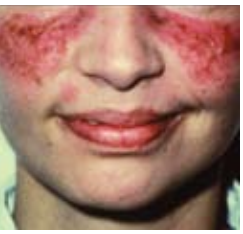


EliA™ Autoimmune assays
Excellence in Autoimmunity

ANA (anti-nuclear antibodies)

Relevant markers for connective tissue disease (CTD)

Clinical rationale

- Aids in differentiating patients with and without autoimmune disease
  — CTDs have symptoms that overlap[1]
- The presence and specificity of certain autoantibodies strongly indicate the likely CTD involved
  — Specificity is needed to reduce false positive results
- Accurately directs reflex testing for further disease differentiation
- Allows continuous assessment during disease progression

The selected antigens are based on the related individual antibody's proven association with a specific autoimmune connective tissue disease.

Marker autoantibodies in CTD[2]

Marker autoantibody	Associated CTD
U1RNP	MCTD, SLE
Sm	SLE
SS-A/Ro	Sjögren syndrome, SLE
SS-B/La	Sjögren syndrome, SLE
Scl-70	Systemic sclerosis
CENP	Limited systemic sclerosis (CREST)
Jo-1	(Poly)dermatomyositis
dsDNA[3]	SLE

EliA™: Results make the difference

Symphony ANA and dsDNA antibodies

- High-quality antigens
  - — EliA Symphony: Human recombinant U1RNP (70 kDa, A, C), Ro (60 kDa, 52 kDa), La, CENP-B, Scl-70 and Jo-1 proteins, highly purified native Sm protein
  - — EliA dsDNA: Circular, double-stranded plasmid DNA with no ssDNA, which might give false positive results
- Human recombinant antigen produced in a eukaryotic expression system
  - — Retains native conformation and epitopes, which is essential for antibody recognition
  - — Provides excellent assay stability and reproducibility

ANA

Outstanding sensitivity even for difficult-to-detect antibodies[4]

Number of samples	Target specificity	EliA Symphony Positive
51	SS-A/Ro*	51
45	SS-B/La	45
44	RNP	44
5	Sm	5
17	Jo-1*	17
13	Scl-70	12

Study evaluating EliA Symphony in 175 sera with predefined specificities.
*Typically difficult to detect using indirect immunofluorescence.

dsDNA

Unmatched sensitivity while maintaining specificity, particularly in active SLE[5]

		EliA dsDNA	Farr-RIA	CLIFT
Sensitivity	SLE	39.5%	31.6%	13.2%
Sensitivity	Active SLE	70.8%	66.7%	29.2%
Sensitivity	SLE nephritis	55.0%	50.0%	25.0%
Specificity	Control group†	93.2%	96.1%	99.0%

Study evaluating diagnostic sensitivity of different methods.
†Patients with non-SLE autoimmune disease and positive antinuclear antibody test results.

EliA: Automation makes it easy and economical

- Using the proven ImmunoCAP® 100ᵉ and ImmunoCAP 250 *automated* laboratory systems
- Moderately complex
- High efficiency for reduced labor costs and hands-on time
  - — Discrete single-well testing
  - — One calibration curve per isotype stored for 28 days
    - – IgA, IgE, IgG, IgM
- Onboard dilutions

References

1. Lupus Foundation of America. Lupus and overlap. http://www.lupus.org/webmodules/webarticlesnet/templates/new_aboutaffects.aspx?articleid=101&zoneid=17. Accessed April 25, 2008. **2.** Peter JB, Shoenfeld Y, eds. *Autoantibodies.* Amsterdam, The Netherlands: Elsevier Science BV; 1996. **3.** Tzioufas AG, Tergoglou C, Stavropoulos ED, et al. Determination of anti-dsDNA antibodies by three different methods: comparison of sensitivity, specificity and correlation with lupus activity index (LAI). *Clin Rheumatol.* 1990;9:186-192. **4.** Oris E, Bunn C, Godefridis G, Kolbus N, Papisch W, Bossuyt X. Evaluation of EliA™ screening and detection of antibodies directed against extractable nuclear antigens. Poster presented at: 6th Dresden Symposium on Autoantibodies; September 4-7, 2002; Dresden, Germany. **5.** Hernando M, González C, Sánchez A, et al. Clinical evaluation of a new automated anti-dsDNA fluorescent immunoassay. *Clin Chem Lab Med.* 2002;40(10):1056-1060.

www.phadia.us

Phadia

Phadia US Inc
4169 Commercial Avenue
Portage, MI 49002
800.346.4364

08020.01