Elecsys Anti-HCV II

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REF		Σ	IVD	Rx Only	SYSTEM
08837058162	08837058502	16 x 300			**cobas pro** serology solution

English

For use in the USA only

System information

Short name	ACN (application code number)
AHCV2B	10501
AHCV2BE (embedded application)	11501
AHCV2BR (for use with **cobas e** flow)	12501

Intended use

Elecsys Anti-HCV II is an in vitro immunoassay for the qualitative detection of antibodies to hepatitis C virus (HCV) in human serum and plasma. Elecsys Anti-HCV II is intended to screen individual human donors, including volunteer donors of whole blood, blood components and source plasma. The assay is also intended to be used to screen organ, tissue and cell donors, when donor samples are obtained while the donor's heart is still beating. It is not intended for use on cord blood specimens.

The **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use with **cobas pro** serology solution equipped with a **cobas e** 801 analytical unit.

Summary

The hepatitis C virus (HCV), first identified in 1989, is a member of the Flaviviridae family and has a single-stranded positive-sense RNA genome encoding 3 structural (Core, Envelope 1 and 2) and 7 non-structural (p7, NS2, NS3, NS4, NS4B, NS5A, NS5B) proteins[1,2,3,4]. Currently 90 subtypes have been identified, which have been classfied into 8 genotypes[5]. Globally, genotype 1 is the most common accounting for 46 % of all infections, followed by genotype 3 (22 %) and genotypes 2 and 4 (13 % each)[6].

The total global seroprevalence of antibodies against HCV (indicating past exposure to HCV) was estimated to be 1.6 %, corresponding to approximately 115 million past infections[6]. The prevalence of HCV RNA positivity indicating active HCV infection was determined to be 1 % corresponding to 71.1 million viremic infections[7]. 1.7 million new infections occur annually[8]. Prevalence of HCV infection shows considerable variation across the globe. The most affected regions are Eastern Europe, Nothern Africa and Central Asia, with the highest infection rate found in countries with a past or present history of infections due to the activity of a physician or medical therapy.

Transmission of HCV occurs by percutaneous exposure to blood, blood products or organs from an infected person. In developed regions where blood donor screening programs have operated for many years, the major mode of HCV transmission is through intravenous drug use. In less developed regions, the major routes of transmission are through medical treatment with unsterilized equipment or unscreened blood[4,7,8].

Infection with HCV can lead to acute and chronic liver inflammation (hepatitis). Approximately 70-85 % of patients exhibit no symptoms, in the remainder, non-specific symptoms and jaundice are observed around this time. Symptoms last for several weeks before spontaneous resolution, which occurs in 15-30 % of patients[1,2,3,4,8,9]. Patients who develop chronic HCV infection are much less likely to exhibit symptoms, but can develop long-term complications. If untreated, 20 % of patients develop liver cirrhosis, and a fraction of these progress to hepatocellular carcinoma (HCC). Annually, 400000 patients die globally due to HCV infection. Advanced, highly efficacious direct-acting antivirals (DAAs) combination therapies cure more than 95 % of treated patients[10].

The Elecsys Anti-HCV II assay uses peptides and recombinant proteins representing HCV core, NS3 and NS4 antigens for the determination of anti-HCV antibodies.

Test principle

Double antigen sandwich principle. Total duration of assay: 18 minutes.

- 1st incubation: 30 µL of sample, biotinylated HCV-specific recombinant and synthetic antigens and HCV-specific recombinant and synthetic antigens labeled with a ruthenium complex[a)] 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 II 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 sample with the cutoff value obtained by the Elecsys Anti-HCV II embedded calibration. The Elecsys Anti-HCV II result is calculated automatically based on signal to cutoff ratio (cutoff index, COI).

a) Tris(2,2'-bipyridyl)ruthenium(II)-complex ($Ru(bpy)_3^{2+}$)

Reagents - working solutions

The **cobas e** pack (M, R1, R2) is labeled as AHCV2B.

M Streptavidin-coated microparticles, 1 bottle, 14.1 mL:
Streptavidin-coated microparticles 0.72 mg/mL; preservative.

R1 HCV-specific recombinant and synthetic antigens~biotin, 1 bottle, 14.8 mL:
Biotinylated HCV-specific recombinant and synthetic antigens ≥ 0.3 mg/L, HEPES[b)] buffer, pH 7.4; preservative.

