



Systemic autoimmune disease diagnosis

ENA screen plus Individual ENA antigens Centromere dsDNA

Diagnostic panels: Rheumatic diseases



CE The kits are CE-IVD certified and intended for professional use.

CLIA kits are optimized and validated for the determination of antibodies in human serum and plasma

Designed for the platform





Introduction

Determination of antinuclear antibodies is important for diagnosis of systemic autoimmune diseases. These non-organ specific auto-antibodies are directed to intracellular antigens located mainly in the nucleus of the cell. Their detection can indicate the presence of some systemic autoimmune pathology – especially: **systemic lupus erythematosus (SLE), Sjögren's syndrome (SS), scleroderma, mixed connective tissue disease (MCTD), systemic sclerosis, polymyositis and dermatomyositis.**

An important group of antinuclear antibodies represents antibodies against ENA (extractable nuclear antigens: SS-A/Ro, SS-B/La, Sm, RNP, ScI-70 and Jo-1). They are mainly ribonucleoproteins and nuclear enzymes.

Identification of single auto-antibody specificity is an important tool for differential diagnosis of systemic autoimmune diseases.

Antibodies against SS-A/Ro and SS-B/La often occur in patients with SS and SLE. They can also be found in mothers of children with neonatal lupus and congenital heart block. Sm antibodies are a highly specific marker, and part of the criteria for the diagnosis and classification of SLE. Also RNP antibodies (part of the Sm/RNP complex) are also often detected in patients with SLE. Presence of these antibodies is highly specific for MCTD (particularly when Sm antibodies are missing). Detection of Jo-1 antibodies is significant for another group of organ non-specific autoimmune diseases – myositis. Antibodies against antigen ScI-70 and centromere B are typical for diagnosis of systemic sclerosis (particularly its progressive forms).

The group of antinuclear antibodies also includes antibodies against nucleic acids (ssDNA, dsDNA), complexes of nuclear proteins (DNP, RNP) and histones.

Antibodies to double-stranded DNA (anti-dsDNA) fall in the group of antinuclear antibodies. This is a heterogeneous group of antibodies that are directed against various epitopes on a native double-stranded DNA molecule. The antibodies are considered highly specific for systemic lupus erythematosus (SLE).

Antinuclear antibody testing may also be included in the diagnosis of autoimmune diseases, such as primary biliary cirrhosis.



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Clinical applications

- Differential diagnosis of autoimmune disorders
- Disease stage and progress determination
- Treatment effectivity monitoring

Antigens

CLIA ENA screen plus

SS-A/Ro52, SS-A/Ro60, SS-B/La, RNP-A, RNP-C, RNP68, Sm, ScI-70, Jo-1 and centromere B

CLIA dsDNA

native human dsDNA

CLIA ScI-70

mix of native and recombinant Scl-70

CLIA SS-A

native SS-A/Ro60 (60 kDa) and recombinant SS-A/Ro52 (52 kDa) antigen

CLIA SS-A/Ro60

highly purified native SS-A/Ro60 (60 kDa) antigen

CLIA U1RNP

mix of recombinant RNP-A, RNP-C and RNP68 antigens

CLIA Centromere

mix of recombinant antigens CENP B and CENP A

CLIA Jo-1

recombinant Jo-1

CLIA Sm

native Sm antigen

CLIA SS-A/Ro52

recombinant SS-A/Ro52 (52 kDa) antigen

CLIA SS-B

recombinant SS-B/La antigen

Test characteristics

Kit	Calibration range	Diangostic sensitivity	Diagnostic specificity
CLIA ENA screen plus	3-320 U/ml	92.52 %	99.30 %
CLIA Centromere	0.5-320 U/ml	99.99 %	99.99 %
CLIA dsDNA	5-320 IU/ml	95.92 %	99.99 %
CLIA Jo-1	0.5-320 U/ml	99.99 %	99.99 %
CLIA ScI-70	3-320 U/ml	99.99 %	99.99 %
CLIA Sm	0.5-320 U/ml	92.86 %	99.99 %
CLIA SS-A	0.5-320 U/ml	97.80 %	99.99 %
CLIA SS-A/Ro52	0.5-180 U/ml	96.00 %	99.99 %
CLIA SS-A/Ro60	0.5-180 U/ml	99.99 %	99.99 %
CLIA SS-B	0.5-320 U/ml	91.43 %	99.99 %
CLIA U1RNP	3-320 U/ml	99.99 %	99.00 %





CLIA is a fully automated, fast, specific and sensitive method. It combines the use of magnetic particles for immunocomplex separation of the antigen and flash chemiluminescence for sensitive detection. The use of magnetic particle suspension facilitates automation, significantly shortens reaction times and improves the specificity of the determination. Flash chemiluminescence of acridinium ester provides an intense light signal even at very low concentrations and its intensity is measured in relative units of light (RLU). CLIA kits are designed for use on the KleeYa[®] automated platform.





CLIA kits

Diagnostic CLIA kits are used to determine specific antibodies in human serum or plasma on a KleeYa® analyzer.



Control set CLIA

Control sera verify the accuracy of results obtained by the CLIA kits.





- Fully automated method
- Kits include all necessary reagents, incl. calibrators
- Ready-to-use reagents in the reaction cartridges
- Control sera available as independent sets
- Results in U/ml, IU/ml

Advantages

- High diagnostic sensitivity and specificity
- Low sample (10 µl) and reagent consumption
- Short test time (30 min)
- Wide measuring range
- Full traceability of reagent consumption and number of tests available using RFID tags
- LIS connectivity available
- Superior customer service



Ordering information

CLIA kits

CLIA diagnostic kits are used to determine IgG antibodies in patient serum or plasma on a KleeYa® analyzer.

Control set CLIA

Each set contains two vials with positive and two vials with negative control serum with predetermined level of specific antibodies. They are designed to verify the accuracy of results obtained with CLIA kits.

Kit	Catalogue	Number
	number	of tests
CLIA ENA screen plus	CL-ENA100	100
CLIA Centromere	CL-CEN050	50
CLIA dsDNA	CL-DNA050	50
CLIA Jo-1	CL-Jo1050	50
CLIA ScI-70	CL-Scl050	50
CLIA Sm	CI-Sm0050	50
CLIA SS-A	CL-SSA050	50
CLIA SS-A/Ro52	CL-Ro5250	50
CLIA SS-A/Ro60	CL-Ro6050	50
CLIA SS-B	CL-SSB050	50
CLIA U1RNP	CL-RNP050	50

Control set	Catalogue	Number
	number	of tests
Control set CLIA ENA screen plus	CL-ENACON	2 x 20
Control set CLIA Centromere	CL-CENCON	2 x 20
Control set CLIA dsDNA	CL-DNACON	2 x 20
Control set CLIA Jo-1	CL-Jo1CON	2 x 20
Control set CLIA ScI-70	CL-ScICON	2 x 20
Control set CLIA Sm	CL-Sm0CON	2 x 20
Control set CLIA SS-A	CL-SSACON	2 x 20
Control set CLIA SS-A/Ro52	CL-Ro52CON	2 x 20
Control set CLIA SS-A/Ro60	CL-Ro60CON	2 x 20
Control set CLIA SS-B	CL-SSBCON	2 x 20
Control set CLIA U1RNP	CL-RNPCON	2 x 20

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