



Bio-Plex™

System Tools

A Solid Foundation

BIO-RAD

Build Reliable Results

Reliable and reproducible multiplex assays require an instrument with proper optical alignment, reporter performance, and fluidics integrity. Only the Bio-Plex system includes tools to ensure that all system parameters are within specifications and that the signal output has been calibrated. Performing system validation and reader calibration is the best way to ensure the precision of your assay results and to make comparisons between data sets with confidence. System calibration and validation results are documented in the Bio-Plex Manager™ database from the date of installation for system performance monitoring. The validation and calibration protocols are automated by Bio-Plex Manager software using the Bio-Plex maintenance, calibration, and validation (MCV) plate.



Tools for Optimal Assay

System Performance Verification Simplified

Central to the validation and calibration kits is the Bio-Plex MCV plate. The MCV plate is a specially designed microplate that holds the reagents required for validation and calibration as well as the wash solutions. With Bio-Plex Manager software and the MCV plate, system tool processes are automated. Simply load the kit reagents and wash solutions for walk-away performance. The MCV plate also functions as a general tool when operating the Bio-Plex system and greatly reduces the time and labor required for routine operations. Use the MCV plate for:

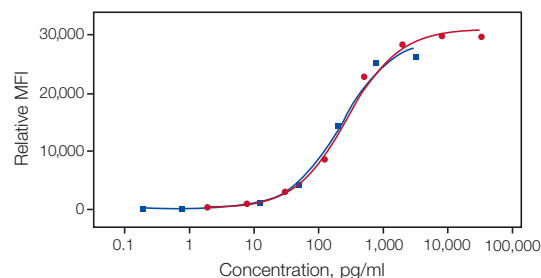
- Automated calibration and validation protocol
- Automated system startup and shutdown routines
- Automated washes between assay plates
- Easy adjustment of sample needle height



Assay Reporter Signals Standardized

Daily calibration with the Bio-Plex calibration kit ensures optimal assay reproducibility and facilitates comparison of data both within and across laboratories. Calibration is also an important tool for monitoring instrument reliability. Perform daily calibration to:

- Standardize daily signal output
- Optimize laser output for low range sensitivity or broad range detection
- Monitor laser life



Concentration ranges for Bio-Plex human IL-1 β high-sensitivity (■) and broad range (●) standards. The Bio-Plex calibration kit allows calibration at a high photomultiplier tube (PMT) target value for high-sensitivity standards or a low target value for broad range standards to maximize the % recovery for each standard point. Use the high-sensitivity standards for low range detection and broad range standards for detection over a broader dynamic range.

Performance

Critical System Parameters Validated

The Bio-Plex validation kit is used to verify instrument performance during system installation and for monthly operational certification (IQ/OQ). This kit also helps to distinguish between instrumentation and assay reagents when troubleshooting suboptimal results. The validation kit consists of four special bead sets to validate the following performance specifications of the array reader:

Optical Alignment

Optics validation uses a set of two beads containing dyes with signals that fall into all optical channels.

- Confirms assay sensitivity and well-to-well precision
- Verifies that array reader optics are properly aligned

Reporter Performance

Reporter validation uses a set of seven beads dyed to varying intensities with a fluorophore that is spectrally matched to Bio-Plex reporter molecules.

- Measures linearity, instrument threshold, dynamic range, slope, and accuracy
- Optimizes quantitation

Classification Accuracy

Classify validation uses a set of five beads containing varying ratios of the two Bio-Plex classification dyes.

- Measures efficiency of determining bead regions
- Ensures proper bead classification, which is critical for multiplexing

Fluidics Integrity

Fluidics validation uses a set of two beads containing varying relative quantities of beads.