R2 HCV-specific recombinant and synthetic antigens~$Ru(bpy)_3^{2+}$, 1 bottle, 14.8 mL:
HCV-specific recombinant and synthetic antigens labeled with ruthenium complex ≥ 0.3 mg/L, HEPES[b)] buffer, pH 7.4; preservative.

b) HEPES = [4-(2-hydroxyethyl)-piperazine]-ethane sulfonic acid

AHCV2B Cal1 Non-reactive calibrator 1, 2 vials of 1.3 mL each:
Human serum, non-reactive for anti-HCV antibodies; preservative.

AHCV2B Cal2 Reactive calibrator 2, 2 vials of 1.3 mL each:
Human serum, reactive for anti-HCV antibodies; preservative.

Precautions and warnings

For in vitro diagnostic use.

This test is not intended for use as an aid in diagnosis of hepatitis C infection.

Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Warning

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

Prevention:

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P261 Avoid breathing mist or vapours.

P280 Wear protective gloves/ eye protection/ face protection.

Response:

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P337 + P313 If eye irritation persists: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

P501 Dispose of contents/container to an approved waste disposal plant.

Product safety labeling follows EU GHS guidance.

Contact phone: 1-866-744-6397

All human material should be considered potentially infectious.

The calibrators (AHCV2B Cal1, AHCV2B Cal2) have been prepared exclusively from the blood of donors tested individually and shown to be free from HBsAg and antibodies to HCV (AHCV2B Cal1 only) and HIV. The testing methods use assays that have been approved or cleared by the FDA or that are in compliance with the legal rules of the European Union (IVDR 2017/746/EU, IVDD 98/79/EC, Annex II, List A).

The serum containing anti-HCV (AHCV2B 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 donor specimen. In the event of exposure, the directives of the responsible health authorities should be followed.[11,12]

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

Reagent handling

The reagents (M, R1, R2) in the kit are ready-for-use and are supplied in **cobas e** packs.

Calibrators:

The calibrators are supplied ready-for-use in vials compatible with the system.

Perform **only one** calibration procedure per vial.

All information required for correct operation is available via the **cobas** link.

Storage and stability

Store at 2-8 °C.

Do not freeze.

Store the **cobas e** pack **upright** in order to ensure complete availability of the microparticles during automatic mixing prior to use.

Stability of the **cobas e** pack:

unopened at 2-8 °C	up to the stated expiration date
on the **cobas e** 801 analytical unit	31 days

Stability of the calibrators:

unopened at 2-8 °C	up to the stated expiration date
on the **cobas e** 801 analytical unit at 20-25 °C	use only once, stable onboard for up to 5 hours

Store calibrators **upright** in order to prevent the calibrator solution from adhering to the lid of the vials.

Specimen collection and preparation

Only the specimens listed below were tested and found acceptable.

Serum and Li-heparin, K_2-EDTA, K_3-EDTA, CPD and Na-citrate plasma collected using standard sampling tubes.

Serum and Li-heparin and K_2-EDTA plasma collected in tubes containing separating gel.

Samples on-the-clot are stable for 7 days at 15-30 °C and 14 days at 2-8 °C. Do not freeze samples on-the-clot.

Samples off-the-clot are stable for 7 days at 20-25 °C, 14 days at 2-8 °C and 12 months at -20 °C (± 5 °C). Samples off-the-clot may be frozen up to 4 times.

Specimens collected by plasmapheresis, which have not been frozen, do not require centrifugation. All other whole-blood samples and samples containing precipitates need to be centrifuged before performing the assay for 10 to 15 minutes at 2000 to 4000 RCF (relative centrifugal force = x g).

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/collection system manufacturer.

Do not use pools of samples.

Do not use heat-inactivated samples.

Do not use samples and controls stabilized with azide.

The performance of the Elecsys Anti-HCV II assay has not been established with cadaveric samples or body fluids other than serum and plasma.

Sample stability claims were established by experimental data by the manufacturer only for the temperatures/time frames as stated in the method sheet.

Materials provided

See "Reagents – working solutions" section for reagents.

Materials required (but not provided)

- REF 03290379162, PreciControl Anti-HCV, 16 x 1.3 mL
- REF 09366652190, PreciControl Release Anti-HCV, 16 x 1.3 mL
- General laboratory equipment
- The **cobas pro** serology solution is a combination of the **cobas pro** serology controller, **cobas pro** integrated solutions (**cobas e** 801 analytical units only) and applicable licensed or cleared donor screening assays.

