

MAGLUMI Anti-HBc (CLIA)



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FOR PROFESSIONAL USE ONLY

Store at 2-8°C



CAUTION: COMPLETELY READ THE
INSTRUCTIONS BEFORE PROCEEDING

SYMBOLS EXPLANATIONS



MANUFACTURER



CONSULT INSTRUCTIONS FOR USE



KIT COMPONENTS



IN VITRO DIAGNOSTIC MEDICAL
DEVICE



BATCH CODE



CATALOGUE NUMBER



USE BY



TEMPERATURE LIMITATION
(STORE AT 2-8 °C)



SUFFICIENT FOR



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INTENDED USE

The kit has been designed for the qualitative determination of total Hepatitis B core antibodies (Anti-HBc) in human serum.

The test has to be performed on MAGLUMI Fully-auto chemiluminescence immunoassay (CLIA) analyzer (Including Maglumi 600, Maglumi 800, Maglumi 1000, Maglumi 1000 Plus, Maglumi 2000, Maglumi 2000 Plus, Maglumi 4000 and Maglumi 4000 Plus).

Catalog Number	Specification
130210005M	100 tests
130610005M	50 tests

SUMMARY AND EXPLANATION OF THE TEST

HBV is transmitted through infected body fluids, including blood, semen, and vaginal fluids (including menstrual blood). It also can be transmitted from a pregnant woman to her child at or near the time of delivery.

Hepatitis B surface antigen (HBsAg) is one of the most frequently performed tests for HBV. This HBV antigen is the earliest indicator of an active hepatitis B infection. This antigen may be present before symptoms of an HBV infection are present. If this antigen level remains high for more than 6 months, then people will probably become a carrier of HBV, meaning people can transmit it to others throughout people's life.

Hepatitis B surface antibody (HBsAb) is also one of the most common tests for HBV. Usually this antibody appears about 4 weeks after HBsAg disappears and means that the infection is at the end of its active stage and people cannot pass the virus to others (people are no longer contagious). This antibody also protects people from getting HBV again in the future. The test is done to determine the need for vaccination; the antibody will be present after receiving the HBV vaccine series, showing that people have protection (immunity) from the virus. Occasionally people's test may show that people have both the HBsAb antibodies and HBsAg antigen; in this case, people are still contagious with hepatitis B core antigen (HBcAg). Currently, there is no test to find this antigen. Hepatitis B core antibody (HBcAb) is an antibody to the hepatitis B core antigen. This antibody appears about 1 month after an active HBV infection. It can be found in people who had an infection in the past and in those with long-term (chronic) HBV. It usually is present for life.

Hepatitis B e-antigen (HBeAg) is an HBV protein that is only present during an active HBV infection. This test determines how contagious people are. Testing for this antigen can also be used to monitor the effectiveness of treatment for HBV. Hepatitis B e-antibody (HBeAb) shows that the active stage of the HBV infection is almost over and people's risk of being contagious is greatly reduced. HBeAb is usually present during chronic HBV infections.

PRINCIPLE OF THE TEST

Competitive chemiluminescence immunoassay;

Use ABEI to label anti-HBc an monoclonal antibody, use FITC to label purified HBc antigen, use an anti-FITC polyclonal antibody to coat magnetic microbeads. Sample (or calibrator/control, if applicable), ABEI Label, FITC Label and magnetic microbeads coated are mixed thoroughly and incubated at 37°C, forming antibody-antigen complexes. After precipitation in a magnetic field, decant the supernatant, and perform a wash cycle. Subsequently, the Starter 1+2 are added to initiate a flash chemiluminescent reaction. The light signal is measured by a photomultiplier within 3 seconds as RLU, which is inversely proportional to the concentration of Anti-HBc present in samples.

