# MAGLUMI Anti-HCV (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

CONTENTS — KIT COMPONENTS

IVD — IN VITRO DIAGNOSTIC MEDICAL DEVICE

LOT — BATCH CODE

REF — CATALOGUE NUMBER

USE BY

TEMPERATURE LIMITATION
( STORE AT 2-8 °C)

SUFFICIENT FOR

KEEP AWAY FROM SUNLIGHT

THIS WAY UP

## INTENDED USE

The kit has been designed for the qualitative determination of Hepatitis C virus antibody (Anti-HCV) 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 |
|---|---|
| 130210006M | 100 tests |
| 130610006M | 50 tests |

## SUMMARY AND EXPLANATION OF THE TEST

Hepatitis C virus (HCV) is a small (55-65 nm in size), enveloped, positive sense single-stranded RNA virus of the family *Flaviviridae*. Hepatitis C virus is the cause of hepatitis C in humans.
Hepatitis C virus has a positive sense single-stranded RNA genome. The genome consists of a single open reading frame that is 9600 nucleotide bases long his single open reading frame is translated to produce a single protein product, which is then further processed to produce smaller active proteins. At the 5' and 3' ends of the RNA are the UTR, which are not translated into proteins but are important to translation and replication of the viral RNA. The 5' UTR has a ribosome binding site (IRES-Internal ribosome entry site) that starts the translation of a very long protein containing about 3,000 amino acids. This large pre-protein is later cut by cellular and viral proteases into the 10 smaller proteins that allow viral replication within the host cell, or assemble into the mature viral particles.
HCV mainly spread through blood, sexual transmission, mother to child transmission, etc. The major route of the HCV infection is through blood transmission.

## PRINCIPLE OF THE TEST

Sandwich chemiluminescence immunoassay:
The MAGLUMI Anti-HCV assay is a one-step immunoassay. Sample (or calibrator/control, if applicable) anti-HCV binds the added biotinylated antigens and FITC-antigen, forming sandwich complex. After incubated at 37°C, the complex is then bound to the added ABEI labeled and magnetic microbeads via interaction of biotin and streptavidin. After washing, 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 proportional to the concentration of Anti-HCV present in samples.

## CONTENTS KIT COMPONENTS

**Material Supplies**

| **Component** | 100 tests | 50 tests |
|---|---|---|
| **Magnetic Microbeads**: Streptavidin-coated microparticles. TRIS buffer, 0.09%$NaN_3$. | 2.5 mL | 2.0 mL |
| **Calibrator Low:** TRIS buffer, containing BSA and anti-HCV, 0.09%$NaN_3$. | 2.5 mL | 2.0 mL |
| **Calibrator High:** TRIS buffer, containing BSA and anti-HCV, 0.09%$NaN_3$. | 2.5 mL | 2.0 mL |
| **Mixed Antigens:** Biotinylated antigens, HCV-Core+NS3+ NS4+NS5 antigen labelled with FITC, Tris buffer , containing BSA, 0.09%$NaN_3$. | 12.5 mL | 7.5 mL |
| **ABEI Label**: sheep anti-FITC polyclonal antibody labelled with ABEI, containing | 12.5 mL | 7.5 mL |

| | | |
|---|---|---|
| BSA, 0.09%$NaN_3$. | | |
| All reagents are provided ready-to-use. | | |

| Reagent Vials in kit box | |
|---|---|
| **Internal Quality Control:** TRIS buffer, containing BSA and anti-HCV, 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 SNIBE internal reference substance.

**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 lots (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 you have any doubt.

**Specimen Conditions**

- Do not use specimens with the following conditions:
  (a) heat-inactivated specimens;
  (b) Cadaver specimens;
  (c) 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 ⩾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.
- Pay attention to the residual liquids which has dried on the kit surface.
- For detailed 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 .

| | |
|---|---|
| +20 µL<br>+100 µL | Sample, calibrator or controls<br>Mixed antigens |
| 10 min | Incubation |
| +100 µL<br>+20 µL | ABEI label<br>Magnetic microbeads |
| 10 min | Incubation |
| 400 µL | Wash cycle |
| 3 s | Measurement |

## DILUTION

Sample dilution by analyzer is not available in this reagent kit

Samples with concentrations above the measuring range can be diluted manually. After manual dilution, multiply the result by the dilution factor.

