peer mean regression line will be plotted.

Mean Z-score Report

Your laboratory’s mean bias (mean absolute Z-score across all batches) is shown numerically for each reported analyte. Also shown is a linear scale of the overall bias for the analyte for all participants in the same comparator group. The best 10%, 50%, and 90% is reflected on this scale with the participating laboratory’s mean method Z-score across all batches.

- A percentile value is calculated for each reported analyte. It indicates how your laboratory’s value corresponds to the location of the mean Z-score for the particular instrument and analyte combination in relation to your comparator group.
- A lower percentile indicates better performance in relation to your comparator group.
- If you are the only lab in the comparator group, no comparison will be possible and a dash (-) will be displayed.

National and Worldwide Performance Score Histograms

- Your laboratory is ranked in quintiles based on your performance against national and overall participants as two separate histograms.
- The Y-axis is the number of laboratories.
- The X-axis is unnamed and shows the “best” performance at the far left.
- The laboratory’s overall performance is noted as to which quintile they fall in and scored based on the following algorithms:
  - Late result: |Z-score| + 0.2
  - Amended result: |Z-score| + 0.4
  - Your laboratory’s results are then normalized based on the number of results reported.

Method Summary and Subgroup Report Statistics

All statistics presented in the Method Summary and Subgroup reports have been covered in the “Statistics Used in the Sample Report” section. Please refer to that section if additional information is required.

chapter 9

Frequently Asked Questions

Question: Can I join an EQAS Program after a cycle has started?
Answer: Yes, however it is subject to the availability of inventory.

Question: What if I make an error in reconstituting the sample?
Answer: Contact your local Bio-Rad representative. Bio-Rad can supply another vial for you to assay (subject to available inventory). Full instructions on reconstitution and storage are described in the package insert that comes with the product.

Question: Are the samples animal or human-based?
Answer: EQAS Samples are human based when technically feasible.

Question: How do I change my test method?
Answer: Changes may be made in the Test Setup menu of EQAS Online or EQAS Mobile at any time during the cycle. Remember to select the sample number from which the changes will apply.

Question: Some assays are carried out infrequently in my laboratory. Can I submit results after the Sample Due Date?
Answer: Yes. Results may be submitted at anytime within the cycle (and within the sample expiration date). A retrospective, updated report will be available on-line within 24 hours. Late results will be flagged on your report, and your results will not be part of the
comparator statistics.

Question: Do you have a customer complaint procedure?

Answer: We hope you do not have cause to complain. If this occurs, please contact our Customer Support by email or telephone as soon as possible so that we can act promptly. All complaints are logged into a database and given a reference number. We are continually reviewing our database to improve our service to you. See Chapter 2, “EQAS Contact Information” for details.

Question: Can Bio-Rad provide technical advice and help?

Answer: Yes. Bio-Rad has qualified staff that can help you on technical issues relating to our EQAS Programs or quality control in general. Bio-Rad can also provide you with additional data to assist in solving quality control related problems. Please contact EQAS Technical Support. See Chapter 2, “EQAS Contact Information” for details.

Question: Why am I compared using the Method comparator instead of the Peer comparator?

Answer: There were an insufficient number of participants reporting on the same instrument/ reagent for that sample at the time of the sample close. Although there must be at least 9 accepted peer-specific results for a formal comparison to be made at the Peer level, laboratories should evaluate their peer comparison when fewer than 9 participants’ results were accepted. The EQAS Program comparator for that analyte/sample combination will, however, be made at a Method or Mode/All Results level depending on the number of accepted results.

Question: My data more closely reflects a different Mode. How can I change modes?

Answer: We appreciate that you are carefully reviewing the comparisons in your EQAS report. If you feel that your comparison better fits another mode, contact your local Bio-Rad representative or email EQAS Technical Support at eqas_support@bio-rad.com. You will work with Technical Support personnel to establish if your method should be placed in another mode and if so, what configuration is appropriate to use.

Question: What does it mean when “Insufficient results for calculation of your statistics” appears on the Coversheet of my End-of-Cycle Report?

Answer: The data submitted for the analyte during the program cycle did not include at least 9 results on the same instrument/reagent. Although you will receive some statistical calculations of your laboratory’s performance, there are an insufficient number of acceptable results for credible analysis.

Question: I sent in corrected (or late) data. When will the updated report be posted to EQAS Online?

Answer: Your update report will be available on EQAS Online within 24 hours of submitting your results.

Question: Why did I not receive my Certificate of Achievement for the last program cycle?

