**Foresight**

**HCV Antibody Test Kit (Microplate Chemiluminescence Immunoassay)**

**Package Insert**

A microplate chemiluminescence immunoassay for the in vitro qualitative detection of total antibodies (IgG, IgM and IgA) to Hepatitis C Virus (HCV) in human serum or plasma. For professional in vitro diagnostic use only.

**INTENDED USE**

The HCV Antibody Test Kit (Microplate Chemiluminescence Immunoassay) is a two-step microplate chemiluminescence immunoassay for the in vitro qualitative detection of total antibodies (IgG, IgM and IgA) to Hepatitis C Virus (HCV) in human serum or plasma. It is intended for screening and as an aid in the diagnosis of possible HCV infection.

**PRESERVATION**

Hepatitis C Virus is a small, enveloped, positive-strand, single-stranded RNA virus. HCV is now known to be the major cause of parenterally transmitted non-A, non-B hepatitis. HCV infection causes a wide variety of disease manifestations, ranging from asymptomatic inapparent infection of the virus is via transfusion of blood and blood products, organ transplantation, and sharing contaminated needles and syringes. Antibodies to HCV is found in over 85% of patients with well-documented non-A, non-B hepatitis. At the time it is possible to develop screening tests to use recombinant antigens.1,2 Compared to the first generation HCV immunoassay tests using recombinant antigens, the second generation recombinant protein and, thus, the sensitivity and specificity of anti-HCV to non-specific cross-reactivity and to increase the sensitivity.1

The HCV Test Kit (Microplate Chemiluminescence Method) is a third generation immunosassay for the qualitative detection of the presence of IgG antibodies to HCV in serum or plasma specimen. The test utilizes recombinant HCV antigens encoded by the genes for both structural (nucleocapsid) and non-structural proteins to selectively detect antibodies to HCV in serum or plasma.

**PRECAUTIONS**

- For professional in vitro diagnostic use only. Do not use it after expiration date.
- Do not mix reagents from other kits with different lot numbers.
- Avoid cross-contamination between reagents to avoid test results.
- Wash the microwell plate after use to ensure optimum assay performance.
- Do not touch the bottom of the wells with pipette tips. Do not touch the bottom of the microwell plate with fingers.
- Do not allow sodium hypochlorite fumes from chlorine bleach or other sources to contact the kit reagents, substrate, test strips or control wells. Avoid any contact with skin or eyes.

**HCV**

Human specimens should be considered potentially hazardous. It is recommended that the reagents and human specimens be handled using established good laboratory working practices.

- Wear protective gloves and other protective clothing, such as laboratory coats and eye protection while handling kit reagents and specimens. Wash hands thoroughly when finished.

**STORAGE AND SAFETY INFORMATION**

- Non-disposable apparatus should be sterilized after use. The preferred Immunoassay is to observe the test results in accordance with the precautions below. Only antigens obtained from local microorganism hazards. Throughout all the procedures and follow the standard procedures for proper disposal of specimens.
- Observe Good Laboratory Practices when handling chemicals and potentially infectious materials. All contamination of chemicals and reagents of human origin after proper decontamination and by following local, state, and federal regulations.
- Neutralize acid and base by adding sufficient volume of sodium bicarbonate to obtain a final concentration of at least 1.0%. A 30 minute exposure to 1.0% sodium bicarbonate may be necessary to ensure effective decontamination.

**MATERIALS REQUIRED BUT NOT PROVIDED**

- Do not eat, drink or smoke in the area where the specimens or kits are handled. Do not pipette by mouth.
- Do not use Substrate A and Substrate B for test light, metal or oxidant.
- Do not pipette by mouth.
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**SPECIMEN COLLECTION AND PREPARATION**

- Material transport may be necessary to ensure effective decontamination.

**STORAGE**

- Store all reagents at room temperature (2-8°C) immediately after use.
- From well A1, arrange the controls in a horizontal or vertical configuration. The procedure below assigns specific wells to the procedures and follow the standard procedures for proper disposal of specimens.

**CAUTION**

- 1.0% sodium hypochlorite may be necessary to ensure effective decontamination.
- Allow the sealed pouch to reach room temperature before opening the pouch and remove the materials contained.
- Add 50 μL of Positive Control to each well (Red Reagent).
- For professional in vitro diagnostic use only.
- Place the Plate Sealer and incubate at 37°C for 30 min ± 2 minutes.
- Do not allow sodium hypochlorite fumes from chlorine bleach or other sources to contact the kit reagents, substrate, test strips or control wells. Avoid any contact with skin or eyes.

**Packaging**

- Pack the specimens to reach room temperature (2-8°C) immediately after use.
- From well A1, arrange the controls in a horizontal or vertical configuration. The procedure below assigns specific wells to the procedures and follow the standard procedures for proper disposal of specimens.

**PRECAUTIONS**

- All equipment should be used with care, calibrated regularly and maintained following the equipment manufacturer’s instructions.

**REAGENTS AND COMPONENTS**

- Do not expose reagents especially the Substrate to light or hypochlorite fumes during storage or incubation steps.

**SPECIFIC NEEDS**

- Wash Buffer, warm it up at 37°C until all crystals dissolve.

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**SPECIFIC NEEDS**

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**Validation Requirements and Quality Control**

1. Calculate the Cut-Off Value by referring to the table below. Example of Cut-Off Value Calculation:

<table>
<thead>
<tr>
<th>Item</th>
<th>RLU</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative Control: Well A1</td>
<td>1125</td>
</tr>
<tr>
<td>Negative Control: Well B1</td>
<td>1135</td>
</tr>
<tr>
<td>Positive Control: Well C1</td>
<td>1828200</td>
</tr>
<tr>
<td>Positive Control: Well D1</td>
<td>1737875</td>
</tr>
</tbody>
</table>

2. Check the validation requirements below to determine if the test results are valid. Example of Sample Result:

<table>
<thead>
<tr>
<th>Item</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1: Well E1</td>
<td>RLU: 23029208</td>
</tr>
<tr>
<td>Cut-Off Value</td>
<td>17830</td>
</tr>
</tbody>
</table>

**Interpretation of Results**

Specimens with S/CO values ≥ 0.9 are considered reactive (R). Specimens with S/CO values < 0.9 are considered non-reactive (NR).

**Limitations**

1. The HCV Antibody Test Kit (Microplate Chemiluminescence Immunoassay) is used for the detection of T. Pallidum antibodies in human serum or plasma. Diagnosis of an infectious disease should not be established based on a single test result. Further testing, including confirmatory testing, should be performed before a specimen is considered positive. A non-reactive test result does not exclude the possibility of exposure. Specimens containing precipitate may give inconsistent test results. Repeat the test or contact your local distributor.

2. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

3. As with other sensitive immunoassays, there is the possibility that non-repeatable reactive reaction may occur due to inadequate washing. The results may be affected due to procedural or instrument error.

4. The Positive Controls in the test kit are not to be used to quantify assay sensitivity. The Positive Controls are used to verify that the test kit components are capable of detecting a reactive specimen provided the procedure is followed as defined in the kit and the storage conditions have been strictly adhered to.

**Performance Characteristics**

1. Claire FM. Complete Genome Sequence of Treponema Pallidum, the HCV Spirochete, Science 1998; 281:751-375.


**BIBLIOGRAPHY**

**Cut-Off Value 17830**

**Reproducibility**

**Sensitivity and Specificity**

The HCV Antibody Test Kit has been directly compared with a leading commercial HCV Antibody EIA Test Kit using clinical specimens. The results show that the clinical sensitivity of the HCV Antibody CLIA Test Kit is > 99.9%, and the clinical specificity is 99.9%.