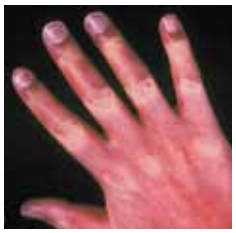





EliA®
Autoimmune assays
Excellence in Autoimmunity

ENA (extractable nuclear antigens)
Reflex testing for connective tissue diseases (CTDs)

Clinical rationale

- A positive anti-nuclear antibody (ANA) screen result is the first step in diagnosing CTDs[1]
  - Further antibody differentiation is necessary to aid in the diagnosis of specific CTDs
- EliA ENA assays aid in reflex testing for patients testing positive to an ANA screen, such as EliA Symphony[1]

The presence of specific autoantibody markers strongly relates to 1 or more of the CTDs

Specificity is needed to differentiate these difficult-to-diagnose diseases

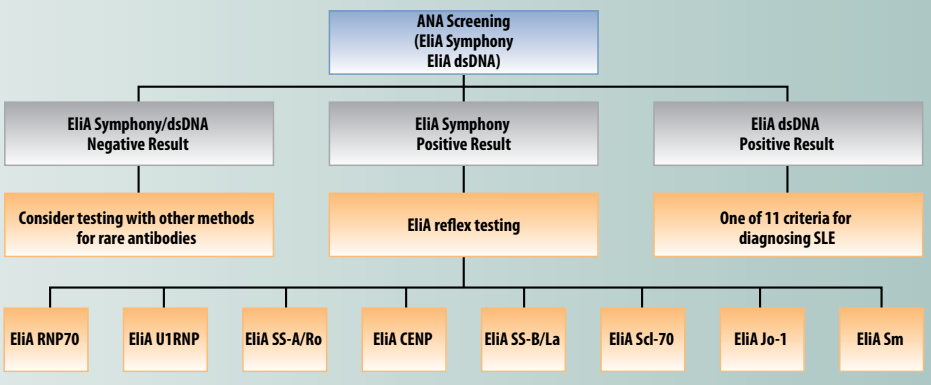
Prevalence of autoantibodies in CTDs[2]

Marker autoantibody	Associated CTD	Autoantibody prevalence
Sm	SLE	20%-30%
U1RNP	MCTD	100%
	SLE	30%-40%
RNP70	MCTD	75%-95%
	SLE	10%-15%
SS-A/Ro	Sjögren's syndrome	60%-90%
	SLE	40%-50%
SS-B/La	Sjögren's syndrome	50%-95%
	SLE	6%-15%
Scl-70	Systemic sclerosis	30%-60%
CENP	Limited systemic sclerosis (CREST)	70%-80%
Jo-1	Poly-/dermatomyositis	25%-35%

Detection of clinically relevant antibodies is essential to help guide physician diagnosis of CTDs

Optimal sensitivity is needed to ensure the detection of all relevant autoantibodies

Suggested algorithm for EliA ANA reflex testing[1,3]



EliA: Results make the difference

EliA ENA antibodies

- High-quality human recombinant antigens produced in a eukaryotic (Baculovirus/insect cell) expression system retain native conformation and epitopes essential for antibody recognition
  - Provide excellent assay stability and reproducibility
  - Human recombinant U1RNP (70 kDa, A, C) Ro, La, CENP-B, Scl-70, and Jo-1 proteins
  - EliA Ro assay includes both 52 and 60 kDa antigens
- EliA Sm assay includes the highly purified native SmD protein to provide the specificity needed to confirm a diagnosis and assess therapy specific to SLE
- EliA Symphony, EliA dsDNA, and EliA ENA assays are an ideal combination to evaluate suspected autoimmune disorders
  - The clinically relevant ENA antigens are precisely the same as those used in the EliA Symphony assay
  - The combination of EliA Symphony and EliA dsDNA may result in fewer false positives when detecting CTDs[4]
  - The >95% specificity of the EliA ENA assays helps clinicians differentiate between various CTDs with overlapping symptoms[2]

Excellent correlation between EliA Symphony ANA screen and specific CTD antibodies[2]

CDC sera	Target	EliA Symphony (ANA screen)	EliA Sm	EliA U1RNP	EliA RNP70	EliA Ro	EliA La	EliA Scl-70	EliA CENP	EliA Jo-1
CDC1	dsDNA, weak Sm	+/-	+	-	-	-	-	-	-	-
CDC2	La, weak Ro	+	-	-	-	+	+	-	-	-
CDC3	Weak Sm, U1RNP, Ro, La	+	+	+	+	+	+	-	-	-
CDC4	U1RNP	+	-	+	+	-	-	-	-	-
CDC5	Sm	+	+	+[a]	-	-	-	-	-	-
CDC6	Nucleolar	-	-	-	-	-	-	-	-	-
CDC7	Ro	+	-	-	-	+	-	-	-	-
CDC8	Centromere	+	-	-	-	-	-	-	+	-
CDC9	Scl-70	+	-	-	-	-	-	+	-	-
CDC10	Jo-1	+	-	-	-	+[b]	-	-	-	+

Performance of EliA ANA assays with CDC serum panel.

Key: a=Sm is associated with RNP and hence a parallel detection of the 2 antigens is possible; b=Anti-Jo-1 sera often show anti-Ro-52 activities.

EliA: Automation makes it easy and economical

- Using proven *automated* Phadia laboratory systems, ImmunoCAP® 100[e] and ImmunoCAP® 250
- CLIA moderately complex
- Onboard sample dilutions
- High efficiency for reduced labor costs and hands-on time
  - Discrete single-well testing
  - Single IgG calibration curve stored for 28 days for all ENA assays

References

1. Homburger HA. Cascade testing for autoantibodies in connective tissue diseases. *Mayo Clin Proc.* 1995;70(2):183-184. **2.** Data on file, Phadia AB. **3.** Tan EM, Cohen AS, Fries JF, et al. The 1982 revised criteria for the classification of systemic lupus erythematosus. *Arthritis Rheum.* 1982;25(11):1271-1277. **4.** Casas MI, Cava F, Fernandez FJ, et al. Comparison of screening by IIF (HEp 2) and an ANA ELISA vs a new automated ANA/ENA screening (EliA) in patients from routine. In: 6th Dresden Symposium; September 4-7, 2002; Dresden, Germany. Abstract.

Phadia
Setting the Standard

Phadia US Inc
4169 Commercial Avenue
Portage, MI 49002
800.346.4364

www.phadia.us

428019.01