Anti-HCV II
Antibody to hepatitis C virus (anti-HCV)

<table>
<thead>
<tr>
<th>REF</th>
<th>SYSTEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>06368921</td>
<td>Elecsys 2010</td>
</tr>
<tr>
<td></td>
<td>MODULAR ANALYTICS E170</td>
</tr>
<tr>
<td></td>
<td>cobas e 411</td>
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<tr>
<td></td>
<td>cobas e 601</td>
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<td>cobas e 602</td>
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</table>

**English**

**Intended use**
Anti-HCV II 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 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. Anti-HCV II is not intended for screening donors of blood and blood products. The electrochemiluminescence immunoassay “ECLIA” is intended for use on Elecsys and cobas e immunoassay analyzers.

Important Patent License Information Anti-HCV II assay shall not be used by blood banks, donor centers, or other institutions which exclusively or predominantly use the test for the safety of screening of blood and blood products.

**Note**
Please note that the catalogue number appearing on the package insert retains only the first 8 digits of the licensed 11-digit Catalog Number: 06368921190 for the 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 The last 3 digits -190 have been replaced by -119 for logistic purposes.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 50 subtypes have been identified and these have been classified into 6 genotypes (1-6). Due to the high rate of asymptomatic infections, clinical diagnosis is difficult and screening assays are of major importance. Infection 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. Chronic 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 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 (e.g. HCV-RNA) to detect an infection with hepatitis C virus and to identify blood and blood products of individuals infected with HCV. The Elecsys Anti-HCV II assay is a third-generation test. The Elecsys Anti-HCV II assay uses peptides and recombinant antigens representing core, NS3 and NS4 proteins for the determination of anti-HCV antibodies.

**Test principle**

**Sandwich principle.** Total duration of assay: 18 minutes.

- **1st incubation:** 50 µL of sample, 55 µL of a reagent containing biotinylated HCV-specific antigens and 55 µL of a reagent containing HCV-specific antigens labeled with a ruthenium complex react to form a sandwich complex.

- **2nd incubation:** After addition of streptavidin-coated microparticles, the complex becomes bound to the solid phase via interaction of biotin and streptavidin.

- The reaction mixture is aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then removed with ProCell/ProCell M. Application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier.

- Results are determined automatically by the software by comparing the electrochemiluminescence signal obtained from the reaction product of the sample with the signal of the cutoff value previously obtained by calibration.

**Reagents – working solutions**
The reagent back pack (M, R1, R2) is labeled as A-HCV II.

- M Streptavidin-coated microparticles (transparent cap), 1 bottle, 6.5 mL: Streptavidin-coated microparticles 0.72 mg/mL; preservative.
- R1 HCV-specific antigens–biotin (gray cap), 1 bottle, 18 mL: Biotinylated HCV-specific antigens, HEPES buffer, pH 7.4; preservative.
- R2 HCV-specific antigens–Ru(bpy)_3^2+ (black cap), 1 bottle, 18 mL: HCV-specific antigens labeled with ruthenium complex ≥ 0.3 mg/L; HEPES buffer, pH 7.4; preservative

**Precautions and warnings**
For in vitro diagnostic use.

Exercise the normal precautions required for handling all laboratory reagents.

Disposal of all waste material should be in accordance with local guidelines. Safety data sheet available for professional user on request.

All human material should be considered potentially infectious. All products derived from human blood are prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV (A-HCV II Cal1 only) and HIV. The testing methods applied were FDA-approved or cleared in compliance with the European Directive 98/79/EC, Annex II, List A.

The serum containing anti-HCV (A-HCV II Cal2) was inactivated using β-propiolactone and UV-radiation.

However, as no inactivation or testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen. In the event of exposure, the directives of the responsible health authorities should be followed.

Avoid foam formation in all reagents and sample types (specimens, calibrators and controls).

The Elecsys Anti-HCV II assay has a high dilution sensitivity. Avoid any sample cross-contamination during sample pre-analytics.

**Reagent Handling**
The reagents in the kit are ready for use and are supplied in bottles compatible with the system.

Elecsys 2010 and cobas e 411 analyzers: The calibrators should only be left on the analyzers during calibration at 20-25 °C. After use, close the bottles as soon as possible and store upright at 2-8 °C.
Due to possible evaporation effects, not more than 5 calibration procedures per bottle set should be performed.

MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers: Unless the entire volume is necessary for calibration on the analyzers, transfer aliquots of the ready-for-use calibrators into empty snap-cap bottles (CalSet Vials). Attach the supplied labels to these additional bottles. Store the aliquots at 2-8 °C for later use.

Perform only one calibration procedure per aliquot.

All information required for correct operation is read in from the respective reagent barcodes.

Please note: Both the vial labels, and the additional labels (if available) contain 2 different barcodes. The barcode between the yellow markers is for cobas 8000 systems only. If using a cobas 8000 system, please turn the vial cap 180° into the correct position so the barcode can be read by the system. Place the vial on the instrument as usual.

Storage and stability

Store at 2-8 °C. Do not freeze.

Store the Elecsys reagent kit upright in order to ensure complete availability of the microparticles during automatic mixing prior to use.

### Stability of the reagent rackpack

<table>
<thead>
<tr>
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<th></th>
</tr>
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<tbody>
<tr>
<td>unopened at 2-8 °C</td>
<td>up to the stated expiration date</td>
</tr>
<tr>
<td>after first opening at 2-8 °C</td>
<td>8 weeks</td>
</tr>
<tr>
<td>on the analyzers</td>
<td>31 days of continuously stored onboard (20-25 °C) or 7 weeks and up to 80 hours in total onboard (20-25 °C) if stored alternately in the refrigerator and on the analyzer</td>
</tr>
</tbody>
</table>

### Stability of the calibrators

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<td>unopened at 2-8 °C</td>
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<tr>
<td>after opening at 2-8 °C</td>
<td>8 weeks</td>
</tr>
<tr>
<td>on Elecsys 2010 and cobas e 411 at 20-25 °C</td>
<td>up to 5 hours</td>
</tr>
<tr>
<td>on MODULAR ANALYTICS E 170, cobas e 601 and cobas e 602 at 20-25 °C</td>
<td>use only once</td>
</tr>
</tbody>
</table>

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 in a sufficient number and found acceptable.

Serum collected using standard sampling tubes or tubes containing separating gel.

Li-heparin, Na-heparin, K2-EDTA, K2-EDTA, serum gel separation, plasma gel separation and sodium citrate plasma.

Criterion: Correct assignment of positive and negative samples within a recovery of 80-120 % of serum value.

Stable for 7 days at 2-8 °C, 3 days at 25 °C, 3 months at -20 °C. Freeze no more than 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 different 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, calibrators and controls are at 20-25 °C prior to measurement.

Due to possible evaporation effects, samples, calibrators and controls on the analyzers 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 bottles labels

### Materials required (but not provided)

- **REF** 03290379190, PreciControl Anti-HCV, for 8 x 1.3 mL each of PreciControl Anti-HCV 1 and 2
- General laboratory equipment
- Elecsys 2010, MODULAR ANALYTICS E170 or cobas e analyzer
- Accessories for Elecsys 2010 and cobas e 411 analyzers.
- **REF** 11662988122, ProCell, 6 x 380 mL system buffer
- **REF** 11662970122, CleanCell, 6 x 380 mL measuring cell cleaning solution
- **REF** 11930346122, Elecsys SysWash, 1 x 500 mL washer additive
- **REF** 11933159001, Adapter for SysClean
- **REF** 11706802001, Elecsys 2010 AssayCup, 60 x 60 reaction vessels
- **REF** 11706799001, Elecsys 2010 AssayTip, 30 x 120 pipette tips
- Accessories for MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers:
  - **REF** 04880340190, ProCell M, 2 x 2 L system buffer
  - **REF** 04880293190, CleanCell M, 2 x 2 L measuring cell cleaning solution
  - **REF** 03023141001, PC/CC-Cups, 12 cups to prewarm ProCell M and CleanCell M before use
  - **REF** 03005712190, ProbeWash M, 12 x 70 mL cleaning solution for run finalization and rinsing during reagent change
  - **REF** 03004899190, PreClean M, 5 x 600 mL detection cleaning solution
  - **REF** 12102137001, AssayTip/AssayCup Combimagazine M, 48 magazines x 84 reaction vessels or pipette tips, waste bags
  - **REF** 03023150001, WasteLiner, waste bags
  - **REF** 03027651001, SysClean Adapter M
- Accessories for all analyzers:
  - **REF** 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. Read in the test-specific parameters via the reagent barcode. If in exceptional cases the barcode cannot be read, enter the 15-digit sequence of numbers. MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers: PreClean M solution is necessary.