Answer: To receive a Certificate of Achievement, a laboratory must submit a minimum amount of acceptable data for at least one analyte in a program cycle. The minimal amount is 9* results for the same analyte within ± 3.0 Z-score of the comparator during the cycle.

(* a minimum of 6 results are required for EQAS Blood Typing)

Question: Can I report both qualitative and quantitative results for my tests?

Answer: Yes. For the Infectious Disease Programs, you will find two programs to register and enroll in through EQAS Online; one for Quantitative and one for Qualitative reporting. Results can be entered for both programs and corresponding reports retrieved through
EQAS Online.

chapter 10

Glossary

Algorithm A

The robust mean and standard deviation (SD) algorithm described in ISO 13528, “Statistical methods for use in proficiency testing by interlaboratory comparisons.” This is the primary algorithm used in the EQAS Program to calculate (estimate) the robust mean and SD of each comparator.

All Results

One of the consensus groups in the EQAS Program. “All Results” is a comparator that includes all users reporting the same analyte for a specific EQAS sample. No differentiation is made between instruments, methods, or reagents. This comparator has the most data points, but is the least specific group of comparison for EQAS results. The All Results comparator is only provided for uni-modal analytes.

Amended Result

A result sent to Bio-Rad after a sample close that replaces a previously reported result. An amended result submitted by the laboratory is identified in the EQAS reports by an asterisk (*) next to the result. Amended results are compared to the dataset that was in place at the time the sample closed. These are not included in the dataset until a recalculation at the end of a cycle to include all late and amended results.

An amendment to a submitted result will be made as requested by the participant. Such amended results will be flagged in your EQAS reports. Your laboratory should note the reason for the amended result in the comment section of your EQAS report. Corrections made on Bio-Rad’s behalf (error in data entry) will be corrected and an amended result flag will not appear in your EQAS report for that result.
The comparison will be to the dataset that was in place at the time of sample close.

Analyte

A substance or constituent for which the laboratory conducts testing.

Arithmetic Mean (Non-Robust Mean)

1) The sum of values divided by the number of values.
2) The Bio-Rad EQAS Program uses this formula when a robust calculation of the comparator mean is not possible.

Assay

1) A quantitative determination or measurement of the amount, activity, or potency of a constituent; a quantitative assessment of an analyte.
2) To analyze or measure a sample of a specimen to determine the amount, activity or potency of a specific analyte or substance.

Assay Range

The upper and lower limits of the amount, activity, or potency of a specific analyte between which measurement is possible.

Batch

A single, homogeneous quantity of product manufactured at the same time. For EQAS, there are typically four batches in each program cycle, with each batch comprised of three replicate samples.

Batch Z-score Histogram

A visual representation (see histogram) of participants' Z-score distribution in a given batch. The X-axis (horizontal) shows the Z-score value (0 as central value). The Y-axis (vertical) shows the highest number of results in a given bar.

Bias

1) A measurement of how far an observed value is from the consensus value. This can be expressed as a percentage (as in percentage deviation) or as a Z-score.
2) The systematic deviation of the test results from the consensus value. One or more systematic error components may contribute to the bias.

Comparator or Consensus Group

Laboratories' submitted results that are statistically compared together for a select analyte/parameter within a defined EQAS sample. Your comparator is that against which your own result was evaluated for a determination of laboratory performance and is the value plotted on the top of the Levey-Jennings chart. Your comparator is dependent on the dataset being uni-modal or multi-modal. At each
comparator level, at least 9 results should be received for your lab's comparison to be made at that level. The comparators or consensus groups are (from most specific to least specific): Peer, Method, Mode, All Results.

- Peer (most specific)
  The Peer consensus group consists of all laboratories using the same instrument, reagent, and analytical method of a test. This is the ideal group for comparison.
- Method (next specific)
  The Method consensus group includes laboratories using the same analytical method of a test. If there are an insufficient number of laboratories in the Peer group, the Method group will be your next level of comparison with the following exception: Should a Method have a multi-modal distribution of results, your comparator level will go from Peer to the Mode level.
- Mode (less specific)
  The Mode consensus group is comprised of methods (can be one or more) or instrument and reagent (peer) combinations that together produce a similar result that is significantly different than other results being reported for the same analyte or parameter. When all instruments and methods produce similar results for a given analyte or parameter, there is no need to establish modes. Instead, the comparison will be to all returned results (All Results).
- All Results (least specific)
  The All Results consensus group includes results from all laboratories reporting for the same analyte in the sample.

Comparison

An assessment or correlation of two or more things such that similarities and differences between them are identified.

Concentration

A measure of the amount of dissolved substance per unit of volume.

