



## More Complete—Less Complex: Lyphochek® Allergen sIgE Control

A consolidated, independent control that increases confidence and ease.  
A rare combination.





## Lyphochek® Allergen sIgE Control

# More Complete

for more confidence in your allergy results

### Secure more reliable results and more predictable proficiency test performance

A consolidated, independent control, Lyphochek® Allergen sIgE Control is the most complete quality control solution for your *in vitro* allergy test systems. Combined with Unity™ QC Data Management Solutions, it enables you to improve the reliability of your allergy results and face proficiency testing more confidently.

#### Reduce variability of results and end control bias:

Eliminate the QC result variability of pooled samples and bias of manufacturer-provided controls by using an independent control, Lyphochek® Allergen sIgE.

#### Utilize distinct controls:

Lyphochek® Allergen sIgE offers two distinct control levels—Negative and Positive, to improve your confidence in test results.

#### Monitor precision:

Lyphochek® Allergen sIgE utilizes human source material that closely mimics patient samples, leading to more reliable results.

#### Catch trends as they develop:

The Unity™ Interlaboratory Program's real-time access to worldwide peer data enables more timely monitoring of QC result ranges and trends, making it possible for you to take corrective action long before your periodic proficiency testing.





## The security of partnering with the leader in third party controls

### **Trust in the security of unbiased QC**

Any patient result reported without evaluating quality control is at risk, and the best method for evaluating QC is with an independent control solution. Bio-Rad controls are not optimized for a specific instrument or reagent and, therefore, provide an independent assessment of a test system or method.

### **Experience the confidence that comes with working with the leader**

More laboratories trust Bio-Rad for quality control products and services than any other manufacturer. Our decades of industry leadership give our customers the security of consistent product quality they can count on to help ensure they report reliable results.

### **Improve efficiency through a supportive partnership**

Nothing impacts your laboratory's efficiency more than equipment taken offline to troubleshoot QC failures.

That's why, as your QC partner, Bio-Rad provides comprehensive service, support and consultation to our customers. Bio-Rad Technical Services is focused on providing you with the support and education you need to detect shifts, drifts and imprecision proactively—and to troubleshoot efficiently when more significant reliability errors occur.

### **Ensure the reliability of your results in real-time**

With Bio-Rad, you can consolidate your entire laboratory into one QC system with Unity Real Time<sup>®</sup>, which includes best-in-class tools to support run-time decision making, troubleshooting and QC design. With UnityConnect<sup>™</sup>, QC data can be quickly and easily imported from LIS, middleware or instruments directly. No program in the world can more effectively provide information about your Bio-Rad QC performance than the suite of Unity<sup>™</sup> QC Data Management Solutions.

Leverage our leadership to make your allergy laboratory best in class



## Consolidate allergy controls with Lyphochek® Allergen sIgE Control

An assayed, lyophilized control with quantitative insert values for fifteen allergen-specific IgE antibodies, Lyphochek® Allergen sIgE Control is designed to monitor the precision of *in vitro* allergy testing procedures.

- Human sourced material
- Two individual levels
- Assayed values in package insert
- 3 year shelf life at 2-8°C
- 28 day open-vial stability at 2-8°C

### Analytes

- D1 House Dust Mite (*Dermatophagoides pteronyssinus*)
- D2 House Dust Mite (*Dermatophagoides farinae*)
- E1 Cat Dander (*Felis domesticus*)
- E3 Horse Dander (*Equus caballus*)
- E5 Dog Dander (*Canis familiaris*)
- F1 Egg White (*Gallus spp.*)
- F2 Cow Milk (*Bos. spp.*)
- F13 Peanut (*Arachis hypogaea*)
- G2 Bermuda Grass (*Cynodon dactylon*)
- G3 Cocksfoot/Orchard Grass (*Dactylis glomerata*)
- G6 Timothy Grass (*Phleum pratense*)
- M3 Mold (*Aspergillus fumigatus*)
- M6 Mold (*Alternaria tenuis*)
- T3 Birch (*Betula*)
- W6 Mugwort (*Artemisia vulgaris*)

Refer to the package insert of currently available lots for specific analyte and stability claims

## The role of specific IgEs in an allergy diagnosis.

A definitive allergy diagnosis helps reduce the number of unnecessary tests performed and ultimately contributes to better patient management.

*In vitro* testing for specific IgEs is an important component of the diagnostic process. A specific IgE is that fraction of total IgE antibodies in serum whose specificity for particular allergens can be determined by *in vitro* tests.

If a specific IgE is detected in serum, it indicates that the patient is sensitized to that allergen and then clinical relevance is determined by evaluating the patient's history and the remaining pillars—skin testing and provocation testing, if applicable.



## Less Complex for more control over productivity

### Streamline QC procedures to increase efficiency and simplify compliance

With assayed values for 15 frequently tested allergen specific IgE antibodies and easy access to the world's largest interlaboratory program, Lyphochek® Allergen sIgE Control is the least complex QC solution, giving you more control over your laboratory's productivity.

