

## HCV Ab PLUS REF 34330

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**Intended Use** The Access HCV Ab PLUS assay is an immunoenzymatic method for the detection of antibodies to the hepatitis C virus in human serum or plasma, using the Access Immunoassay Systems (Access, Access 2, UniCel<sup>®</sup> DxI<sup>®</sup>).

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For *In Vitro* Diagnostic Use

All manufactured and commercialized reagents are under complete quality system starting from reception of raw material to the final commercialization of the product.

Each lot is submitted to a quality control and is only released on the market when conforming to the acceptance criteria.

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**Summary and Explanation** Hepatitis C virus (HCV) is considered to be the major cause of post transfusional non-A - non-B hepatitis (NANBH), as well as that transmitted by non-transfusional parenteral routes (toxicomaniacs, hemodialysis patients, transplant patients).<sup>1,2,3,4,5,6,7</sup> Fifty to sixty percent of hepatitis C infected patients are likely to develop chronic hepatitis, and risk the development of cirrhosis or hepatocellular carcinoma.<sup>8,9</sup>

The practice of compulsory screening of every blood donation (for anti-HCV antibodies) has significantly decreased the risk of transmission by infected blood.<sup>10,11</sup>

The Access HCV Ab PLUS assay is intended for the detection of anti-HCV antibodies in human serum or plasma, and thus contributes to the prevention of parenteral contamination. It is also useful for the diagnosis of HCV infection. In both cases, results should be interpreted in conjunction with clinical data and other serological markers.

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**Principles of the Procedure** The Access HCV Ab PLUS assay is an indirect immunoenzymatic assay. The sample (serum, plasma or control) is added to a reaction vessel with paramagnetic particles coated with a peptide mimicking immunodominant epitopes of the capsid region and recombinant proteins (NS3 and NS4). During incubation both IgG and IgM present in the sample are captured by the solid phase. After incubation, the solid phase is collected by a magnetic field and unbound materials are removed by a series of washes. In the second step, conjugate (anti-human IgG goat antibody, labeled with alkaline phosphatase) is added to the reaction vessel. Following incubation, another series of washes eliminate the excess conjugate. A chemiluminescent substrate, Lumi-Phos\* 530, is added and photons generated by the enzymatic reaction are measured with a luminometer. The emitted signal intensity is proportional to the amount of enzyme conjugate present, and thus to the titer of anti-HCV antibodies present in the test sample. By comparing the cut-off value, established by the assay calibration, to the signal present in the sample, the presence or absence of anti-HCV antibodies is determined.

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**Product Information**    **Access HCV Ab PLUS Reagent Pack**  
**Cat. No. 34330: 100 determinations, 2 packs, 50 tests/pack**

- Provided ready to use.
- Store upright and refrigerate at 2 to 10°C before use on the instrument.
- Under these conditions, a reagent pack is stable until the expiration date stated on the label.
- Upon initial loading of the reagent pack, mix contents by gently inverting pack several times until particles are completely resuspended.
- After initial use, keep it loaded on the instrument or refrigerated (upright), and use it within 28 days.
- Signs of possible deterioration are a broken elastomeric layer on the pack or quality control values out of range.

<b>R1a:</b>	Paramagnetic particles coated with recombinant proteins (NS3/NS4) and peptide (Capside) suspended in TRIS buffer, with < 0.1% sodium azide
<b>R1b:</b>	Sample diluent with < 0.1% sodium azide
<b>R1c:</b>	Conjugate diluent, with surfactant, < 0.1% sodium azide
<b>R1d:</b>	Goat anti-human IgG alkaline phosphatase conjugate in TRIS Buffer, with surfactant, < 0.1% sodium azide, and < 0.1% ProClin ** 300

**Warnings and Precautions**

- Upon initial loading in the carousel, shake the pack until particles are completely resuspended.
- For in vitro diagnostic use.
- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with a large volume of water to prevent azide build-up.<sup>12</sup>
- ProClin\*\* 300 is a potential skin sensitizer. Avoid spilling or splashing this reagent on skin or clothing. In case of contact with the reagent, thoroughly flush with water.