CV

Coefficient of variation.

1) A measure of relative precision.
2) For a non-negative characteristic, the ratio (displayed as a percentage) of the standard deviation to the mean.
3) The CV is useful because it is concentration independent. CV = (SD / mean) × 100

EQA

External quality assessment.

EQAS

External Quality Assurance Services.

Histogram

1) A graph that uses bars (rectangles) to display the frequency of the values (reported or calculated dataset) by their relative height.
2) A visual interpretation of a dataset in which individual points are grouped in ranges or bins and the frequency of their occurrence displayed.

Interlaboratory

Between different laboratories.

ISO

1) International Organization for Standardization.
2) An international body of experts that sets general standards of performance.

Late Result

A participant submitted result for a select sample that is received at Bio-Rad EQAS after that sample has closed (Sample Due Date). Late results are identified in EQAS reports by a symbol 1 or as text. Late results are compared to the dataset that was in place at the time the sample was closed. They are not included in the dataset until a recalculation at the end of a cycle to include all late and amended results.

Levey-Jennings Chart

A commonly used trend chart in which individual deviation measurements are plotted around a line representing zero deviation. Allowable limits of error (Z-score lines) are displayed in parallel to the zero deviation line. These limits being defined deviations from the consensus mean, ± 1.0, 2.0 and 3.0 Z-score. Time is displayed on the X-axis (horizontal). The consensus mean for your comparator is noted on the top of the Levey-Jennings chart. This chart provides a visual representation of how well a laboratory test is working.

Lyophilized

The characteristic describing the result of the process of vacuum-freeze-drying a liquid material to make its components more stable.

Matrix

Refers to the physical and chemical nature of the specimen, the substances present and their concentration.

For example: urine, serum, plasma, or whole blood.

Method

1) Method is a comparator encompassing users reporting on the same analyte using a specific methodology. This is generally the second level of comparison for your results. There is no differentiation between instruments or reagents at this comparator. There must be at least 9 results present at the Method comparator level, or your comparison assessment moves to the next level (All Results). For multi-modal data distributions, comparison at Your Method is provided for informational purposes only.
2) Methodology.

Methodology

The means by which an analyte is measured.

Missing Result

A laboratory result that was expected by Bio-Rad EQAS for a registered test but not received prior to the close of a sample (Sample Due Date). A missing result is identified in your EQAS reports with the symbol and a dash (-) in place of the missing value.

Mode

A comparator comprised of methods (can be more than one) or instrument and reagent (peer) combinations that together, produce a similar result that is significantly different than other results being reported for the same analyte or parameter. The Mode is a subset of the “All Results” comparator.
Modes are only created when there is a multi-modal distribution of the results. This allows for a more specific estimation of a laboratory’s comparison versus the use of all reported results.

N

Used to indicate the number of results received or the number of values in a dataset.

National Performance Score Histogram

A visual representation of the performance scores of all laboratories within the same country in a given program cycle. The X-axis (horizontal) shows a quintile distribution of performance scores for participating laboratories. The best scores are located to the left side of the graph. The Y-axis (vertical) reflects the number of participants. The number of participants in each quintile is displayed above
the associated histogram bar. The performance score for each laboratory is calculated by creating an overall peer mean, absolute Z-score across all samples and analytes. Penalties are applied for late and amended results submitted by the laboratory, then normalized based on the number or results the laboratory reported in the cycle. Your laboratory’s performance relative to others in your country is indicated as placement in one of the quintiles.

Peer

Peer describes the comparator level where participants are reporting the same analyte with the same methodology on the same instrument or instrument grouping with similar reagents. This is the most specific level of comparison for your results. If there are less then 9 results present in the dataset, your comparator level will move to the next level (Method or Mode).

Percentage Deviation (%)

The bias of your laboratory’s result expressed as a percentage of the reported comparator mean.

$$\frac{\text{Your result} - \text{Comparator mean}}{\text{Comparator mean}} \times 100$$

Proficiency Testing/External Quality Assessment

A program in which multiple blind specimens are periodically evaluated by a group of laboratories for interlaboratory analysis and/or identification. Each laboratory’s results are compared with those of the other laboratories in the group and/or with an assigned value, and reported to the participating laboratory and others.

Quality Specifications

Criteria for evaluation of acceptable analytical performance based on clinical outcome, biological variation, expert opinion, or State-of-the-Art statistical analysis.

Quintile

A data set representing 20% of the total population. The first quintile represents the first one-fifth of the population (1%–20%); the second quintile represents the second fifth (21%–40%) etc.

