MAGLUMI® ANA Screen (CLIA) Assay
Device Description and Specification

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1 Device description and specification

1.1 Device Identification

1.1.1 Device name

Name of the device	MAGLUMI ANA Screen (CLIA)	MAGLUMI® ANA Screen (CLIA) Controls
Catalog No.	130217503M (100 Tests/kit) 130617503M (50 Tests/kit) 130717503M (30 Tests/kit)	160201405MT (Controls)

1.1.2 Intended purpose

The kit is an *in vitro* chemiluminescence immunoassay for the quantitative determination of IgG class antinuclear antibodies (ANA) in human serum and plasma using the MAGLUMI series Fully-auto chemiluminescence immunoassay analyzer and Biolumi series Integrated System, and the assay is used for an aid in the diagnosis of multiple systemic autoimmune diseases (Systemic Lupus Erythematosus (SLE), Mixed Connective Tissue Disease (MCTD), Sjögren's Syndrome (SS), Systemic Sclerosis (SSc), Polymyositis/Dermatomyositis (PM/DM), etc.).

Antinuclear antibodies (ANA) are a diverse group of autoantibodies that recognize multiple intracellular antigens, classically consisting of nuclear specificities such as deoxyribonucleic acid or small nuclear ribonucleoproteins. It is currently accepted that ANA contain two major types of antibodies, the first group includes antibodies against DNA and histones and the second group includes autoantibodies to extractable nuclear antigens (ENA). Among the most important nuclear antigens are dsDNA, Histones, Rib-P, Sm/RNP, Sm, SS-A/Ro, SS-B, Scl-70, Jo-1, Centromeres and mitochondria M2 antigens. These nuclear particles recognized by ANA have essential intracellular functions such as replication and transcription, and thus are structurally conserved among species.

ANA are key biomarkers in the diagnosis of rheumatic diseases such as Systemic Lupus Erythematous (SLE), Sjögren's Syndrome (SS), Systemic Sclerosis (SSc), Mixed Connective Tissue Disease (MCTD), Polymyositis/Dermatomyositis (PM/DM) and Primary Biliary Cirrhosis (PBC). ANA can be detected in 90-95% of patients with SLE, 50-60% of patients with SS, 85-95% of patients with SSc, 90-100% of patients with MCTD, 50-60% of patients with PM/DM and 50-80% of patients with PBC. The number of different ANA specificities is large and, whereas some antibodies are highly associated with particular diseases, others are expressed more widely among patients. The association between ANA and certain disease entities suggests that these antibodies could be useful biomarkers for screening and diagnosis and could provide insights for understanding disease mechanisms.

1.1.3 Intended Users

For professional use only.

1.1.4 Basic UDI-DI

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1.1.5 Principle of the assay

Indirect chemiluminescence immunoassay.

The prediluted sample, buffer, magnetic microbeads coated with nuclear antigens (dsDNA, Histones, Rib-P, Sm/RNP, Sm, SS-A/Ro, SS-B, Scl-70, Jo-1, Centromeres, mitochondria M2 antigens together with HEp-2 cell nuclear extract) mixed thoroughly and incubated to form immune-complexes. After incubation, materials bound to the magnetic microbeads are held in a magnetic field while unbound materials are washed

away during a wash cycle. Then adding ABEI labeled with mouse monoclonal anti-human IgG antibody, incubated to form sandwich complexes. After precipitation in a magnetic field, the supernatant is decanted and then another wash cycle is performed. Subsequently, the Starter 1+2 are added to initiate a chemiluminescent reaction. The light signal is measured by a photomultiplier as relative light units (RLUs), which is proportional to the concentration of antinuclear antibodies present in the sample.

1.1.6 The rationale for the qualification of the product as a device

The ANA Screen (CLIA) kit is used *in vitro* for the examination of blood, principally for the purpose of providing information on concerning a physiological or pathological process or state.

1.1.7 Risk class

Class B according to Regulation (EU) 2017/746, ANNEX VIII, Rule 6, Devices not coved by Class A, Class C and Class D.