Bring the cooled reagents to approximately 20 °C and place on the reagent disk (20 °C) of the analyzer. Avoid foam formation. The system automatically regulates the temperature of the reagents and the opening/closing of the bottles.

Place the calibrators in the sample zone.

All the information necessary for calibrating the assay is automatically read into the analyzer.

After calibration has been performed, store the calibrators at 2-8 °C or discard (MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers).

### Calibration

No internationally accepted standard for anti-HCV exists.

Every Elecsys Anti-HCV II reagent set has a barcoded label containing specific information for calibration of the particular reagent lot. The predefined master curve is adapted to the analyzer using the A-HCV II Cal1 and A-HCV II Cal2.

Calibration frequency: Calibration must be performed once per reagent lot using fresh reagent (i.e. not more than 24 hours since the reagent kit was opened at 2-8 °C or up to the stated expiration date.
In vitro tests were performed on 18 commonly used pharmaceuticals and 3 No interference was observed from rheumatoid factors up to a concentration of 2000 μg/mL. In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design. Studies have been performed to assess the high-dose hook effect. Out of 765 positive samples no false negative result was found. Occurrence of high-dose hook effect cannot be completely excluded. For diagnostic purposes, the results should always be assessed in conjunction with the patient’s medical history, clinical examination and other findings. Due to a long time period from infection to seroconversion, negative anti-HCV test results may occur during early infection. If acute hepatitis C infection is suspected, measuring of HCV RNA by reverse transcriptase polymerase chain reaction (RT-PCR e.g. by COBAS AMPLICOR) may give evidence of HCV infection. The detection of anti-HCV antibodies indicates a present or past infection with hepatitis C virus, but does not differentiate between acute, chronic or resolved infection. It is recognized within the scientific community that presently available methods for anti-HCV detection are not sensitive enough to detect all potentially infectious units of blood or possible cases of HCV infection. The antibody concentration may be beneath the detection limit of this assay or the patient’s antibodies do not react with the antigens used in this test. In addition, non-specific results cannot be ruled out with the Elecsys Anti-HCV II assay.

Specific performance data
Representative performance data on the analyzers are given below. Results obtained in individual laboratories may differ.

Precision
Precision was determined using Elecsys reagents, samples and controls in a protocol (EP5-A2) of the CLSI (Clinical and Laboratory Standards Institute): 2 runs per day in duplicate each for 21 days (n = 84). The following results were obtained:

### Elecsys 2010 and cobas e 411 analyzers

<table>
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<tr>
<th>Sample</th>
<th>Mean COI</th>
<th>SD COI</th>
<th>CV %</th>
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<tr>
<td>HS®, negative</td>
<td>0.071</td>
<td>0.001</td>
<td>1.6</td>
<td>0.071</td>
<td>0.003</td>
<td>4.1</td>
</tr>
<tr>
<td>HS, weakly positive</td>
<td>1.86</td>
<td>0.049</td>
<td>2.7</td>
<td>1.86</td>
<td>0.085</td>
<td>4.6</td>
</tr>
<tr>
<td>HS, positive</td>
<td>20.0</td>
<td>0.476</td>
<td>2.4</td>
<td>20.0</td>
<td>1.04</td>
<td>5.2</td>
</tr>
<tr>
<td>PreciControl A-HCV1</td>
<td>0.097</td>
<td>0.001</td>
<td>1.4</td>
<td>0.097</td>
<td>0.004</td>
<td>3.8</td>
</tr>
<tr>
<td>PreciControl A-HCV2</td>
<td>4.39</td>
<td>0.113</td>
<td>2.6</td>
<td>4.39</td>
<td>0.185</td>
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<td>0.034</td>
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<tr>
<td>HS, weakly positive</td>
<td>1.89</td>
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<td>1.8</td>
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<td>0.7</td>
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<td>0.339</td>
<td>1.6</td>
</tr>
<tr>
<td>PreciControl A-HCV1</td>
<td>0.055</td>
<td>0.001</td>
<td>1.1</td>
<td>0.055</td>
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<td>2.3</td>
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<tr>
<td>PreciControl A-HCV2</td>
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<td>0.028</td>
<td>0.7</td>
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<td>0.160</td>
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</table>

