



# BioPlex™ 2200 HSV-1 & HSV-2 IgG

The first and only fully-automated, multiplexed solution  
for Herpes Simplex virus testing





# Like No Other

By detecting and differentiating Herpes Simplex Virus type-specific antibodies, the BioPlex™ 2200 HSV-1 & HSV-2 kit provides laboratories with more diagnostically useful information for enhanced patient management with highly reproducible results and faster turnaround time.

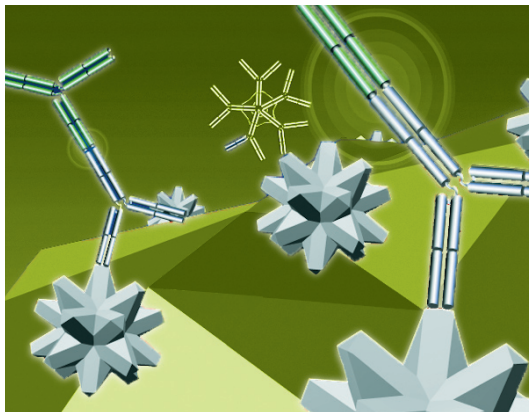
**BioPlex™ 2200 HSV-1 & HSV-2 kit reports results for the following:**

- HSV-1 IgG
- HSV-2 IgG



## Efficiency

- High throughput – up to 200 HSV results per hour for reduced hands-on time and labor costs
- Multiplex workflow – two test results available simultaneously for improved turnaround time
- LIS Connectivity – Bi-directional communication for automated ordering and reporting



## Quality

- Excellent agreement with EIA and Immunoblot methods in the testing population
- Novel chemistry – only fully-automated, random access magnetic bead multiplex method
- Market leading precision and reproducibility with CV's less than 7%



## Confidence

- Full automation from primary tube to final result, minimizing the chance of human error
- Minimum of 150 measurements per analyte per reaction compared to single photometric measurement in microplate methods
- Internal Quality Control beads included with each sample to verify serum addition, standardize detector performance and detect sample problems with non-specific binding

## Comparison with Immunoblot Method

| Population                                  | BioPlex™ 2200 HSV-1 IgG                        |  | BioPlex™ 2200 HSV-2 IgG                        |  |
|---|--|--|--|--|
|   | % Sensitivity                                  | % Specificity                                  | % Sensitivity                                  | % Specificity                                  |
| Sexually Active Individuals<br>(N = 575)    | <b>97.6%</b><br>(400/410)<br>CI 95.6% to 98.7% | <b>94.5%</b><br>(155/164)<br>CI 89.9% to 97.1% | <b>90.7%</b><br>(223/246)<br>CI 86.4% to 93.7% | <b>98.8%</b><br>(325/329)<br>CI 96.9% to 99.5% |
| Expectant Mothers<br>(N = 399)              | <b>96.3%</b><br>(287/298)<br>CI 93.5% to 97.9% | <b>99.0%</b><br>(100/101)<br>CI 94.6% to 99.8% | <b>96.9%</b><br>(157/162)<br>CI 93.0% to 98.7% | <b>100%</b><br>(237/237)<br>CI 98.4% to 100%   |
| Low Prevalence:<br>16–19 years<br>(N = 200) | <b>93.3%</b><br>(97/104)<br>CI 86.7% to 96.7%  | <b>97.9%</b><br>(94/96)<br>CI 92.7% to 99.4%   | N/A  | <b>97.8%</b><br>(181/185)<br>CI 94.6% to 99.2% |

## Comparison with ELISA Method

| Population                                  | BioPlex™ 2200 HSV-1 IgG                        |  | BioPlex™ 2200 HSV-2 IgG                        |  |
|---|--|--|--|--|
|   | % Positive Agreement                           | % Negative Agreement                           | % Positive Agreement                           | % Negative Agreement                           |
| Sexually Active Individuals<br>(N = 575)    | <b>98.5%</b><br>(199/202)<br>CI 95.7% to 99.5% | <b>86.2%</b><br>(75/87)<br>CI 77.4% to 91.9%   | <b>94.7%</b><br>(108/114)<br>CI 89.0% to 97.6% | <b>99.4%</b><br>(171/172)<br>CI 96.8% to 99.9% |
| Expectant Mothers<br>(N = 399)              | <b>96.9%</b><br>(285/294)<br>CI 94.3% to 98.4% | <b>97.1%</b><br>(102/105)<br>CI 91.9% to 99.0% | <b>96.9%</b><br>(156/161)<br>CI 92.9% to 98.7% | <b>99.6%</b><br>(237/238)<br>CI 97.7% to 99.9% |
| Low Prevalence:<br>16–19 years<br>(N = 200) | <b>92.3%</b><br>(96/104)<br>CI 85.5% to 96.1%  | <b>96.9%</b><br>(93/96)<br>CI 91.2% to 98.9%   | N/A  | <b>97.3%</b><br>(182/187)<br>CI 93.9% to 98.9% |

