

# Human Anti-dsDNA ELISA (IgG)

## (Catalogue number: 31A040)

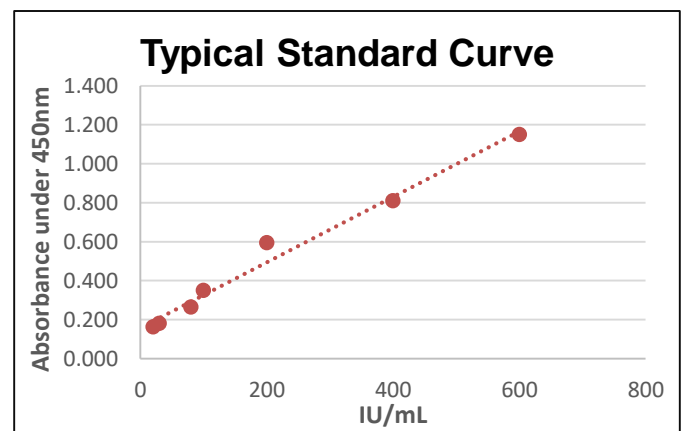
◆ The dsDNA-specific autoantibodies (anti-dsDNA) are considered a specific marker for systemic lupus erythematosus (SLE), due to the high clinical associations<sup>1,2</sup>. The presence of anti-dsDNA autoantibodies in other pathological conditions and in healthy subjects is very rare (< 0.5%)<sup>3</sup>, in contrast, they may be present in SLE patients even before they develop clinical symptoms<sup>2,3</sup>. Therefore, regular measurement of anti-dsDNA autoantibodies in blood is important for early diagnosis, as well as monitoring the progression of SLE.

◆ ImmunoDiagnostics has developed an Elisa kit for quantitative measurement of anti-dsDNA autoantibodies in human blood samples, with superior reproducibility, specificity and sensitivity, ready for clinical application:

### Typical results

(Example only, not for calculation of actual results)

Calibrator*	Concentration (IU/mL)	OD450 (Blanked)
1	600	1.149
2	400	0.809
3	200	0.594
4	100	0.350
5	80	0.265
6	30	0.180
7	20	0.163
Negative Control	0	0.049
Positive Control	210	0.538



\*Calibrator standardised against International Standard WHO Wo/80.

Cut-off	IU/mL
Negative	< 25 IU/mL
Positive	≥ 25 IU/mL

\*This cut off has been validated at ImmunoDiagnostics. However, we recommend each laboratory establish its own reference ranges of GADA levels to distinguish healthy and pathological subjects, as well as include its own internal control samples in the assay.

Clinical Evaluation		
Sensitivity	79.69% (n=64)	
Specificity	96.77% (n=40)	
Inter Assay Precision		
Sample	IU/mL (n=20)	CV
1	394	2.6%
2	144	8.4%
3	81	9.4%
Intra Assay Precision		
Sample	IU/mL (n=20)	CV
1	375	2.5%
2	120	8.4%
3	73	9.3%

### References:

1. D. A. Isenberg, et al. Fifty Years Of Anti-ds Dna Antibodies: Are We Approaching Journey's End? Rheumatology, Vol. 46, No. 7, Pp. 1052–1056, 2007.
2. G. C. Tsokos. Systemic Lupus Erythematosus. The New England Journal Of Medicine, Vol. 365, No. 22, Pp. 2110–2121, 2011.
3. E. Cozzani, et al. Serology Of Lupus Erythematosus: Correlation Between Immunopathological Features And Clinical Aspects," Autoimmune Diseases, Vol. 2014, Article Id 321359, 13 Pages, 2014.



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