Additional materials for **cobas e** 801 analytical unit:

- REF 06908799190, ProCell II M, 2 x 2 L system solution
- REF 04880293190, CleanCell M, 2 x 2 L measuring cell cleaning solution
- REF 07485409001, Reservoir Cup, 8 cups to supply ProCell II M and CleanCell M
- REF 06908853190, PreClean II M, 2 x 2 L wash solution
- REF 05694302001, Assay Tip/Assay Cup tray, 6 magazines x 6 magazine stacks x 105 assay tips and 105 assay cups, 3 wasteliners
- REF 07485425001, Liquid Flow Cleaning Cup, 2 adaptor cups to supply ISE Cleaning Solution/Elecsys SysClean for Liquid Flow Cleaning Detection Unit
- REF 07485433001, PreWash Liquid Flow Cleaning Cup, 1 adaptor cup to supply ISE Cleaning Solution/Elecsys SysClean for Liquid Flow Cleaning PreWash Unit
- REF 11298500160, 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 analytical unit concerned. Refer to the appropriate user guide for analytical unit-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.

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Calibration

Calibration frequency: Calibration must be performed once per reagent lot using AHCV2B Cal1, AHCV2B Cal2 and fresh reagent (i.e. not more than 24 hours since the **cobas e** pack was registered on the analytical unit).

Recalibration is required as follows:

- after 12 weeks when using the same reagent lot
- after 28 days when using the same **cobas e** pack on the analytical unit
- as required: e.g. quality control findings outside the defined limits

Quality control

For quality control, use PreciControl Anti-HCV.

Controls for the various concentration ranges must be run individually at least once every 24 hours when the test is in use, once per **cobas e** pack, and following each calibration.

PreciControl Anti-HCV values must be within the ranges specified in the control value sheet. When the assay control values are within range, sample results are generated, and a valid release control result is required to release test results. If an assay control value is not within range, sample results are not generated for in-process or scheduled samples. For troubleshooting information, refer to User Assistance **cobas pro** serology solution or contact US Customer Technical Support.

Release control

For release control, use PreciControl Release Anti-HCV.

Result validation is based on test result batches that are concluded by release control measurements. A release control result within defined limits is required to validate a batch of previously measured test results utilizing the **cobas pro** serology controller software. Initial reactive results will not be invalidated by a failed release control and must be retested in duplicate. Repeatedly reactive results will not be invalidated by a failed release control and stay reactive. Other results rendered invalid due to a failed release control result must be retested after resolving the cause for the failed control measurement.

For a valid batch of sample results, the release control is tested at user-defined intervals with a maximum span of every 300 samples or 350 determinations within 24 hours from the PreciControl and must be tested in order to release the test results. Reactive results will not be invalidated. The release control must meet specifications defined in the PreciControl Release Anti-HCV value sheet in order to validate the system functionality and release test results. For troubleshooting information, refer to User Assistance **cobas pro** serology solution or contact US Customer Technical Support.

Calculation

The analytical unit automatically calculates the cutoff based on the measurement of AHCV2B Cal1 and AHCV2B Cal2.

The result of a sample is given either as reactive or non-reactive as well as in the form of a cutoff index (signal sample/cut-off).

Interpretation of the results

Initial result

Numeric result	Result	Interpretation/further steps
COI < 1.00	Non-reactive	Non-reactive for anti-HCV antibodies. No further testing needed.
COI ≥ 1.00	Reactive	Reactive in the Elecsys Anti-HCV II assay. All initially reactive samples should be retested in duplicate with the Elecsys Anti-HCV II assay. Redetermination of samples with an initial COI ≥ 1.00 can be performed automatically (see section **cobas e** flow).

Final result

Numeric result	Final Result	Interpretation/further steps
One or both of the duplicate retests have a COI ≥ 1.00	Repeatedly Reactive	Repeatedly reactive samples must be confirmed according to supplementary algorithms.
Both of the duplicate retests have a COI < 1.00	Non-reactive	Non-reactive for anti-HCV antibodies. No further testing needed.

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A **cobas e** flow is a procedure programmed into the system to enable a fully automated sequence of measurements and the calculation of assay combinations to perform decision algorithms.
A **cobas e** flow is available to perform a repetition of measurements in duplicate automatically for samples with an initial cutoff index ≥ 1.00 (AHCV2BR).