### MODULAR ANALYTICS E170, cobas e 601 and cobas e 602 analyzers

#### Repeatability

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#### Analytical specificity

1037 samples containing potentially interfering substances or derived from high-risk groups were tested with the Elecsys Anti-HCV II assay comprising specimens:

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Detection Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-HCV</td>
<td>1.0 IU/mL</td>
</tr>
</tbody>
</table>

Note:
- For technical reasons re-assigned target values valid only for a specific reagent and control lot combination, must be entered manually on all analyzers (except for the cobas e 602 analyzer). Therefore always refer to the value sheet included in the reagent kit or PreciControl kit to make sure that the correct target values are used.
- When a new reagent or control lot is used, the analyzer will use the original values encoded in the control barcodes.

Calculation
The analyzer automatically calculates the cutoff based on the measurement of A-HCV II Cal1 and A-HCV II Cal2.

Interpretation of the results:
- Samples with a cutoff-index > 0.9 are reactive in the Elecsys Anti-HCV II assay.
- Samples with a cutoff-index ≥ 0.9 and < 1.0 are considered borderline in the Elecsys Anti-HCV II assay.
- Samples with a cutoff-index ≥ 1.0 are reactive in the Elecsys Anti-HCV II assay.

All initially reactive or borderline samples should be redetermined in duplicate using the Elecsys Anti-HCV II assay. If no reactivity is found in both cases, the sample is negative for anti-HCV. If the result from either of the two measurements is reactive or borderline then the sample is repeatedly reactive.

Repeatedly reactive samples must be investigated by 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.

Limitations – interference
The assay is unaffected by icterus (bilirubin < 1129 μmol/L or < 66 mg/dL), hemolysis (HB < 0.621 mmol/L or < 1.00 g/dL), lipemia (Intralipid < 2000 mg/dL) and biotin (< 172 μmol/L or < 42 ng/mL).

Criterion: Recovery of positive samples within ± 20 % of initial value, cutoff-index for negative samples ± 0.2 of initial value.

Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.

No interference was observed from rheumatoid factors up to a concentration of 1200 IU/mL.

In vitro tests were performed on 18 commonly used pharmaceuticals and 3 drugs used in HCV therapy. No interference with the assay was found.
**Anti-HCV II**

Antibody to hepatitis C virus (anti-HCV)

- containing antibodies against HBV, HAV, HEV, EBV, CMV, HSV, HIV, VZV, Parvovirus, Mumps, Dengue, tick-borne encephalitis virus (TBEV), Rubella, Toxoplasma gondii, Treponema pallidum
- containing autoantibodies and elevated titters of rheumatoid factor, IgG, IgM or IgA antibodies
- positive for HBsAg and E. coli
- after vaccination against HBV and Influenza
- non-viral liver diseases
- alcoholic liver disease
- high-risk groups: hemophiliacs, homosexuals and intravenous drug abusers

<table>
<thead>
<tr>
<th>Specimens containing potentially interfering substances</th>
<th>Elecsys Anti-HCV II reactive</th>
<th>Positive by immunoblot or indeterminate</th>
<th>Negative by immunoblot</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>1037</td>
<td>59</td>
<td>58 positive</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 found 99.84 % (RR). The 95 % lower confidence limit (2-sided) was 99.71-99.92 %.

The diagnostic specificity of the Elecsys Anti-HCV II assay in a group of hospitalized patients was found 99.86 %. The 95 % lower confidence limit (2-sided) was 99.41-99.82 %.

**References**


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.

- CONTENT
- SYSTEM
- REAGENT
- CALIBRATOR
- DIN

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