1.1.8 Description of the components

Component	Contents	100 tests	50 tests	30 tests
Lyophilized Magnetic Microbeads	Magnetic microbeads coated with nuclear antigens (dsDNA, Histones, Rib-P, Sm/RNP, Sm, SS-A/Ro, SS-B, Scl-70, Jo-1, Centromeres, mitochondria M2 antigens together with HEp-2 cell nuclear extract) (~58.8 μg/bottle) in PBS buffer, NaN3 (<0.1%).	1 bottle	1 bottle	1 bottle
Magnetic Microbeads Buffer	PBS buffer, NaN3 (<0.1%).	2.8 mL	2.8 mL	2.8 mL
Calibrator Low	A low concentration of antinuclear antibodies in PBS buffer, NaN3 (<0.1%).	1.0 mL	1.0 mL	1.0 mL
Calibrator High	A high concentration of antinuclear antibodies in PBS buffer, NaN3 (<0.1%).	1.0 mL	1.0 mL	1.0 mL
Buffer	BSA, NaN3 (<0.1%).	13.5 mL	8.0 mL	4,8 mL
ABEI Label	ABEI labeled with anti-human IgG monoclonal antibody (mouse) (~25.0 ng/mL) in Tris-HCl buffer, NaN3 (<0.1%).	23.5 mL	13.0 mL	7.8 mL
Diluent	PBS buffer, NaN3 (<0.1%).	25.0 mL	15.0 mL	8.0 mL
Control 1	A low concentration of antinuclear antibodies (20.0 AU/mL) in PBS buffer, NaN3 (<0.1%).	1.0 mL	1.0 mL	1.0 mL
Control 2	A high concentration of antinuclear antibodies (100 AU/mL) in PBS buffer, NaN3 (<0.1%).	1.0 mL	1.0 mL	1.0 mL
All reagents are provided ready-to-use.				

Component	Description	Contents
Control 1	A low concentration of antinuclear antibodies (20.0 AU/mL) in PBS buffer, NaN3 (<0.1%).	1×1.0 mL
Control 2	A high concentration of antinuclear antibodies (100 AU/mL) in PBS buffer, NaN3 (<0.1%).	1×1.0 mL
All reagents are provided ready-to-use.		

1.1.9 Description of the specimen collection and transport materials

Serum collected using tubes without additive/accessory, or tubes containing clot activator or clot activator with gel and plasma collected using K2- EDTA or sodium heparin tubes have been verified and could be applied to the assay. Collect blood aseptically following the universal precautions for venipuncture.

Package and label specimens in compliance with applicable local regulations covering the transport of clinical specimens and infectious substances.

When shipped, do not exceed the storage limitations

1.1.10 Description of the appropriate assay characteristics

Because there are differences between the actual working environment and laboratory environment, the master curve should be adjusted to generate the working curve that meets the actual work environment.

Brief description: The master curve is determined by 10 standard calibrators.

Compare two calibration RLUs obtained by calibrators with RLUs of related concentration on the master curve.

Calculate the difference between two calibration RLUs obtained by calibrators and RLUs of related concentration on the master curve, and carry out linear inference using the recalculated RLU (Y-axis) and concentration (X-axis).

Calculate RLU differences of other calibrators on the master curve with the correction carve and recalculate the RLU and concentration.

The recalculated curve is a valid working curve.