Limitations of the test

A non-reactive test result does not completely rule out the possibility of an infection with HCV. Serum or plasma samples from the very early (pre-seroconversion) phase or the late phase of an HCV infection can occasionally yield non-reactive findings. New HCV variants may also lead to non-reactive anti-HCV results.

The detection of HCV antibodies is not a diagnosis of HCV. It is recommended that repeatedly reactive specimens be confirmed by supplemental testing. Individuals who are repeatedly reactive should be referred for medical evaluation which may include additional testing.

Specific performance data

Representative performance data is given below. Results obtained in individual laboratories may differ.

Precision

A study was performed based on guidance from CLSI EP05-A3 (n = 84). Testing was conducted at 1 site using 1 lot of the Elecsys Anti-HCV II assay and 1 lot of PreciControl Anti-HCV. Panel members and controls were tested in 4 replicates, 1 run per day for 21 days. The following results were obtained:

Overall precision for Elecsys Anti-HCV II

Sample	Mean (COI)	Repeatability SD (COI)	Repeatability % CV	Within-laboratory SD (COI)	Within-laboratory % CV
HSP 01 c)	0.0356	0.000432	1.2	0.000589	1.7
HSP 02	0.893	0.0237	2.7	0.0260	2.9
HSP 03	1.12	0.0178	1.6	0.0225	2.0
HSP 04	1.39	0.0285	2.1	0.0300	2.2
HSP 05	5.79	0.0810	1.4	0.101	1.7
HSP 06	7.69	0.155	2.0	0.155	2.0
PC AHCV1 B d)	0.0471	0.000656	1.4	0.000793	1.7
PC AHCV2 B	3.38	0.0292	0.9	0.0429	1.3

c) HSP = human specimens

d) PC = PreciControl

Reproducibility

A study was performed based on guidance from CLSI EP05-A3 (n = 270). Testing was conducted at 3 external sites using 3 lots of the Elecsys Anti-HCV II assay and 1 lot each of PreciControl Anti-HCV and PreciControl Release Anti-HCV. Panel members and controls were tested in 2 runs per day for 5 days with 3 sample replicates per run. HSP 09 had a total of 269 data points (one sample was discarded due to a processing issue). The results for Elecsys Anti-HCV II are presented in the following tables.

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Overall repeatability and reproducibility for Elecsys Anti-HCV II

Sample	Mean (COI)	Repeatability SD (COI)	Repeatability % CV	Between run SD (COI)	Between run % CV
HSP 08 e)	1.81	0.023	1.25	0.011	0.592
HSP 09	11.6	0.140	1.21	0.104	0.899
PC AHCV1 B f)	0.047	0.001	1.12	0.000	0.314
PC AHCV2 B	3.57	0.040	1.12	0.034	0.949

e) HSP = human specimens

f) PC = PreciControl

Overall repeatability and reproducibility for Elecsys Anti-HCV II

Sample	Mean (COI)	Between day SD (COI)	Between day % CV	Intermediate precision SD (COI)	Intermediate precision % CV
HSP 08	1.81	0.016	0.898	0.030	1.65
HSP 09	11.6	0.124	1.08	0.214	1.85
PC AHCV1 B	0.047	0.001	1.76	0.001	2.10
PC AHCV2 B	3.57	0.027	0.746	0.059	1.65

Overall repeatability and reproducibility for Elecsys Anti-HCV II

Sample	Mean (COI)	Between site SD (COI)	Between site % CV	Between lot SD (COI)	Between lot % CV
HSP 08	1.81	0.005	0.256	0.108	5.97
HSP 09	11.6	0.038	0.324	0.516	4.46
PC AHCV1 B	0.047	0.000	0.722	0.001	2.68
PC AHCV2 B	3.57	0.013	0.368	0.091	2.54

Overall repeatability and reproducibility for Elecsys Anti-HCV II

Sample	Mean (COI)	Reproducibility SD (COI)	Reproducibility % CV
HSP 08	1.81	0.113	6.20
HSP 09	11.6	0.560	4.84
PC AHCV1 B	0.047	0.002	3.48
PC AHCV2 B	3.57	0.109	3.05

Results: The precision and reproducibility of the Elecsys Anti-HCV II assay demonstrated minor variability from run to run, day to day and between reagent lots.

Analytical specificity

The effect of the following endogenous substances on assay performance was tested. Interferences were tested up to the listed concentrations and no impact on results was observed.