Please choose applicable diluents or ask SNIBE for advice before manual dilution must be processed.

## 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**

Assay results should be utilized in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions.

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

Procedural directions must be followed exactly and careful operation 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, hemoglobin<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 concentrations may occasionally influence results.

## RESULTS

**1) Calculation of Results**

- The analyzer automatically calculates the Anti-HCV 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 AU/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-HCV assay can be interpreted as follows:

- Non-reactive: A result less than 20 AU/mL (< 20 AU/mL) is considered to be negative.
- Reactive: A result greater than or equal to 20 AU/mL l is (≥20 AU/mL) considered to be positive.

## PERFORMANCE CHARACTERISTICS

**1) Precision**

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

| **Intra-assay precision** | | | |
|---|---|---|---|
| Control | Mean(AU/mL) | SD(AU/mL) | CV% |
| Level 1 | 3.03 | 0.11 | 3.63 |
| Level 2 | 122.74 | 4.70 | 3.83 |
| Level 3 | 400.11 | 16.08 | 4.02 |

Inter-assay coefficient of variation was evaluated on three batches of kits. Repeatedly measured 3 different levels of control 10 times

in the same run, and 30 times for each levels to calculate the coefficient of variation.

| Inter-assay precision | | | |
|---|---|---|---|
| Control | Mean(AU/mL) | SD(AU/mL) | CV% |
| Level 1 | 3.17 | 0.13 | 4.10 |
| Level 2 | 126.64 | 5.48 | 4.33 |
| Level 3 | 410.61 | 17.74 | 4.32 |

**2) Analytical Sensitivity**

<2 AU/mL.

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

**3) Specificity**

The specificity of the Anti-HCV 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, HBV, HIV, Syphilis. Non HCV infected sample which is RF or ANA positive, , this reagent's determination results show negative. When Anti-HBe=282.843 index/mL, the Anti-HCV 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 expected concentration and recovery of measured concentration.The recovery should be within 90% -110%.

| Expected | Mean Measuring | Recovery |
|---|---|---|
| 281.083 AU/mL | 269.423 AU/mL | 95.9 % |

**5) Clinical Sensitivity**

400 samples from HCV infected patients with different stages of disease and infected with different HCV genotypes (type1, 2, 3, 4, 5 and 6). The resulting sensitivity of confirmed positive samples is 100%. The data from the study are summarized in the following table.

| Group | N | Reactive |
|---|---|---|
| HCV infected persons with different stages of disease | 274 | 274 |
| HCV genotypes (type 1, 2, 3, 4, 5, 6) | 126 | 126 |

**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-HCV assay was found to be 99.8%.

| Group | N | Initially Reactive | Non-reactive | Repeat Reactive |
|---|---|---|---|---|
| Unselected donors | 5053 | 10 | 5043 | 10 |
| Hospitalized patients | 200 | 0 | 200 | 0 |
| Potentially cross-reacting blood-specimens (RF+, related viruses, pregnant women,etc.) | 100 | 0 | 100 | 0 |
| Total | 5353 | 10 | 5343 | 10 |

**7)Seroconversion sensitivity**

The ability of the MAGLUMI Anti-HCV assay to detect anti-HCV was evaluated by testing 19 HCV seroconversion panels from serum and plasma donors who seroconverted over the course of their donation history. The panels were also tested by an approved assay. The MAGLUMI Anti-HCV assay detected anti-HCV three to five days (one bleed) earlier than the comparator assay in 2 of the 19 panels. The comparator assay detected anti-HCV three days (one bleed) earlier than MAGLUMI Anti-HCV in 2 of the 19 panels. Both assays exhibited equivalent detection of anti-HCV in 15 of the 19 panels.

## REFERENCES


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