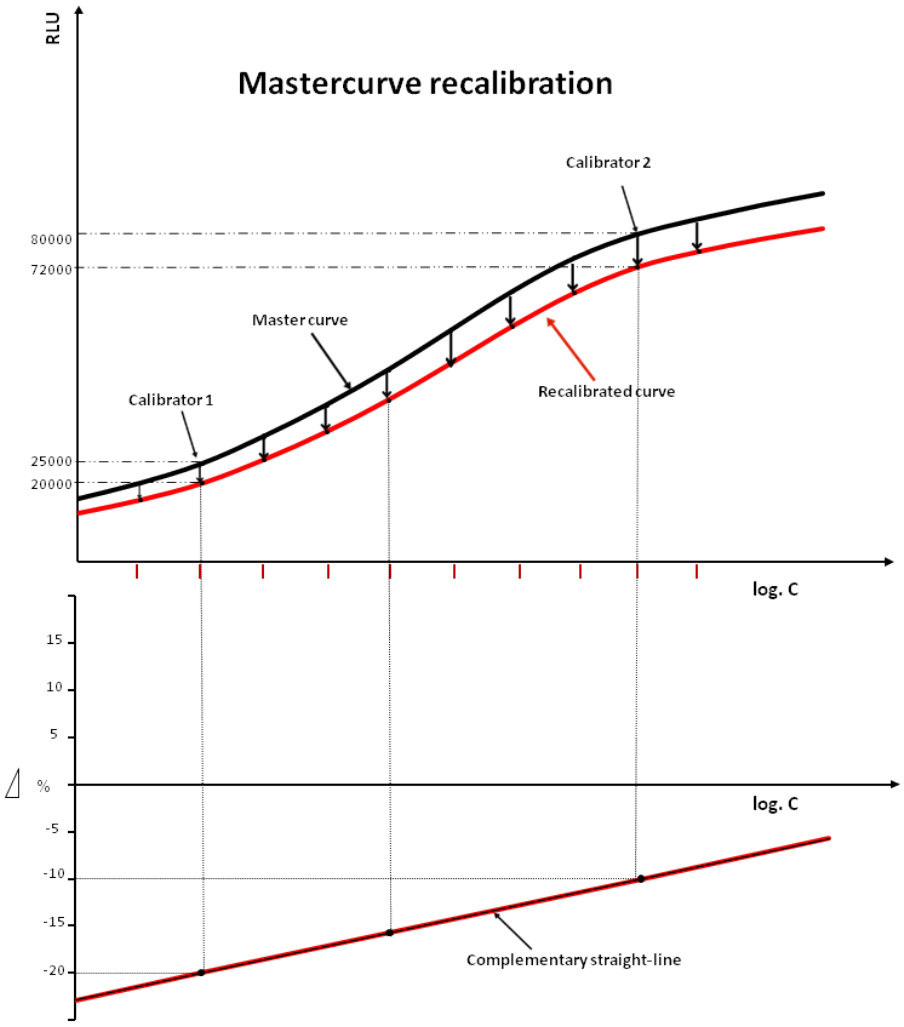

Figure 1 Calibration Principle

1.1.11 Material required but not provided

Fully-auto chemiluminescence immunoassay analyzer or Integrated System Biolumi 8000.

Additional accessories of test required for the above analyzers, specific accessories and accessories' specification for each model refer to corresponding Analyzer Operating Instructions.

2 Reference to previous generation and similar devices

Current device:

Manufacturer	Name of the device	Principle of the assay	Qualitative or quantitative	Sample type	Reference range	Intended use
Snibe	MAGLUMI® ANA Screen (CLIA)	Chemiluminescence immunoassay (CLIA)	Quantitative	Serum and plasma	<40.0 AU/mL	Quantitative determination of IgG class antinuclear antibodies (ANA) in human serum and plasma. Aid in the diagnosis of multiple systemic autoimmune diseases (Systemic Lupus Erythematosus (SLE), Mixed Connective Tissue Disease (MCTD), Sjögren's Syndrome (SS), Systemic Sclerosis (SSc), Polymyositis/Dermatomyositis (PM/DM), etc.).

Previous generation and similar devices:

Manufacturer	Name of the device	Principle of the assay	Qualitative or quantitative	Sample type	Reference range	Intended use
YHLO	ANA (chemiluminescence)	Chemiluminescence	Quantitative	Serum and plasma	≤40 AU/mL	Quantitative determination of antinuclear antibodies (ANA) in human serum and plasma.
EUROIMMUN	ANA Screen ELISA (IgG)	Enzyme-Linked Immunosorbent Assay (ELISA)	Semi-quantitative	Serum and plasma	Ratio< 1.0	Qualitative determination of IgG class antibodies against nuclear antigens (mixture of dsDNA, histones, ribosomal P-proteins, nRNP, Sm, SS-A, SS-B, Scl-70, Jo-1 and centromeres) in human serum and plasma.
QUANTA Lite	QUANTA LiteTM ANA ELISA	Enzyme-Linked Immunosorbent Assay (ELISA)	Semi-quantitative	Serum	<20 Units	Semi-quantitative detection of anti-nuclear antibodie (ANA) in human serum.