

READS Anti-dsDNA Quantitative Test Kit For In Vitro Diagnostic Use

The READS Anti-dsDNA test is a quantitative indirect enzyme linked immunosorbent assay (ELISA) for the detection of IgG/IgM anti-double stranded deoxyribonucleic acid (dsDNA) antibodies in human serum as an aid in the diagnosis and management of systemic lupus erythematosus (SLE).



- Detects IgG and IgM anti-dsDNA antibodies in human serum or plasma
- Highly sensitive and specific for the detection of anti-dsDNA autoantibodies associated with the diagnosis of SLE
- Results are reported in either IU/mL (International Units, standardized against the World Health Organization (WHO) reference preparation) or AU/mL (Arbitrary Units that are traceable to the Centers of Disease Control (CDC) reference preparation)
- 40 minute total incubation time, assay can be easily automated minimizing result turnaround time

Clinical Performance:

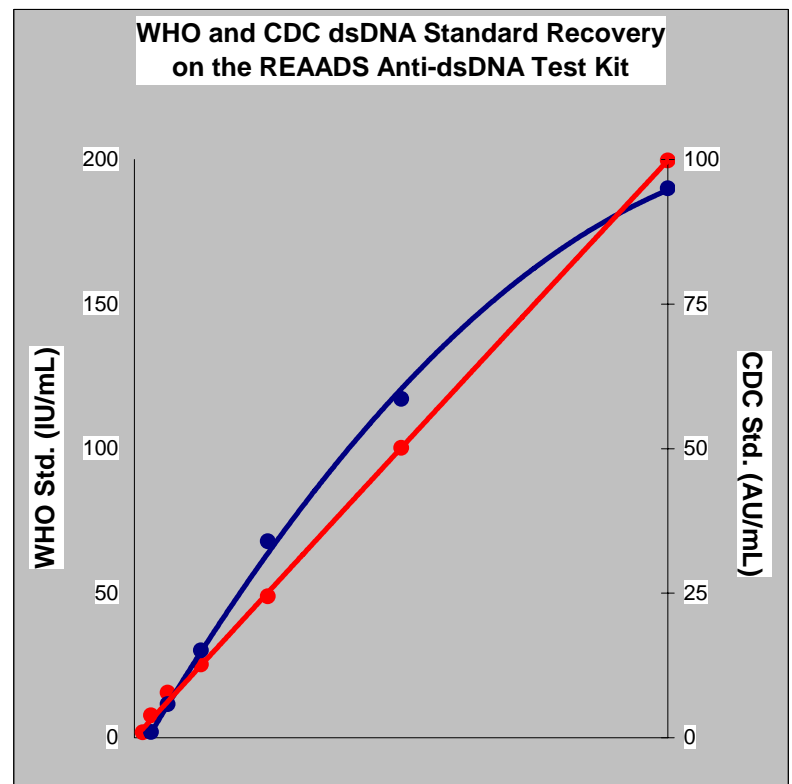
Specificity

Serum samples from 90 healthy donors were assayed for the presence of anti-dsDNA antibodies with the READS Anti-dsDNA Test Kit. Using the kit cutoff value, the clinical specificity of the test was 98%.

Sensitivity

Serum samples from 100 individuals diagnosed with SLE were tested with the READS Anti-dsDNA Test Kit. Patients with both active and inactive disease were included. Sixty-five (65%) of these samples were positive for anti-dsDNA antibodies. The expected prevalence of elevated levels of anti-dsDNA antibodies in this group (SLE with varying levels of disease activity) is 50-75%.

The cross-reactivity of anti-single stranded DNA (ssDNA) antibodies was evaluated on the READS Anti-dsDNA Test Kit with the use of a monoclonal ssDNA antibody and was found to be negative. Additional ssDNA antibody positive patient samples evaluated by the READS Anti-dsDNA kit were also negative.

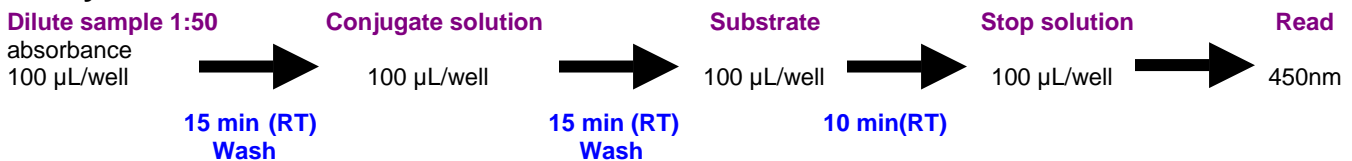


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For In Vitro Diagnostic Use

Antibodies directed against deoxyribonucleic acid (DNA) were first detected in the serum of patients with systemic lupus erythematosus (SLE) in the late 1950s. The presence of anti-dsDNA autoantibodies is one of the four highly specific serologic markers included in the 1982 ARA (ACR) revised criteria for the classification of SLE. The detection of elevated levels of anti-dsDNA antibodies and decreased serum levels of complement component C3 have been found to be 100% specific for SLE. Antibodies against native, or double stranded DNA (dsDNA) are found almost exclusively in patients with SLE, while antibodies against denatured, or single stranded DNA (ssDNA) can also be detected in patients with SLE, as well as in patients with many other diseases, including rheumatic diseases and chronic infections. The serum level of anti-dsDNA antibodies in patients with SLE correlates significantly with the level of disease activity, particularly when there is renal involvement. Therefore, testing for anti-dsDNA antibodies is useful for monitoring disease activity and the progress of therapy in patients with SLE.

Assay Procedure



Correlation with Indirect Immunofluorescence (IIF) method

A comparison analysis was performed using 100 patient samples with various autoimmune diseases, including SLE, RA, MCTD, and Sjogren's Syndrome, on the READS Anti-dsDNA ELISA Test Kit and an IIF method (crithidia) resulting in a 98% relative agreement.

		IIF method	
		Positive	Negative
READS	Positive	11	1
	Negative	1	78

Kit Contents

96 antigen coated microwells in frame	12 x 8 strips
Sample Diluent I	60 mL
Calibrator (AU/mL & IU/ml) (ready to use)	0.250 mL
Positive Control	0.250 mL
Normal Control	0.250 mL
Conjugate Reagent (IgG and IgM)	15 mL
Wash Concentrate	2 x30 mL
Substrate (ready to use)	15 mL
Stop Solution (ready to use)	15 mL

READS Anti-dsDNA Test Kit

Product # 022-001
 Quantity: 96 tests
 Storage: 2 – 8° C
 Stability: 12 months

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 Rev. 2004-02-04
 900003



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