**Specimen Collection and Preparation**

1. Serum or plasma (heparin, EDTA or citrate) are the recommended samples.
2. Apply the following standards for handling and processing blood samples:<sup>13, 14</sup>
  - Collect all blood samples observing routine precautions for venipuncture.
  - Allow samples to clot adequately before centrifugation, 1 hour minimum.
  - Keep tubes stoppered at all times.
  - Centrifuge samples, 15 minutes at 1,500 g minimum.
3. Apply the following standards for storing blood samples:<sup>13, 14</sup>
  - Store sample at room temperature for no longer than 8 hours.
  - If the assay will not be completed within 8 hours, refrigerate at +2-10°C.
  - If the assay will not be completed within 48 hours, or for shipment of samples, freeze at -20°C.<sup>13</sup>
  - Thaw samples once only, rapid thawing by heating a few minutes in a 40°C water bath
  - After thawing, centrifuge the sample 15 minutes at 3,000 g and transfer to an assay cup, to eliminate suspended fibrin particles or aggregates that may give false positive results.
4. Samples containing up to 200 mg/L bilirubin, up to 90 g/L albumin, lipemic samples containing the equivalent of 36 g/L triolein (triglyceride), and hemolyzed samples containing up to 5g/L hemoglobin do not affect the results.

**Materials Provided**

R1    Access HCV Ab PLUS Reagent Packs

**Materials Required But Not Provided**

1. Access HCV Ab PLUS Calibrators for calibration: Negative serum and positive serum for anti-HCV antibody  
Cat. N° 34335
2. Quality control materials: Access HCV Ab PLUS QC  
Cat. N° 34339 - or other commercial control sera
3. Access Substrate  
Cat. N° 81906
4. Access, Access 2 :  
Wash buffer: Access Wash Buffer II, Cat. No. A16792
5. UniCel DxI :  
Wash Buffer: UniCel DxI Wash Buffer II, Cat. No. A16793
6. Systems:  
Access, Access 2, UniCel DxI.

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**Procedural Comments**

1. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, principles of operation, system performance characteristics, operating instructions, calibration procedures, operational limitations and precautions, hazards, maintenance, and troubleshooting.
2. Twenty five (25)  $\mu$ L of sample is used for each determination (in addition to dead volume).
3. The assay incubates at 37°C and takes 55 minutes

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**Procedure** Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests and reviewing results.

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**Calibration Details** An active calibration curve is required for all tests. The calibration data to determine the Cut-Off are valid for 28 days. Consequently, for the Access HCV Ab PLUS assay, calibration is required every 28 days using C0 and C1 from the Access HCV Ab PLUS Calibrators kit. Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, calibrator test request entry, and reviewing calibration data.

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**Quality Control** Quality control is recommended, at least, every 24 hours and upon the system start-up prior to running patient samples. Use the suggested product Access HCV Ab PLUS QC or include control sera from other origins. Follow manufacturer's instructions for reconstitution and storage. Each laboratory should establish a mean value and acceptable range to follow the analytical performance of the test. Control sera results that do not fall within the acceptable range may indicate invalid test results. In that case, examine all test results generated since the last acceptable quality control test point for this analysis.

For optimal results, assay calibration and patient sample testing should be conducted under similar temperature conditions. If ambient laboratory temperature varies more than  $\pm 5^{\circ}\text{C}$  from the temperature of calibration, review quality control results and recalibrate as necessary.

Refer to the appropriate system manuals and/or Help system for information about reviewing control sera results.

