

ImmuLisa™ dsDNA Antibody

An enhanced assay for superior specificity and clinical agreement

INTRODUCTION

ImmuLisa™ dsDNA Antibody ELISA is a superior method for the detection and semi-quantitation of IgG antibodies to double stranded DNA (dsDNA) in human serum to aid in diagnosis of systemic lupus erythematosus (SLE).

Antinuclear antibodies (ANA) are a class of auto-antibodies found in various autoimmune connective tissue diseases. ANA include antibodies to antigens of the nucleus such as DNA, histone and various extractable nuclear antigens such as RNP, Sm, SS-A, SS-B and others. There are three types of DNA antibodies:

- dsDNA antibodies that react only with dsDNA
- Single stranded DNA (ssDNA) antibodies that react only with ssDNA
- ds/ssDNA antibodies that react with both dsDNA and ssDNA

Of these three types, dsDNA antibodies are an important diagnostic marker for diagnosis of SLE.

DISEASE

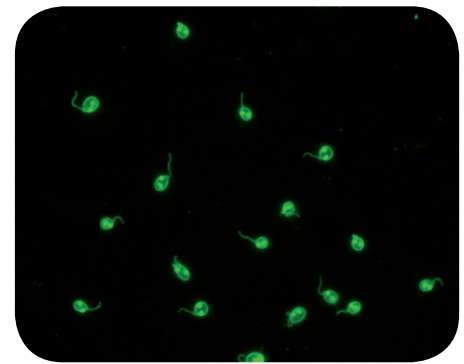
SLE is an autoimmune disease that can affect and damage any part of the body, including the skin, joints and internal organs. It is a chronic disease marked by remission and relapse. With proper diagnosis and good medical care, most people with lupus can lead a full life.

DIAGNOSIS

SLE is an inflammatory autoimmune disease with multi-systemic and multi organ manifestations evidenced by a wide variety of antibodies to nuclear and cytoplasmic antigens. SLE is diagnosed on the basis of an array of clinical symptoms and immunologic markers. ANA, dsDNA,



Addition of substrate



dsDNA antibodies on *Crithidia luciliae*

and Sm antibodies are immune markers of diagnostic importance. The revised American College of Rheumatology criteria for diagnosis of SLE classifies dsDNA as one of the most important serological markers. Antibodies to dsDNA have specificity of 95% in diagnosis of SLE. There is also a good correlation between SLE disease activity and dsDNA antibody levels. The frequency and levels of dsDNA antibodies fluctuate with disease activity occurring overall in about 50-55% of SLE cases and in about 89% of SLE patients with active renal disease. Antibodies to dsDNA may disappear with immunosuppressive treatment and during remission.

Several techniques have been developed for the measurement of dsDNA antibodies. The two most routinely used in the

laboratory are the ELISA and the indirect immunofluorescence (IFA) method on *Crithidia luciliae* substrate. The ELISA method is automatable and provides quantitative results.

ImmuLisa™ dsDNA ANTIBODY

The ImmuLisa™ dsDNA Antibody ELISA assay detects dsDNA antibodies of the IgG class. Anti-DNA antibodies of IgM and IgA isotypes also occur, but IgG class antibodies have been shown to be clinically significant markers. Results are reported in International Units (IU)/ml. This kit has been calibrated against the World Health Organization (WHO) Reference Reagent Wo/80.

	IMMCO	Competitor
Sensitivity	88%	87%
Specificity	98%	94%
Clinical Agreement	94%	91%

IMMCO's ImmuLisa™ dsDNA Antibody test demonstrates superior sensitivity, significantly higher specificity and clinical agreement to support the diagnosis of SLE.

SUPERIOR ACCURACY

A study on 245 serum specimens obtained from patients suspected of SLE and disease controls were tested for dsDNA antibody levels. The results of this study show a high degree of specificity and sensitivity of Immulisa™ dsDNA Antibody test as compared to others in the marketplace. Immulisa™ dsDNA antibody test incorporates optimal presentation of a highly purified antigen to minimize non-specific reactions.

SINGLE POINT AND 5 POINT CALIBRATION

Immulisa™ dsDNA Antibody test results may be determined using single point

(qualitative) or 5 point (semi-quantitative) analysis. This provides flexibility to process samples as efficiently as possible or provide the best quantitation possible. The other products yield less accurate results throughout the assay range.

IMMCO Product Performance

Superior Sensitivity
Superior Specificity
Superior Clinical Agreement
Single Point and 5 Point Calibrators
Significantly Greater Calibration Precision vs International Wo/80 Standard

CALIBRATION TO INTERNATIONAL STANDARD

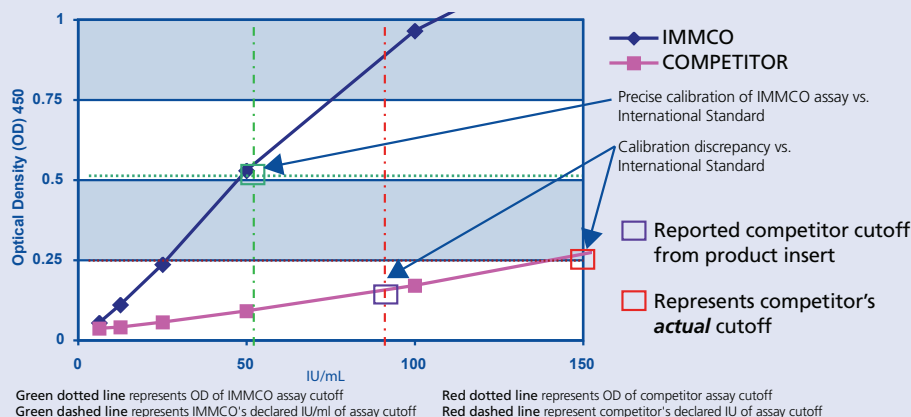
The Wo/80 standard was developed in 1988 as an international reference for anti-dsDNA activity for use in the Farr assay and immunofluorescence by *Crithidia luciliae*. Subsequently, the utility of the Wo/80 standard has been expanded to include dsDNA antibody ELISAs. The Immulisa™ dsDNA Antibody ELISA is calibrated against this standard. Studies of dsDNA assay calibration suggest the inaccuracy of competitor assays.

A comparison of calibrations appears on the graph below. The Immulisa™ dsDNA Antibody shows a higher degree of discrimination and better calibration than the competitor versus the international standard.

SELECTED REFERENCES

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PERFORMANCE TESTING USING INTERNATIONAL REFERENCE STANDARD (WO/80)



ORDERING INFORMATION

Code	Description	Determinations
Immulisa™ ELISA 5120*	dsDNA Antibody	96
Other Related Tests:		
Immulisa™ ELISA 1121*	Immulisa™ ssDNA Antibody	96
Immulo™ Immunofluorescence		
1106	nDNA Antibody (<i>Crithidia luciliae</i>)	48
1106-2	nDNA Antibody (<i>Crithidia luciliae</i>)	96
1106-6	nDNA Antibody (<i>Crithidia luciliae</i>)	120

All kits are FDA approved and CE marked for IVD use unless otherwise noted.

* For research use only in the U.S.

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