CONTENTS KIT COMPONENTS

Material Supplies

Component	100 tests	50 tests
Magnetic Microbeads: TRIS buffer, 0.09%NaN ₃ , coated with sheep anti-FITC polyclonal antibody.	2.5 mL	2.0 mL
Calibrator Low: phosphate buffer containing bovine serum and anti-HBc, 0.09% NaN ₃ .	2.5 mL	2.0 mL
Calibrator High: phosphate buffer containing bovine serum and anti-HBc, 0.09% NaN ₃ .	2.5 mL	2.0 mL
FITC Label: HBc recombinant antigen labeled with FITC, containing BSA, 0.09%NaN ₃ .	6.5 mL	4.5 mL
ABEI Label: anti-HBc monoclonal antibody labeled with ABEI, containing BSA, 0.09%NaN ₃ .	6.5 mL	4.5 mL
All reagents are provided ready-to-use.		

Reagent Vials in kit box	
Internal Quality Control: phosphate buffer containing bovine serum and anti-HBc, 0.09% NaN ₃ . (For target value, refer to Quality Control Information data sheet)	2.0 mL

Internal quality control is only applicable with MAGLUMI system. For instructions for use and target value, refer to Quality Control Information data sheet. User needs to judge results with their own standards and knowledge.

Accessories Required But Not Provided

MAGLUMI Reaction Module	REF: 630003
MAGLUMI Starter 1+2	REF: 130299004M
MAGLUMI Wash Concentrate	REF: 130299005M
MAGLUMI Light Check	REF: 130299006M

Please order accessories from Shenzhen New Industries Biomedical Engineering Co., Ltd (SNIBE) or our representative.



Preparation of the Reagent Integral

Mix contents of new (unopened) reagent packs by gently inverting pack several times. Resuspension of the microbeads takes place automatically prior to use. Visually verify that the microbeads are completely resuspended in brown color. In case microbeads are not resuspended, it is recommended to perform a gentle horizontal motion until the microbeads are completely resuspended.

Do not interchange integral components from different reagents or lots!

Storage and Stability

- Sealed: Stored at 2-8°C until the expiration date.
- On-board: Stable for 4 weeks. To ensure the best kit performance, it is recommended to place opened kits in the refrigerator if it's not going to be used on-board during the next 12 hours.



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CALIBRATION AND TRACEABILITY

1) Traceability

To perform an accurate calibration, we have provided the test calibrators standardized against the WHO 1st International Standard 95/522.

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2) 2-Point Recalibration

Via the measurement of calibrators, the predefined master curve is adjusted (recalibrated) to a new, instrument-specific measurement level with each calibration.

3) Frequency of Recalibration

- After each exchange of lot (Reagent Integral or Starter Reagents).
- Every week and/or each time a new Integral is used (recommended).
- After each servicing of MAGLUMI Fully-auto chemiluminescence immunoassay (CLIA) analyzer.
- If controls are beyond the expected range.
- Whenever room temperature changes exceed 5 °C (recommended).

SPECIMEN COLLECTION AND PREPARATION

Sample material: serum

Collect 5.0mL venous blood into Blood Collection Tube. Separate serum by centrifugation after standing whole blood at room temperature.

Avoid repeated freezing and thawing. The serum sample can be frozen and thawed for only two times. Stored samples should be thoroughly mixed prior to use (Vortex mixer).

Please ask local representative of SNIBE for more details if people have any doubt.

Specimen Conditions

- Do not use specimens with the following conditions:
 - heat-inactivated specimens;
 - Cadaver specimens;
 - Obvious microbial contamination.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- Inspect all samples for bubbles. Remove bubbles with an applicator stick prior to analysis. Use a new applicator stick for each sample to prevent cross contamination.
- Serum specimens should be free of fibrin, red blood cells or other particulate matter.
- Ensure that complete clot formation in serum specimens has taken place prior to centrifugation. Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may exhibit increased clotting time. If the specimen is centrifuged before a complete clotting, the presence of fibrin may cause erroneous results.