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**Results** Patient test results are calculated automatically by the system software using the cut-off value [cut-off = mean of positive calibrators (RLU)  $\times$  0.23] determined by active calibration. Results (Signal/Cut-Off = S/CO) are reported to be "reactive" or "non-reactive" as a function of their relationship with the "cut-off" (signal greater than or signal equal to or less than the cut-off value, respectively). However, results  $\sim$ 10% lower than the "cut-off value" should be prudently interpreted and retested in duplicate. This recommended gray zone (from 0.9 to less than 1.0) should be stored by the user in the system software (refer to the appropriate system manuals and/or Help system for complete instructions on gray zone for a qualitative assay). In this way a distinctive mark automatically will be reported, permitting rapid identification of a result situated in the gray zone. Patient test results can be reviewed using the Sample

Results screen. Refer to the appropriate system manuals and/or Help system for complete instructions on reviewing results.

Any sample with ratio (S/CO) lower than 0.9 is considered to be non-reactive with the Access HCV Ab PLUS test. Samples with ratio (S/CO) equal or greater than 1 are initially considered to be reactive with the Access HCV Ab PLUS test and such samples should be retested in duplicate before final interpretation.

All samples that are initially reactive or with results in the gray zone should be retested in duplicate using the Access HCV Ab PLUS:

- If the results of the duplicates are  $<1.0$  S/CO, the sample must be considered non-reactive (negative) for HCV Ab PLUS assay.
- If one of the 2 results is  $\geq 1.0$  S/CO, the initial result is non repeatable and the sample is declared as "reactive" for the Access HCV Ab PLUS test.

However, it is advised that any repeatable reactive sample be retested by a second line EIA assay and by a confirmatory method to ensure its positivity.

Result interpretation of the HCV Ab PLUS assay		
Result Ratio : Signal/Cut-Off	Interpretation	Supplementary tests
S/CO $< 0.9$	Non reactive	
S/CO $\geq 1$	Reactive	To retest in duplicate
S/CO: 0.9 - 1.0	Gray zone	To retest in duplicate
Retest: S/CO $< 1$	Non reactive	
Retest: if one of the 2 results is $\geq 1$	Reactive	Confirmatory method

### Limitations of the Procedure

The Access HCV Ab PLUS assay is strictly for the detection of anti-HCV antibodies in human serum or plasma. A positive result with the Access HCV Ab PLUS assay should be considered together with clinical data and confirmed by other diagnostic tests, including a confirmatory method (immunoblot) before reporting as positive for infection.

Given the diversity of the immunological reactions of infected patients by the Hepatitis C Virus (especially during seroconversions), some differences of detection between tests can be observed depending on the kind of antigenic proteins used. A negative result with a screening test does not exclude the possibility of exposition or infection by Hepatitis C Virus.

All ELISA techniques are liable to produce false positive reactions. It is recommended to verify the specificity of the reaction for any sample found to be a repeatable positive, using a suitable method to prove the presence of anti-HCV antibodies.

### Specific Performance Characteristics

#### Sensitivity

Sensitivity of Access HCV Ab PLUS was evaluated by testing 511 well documented positive samples including:

101 PCR positive serums collected from HCV chronic patients follow-up, 145 positive samples from HCV infected patients, 77 HCV RNA PCR positive plasma sourced from BBI, 122 genotyped HCV positive samples.

SFTS 97 panel compound of 36 positive samples 26 genotyped and HCV RNA PCR positive samples; 10 positive (PCR negative) samples with at least 2 HCV Ab reactivities.

Also were included the 30 positive samples found in the prospective specificity studies.

All these samples are representative of the different serotype profiles (isolated reactivity, 2 or 3 reactivities) and of the most widespread HCV genotypes 1 to 4, plus a few uncommon 4c/d and 5 genotypes.

All these samples were found positive with Access HCV Ab PLUS.

No apparent difference was evidenced in detection of the various HCV genotyped tested.

Sensitivity of Access HCV Ab PLUS was evaluated by testing 74 seroconversion panels.

Among the 29 commercial panels tested, Access HCV Ab PLUS detected anti-HCV Ab rising as soon as RIBA 3.0 complementary test or in a very short delay later (few days).

Among the 45 tested panels by the experts, Access HCV Ab PLUS test was positive as the same time (i.e. positive with the same bleed) than the more sensitive tests used for comparison. Only 2 seroconversions were detected few days later and inversely 2 seroconversions were earlier positive with Access HCV Ab PLUS.

