



## BioPlex<sup>®</sup> 2200 Celiac IgA and IgG Kits

**The first and only fully automated, random access, multiplex solution for Celiac IgA and Celiac IgG autoantibody testing.**

The BioPlex<sup>®</sup> 2200 System is designed to handle increasing testing volumes while streamlining workflow.





# Like no other

The Celiac IgA and IgG kits are multiplex flow immunoassays for the semi-quantitative detection of IgA and IgG autoantibodies to tissue Transglutaminase (tTG) and deamidated gliadin peptide (DGP). These tests are used as an aid in the diagnosis of Celiac Disease (gluten-sensitive enteropathy).

Celiac Disease is an autoimmune disorder characterized by gluten-sensitivity. The prevalence of the disease is increasing worldwide in both children and adults. This condition may present with classic symptoms such as failure to thrive, short stature and gastrointestinal disorders or more non-specific symptoms such as anemia and chronic fatigue. Some patients with Celiac Disease may even be asymptomatic.

## BioPlex® 2200 Celiac IgA kit contains:

- Anti-tTG IgA
- Anti-DGP IgA
- IgA Verification Bead

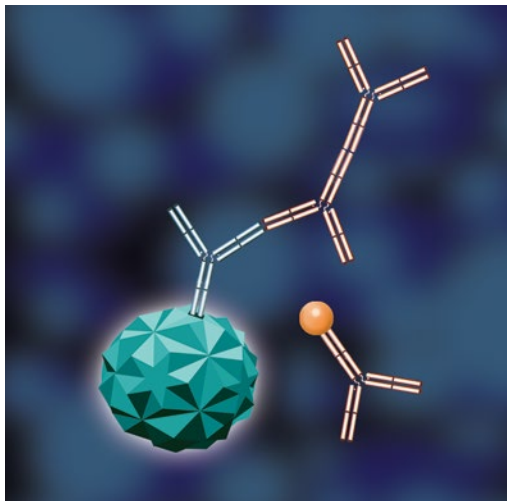
## BioPlex® 2200 Celiac IgG kit contains:

- Anti-tTG IgG
- Anti-DGP IgG

Early diagnosis and adherence to a gluten-free diet are critical in relieving symptoms and reducing the risk of complications including secondary autoimmune disorders and lymphoma. An accurate and timely diagnosis is imperative to improving patient outcomes.

The BioPlex® 2200 Celiac IgA and IgG kits incorporate unique bead technology, like no other, for efficient laboratory workflow, excellent clinical performance, high throughput and timely reporting of results.

## Unique IgA Verification Bead Ensures Confidence in Patient Results



*The AVB identifies patient samples with low IgA levels.*

The Celiac IgA kit includes a novel IgA Verification Bead (AVB) to detect low levels of IgA that may require additional testing. This condition is more prevalent in Celiac Disease patients than in the general population. It is important to recognize this condition in the diagnostic workup, because many antibody tests used to diagnose Celiac Disease detect autoantibodies of the IgA isotype.

The flag is based on the actual measurement of Total IgA. This is in contrast to the estimation of the IgA level using the anti-tTG IgA signal as is sometimes done with traditional Celiac immunoassays.

- AVB identifies the 2-5% of Celiac patients with low IgA levels, so Celiac IgG autoantibodies may be assayed
- This reduces false-negative results compared to traditional immunoassays for a comprehensive diagnostic workup

## Improved Lab Workflow

### Faster turnaround time

- Time to first result is approximately 45 minutes
- 100 samples per hour or 200 test results per hour for anti-tTG & anti-DGP IgA or IgG
- Eliminate batching and reduce turnaround time
- The BioPlex® 2200 System demonstrates the highest throughput in the market for Celiac testing

### Simplify workflow

- With the AVB, it may no longer be necessary to order a Total IgA test before running Celiac Disease serological tests for IgA autoantibodies
- Two small 5 µL samples for four analytes significantly reduces sample volume requirements and tube handling
- Unlike traditional EIA kits, the Celiac IgA and Celiac IgG kits employ a 30-day calibration curve eliminating the cost of daily calibration

# Market Leading Performance

## Clinically relevant results

- Measures anti-tTG autoantibodies to greater than ten times the cutoff as recommended by current clinical guidelines
- Detects autoantibodies to deamidated gliadin peptide offering increased sensitivity and specificity over native gliadin assays
- Provides an optimal method for evaluating levels of multiple antibodies

## Better accuracy and precision

- Full automation ensures excellent assay performance
  - Minimizes errors associated with specimen and reagent handling
- Heterogeneous assay format with magnetic beads
  - Limits interferences and reduces non-specific binding to improve specificity
- Excellent reproducibility with total precision at <10% CV for all analytes