Preparation for Analysis

- Patient specimens with a cloudy or turbid appearance must be centrifuged prior to testing. Following centrifugation, avoid the lipid layer (if present) when pipetting the specimen into a sample cup or secondary tube.
- Specimens must be mixed **thoroughly** after thawing by **low** speed vortexing or by gently inverting, and centrifuged prior to use to remove red blood cells or particulate matter to ensure consistency in the results. Multiple freeze-thaw cycles of specimens should be avoided.
- All samples (patient specimens or controls) should be tested within 3 hours of being placed on board the MAGLUMI System. Refer to the SNIBE service for a more detailed discussion of onboard sample storage constraints.
- To ensure consistency in results, specimens must be transferred to a centrifuge tube and centrifuged at $\geq 1,000$ RCF (Relative Centrifugal Force) for 15 minutes before testing if they contain fibrin, red blood cells, or other particulate matter, or they were frozen and thawed.

Storage

- If testing will be delayed for more than 8 hours, remove serum

from the serum separator, red blood cells or clot. Specimens removed from the separator gel, cells or clot may be stored up to 12 hours at 2-8°C.

- Specimens can be stored up to 30 days frozen at -20°C or colder.

Shipping

- Before shipping specimens, it is recommended that specimens be removed from the serum separator, red blood cells or clot. When shipped, specimens must be packaged and labeled in compliance with applicable state, federal and international regulations covering the transport of clinical specimens and infectious substances. Specimens must be shipped frozen (dry ice).

WARNING AND PRECAUTIONS FOR USERS

IVD

- For use in *IN-VITRO* diagnostic procedures only.
- Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Safety Precautions

CAUTION: This product requires the handling of human specimens.

- All samples, biological reagents and materials used in the assay must be considered potentially able to transmit infectious agents. They should therefore be disposed of in accordance with the prevailing regulations and guidelines of the agencies holding jurisdiction over the laboratory, and the regulations of each country. Disposable materials must be incinerated; liquid waste must be decontaminated with sodium hypochlorite at a final concentration of 5% for at least half an hour. Any materials to be reused must be autoclaved using an overkill approach. A minimum of one hour at 121°C is usually considered adequate, though the users must check the effectiveness of their decontamination cycle by initially validating it and routinely using biological indicators.
- It is recommended that all human sourced materials be considered potentially infectious and handled in accordance with the 29 CFR. 1910.1030 Occupational exposure to bloodborne pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.
- This product contains Sodium Azide; this material and its container must be disposed of in a safe way.
- Safety data sheets are available on request.

Handling Precautions

- Do not use reagent kits beyond the expiration date.
- Do not mix reagents from different reagent kits.
- Prior to loading the Reagent Kit on the system for the first time, the microbeads requires mixing to re-suspend microbeads that have settled during shipment.
- For microbeads mixing instructions, refer to the KIT COMPONENTS, Preparation of the Reagent Integral section of this package insert.
- To avoid contamination, wear clean gloves when operating with a reagent kit and sample.
- Over time, residual liquids may dry on the kit surface, please pay attention the silicon film still exists on the surface of the kit.
- For detailed discussion of handling precautions during system operation, refer to the SNIBE service information.

TEST PROCEDURE

To ensure proper test performance, strictly adhere to the operating instructions of MAGLUMI Fully-auto chemiluminescence immunoassay (CLIA) analyzer. Each test parameter is identified via a RFID tag on the Reagent Integral. For further information please refer to the operating instructions of MAGLUMI Fully-auto

chemiluminescence immunoassay (CLIA) analyzer .

40 µL	Sample, calibrator
+40 µL	ABEI label
+40 µL	FITC label
+20 µL	Magnetic microbeads
15 min	Incubation
400 µL	Wash cycle
3 s	Measurement

DILUTION

Samples with concentrations above the measuring range can be diluted. After manual dilution, multiply the result by the dilution factor. After dilution by the analyzers, the analyzer software automatically takes the dilution into account when calculating the sample concentration.

The automatic sample dilution is available after dilution settings are done in the MAGLUMI analyzer user software. Please follow MALGUMI analyzer operating instructions.