25 additional HCV fresh positive samples (within 1 day after blood collection) were tested and all were found positive.

### Specificity

The specificity of the test has been evaluated:

- as 99.83% (95% CI: 99.7-99.9) on a population of 5995 non selected blood donors samples
- on a population of 472 hospitalized patients, 469 were found negative and 3, which were undetermined with Chiron Riba HCV 3.0, were found low positive with Access HCV Ab PLUS.

The analysis of 108 samples from patients showing different pathologies not linked to the Hepatitis C virus (Hepatitis A or B, Herpes, EBV, Rheumatoid factor...) showed no significant nonspecific cross reactivity.

### Precision

The precision of Access HCV Ab PLUS has been determined by the analysis of negative and positive samples. The intra-assay reproducibility has been evaluated by testing 4 samples 30 times in the same run, the inter-assay reproducibility has been evaluated by testing 4 samples in triplicate, 2 times a day during 5 days. The results are shown in the following tables:

#### Intra-assay reproducibility

n = 30	NEG 1	NEG 2	POS 1	POS 2
Mean (RLU)	251824	1378166	10966900	12615243
S.D.	10202	43987	320857	309281
C.V.%	4.05	3.19	2.93	2.45

C.V. are less than 5%.

#### Inter-assay reproducibility

n = 30	NEG 1	NEG 2	POS 1	POS 2
Mean of ratios (Sample/Cut-off)	0.07	1.34	3.18	4.42
S.D.	0.01	0.09	0.21	0.39
C.V.	9.9	6.89	6.64	8.78

C.V. are less than 10%.

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\* Lumi-Phos is a trademark of Lumigen, Inc., a subsidiary of Beckman Coulter, Inc.

\*\* ProClin is a trademark of Rohm and Haas Company or of its subsidiaries or affiliates.

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## HCV Ab PLUS CALIBRATORS

### REF 34335

**Intended Use** The Access HCV Ab PLUS Calibrators are intended for use with the Access HCV Ab PLUS assay for the detection of anti-HCV antibodies in human serum and plasma, using the Access Immunoassay Systems (Access, Access 2, UniCel<sup>®</sup> DxI<sup>®</sup>).



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**Summary and Explanation** The Access HCV Ab PLUS Calibrators are used to establish calibration (determine the cut-off value) for the Access HCV Ab PLUS assay. By comparing the light intensity generated by a sample to the cut-off value, it is possible to determine the presence or absence of anti-HCV antibodies in the sample.

**Product Information** **Access HCV Ab PLUS Calibrators**  
**Cat. No. 34335: C0–C1, 1 mL/vial**

- Provided ready to use.
- Store at 2-10°C.
- Mix contents by gently inverting before use. Avoid foam formation.
- The content of opened vial will remain stable until the expiration date stated on the vial labels when stored at + 2-10°C.
- Quality Control values out of range are a sign of possible deterioration

<b>C0:</b>	Negative (non-reactive) human serum for anti-HCV antibody, with < 0.1% sodium azide
<b>C1:</b>	Positive (reactive) human serum for anti-HCV antibody, inactivated, with < 0.1% sodium azide
<b>Calibration Card:</b>	1

**Warnings and Precautions**

- For in vitro diagnostic use
- Human source material used in the preparation of the reagent has been tested and found non reactive for hepatitis B surface antigen (HBs Ag), antibodies to human immunodeficiency virus (HIV-1 and HIV-2) and antibodies to hepatitis C virus (HCV), excluding the positive calibrator C1 which is positive for anti-HCV antibody. Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting

infectious disease.

- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. One disposal of liquids, flush with a large volume of water to prevent azide build-up.<sup>12</sup>
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**Procedure** For calibration procedures, follow the instructions in the appropriate system manuals and/or Help system.

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**Calibration Details** The Access HCV Ab PLUS Calibrators are provided in two forms: negative calibrator C0 (prepared from human negative serum pool), and positive calibrator C1 (prepared from human serum positive for anti-HCV antibody), inactivated.