## Comparison with CDC Panel

|                            | BioPlex™ 2200 HSV-1 IgG |                         |                      |                         | BioPlex™ 2200 HSV-2 IgG |                         |                      |                         |
|----------------------------|-------------------------|-------------------------|----------------------|-------------------------|-------------------------|-------------------------|----------------------|-------------------------|
|                            | % Positive Agreement    | 95% Confidence Interval | % Negative Agreement | 95% Confidence Interval | % Positive Agreement    | 95% Confidence Interval | % Negative Agreement | 95% Confidence Interval |
| <b>CDC Panel (N = 100)</b> | 100% (50/50)            | 92.8% to 100%           | 96% (48/50)          | 86.5% to 98.9%          | 100% (50/50)            | 92.8% to 100%           | 100% (50/50)         | 92.8% to 100%           |

### Agreement with CDC Panel

The performance of the BioPlex™ 2200 HSV-1 & HSV-2 IgG kit was assessed using a masked, well-characterized HSV serum panel from the CDC. The panel consists of 24% HSV-1 and HSV-2 dual-positive samples, 50% HSV-1 positive and 50% HSV-1 negative samples and 48% HSV-2 positive and 52% HSV-2 negative samples. The BioPlex™ 2200 had 100% positive and negative agreement with commercially available ELISA assays for each analyte.<sup>1</sup>

<sup>1</sup> Excluding Equivocals

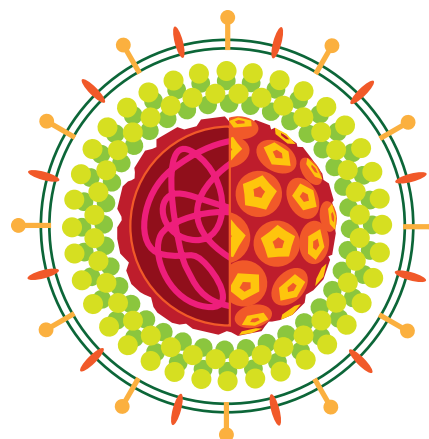
## BioPlex™ 2200 HSV-1 & HSV-2 Design

### BioPlex™ 2200 HSV-1 & HSV-2 Technology

- BioPlex™ 2200 HSV-1 & HSV-2 is type specific
- Targets the gG1 and gG2 antigens
- Targets the 50% homology that differentiates HSV-1 from HSV-2

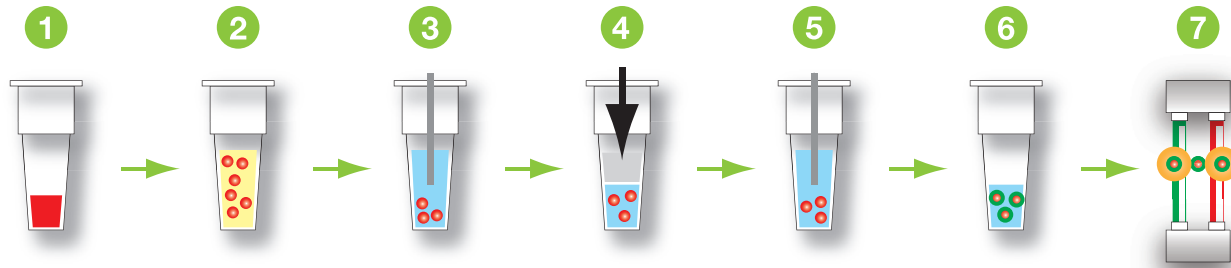
### What Differentiates BioPlex™ 2200 HSV-1 & HSV-2?

- Uses recombinant gG1 and synthetic peptide p8C:BSA derived from gG2 sequence
- Synthetic peptide is unique to HSV-2 (based on sequence analysis) – *patented*
- Allows type-specific recognition without potential non-specific cross-reactivity (that could be seen in other type-specific products)



Herpes Simplex Virus

**BioPlex™ 2200 HSV-1 & HSV-2 IgG**



- 1. Patient sample (5 µL) automatically added to reaction vessel
- 2. Sample diluent and beads (dilution 1:20) added and incubated at 37°C

- 3. Wash step
- 4. Conjugate added and incubated at 37°C
- 5. Wash step

- 6. Bead resuspended in wash buffer
- 7. Flow-based, dual laser detection



**HSV-1 & HSV-2 IgG Reagent Pack**

Contains all the necessary reagents (sample diluent, beads and conjugate) to process 100 samples.



**HSV-1 & HSV-2 IgG Calibrator Set**

Calibrators are ready-to-use and multiplexed. A point-to-point curve fit, using four calibrators, is used to calculate qualitative results.



**HSV-1 & HSV-2 IgG Control Set**

Quality Controls are ready-to-use and multiplexed. The set includes a negative control as well as a multi-analyte positive control containing antibodies present for analytes within the Reagent Pack.

**Ordering Information**

**Catalog No. Description**

**BioPlex™ 2200 HSV-1 & HSV-2 IgG**

|          |   |        |
|----------|---|--------|
| 665-3350 | BioPlex™ 2200 HSV-1 & HSV-2 IgG Reagent Pack.....   | 1 pack |
| 663-3300 | BioPlex™ 2200 HSV-1 & HSV-2 IgG Calibrator Set..... | 1 set  |
| 663-3330 | BioPlex™ 2200 HSV-1 & HSV-2 IgG Control Set.....    | 1 set  |



**Bio-Rad Laboratories**

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

*Clinical Diagnostics Group*

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