Elecsys Anti-HCV II

07026889119
07026889500

English

System information

<table>
<thead>
<tr>
<th>Short name</th>
<th>ACN (application code number)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHCV 2</td>
<td>10104</td>
</tr>
</tbody>
</table>

Intended use

The Elecsys Anti-HCV II assay is an in vitro diagnostic test for the qualitative detection of antibodies to hepatitis C virus (HCV) in human serum and plasma. This assay is indicated as an aid in the diagnosis of infection with HCV. This assay is also indicated as a donor screening test to detect antibodies to HCV in serum or plasma specimens from individual human blood donors. This assay may also be used to detect antibodies to HCV in serum and plasma specimens to screen donors of cells (excluding blood cells and derivatives), tissues and organs intended for transplantation.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on the cobas e 801 immunoassay analyzer.

Note: Please note that the catalogue number appearing on the package insert retains only the first 8 digits of the licensed 11-digit Catalogue Number: 07026889190 for the Elecsys Anti-HCV II assay. The last 3 digits -190 have been replaced by -119 for logistic purposes.

Summary

The hepatitis C virus (HCV), first identified in 1989, is a leading cause of liver disease and a major healthcare concern with over 170 million persons (roughly 3% of the human population), infected worldwide. The highest prevalence is found in Africa, the Eastern Mediterranean and Asian regions. HCV is a member of the Flaviviridae family and has a single-stranded, positive-sense RNA genome. Currently over 67 subtypes have been identified and these have been classified into 7 genotypes. Due to the high rate of asymptomatic infections, clinical diagnosis is difficult and screening assays are of major importance. Injection with HCV can lead to acute and chronic hepatitis disease. Approximately 70-85% of HCV infections progress to chronic disease, although this varies according to patient gender, age, race and immune status.

HCV infection may lead to cirrhosis and hepatocellular carcinoma, therefore, early anti-HCV detection is the first step in the management of chronic hepatitis and in the selection of patients needing treatment. HCV infection can be detected by measuring the amount of HCV RNA, alanine aminotransferase (ALT) and HCV-specific immunoglobulins (anti-HCV) in patient serum or plasma samples. This can also indicate if the infection is acute or chronic. Anti-HCV antibody tests are used alone or in combination with other tests to determine the level of HCV-RNA (e.g. HCV RNA) to detect an infection with HCV and to identify blood and plasma specimens. This can also indicate if the infection is acute or chronic. Early anti-HCV detection is the first step in the management of chronic hepatitis and in the selection of patients needing treatment. HCV infection can be detected by measuring the amount of HCV RNA, alanine aminotransferase (ALT) and HCV-specific immunoglobulins (anti-HCV) in patient serum or plasma samples. This can also indicate if the infection is acute or chronic.

Reagents - working solutions

The cobas e pack (M, R1, R2) is labeled as AHCV 2.
Stability of the calibrators:
- unopened at 2-8 °C up to the stated expiration date
- after opening at 2-8 °C 8 weeks
- on the cobas e 801 analyzer at 20-25 °C use only once

Store calibrators upright in order to prevent the calibrator solution from adhering to the snap-cap.

Specimen collection and preparation
Only the specimens listed below were tested and found acceptable.
Serum collected using standard sampling tubes or tubes containing separating gel.
Li-heparin, Na-heparin, K₂-EDTA, K₃-EDTA, ACD, CPDA and Na-citrate plasma.

Plasma tubes containing separating gel can be used.
CPD and CP2D plasma.
Criterion: Correct assignment of positive and negative samples within a recovery of 80-120 % of serum value.
Stability: For living patients and donor specimens obtained while the donor’s heart is still beating: Stable for 7 days at 20-25 °C, 14 days at 2-8 °C, 3 months at -20 °C (± 5 °C). The samples may be frozen 6 times.
The sample types listed were tested with a selection of sample collection tubes or systems that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.
Centrifuge samples containing precipitates before performing the assay. Ensure the samples and calibrators are at 20-25 °C prior to measurement.
Due to possible evaporation effects, samples and calibrators on the analyzer should be analyzed/measured within 2 hours.
The performance of the Elecsys Anti-HCV II assay has not been established with cadaveric samples or body fluids other than serum and plasma.

Materials provided
See “Reagents – working solutions” section for reagents.
- 2 x 6 bottle labels

Materials required (but not provided)
- 03293079190, PreciControl Anti-HCV, 16 x 1.3 mL
- General laboratory equipment
- cobas e 801 analyzer

Accessories for the cobas e 801 analyzer:
- 06908799190, ProCell II M, 2 x 2 L system solution
- 04880293190, CleanCell M, 2 x 2 L measuring cell cleaning solution
- 074854909001, Reservoir Cups, 8 cups to supply ProCell II M and CleanCell M
- 06908853190, PreClean II M, 2 x 2 L wash solution

- 05694302001, Assay Tip/Assay Cup tray, 6 magazines x 6 magazine stacks x 105 assay tips and 105 assay cups, 3 wasteliners
- 07485425001, Liquid Flow Cleaning Cup, 2 adaptor cups to supply ISE Cleaning Solution/Elecsys SysClean for Liquid Flow Cleaning Detection Unit
- 07485433001, PreWash Liquid Flow Cleaning Cup, 1 adaptor cup to supply ISE Cleaning Solution/Elecsys SysClean for Liquid Flow Cleaning PreWash Unit
- 11298500316, ISE Cleaning Solution/Elecsys SysClean, 5 x 100 mL system cleaning solution

Assay
For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator’s manual for analyzer-specific assay instructions.
Resuspension of the microparticles takes place automatically prior to use.
Place the cooled (stored at 2-8 °C) cobas e pack on the reagent manager. Avoid foam formation. The system automatically regulates the temperature of the reagents and the opening/closing of the cobas e pack.
Calibrators:
Place the calibrators in the sample zone. Read in all the information necessary for calibrating the assay.