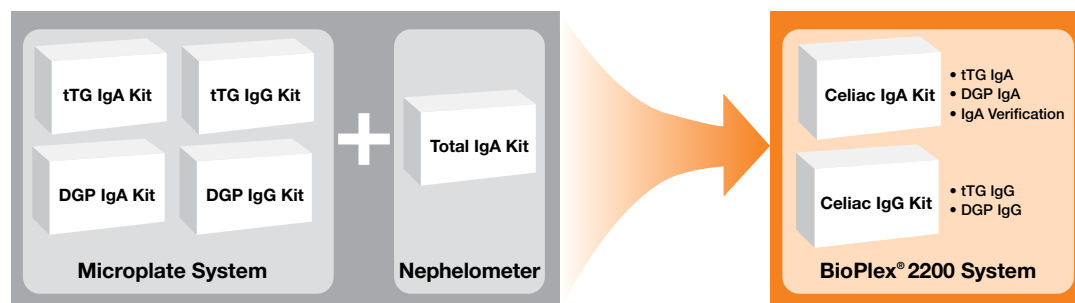
## Quality assurance in every test

- Internal quality beads ensure optimal system performance and result integrity
  - Serum Verification Bead (SVB)—confirms the presence of serum
  - Internal Standard Bead (ISB)—standardizes detector performance
  - IgA Verification Bead (AVB)—flags samples with low IgA levels

# Consolidate Testing Platforms and Reagent Kits

Traditional Celiac serology testing requires multiple platforms such as a microplate system for anti-tTG and anti-DGP as well as a nephelometer for total IgA levels. Sample aliquoting, batching and coordination between multiple instruments slows reporting of results. The BioPlex® 2200 System offers streamlined results reporting.

- Minimize sample aliquoting optimizing lean workflow
- Report out negative results faster for improved client satisfaction
- Streamline reagent kit storage and purchasing activities for improved laboratory efficiency



*The BioPlex® 2200 System simplifies your Celiac testing*

# Excellent Clinical Sensitivity and Specificity

The BioPlex® 2200 Celiac IgA and IgG kits show high clinical sensitivity and specificity using clinically diagnosed, biopsy-positive samples.

Clinical performance of the BioPlex® 2200 Celiac IgA and IgG kits was evaluated in samples from patients previously diagnosed with Celiac Disease (N=156) and samples from patients with other autoimmune, infectious and gastrointestinal disease (N=163).

- The BioPlex® 2200 System provides accurate results for Celiac biomarkers
- High specificity ensures excellent agreement with biopsy results

## BioPlex® 2200 Celiac IgA Kit – Clinical Sensitivity and Specificity (N=319)

Retrospective Samples	BioPlex® 2200 Celiac IgA							
	Anti-tTG IgA				Anti-DGP IgA			
	Pos (+)	Neg (-)	Sensitivity	Specificity	Pos (+)	Neg (-)	Sensitivity	Specificity
Celiac Disease Patients	148	8	94.9%	98.8%	136	20	87.2%	96.9%
Non-Celiac Disease Patients	2	160			5	158		

## BioPlex® 2200 Celiac IgG Kit – Clinical Sensitivity and Specificity (N=319)

Retrospective Samples	BioPlex® 2200 Celiac IgG							
	Anti-tTG IgG				Anti-DGP IgG			
	Pos (+)	Neg (-)	Sensitivity	Specificity	Pos (+)	Neg (-)	Sensitivity	Specificity
Celiac Disease Patients	69	87	44.2%	95.7%	132	24	84.6%	96.9%
Non-Celiac Disease Patients	7	155			5	158		

## BioPlex® 2200 Celiac IgA and IgG Kits

The BioPlex® 2200 Celiac IgA and IgG kits consolidate four traditional single-analyte tests into two disease state panels for lean laboratory workflow. The Calibrator and Control sets offer ease of use and cost savings with 60-day open vial stability and 30-day calibration curve stability.



### Celiac IgA and IgG Reagent Packs

Each reagent pack contains all the necessary reagents (sample diluent, beads and conjugate) to process 100 samples and up to 2 results per sample.

### Celiac IgA and IgG Calibrator Sets

Calibrators are ready to use. A 4PL curve fit, using nine calibrators (5 vials for anti-tTG and 5 vials for anti-DGP), is used to calculate semi-quantitative results.

### Celiac IgA and IgG Control Sets

Quality Controls are ready to use. Each bi-level set includes a negative control as well as a positive control for anti-tTG and anti-DGP.

## Ordering Information

Catalog No.	Description	
665-2350	BioPlex® 2200 Celiac IgA Reagent Kit .....	1 pack
663-2300	BioPlex® 2200 Celiac IgA Calibrator Set .....	1 set
663-2330	BioPlex® 2200 Celiac IgA Control Set .....	1 set
665-2250	BioPlex® 2200 Celiac IgG Reagent Kit .....	1 pack
663-2200	BioPlex® 2200 Celiac IgG Calibrator Set .....	1 set
663-2230	BioPlex® 2200 Celiac IgG Control Set .....	1 set



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