#### **Improve turnaround time (TAT) and simplify set up:**

As a consolidated control, Lyphochek® Allergen sIgE eliminates the need for single analyte controls, facilitating faster set-up, speeding TAT and enabling you to utilize your equipment and staff more efficiently.

#### **Decrease the need for lot crossover studies:**

With a three-year shelf life, single lots of the control may be inventoried, enabling long-term QC monitoring and fewer time-consuming crossover studies.

#### **Ease compliance with ISO 15189, LEAN, CLIA, CAP, COLA and Six Sigma Requirements:**

Unity™ QC Data Management Solutions offers simple, Internet-based tools that enable you to review rule violations and document corrective actions, making it easier for you to improve performance and regulatory compliance.

#### **Reduce barriers to staff compliance**

Far less complex than other solutions, Lyphochek® Allergen sIgE Control and the Unity™ Interlaboratory Program make compliance easier and more convenient for your staff.

### Reduce operating and ordering costs

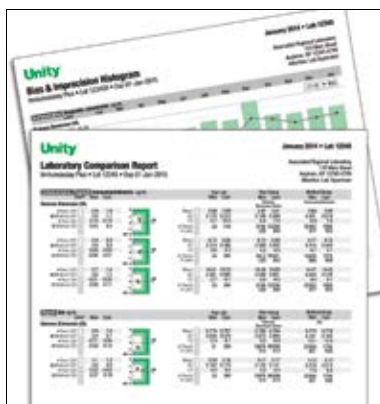
#### **Cut inventory costs and decrease waste:**

As a consolidated control, Lyphochek® Allergen sIgE Control helps you cut SKUs and reduce inventory. But, Bio-Rad goes a step further—we'll reserve lots for you, providing the convenience and cost savings of working with a single lot with a three year shelf life—reducing your cash flow and inventory impacts.

Lyphochek® Allergen sIgE offers an excellent reconstituted open-vial stability of 28 days when stored at 2-8°C.

#### **Consolidate QC for volume cost benefits:**

Working with a single QC partner offers more than simplicity; it also offers the opportunity for volume purchasing.



## Unity™ QC Data Management Solutions

Bio-Rad Quality Controls are part of the Unity™ Program with its industry-leading features for benchmarking laboratory performance.

- Benefit from peer data generated from more than 40,000 instruments worldwide
- Utilize real-time access to peer group comparisons to help with troubleshooting
- Consolidate your entire laboratory into one QC system
- Facilitate run-time decisions with optimized Westgard rules
- Facilitate compliance with simple tools to review rule violations and document corrective actions
- Define your own quality requirements and track key quality performance indicators

You can consolidate your entire laboratory into one QC system through our Unity™ Program. This sophisticated software includes best-in-class tools to support releasing results, benchmarking laboratory performance, and designing your QC system.

## Ordering Information

Cat #	Lyphocheck® Allergen sIgE Control	Configuration
12000141	Negative	6 x 2 mL
12000142	Panel A	6 x 2 mL
12000143	Negative MiniPak	1 x 2 mL
12000144	Panel A MiniPak	1 x 2 mL

### Bio-Rad is Dedicated to Advancing QC Solutions Worldwide

#### Quality Controls

Broad portfolio of independent controls provides an unbiased assessment of methods and system performance.

#### QC Data Management Solutions

Manage and interpret your QC results using the industry-leading Unity™ Interlaboratory Program and benefit from data generated by users worldwide.

#### Customer Support

Receive the backing of full-service technical and customer support trained to handle your inquiries in a prompt, knowledgeable manner.

#### Education

We offer the educational tools and resources to help improve your ability to produce reliable test results.



**Bio-Rad  
Laboratories**

**For further information, please contact the Bio-Rad office nearest you or visit our website at [www.bio-rad.com/qualitycontrol](http://www.bio-rad.com/qualitycontrol)**

Clinical  
Diagnostics Group

Website [www.bio-rad.com/qualitycontrol](http://www.bio-rad.com/qualitycontrol) Australia 61-2-9914-2800 Austria 43-1-877-8901 Belgium 32-9-385-5511 Brazil +55 (31)3689-6600 Canada 1-514-334-4372 China 86-21-61698500 Czech Republic 420-241-430-532 Denmark +45-4452-1000 Finland 358-9-804-22-00 France 33-1-47-95-60-00 Germany +49 (0)89-318-840 Greece 30-210-7774396 Hong Kong 852-2789-3300 Hungary +36-1-459-6100 India 1800-180-1224 Israel 972-3-9636050 Italy +39-02-216091 Japan 81-3-6361-7070 Korea 82-2-3473-4460 Mexico +52 (65)5488-7670 The Netherlands +31-318-540666 New Zealand 64-9-415-2280 Norway +47-23-38-41-30 Poland 48-22-3319999 Portugal 351-21-472-7700 Russia +7-495-721-1404 Singapore 65-6415-3170 South Africa 27-11-442-85-08 Spain 34-91-590-5200 Sweden +46-8-555-127-00 Switzerland +41 (0)26-674-55-05/06 Taiwan 886-2-2578-7189 Thailand 662-651-8311 United Kingdom +44 (0)20-8328-2000