Calibration
No internationally accepted standard for anti-HCV exists.
Calibration frequency: Calibration must be performed once per reagent lot using AHCV 2 Cal1, AHCV 2 Cal2 and fresh reagent (i.e. not more than 24 hours since the cobas e pack was registered on the analyzer).
Calibration interval may be extended based on acceptable verification of calibration by the laboratory.
Renewed calibration is recommended as follows:
- after 12 weeks when using the same reagent lot
- after 28 days when using the same cobas e pack on the analyzer
- as required: e.g. quality control findings outside the defined limits

Quality control
For quality control, use PreciControl Anti-HCV.
In addition, other suitable control material can be used.
Controls for the various concentration ranges should be run individually at least once every 24 hours when the test is in use, once per cobas e pack, and following each calibration.
The control intervals and limits should be adapted to each laboratory’s individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits. If necessary, repeat the measurement of the samples concerned.
Follow the applicable government regulations and local guidelines for quality control.

Calculation
The analyzer automatically calculates the cutoff based on the measurement of AHCV 2 Cal1 and AHCV 2 Cal2.
The result of a sample is given either as reactive, borderline or non-reactive as well as in the form of a cutoff index (signal sample/cutoff).

Interpretation of the results
<table>
<thead>
<tr>
<th>Numeric result</th>
<th>Result message</th>
<th>Interpretation/ further steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>COI&lt; 0.9</td>
<td>Non-reactive</td>
<td>Negative for anti-HCV, no further testing needed.</td>
</tr>
</tbody>
</table>
### Elecsys Anti-HCV II

<table>
<thead>
<tr>
<th>Numeric result</th>
<th>Result message</th>
<th>Interpretation/ further steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>COI ≥ 0.9 to &lt; 1.0</td>
<td>Borderline</td>
<td>All initially reactive or borderline samples should be retested in duplicate using the Elecsys Anti-HCV II assay.</td>
</tr>
<tr>
<td>COI ≥ 1.0</td>
<td>Reactive</td>
<td></td>
</tr>
</tbody>
</table>

**Retesting**

- One or both of the duplicate retests have a COI ≥ 0.9: Repeatedly reactive.
- Both of the duplicate retests have a COI < 0.9: Negative for anti-HCV.

Further steps:
- Confirmation via supplemental methods (e.g. immunoblot or detection of HCV RNA). If one or both measurements remain borderline the analysis of a follow-up sample is recommended.
- No further testing needed.
Elecsys Anti-HCV II

- high-risk groups: hemophiliacs, homosexuals and intravenous drug abusers

<table>
<thead>
<tr>
<th>Specimens containing potentially interfering substances</th>
<th>N</th>
<th>Elecsys Anti-HCV II reactive</th>
<th>Positive or indeterminate by immunoblot</th>
<th>Negative by immunoblot</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1037</td>
<td>59</td>
<td>58 positive</td>
<td>1(1)</td>
</tr>
</tbody>
</table>

h) EBV IgM positive patients: 1 out of 69 samples

Clinical sensitivity

Of 765 samples from HCV infected patients with different stages of disease and infected with different HCV genotypes (type 1, 2, 3, 4, 5 and 6), all samples were found to be reactive with the Elecsys Anti-HCV II assay.

<table>
<thead>
<tr>
<th>Group</th>
<th>N</th>
<th>Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCV infected persons with different stages of disease</td>
<td>224</td>
<td>224</td>
</tr>
<tr>
<td>HCV genotypes (type 1, 2, 3, 4, 5, 6)</td>
<td>541</td>
<td>541</td>
</tr>
</tbody>
</table>

In the above study the diagnostic sensitivity was 100 %. The 95 % lower confidence limit was 99.61 %.

Seroconversion sensitivity

Seroconversion sensitivity of the Elecsys Anti-HCV II assay has been shown by testing 60 commercial seroconversion panels. Elecsys Anti-HCV II detected more positive bleedings than all other registered anti-HCV assays tested and was more sensitive in the recognition of early HCV infection than Elecsys Anti-HCV and the other registered anti-HCV screening assays.

Clinical specificity

In a group of randomly selected European blood donors the specificity of the Elecsys Anti-HCV II assay was 99.85 % (RRR). The 95 % confidence interval (2-sided) was 99.73-99.93 %.

The diagnostic specificity of the Elecsys Anti-HCV II assay in a group of hospitalized patients was 99.66 %. The 95 % confidence interval (2-sided) was 99.73-99.93 %.

Clinical specificity

In a group of randomly selected European blood donors the specificity of the Elecsys Anti-HCV II assay was 99.85 % (RRR). The 95 % confidence interval (2-sided) was 99.73-99.93 %.

For further information, please refer to the appropriate operator’s manual for the analyzer concerned, the respective application sheets, the product information and the Method Sheets of all necessary components (if available in your country).

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see http://www.usdiagnostics.roche.com for definition of symbols used):

- CONTENT
- SYSTEM
- REAGENT
- CALIBRATOR
- QTN

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Additions, deletions or changes are indicated by a change bar in the margin.

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Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim

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References


http://www.who.int/csr/disease/hepatitis/Hepc.pdf