Endogenous substances

Compound	Concentration tested
Bilirubin	≤ 753 µmol/L or ≤ 44 mg/dL
Hemoglobin	≤ 0.311 mmol/L or ≤ 500 mg/dL
Intralipid	≤ 2000 mg/dL
Biotin	≤ 4912 nmol/L or ≤ 1200 ng/mL
Albumin	≤ 7.0 g/dL

Additionally, naturally elevated samples for bilirubin, rheumatoid factor, triglycerides (lipemic), hemoglobin and albumin were tested; no false reactive results were found.

No false non-reactive result due to high-dose hook effect was found with the Elecsys Anti-HCV II assay.

In rare cases, interference due to extremely high titers of antibodies to immunological components, streptavidin or ruthenium can occur and these effects are minimized by assay formulation and design.

Clinical specificity

A total of 5571 fresh serum specimens and 5713 fresh plasma specimens from volunteer whole blood donors and 3002 plasmapheresis samples were collected at 4 blood centers. All initial reactive samples were repeat reactive; therefore, the initial and repeat reactive rates for the serum specimens were 0.20 % (11/5571), the initial and repeat reactive rates for the plasma specimens were 0.14 % (8/5713) and the initial and repeat reactive rates for the plasmapheresis samples were 0.20 % (6/3002). Repeatedly reactive specimens were further tested using an HCV qualitative RNA assay and an FDA-licensed HCV immunoassay. Based on supplemental test results, 7 specimens were positive and 18 specimens were negative.

Specificity based on assumed zero prevalence of HCV in whole blood and plasmapheresis donors was estimated in this study to be 99.87 % (14259/14277) with a 95 % confidence interval of 99.80 % to 99.92 %.

Specificity of Elecsys Anti-HCV II

Specimen category	Number tested	Number IR g) (% of tested)	Number RR h) (% of tested)	Number positive by supplemental testing (% of RR)	Specificity (%) (95 % CI)
Blood Donors - Serum	5571	11 (0.20)	11 (0.20)	6 (54.55)	99.91 5560/5565 (99.79, 99.96)
Blood Donors - Plasma	5713	8 (0.14)	8 (0.14)	1 (12.50)	99.88 5704/5711 (99.75, 99.94)
Source Plasma Donors	3002	6 (0.20)	6 (0.20)	0 (0.00)	99.80 2995/3001 (99.56, 99.91)
Total Donors	14286	25 (0.17) i)	25 (0.17)	7 (28.00)	99.87 14259/14277 (99.80, 99.92)

g) IR = initially reactive

h) RR = repeatedly reactive

i) Repeatedly reactive specimens were further tested using an anti-HCV supplemental assay. A total of 7 specimens were positive and 18 specimens were negative.

Clinical sensitivity

A total of 915 confirmed positive specimens from the categories shown in the table below were tested using the Elecsys Anti-HCV II assay at 3 clinical sites. Sensitivity was estimated to be 99.67 % (912/915) with a 95 % confidence interval of 99.04 % to 99.89 % for preselected positive specimens.

Reactivity of the Elecsys Anti-HCV II assay in individuals known to be positive for anti-HCV antibodies

Specimen category	Number tested	Number positive by supplemental testing	Number RR (% of tested)	Number RR that were positive (% of RR)	Sensitivity (%) (95% CI)
HCV Genotype (1-6)	101	101	101 (100)	101 (100)	100.00 101/101 (96.34, 100.00)
HCV Positive	695	695	692 (99.57)	692 (100)	99.57 692/695 (98.74, 99.85)
HCV Positive (Chronic)	119	119	119 (100)	119 (100)	100.00 119/119 (96.87, 100.00)
Total	915	915	912 (99.67)	912 (100)	99.67 j) 912/915 (99.04, 99.89)

j) 3 non-reactive specimens were positive based on repeatedly reactive results on an FDA-licensed anti-HCV screening assay.

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An additional 409 specimens from an at increased risk cohort for hepatitis were tested using the Elecsys Anti-HCV II assay at 3 clinical sites. There were 291 specimens non-reactive by Elecsys Anti-HCV II with a specimen status of negative and 118 specimens repeatedly reactive on the Elecsys Anti-HCV II assay. A total of 112 specimens were confirmed positive based on supplemental testing using FDA-licensed assays.