The Access HCV Ab PLUS assay requires a calibration curve (cut-off value determination) every 28 days in order to have an active "calibration" for only one lot of reagents well identified by its bar code. At the end of the 28 days or if another lot of reagents is loaded on the system, the curve is automatically invalidated.

A calibration of the Access HCV Ab PLUS assay requires at least 225  $\mu$ L (5 drops)/cup (Access / Access 2) or 305  $\mu$ L (7 drops)/cup (UniCel Dx1) of each calibrator (Cut-off value = RLU<sub>s</sub> C1 X 0.23); the programmed calibration for Access HCV Ab PLUS will test the C0 and C1 in triplicate.

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## HCV Ab PLUS QC REF 34339

**Intended Use** The Access HCV Ab PLUS QC is intended for monitoring system performance of the Access HCV Ab PLUS assay.

**IVD** For *In Vitro* Diagnostic Use

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**Summary and Explanation** The Access HCV Ab PLUS QC control is intended for monitoring system performance of the Access HCV Ab PLUS assay for the detection of anti-HCV antibodies. The use of quality control materials is indicated for detecting and potentially resolving critical testing errors due to test kits, personnel, and instrumentation, and are an integral part of good laboratory practices.<sup>15, 17, 16, 19, 21, 22</sup> One negative and one low positive control level are provided to allow performance monitoring in the most relevant area of the dynamic range of such assays.

**Product Information** **Access HCV Ab PLUS QC**  
**Cat. No. 34339: 2.5 mL/vial**

- Provided ready to use.
- Mix contents by gently inverting before use. Avoid foam formation.
- QC are stable until the expiration date stated on the vial labels when stored at +2-10°C.
- The content of opened vials will remain stable for 30 days if properly handled and stored

<b>QC 1:</b>	Human serum with < 0.1% sodium azide. Negative (non-reactive) for anti-HCV antibodies
<b>QC 2:</b>	Human serum with < 0.1% sodium azide. Positive (reactive) for anti-HCV antibodies, inactivated
<b>QC Value Card:</b>	1

**Warnings and Precautions**

- For in vitro diagnostic use
- Human source material used in the preparation of the reagent has been tested and found non-reactive for hepatitis B surface antigen (HBs Ag), antibodies to human immunodeficiency virus (HIV-1 and HIV-2), and antibodies to hepatitis C virus (HCV), except the QC2 Controls which is positive for anti-HCV. Because no known test method can offer complete assurance that infectious agents are absent, handle reagents and patient samples as if capable of transmitting infectious disease.

- Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal of liquids, flush with a large volume of water to prevent azide build-up.<sup>12</sup>

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**Procedure** The Access HCV Ab PLUS QC controls should be treated the same way as patient specimens and run in accordance with the instructions contained in the kit accompanying the instrument being used. Note: for the Access Immunoassay Systems refer to the appropriate system manuals and/or Help system for information on configuring controls QC sample test request, and reviewing control data. To process the Access HCV Ab PLUS QC Control on the Access Immunoassay Systems a minimum of 175 µL (4 drops)/cup (Access / Access 2) or 255 µL (6 drops)/cup (UniCel DxI) is required for each of the 2 controls (single determination).

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**Limitations of the Procedure** If there is evidence of microbial contamination or excessive turbidity in a control, discard the vial.

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**Expected Values** Control data for the Access HCV Ab PLUS assay are provided for each lot by means of the “QC Data Card” contained in the pack. Individual mean reactivity levels of user laboratories should fall within the corresponding acceptable range, however, each laboratory should assign its own mean reactivity and acceptable ranges after sufficient data had been collected.<sup>18</sup> Given that specific levels of reactivity may vary among various manufacturer's assays, different procedures, different lot numbers and different laboratories, each laboratory should determine the specific level or reactivity and establish its own range of acceptable values.<sup>18,19,20,21</sup> The acceptable range might include all values within  $\pm 2$  SD of the mean of 20 data points out of 20 determinations over a period of 30 days.<sup>22</sup>

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