



# CPAL

Central Pennsylvania Alliance  
Laboratory

# Technical Bulletin

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### Anti-dsDNA - Method Modified -

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**Affected Tests:**

<b>Mnemonics:</b>	<b>NDNA SCR N</b>	<b>NDNA QNT</b>
<b>Test Name:</b>	ANTI dsDNA ANTIBODY SCREEN (Native DNA)	ANTI dsDNA QUANT (Native DNA)
<b>Test Number:</b>	3000195	3000197
<b>Specimen:</b>	0.5 mL Serum, Refrig (2-8°C) 7 days	

**Effective Date:** Anticipate testing will begin on May 27, 2014 with samples received beginning May 23, 2014.

**Performed:** Monday through Friday

**Reference Range:** Negative

**Method Change:**

The manufacturer has discontinued the previous testing kit for Anti-dsDNA due to international testing recommendations. The replacement kit uses goat anti-human IgG (*gamma chain specific*) for the conjugate. The previous kit used goat anti-human IgG (*heavy and light chain*) for the conjugate. Otherwise, the methods are the same. There should be no impact on patient results, according to the manufacturer.

**Background:**

Patients with systemic lupus erythematosus (SLE) may produce antibodies to a variety of nuclear antigens, but antibodies directed against Sm (Smith antigen) and nDNA show the highest correlation with disease. Antibodies directed against Sm demonstrate a speckled ANA staining pattern while antibodies directed against nDNA generally demonstrate a homogeneous ANA staining pattern. Although low levels of nDNA antibodies may be present in the serum of patients with rheumatoid arthritis, Sjögren’s syndrome, progressive systemic sclerosis, dermatomyositis, discoid lupus erythematosus, and mixed connective tissue disease, high levels of nDNA antibodies are seen almost exclusively in SLE. Antibodies against nDNA are thought to be involved in the pathogenesis of the most severe variants of SLE when deposited as immune complexes. Antibodies to nDNA occur in high titer, and, because they correlate with disease activity, their detection is important in the management of SLE patients.

Several assays are available for the detection of nDNA antibodies. The most commonly used methods include indirect immunofluorescence, radioimmunoassay, counterimmunoelectrophoresis, and immunodiffusion. The



***Between Run Reproducibility:***

Three specimens were run on three different days. All three specimens produced the same results when run on three different days. (Table 2)

**Table 2** **Between Run Reproducibility**

<b>Sample</b>	<b>Day 1</b>	<b>Day 2</b>	<b>Day 3</b>
1	Negative	Negative	Negative
2	Positive 1:40	Positive 1:40	Positive 1:40
3	Positive 1:320	Positive 1:160	Positive 1:320

***Method Comparison***

A total of 40 specimens were split and run using each testing kit. Samples were compared qualitatively for interpretation as a screen, i.e., Positive or Negative. There were 100% positive agreement (10 of 10) and 100% negative agreement (30 of 30) for this sample set.

Titers were performed by both methods on all 10 samples with positive screens. The titers spanned the reportable range of the method. One specimen had a titer that was two dilutions different between the two kits, and it was repeated by the old method. After resolution, all titers agreed within one dilution between the two methods (Figure 1).

**Table 3** **Anti-dsDNA Method Comparison**  
**New kit ( $\gamma$  specific) vs Old kit (heavy & light chain)**

<b>Sample</b>	<b>heavy &amp; light chain conjugate</b>	<b><math>\gamma</math> specific conjugate</b>
1	Positive 1:40	Positive 1:20
2	Positive 1:20	Positive 1:40
3	Positive 1:20	Positive 1:20
4	Positive 1:40	Positive 1:80
5	Positive 1:80	Positive 1:40
6	Positive 1:160	Positive 1:160
7	Positive 1:320	Positive 1:320
8	Positive 1:640	Positive 1:640
9	Positive 1:1280; repeat 1:2560	Positive $\geq$ 1:5120
10	Positive $\geq$ 1:5120	Positive $\geq$ 1:5120

**References:**

1. Immuno Concepts IgG ANTI-nDNA Fluorescent Test system package insert, Revision 2.0; 2011.
2. Cayce C. Horner; Southeast Regional Manager/Instrument Specialist Global Focus Marketing & Distribution, Ltd.