QUALITY CONTROL

- Observe quality control guidelines for medical laboratories.
- Use suitable controls for in-house quality control. Controls should be run at least once every 24 hours (a run cannot exceed 24 hours), once per reagent kit and after every calibration. The control intervals should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined ranges. Each laboratory should establish guidelines for corrective measures to be taken if values fall outside the range.

LIMITATIONS OF THE PROCEDURE

1) Limitations

A skillful operation and strict adherence to the instructions are necessary to obtain reliable results.

Procedural directions must be followed exactly and careful technique must be used to obtain valid results. Any modification of the procedure is likely to alter the results.

Bacterial contamination or repeated freeze-thaw cycles may affect the test results.

2) Interfering Substances

The assay is unaffected by bilirubin <0.4 mg/mL, haemoglobin <10 mg/mL or triglycerides <20 mg/mL.

3) HAMA

Patient samples containing human anti-mouse antibodies (HAMA) may give falsely elevated or decreased values. Although HAMA-neutralizing agents are added, extremely high HAMA serum concentrations may occasionally influence results.

RESULTS

1) Calculation of Results

- The analyzer automatically calculates the Anti-HBc concentration in each sample by means of a calibration curve which is generated by a 2-point calibration master curve procedure. The results are expressed in index/mL For further information please refer to the operating instructions of MAGLUMI Fully-auto chemiluminescence immunoassay (CLIA) analyzer.

2) Interpretation of Results

Results obtained with the MAGLUMI Anti-HBc assay can be interpreted as follows:

- Non-reactive: A result less than 100 index/mL (< 100 index/mL) is considered to be negative.
- Reactive: A result greater than or equal to 100 index/mL (≥ 100 index/mL) considered to be positive.

PERFORMANCE CHARACTERISTICS

1) Precision

Intra-assay coefficient of variation was evaluated on 3 different levels of controls. Repeatedly measure 10 times in the same run to calculate the coefficient of variation.

Intra-assay precision			
Control	Mean(index/mL)	SD(index/mL)	CV%
Level 1	39.77	1.49	3.75
Level 2	142.53	4.36	3.06
Level 3	392.02	12.04	3.07

Inter-assay coefficient of variation was evaluated on three batches of kits. Repeatedly measured 3 different levels of controls 10 times in the same run, and 30 times for each levels to calculate the coefficient of variation.

Inter-assay precision			
Control	Mean(index/mL)	SD(index/mL)	CV%
Level 1	40.02	2.81	7.03
Level 2	145.32	9.50	6.54
Level 3	395.12	24.62	6.23

2) Analytical Sensitivity

<6 index/mL.

The detection limit represents the lowest analyte level that can be distinguished from zero.

3) Specificity

The specificity of the Anti-HBc assay system was assessed by measuring the apparent response of the assay to various potentially cross reactive analytes.

No cross reaction with IgG or IgM antibody of HAV, HCV, HIV, Syphilis, EBV. Non HBV infected sample which is RF or ANA positive, this reagent's determination results show negative. When Anti-HBe=282.843 index/mL, the Anti-HBc detects results show negative.

4) Recovery

Consider Calibrator High of known concentration as a sample, dilute it by 1:2 ratio with diluents, and measure the diluted concentration for 10 times. Then calculate the expected concentration and recovery of measured concentration. The recovery should be within 90% -110%.

Expected	Mean Measuring	Recovery
171.914 index/mL	175.068 index/mL	101.8 %

5) Clinical Sensitivity

458 samples which were precharacterized reactive for anti-HBc were found to be reactive with the MAGLUMI Anti-HBc assay.

Group	N	Reactive	Number of Confirmed Positive
Pre-characterized Anti-HBc Reactives	458	458	458

6) Clinical specificity

In a group of randomly selected blood donors, hospitalized patients and potentially cross-reacting blood-specimens, the specificity of the MAGLUMI Anti-HBc assay was found to be 99.69% .

Group	N	Reactive	Non-reactive	Number of Confirmed Positive
Unselected donors	1025	4	1021	2
Hospitalized patients	204	2	202	0
Potentially	65	0	65	0

cross-reacting blood-specimens				
Total	1294	6	1288	2

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