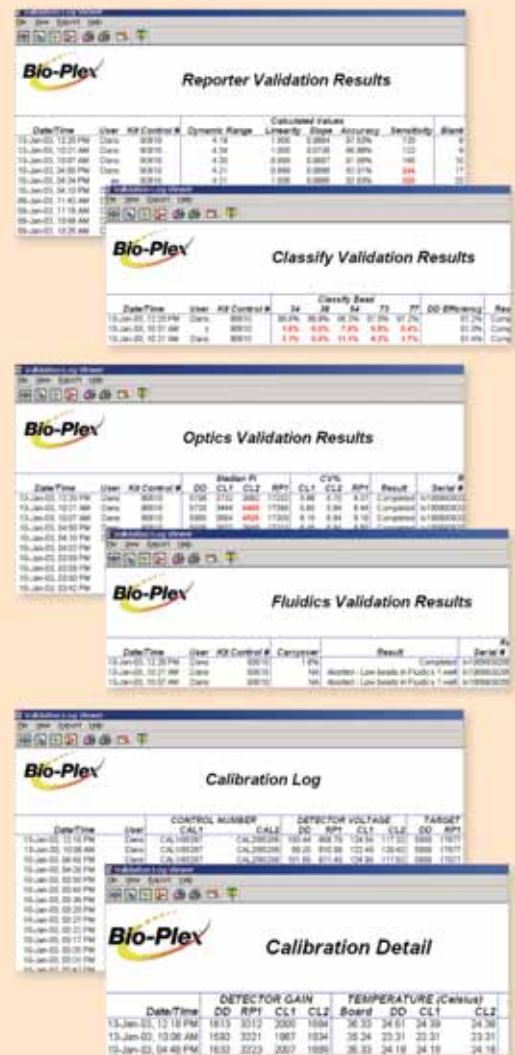
- Monitors fluidics performance
- Prevents cross-contamination



Validation Kit

Integrated System Performance Tracking

The Bio-Plex system integrates system control, system validation, and system calibration within Bio-Plex Manager software. In addition to simplifying workflow with automated procedures, the software documents all validation and calibration results in the Bio-Plex database file. This database tracks the user, date, instrument serial number, and control number of the Bio-Plex validation and calibration kits along with the test results. This log can be used to monitor system performance over time, and to assist in troubleshooting. This record is invaluable for IQ/OQ certification since it is onboard the system for easy access to validation records.



Bio-Plex Validation Kit 4.0 Specifications

Parameter	At High PMT Target Value	At Low PMT Target Value
Optics Validation		
DD median	4,774–6,593	4,774–6,593
CL1 median	3,383–4,135	3,383–4,135
CL1 CV*%	2.0–7.0%	2.0–7.0%
CL2 median	3,520–4,302	3,520–4,302
CL2 CV%	3.0–8.0%	3.0–8.0%
RP1 median	15,205–18,583	3,509–4,290
RP1 CV%	4.0–10.0%	4.0–10.0%
Fluidics Validation		
% Carryover	≤4.0%	≤4.0%
Reporter Validation		
Dynamic range	4.19–4.39	4.33–4.45
Linearity	>0.995	>0.995
Slope	127.3–207.0	33.9–39.4
Accuracy	>90.0%	>90.0%
Instrument threshold	<20 MFI	<6 MFI
Classify Validation		
Bead A (region 1)	>80.0%	>80.0%
Bead B (region 4)	>80.0%	>80.0%
Bead C (region 40)	>80.0%	>80.0%
Bead D (region 54)	>80.0%	>80.0%
Bead E (region 100)	>80.0%	>80.0%
Doublet discrimination efficiency	≥75.0%	≥75.0%

* Coefficient of variation.

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For technical service, call your local Bio-Rad office,
or in the US, call 1-800-4BIORAD (1-800-424-6723).

Ordering Information

Catalog #	Description
171-203001	Bio-Plex Validation Kit 4.0 , includes optics validation, reporter validation, classify validation, and fluidics validation bead sets for approximately 50 validation routines using Bio-Plex Manager version 4.0 and Bio-Plex MCV plate III.
171-203032	Bio-Plex MCV Plate III , for use with Bio-Plex Manager version 4.0 software
171-203060	Bio-Plex Calibration Kit , includes Cal1 and Cal2 calibration beads for approximately 50 daily calibration routines



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