

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 CTDs¹
 - 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 Symphony¹

Prevalence of autoantibodies in CTDs²

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

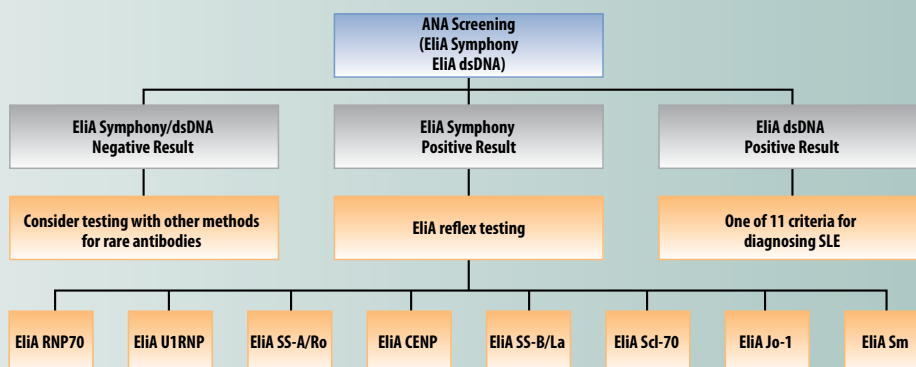
Specificity is needed to differentiate these difficult-to-diagnose diseases

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%

Suggested algorithm for EliA ANA reflex testing^{1,3}

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



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 CTDs⁴
 - The >95% specificity of the EliA ENA assays helps clinicians differentiate between various CTDs with overlapping symptoms²

Excellent correlation between EliA Symphony ANA screen and specific CTD antibodies²

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[®] 100⁶ 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.

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