



# Platform Change: Autoimmune Testing Pertinent to Celiac, Vasculitis, and Lupus Assessments

*Offering our clients state-of-the-art testing is part of CPL's ongoing commitment to excellence.*

Effective June 1<sup>st</sup>, 2020, Clinical Pathology Laboratories will implement the BioRad BioPlex Multiplex Flow Immunoassay to replace traditional ELISA methodology for the following disease state antibody profiles:

- **Antiphospholipid antibody syndrome (APS) or lupus anticoagulant**
  - o Cardiolipin IgA, IgG and IgM Antibody
  - o Beta-2 Glycoprotein 1 IgG and IgM Antibody
- **Celiac disease or gluten-sensitive enteropathy**
  - o Deamidated Gliadin Peptide (DGP) IgA and IgG Antibody
  - o Tissue Transglutaminase (tTG) IgA and IgG Antibody
- **Vasculitis (Wegener granulomatosis, microscopic polyangiitis, Churg-Strauss, others)**
  - o Myeloperoxidase (MPO) Antibody
  - o Serine Proteinase 3 (PR3) Antibody
- **Rheumatoid arthritis**
  - o Cyclic Citrullinated Peptide (CCP) Antibody

The Multiplex Flow Immunoassay comprises collections of polystyrene bead populations distinguished from one another by fluorescence spectra and covalently bound antigen analyzed in a flow cytometry-like detector. This permits simultaneous analysis of multiple antibodies or biomolecules with higher precision and reproducibility than earlier ELISA technology. Aside from distinct units of measure and different cutoffs, the method offers simplified interpretations of Negative or Positive in addition to the raw index values to replace prior interpretations of Indeterminate, Weak Positive, Strong Positive, etc. All assays show the following stability: room temperature 1 day; refrigeration 1 week; frozen 1 month. Additional notes by disease state are given below:

- Antiphospholipid antibody syndrome (APS):
  - o Meets criteria set for test performance in Antiphospholipid Antibody testing as expressed in Eleventh International Congress on antiphospholipid antibodies (Sydney APS Laboratory Testing Criteria).
  - o To achieve optimal specificity, antibody cutoff is set at 95-99<sup>th</sup> percentile of normal controls.
- Celiac disease or gluten-sensitive enteropathy
  - o Clinical sensitivity/specificity for celiac disease:
    - tTG IgA: 94.3% sensitive/98.8% specific; DGP IgA: 86.6% sensitive/96.9% specific.
    - tTG IgG 44.6% sensitive/95.7% specific; DGP IgG 84.7% sensitive/96.9% specific.
    - tTG IgA antibodies correlate closely with the activity of disease and are useful for diet monitoring.
    - IgG antibodies are more useful and informative in patients with selective IgA deficiency. Consider reflex testing (IgA reflex to celiac antibodies; unit code 4739).
- Vasculitis (Wegener granulomatosis, microscopic polyangiitis, Churg-Strauss, others)
  - o MPO shows 95% overall agreement with a prior ELISA method and 93.3% positive agreement with pANCA pattern on indirect immunofluorescence assay (IFA).
  - o PR3 shows 95% agreement with prior ELISA and 95% positive agreement with cANCA pattern on IFA.
- Rheumatoid arthritis
  - o CCP antibody: 83.1% sensitive (known RA patients), 97.8% specific.
  - o With higher specificity than typically seen with rheumatoid factor (RF) assays, positive CCP antibody results are associated with a higher positive predictive value (PPV) for rheumatoid arthritis.

**See page 2 for assay report details and test information**

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Assay report details are given below:

Test(s)	Order Code	CPT Code	Ref. Range, Units	Interpretation
Cardiolipin IgA Antibody	4793	86147	<20 APL-U/mL	Negative/Positive
Cardiolipin IgG Antibody	4791	86147	<20 GPL-U/mL	Negative/Positive
Cardiolipin IgM Antibody	4792	86147	<20 MPL-U/mL	Negative/Positive
Beta-2 Glycoprotein 1 IgG Antibody	3416	86146	<20 U/mL	Negative/Positive
Beta-2 Glycoprotein 1 IgM Antibody	3417	86146	<20 U/mL	Negative/Positive
DGP IgA Antibody	4719	83516	<15 U/mL	Negative/Positive
DGP IgG Antibody	4718	83516	<15 U/mL	Negative/Positive
tTG IgA Antibody	4725	83516	<15 U/mL	Negative/Positive
tTG IgG Antibody	4720	83516	<15 U/mL	Negative/Positive
MPO Antibody	4965	83516	<1.0 AI	Negative/Positive
PR3 Antibody	4967	83516	<1.0 AI	Negative/Positive
CCP Antibody	5390	86200	<3.0 U/mL	Negative/Positive

## Additional Test Information:

<b>Order Codes:</b>	<i>See table above</i>
<b>Specimen Requirements:</b>	0.5 mL serum from SST
<b>Transport Temperature:</b>	Refrigerated
<b>Stability (collection to initiation of testing):</b>	24 hours Room Temperature; 7 days Refrigerated; 1 month Frozen
<b>Performed:</b>	Monday through Friday; PM Shift
<b>Analytic Time:</b>	1 Day
<b>Specimen Retention:</b>	7 Days
<b>CPT Codes:</b>	<i>See table above</i>

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