Reactivity of the Elecsys Anti-HCV II assay in individuals at increased risk for HCV infection

Specimen category	Number tested	Number IR (% of tested)	Number RR (% of tested)	Number positive by supplemental testing (% of RR) k)
Increased risk for Hepatitis infection	409	118 (28.85)	118 (28.85)	112 (94.92)

k) The sensitivity calculation and/or confidence interval are not meaningful due to the small number of positive specimens.

Seroconversion panels

Seroconversion sensitivity of the Elecsys Anti-HCV II assay was shown by testing 26 commercially available seroconversion panels comparing the Elecsys Anti-HCV II assay to an FDA-licensed assay. There were 29 discordant panel members across 15 panels, where the Elecsys Anti-HCV II assay detected seroconversion at an earlier bleed than the comparator assay. There were 2 discordant panel members in 1 panel, where the Elecsys Anti-HCV II assay detected seroconversion at a later bleed than the comparator assay. This discordance in detection of seroconversion by the Elecsys Anti-HCV II assay compared to the comparator assay may be due to Elecsys Anti-HCV II using recombinant antigens representing HCV core, NS3 and NS4, where the optimized NS3 antigen has been developed for earlier detection capability. The summary of the results obtained from 26 commercially available seroconversion panels is in the following table.

Panel ID	Elecsys Anti-HCV II Reactive on bleed no.	Comparator Reactive on bleed no.	Difference in bleeds l)
PHV910	3	3	0
PHV911	3	3	0
PHV912	1	N/A m)	> -3
PHV913	3	N/A m)	> -2
PHV914	4	7	-3
PHV915	2	3	-1
PHV917	5	5	0
PHV918	7	8	-1
PHV919	1	5	-4
PHV920	4	4	0
PHV922	5	3	+2
PHV923	3	5	-2
PHV924	4	4	0
PHV925	3	5	-2
PHV926	1	5	-4
Zeptom6213	10	11	-1
Zeptom6214	8	9	-1
Zeptom6215	4	4	0
Zeptom6222	7	8	-1
Zeptom6224	3	5	-2
Zeptom9041	5	5	0
Zeptom9044	4	5	-1
Zeptom9045	6	7	-1
Zeptom9046	2	2	0
Zeptom9047	7	7	0
Zeptom9054	10	10	0

l) -1 = Elecsys Anti-HCV II 1 bleed earlier, 0 = equal, +1 = Elecsys Anti-HCV II 1 bleed later

m) Comparator result was non-reactive for all available draws.

Other specimen conditions or disease states

280 samples containing potentially interfering substances were tested with the Elecsys Anti-HCV II assay comprising specimens:

- containing antibodies against HAV, HBV, HCV, HDV, HEV, HIV, HTLV-I/II, CMV, EBV, HSV IgG / IgM
- containing autoantibodies (ANA) and elevated titers of rheumatoid factor
- containing antibodies against *Escherichia coli*, *Candida* sp., *Chlamydia trachomatis*, *Toxoplasma gondii*, *Treponema pallidum* (syphilis), systemic lupus, parvovirus, rubella
- containing heterophilic and human anti-mouse antibodies (HAMA)
- after vaccination against HBV and influenza
- from patients with monoclonal gammopathy and non-viral liver disease
- from pregnant women and multiparous pregnancies

Results indicated that there was no interference from the above agents.

References

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3 Ahmad J. Hepatitis C. BMJ 358:j2861.

4 Mauss S, Berg T, Rockstroh J, et al. (2018). Hepatology. A Clinical Textbook. Ninth Edition. Available at: https://www.hepatologytextbook.com Last accessed: Jan 2020.

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8 World Health Organization (2020). Hepatitis C factsheet. Available from: http://www.who.int/mediacentre/factsheets/fs164/en/ Last accessed Feb 2021

9 Kamal SM. (2008). Acute Hepatitis C: A Systematic Review. Am J Gastroenterol 103:1283-1297.

10 Pietschmann T and Brown RJP. (2020). Hepatitis C Virus. Trends in Microbiology 27(4):379-380.

11 Occupational Safety and Health Standards: Bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register.

12 Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

For further information, please refer to the appropriate user guide for the analytical unit concerned and the Method Sheets of all necessary components (if available in your country).

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

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

CONTENT	Contents of kit
SYSTEM	Analyzers/Instruments on which reagents can be used
REAGENT	Reagent
CALIBRATOR	Calibrator
→	Volume for reconstitution

Elecsys Anti-HCV II

cobas®

GTIN Global Trade Item Number

Rx only For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

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