

Bio-Rad Laboratories
The Clear Choice in Autoimmune Testing



ENA Screen

Autoimmune EIA

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Simple, Objective, Sensitive, Specific

Bio-Rad offers the most comprehensive menu of EIA assays available today, with a constantly expanding menu that includes new clinically relevant assays.

The Bio-Rad ENA Plus Screening Test is an enzyme immunoassay (EIA) intended for the detection and qualitative measurement of antibodies against Extractable Nuclear Antigens (SS-A/Ro, SS-B/La, Sm, RNP, Jo-1, and Scl-70) in human serum as an aid in the diagnosis of certain systemic rheumatic diseases.

Product Highlights

- Common assay protocol and reagents
- Color-coded breakaway wells
- Easy-to-automate



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Clinical Utility

Antinuclear antibodies (ANAs) directed against a variety of macromolecules occur in extraordinarily high frequency in systemic rheumatic diseases. Many rheumatic diseases are characterized by the presence of one or more of these antinuclear antibodies. Therefore, the identification of the specific antibody is useful in the detection and diagnosis of the disease.¹

Extractable nuclear antigens (ENAs) are acidic (non-histone) macromolecules extracted from the saline soluble fraction of cell nuclei; hence the term ENA.² There are now 20 different saline-extractable antigens identified.² Antibodies to ENAs are seen in several clinical syndromes including Systemic Lupus Erythematosus (SLE), Mixed Connective Tissue Disease (MCTD), Sjögrens Syndrome (SS), Myositis, and Progressive Systemic Sclerosis (PSS) and are considered to be markers for these diseases.²⁻³

The Bio-Rad ENA Plus Screening Test simultaneously screens in a single well for SS-A/Ro, SS-B/La, Sm, RNP, Jo-1, and Scl-70 autoantibodies. Samples found to be negative can be considered negative for SS-A/Ro, SS-B/La, Sm, RNP, Jo-1, and Scl-70.

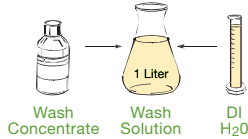
Systemic Autoimmune (ENA Plus Screen)



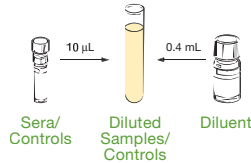
Autoimmune ELISA Procedure

Pre-Test Setup Instructions

- 1 Bring all reagents to room temperature (18-27°C).
- 2 Prepare the Wash Solution.

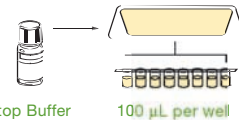
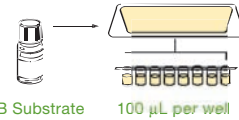
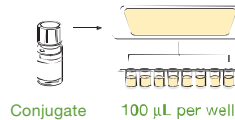
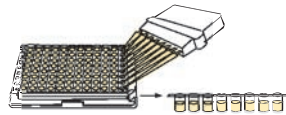
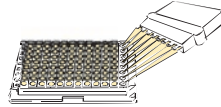


- 3 Make 1:40 working solutions by diluting 10 µL of patient's sera Positive/Negative Controls and Calibrator in 0.4 mL of Diluent.



Test Procedure (See Procedure Notes and Pre-Test Setup Instructions)

- 1 Apply 100 µL diluted patient samples, Controls and Calibrator to wells.
- 2 Incubate wells for 30 min. at room temperature (18-27°C)
- 3 Wash wells 5x with ~200 µL of Wash Solution. Remove all liquid before proceeding.
- 4 Apply 100 µL HRP Conjugate to all wells. Discard excess transferred HRP after use.
- 5 Incubate wells for 30 min. at room temperature (18-27°C).
- 6 Wash wells 5x with ~200 µL of Wash Solution. Remove all liquid before proceeding.
- 7 Develop color by adding 100 µL of TMB Substrate to each well. Discard excess transferred TMB after use.
- 8 Incubate for 30 min. at room temperature (18-27°C)
- 9 Stop color development by adding 100 µL of Stop Buffer to each well.
- 10 Read results within 30 minutes with an EIA reader set to 450 nm.



Result Interpretation	
EU's	Interpretation
<20 (Index <0.8)	Negative
20 to 25 (Index 0.8 – 1.0)	Borderline Positive
>25 (Index >1.0)	Positive

Note: Enzyme Units (EUs) and Index Values are semi-quantitative. They are units defined by Bio-Rad Laboratories.

REFERENCES

1. White RH, Robbins DL: *West J Med.* 147; 210-213, 1987.
2. Moore TL, et. al. *Seminars in Arthritis and Rheum.* 10; 309-318, 1981.
3. Tan EM. *Advances in Immunology.* 44; 93-151, 1989.

Ordering Information

Catalog No.	Description
96EP	Bio-Rad ENA Plus Screen 96 tests

Bio-Rad Autoimmune EIA Kits

Catalog No.	Description
96AN	Bio-Rad ANA Screen 96 tests
425-0000	Bio-Rad ANA Screen 960 tests
96EN	Bio-Rad ENA Screen (4) 96 tests
96DS	Bio-Rad Anti-dsDNA 96 tests
96SS	Bio-Rad Anti-ssDNA 96 tests
96SA	Bio-Rad Anti-SS-A/Ro 96 tests
96SB	Bio-Rad Anti-SS-B/La 96 tests
96SM	Bio-Rad Anti-Sm 96 tests
96SR	Bio-Rad Anti-Sm/RNP 96 tests
96JO	Bio-Rad Anti-Jo-1 96 tests
96SC	Bio-Rad Anti-Scl-70 96 tests
96CE	Bio-Rad Anti-Centromere 96 tests



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For further information, please contact the Bio-Rad office nearest you or visit our website at www.bio-rad.com.

Clinical Diagnostics Group

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