

Human Anti-Histones ELISA (IgG)

(Catalogue number: 31A030)

◆ Histones are DNA-associated cationic proteins in the nucleus of eukaryotic cells to form nucleosomes. Anti-histone autoantibodies are present in a number of clinical conditions, primarily in systemic lupus erythematosus (SLE, ~80%) and drug-induced lupus (DIL, ~95%) by procainamide, hydralazine, chlorpromazine, and quinidine. Additionally, these autoantibodies are also detectable in other rheumatic diseases, including myositis and systemic sclerosis (SSc).

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

Typical results

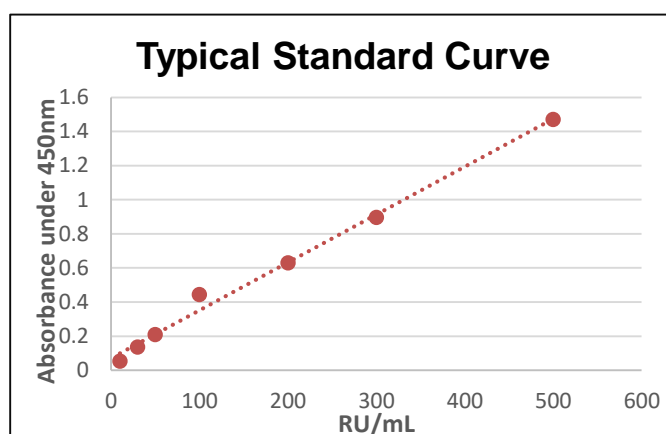
(Example only, not for calculation of actual results)

Calibrator*	Concentration (RU/mL)	OD450 (Blanked)
1	500	1.469
2	300	0.895
3	200	0.629
4	100	0.444
5	50	0.209
6	30	0.136
7	10	0.053
Negative Control	0	0.054
Positive Control	147	0.480

* Calibrator standardised against NIBSC W1064. (RU=Relative Unit)

Cut-off	RU/mL
Negative	< 42 RU/mL
Positive	≥ 42 RU/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	85.29% (n=34)	
Specificity	100% (n=40)	
Inter Assay Precision		
Sample	RU/mL (n=20)	CV
1	64	9.0%
2	173	8.1%
3	363	7.5%
Intra Assay Precision		
Sample	RU/mL (n=20)	CV
1	83	4.0%
2	222	4.6%
3	419	3.1%

References:

- Dumortier, H., & Muller, S. (2007). Histone Autoantibodies. In Autoantibodies (pp. 169-176). Elsevier.
- Dooley, M. A. (2016). Drug-induced Lupus. In Systemic Lupus Erythematosus (pp. 473-479). Academic Press.
- Firestein, G. S., Budd, R., Gabriel, S. E., McInnes, I. B., & O'dell, J. R. (2016). Kelley And Firestein's Textbook Of Rheumatology E-book. Elsevier Health Sciences.
- Portanova, J. P., Arndt, R. E., Tan, E. M., & Kotzin, B. L. (1987). Anti-histone Antibodies In Idiopathic And Drug-induced Lupus Recognize Distinct Intrahistone Regions. The Journal Of Immunology, 138(2), 446-451.
- Portanova, J. P., Rubin, R. L., Joslin, F. G., Agnello, V. D., & Tan, E. M. (1982). Reactivity Of Anti-histone Antibodies Induced By Procainamide And Hydralazine. Clinical Immunology And Immunopathology, 25(1), 67-79.



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