Random Error

An error in measurement that occurs in an unpredictable way. Random errors do not affect measurements the same way. They may produce either a positive or negative deviation, the direction and magnitude of which cannot be predicted. This is in contrast to systematic error, which affects all measurements in the same way. It is not possible to correct for random error.

Reagent

A substance that produces a reaction, especially one that can be used to detect, measure or produce another substance that results in an “answer” for a particular test.

RMZ

Running Mean Z-score. An ongoing (within or across cycles) average of the Z-scores of the last six samples for a given analyte.

Robust Mean

An estimate of the dataset mean using a robust algorithm. This algorithm calculates the mean and standard deviation of the dataset through an iterative statistical process. For additional information, refer to the International Standard, ISO 13528 (2022), Annex C, Robust analysis, Algorithm A.

Robust Statistics

Robust statistics are based on the assumption that a given dataset exhibits a normal distribution of measured values contaminated with a small portion of outliers. The robust statistic is not excessively affected by the outliers. These statistics are calculated by down-weighting the data points that are distant from the mean and then compensating for that down-weighting.

Sample Close

A sample is closed on the Sample Due Date. This is when the dataset is established and a statistical analysis is performed to provide each reporting laboratory a comparison of their performance for that sample.

Sample Due Date

The date on which a sample's results are to arrive at Bio-Rad EQAS for the statistical analysis. The results will be accepted until 20:00 GMT time on the specified date. Sample Due Dates are displayed for each EQAS Program on the sample vial label and in various documents. Results received after this due date will be represented as late in the EQAS reports.

Standard Deviation (SD)

A statistic that quantifies the degree of dispersion or spread of a set of data points around the mean value of a Gaussian or normal distribution.

Standard Deviation Index (SDI)

A statistical measure that is expressed as Z-score in the EQAS Program.

Subgroup

A group or collective of laboratories with a common interest in an EQAS Program. These laboratories are grouped together in special reports that are generated and distributed to a designated subgroup leader.

Systematic Error

An error that affects all measurements in the same way. This error produces measurement bias or deviation in the same direction (positive or negative). Systematic error is predictable and may be corrected.

Test

A unique combination of instrument, reagent, method and unit for a given analyte or parameter.

Trend

1) A gradual often subtle, increase or decrease in a laboratory's values and possibly patient values.
2) A type of systematic error.

Uncertainty (U)

This is a non-negative parameter characterizing the dispersion of the values attributed to a measured quantity. The uncertainty has a probabilistic basis and reflects incomplete knowledge of the quantity. In all EQAS reports, the U represents an expanded uncertainty of the consensus mean expressed at approximately the 95% confidence level using a coverage factor of k=2.

Valid Configuration

An accurate combination of the variables and descriptions for analyte, method, instrument/kit, reagent, and unit(s) for a laboratory test.

For EQAS programs, validity is confirmed by Bio-Rad EQAS on-line or EQAS mobile. Incorrect configurations result in data being placed into the wrong peer group, which in turn results in incorrect comparisons. Data collected using invalid configurations skews peer group results for all participants.

Worldwide Performance Score Histogram

A visual representation of the performance scores of all laboratories worldwide in a given program cycle. The X-axis (horizontal) shows a quintile distribution of performance scores for participating laboratories. The best scores are located to the left side of the graph. The Y-axis (vertical) reflects the number of participants. The number of participants in each quintile is displayed above the associated histogram bar. The performance score for each laboratory is calculated by creating an overall peer mean, absolute Z-score across all samples and analytes. Penalties are applied for late and amended results submitted by the laboratory, then normalized based on the number or results the laboratory reported in the cycle. Your laboratory's performance relative to other participants worldwide is indicated as placement in one of the quintiles.

Yundt Plot

A trend chart in which individual measurements are plotted directly on a control chart around the central mean with Z-score limit lines. In contrast to a Levey-Jennings chart, the X-axis (horizontal) shows the analyte concentration (comparator means). The Yundt Plot can be used to visually detect concentration bias, systematic errors and linearity errors.

Z-score

A statistical measure of SDI in the EQAS Program.

1) A statistic that measures your laboratory's bias relative to your consensus group.
2) The bias of your laboratory's result expressed in standard deviations of the comparator. A Z-score of 1 indicates a 1 SD bias between your result and the comparator mean. The target Z-score is 0, which indicates that your result is identical to the comparator mean. The Z-score can be calculated using the following formula.

$$\frac{\text{Your result} - \text{Comparator mean}}{\text{Comparator SD}}$$

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For further information, please contact your local Bio-Rad office or learn more online at www.bio-rad.com/eqas

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