




ACCESS[®]
Immunoassay System

HCV Ab PLUS

 2 x 50

REF 34330

For the qualitative detection of anti-HCV antibodies in human serum and plasma using the Access Immunoassay Systems.

ACCESS[®]
Immunoassay System

HCV Ab PLUS CALIBRATORS

REF 34335

The Access HCV Ab PLUS CALIBRATORS are intended to calibrate the Access HCV Ab PLUS assay using the Access Immunoassay Systems.

ACCESS[®]
Immunoassay System

HCV Ab PLUS QC

REF 34339

For monitoring system performance of the Access HCV Ab PLUS assay.



A33592D - [EN] - 2016/04


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CE 0459



A33592D - [EN] - 2016/04

1 Intended Use

The Access HCV Ab PLUS assay is a paramagnetic particle, chemiluminescent immunoassay for the qualitative detection of antibodies to the hepatitis C virus in human serum or plasma, using the Access Immunoassay Systems. The Access HCV Ab PLUS is intended to be used as an aid in the diagnosis of HCV infection and as a screening test for blood and plasma donors. The assay is not intended for the testing or screening of pooled specimens.

2 Summary and Explanation of the Test

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)^(1,2,3,4,5,6,7). Fifty to sixty percent of patients infected with hepatitis C are likely to develop chronic hepatitis and risk the development of cirrhosis or hepatocellular carcinoma^(8,9).

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

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

3 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. During the second step, conjugate (anti-human IgG goat antibody, labeled with alkaline phosphatase) is added to the reaction vessel. Following incubation, a further series of washes eliminates 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 therefore 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.

4 Product Information

4.1 Description

Access HCV Ab PLUS Reagent Packs

Identification on label	Description	Presentation/ preparation 34330
R1a Paramagnetic particles	Paramagnetic particles: coated with recombinant proteins (NS3/NS4) and peptide (capside) suspended in TRIS buffer, with sodium azide (< 0.1%)	2 x 50 tests Ready to use
R1b Sample diluent	Sample diluent: with sodium azide (< 0.1%)	
R1c Conjugate diluent	Conjugate diluent: with surfactant, sodium azide (< 0.1%)	
R1d Conjugate	Conjugate: Goat anti-human IgG alkaline phosphatase conjugate in TRIS buffer, with surfactant, sodium azide (< 0.1%) and ProClin 300 (< 0.1%)	

4.2 Storage and Handling Conditions

- Store upright and refrigerate at 2 to 10°C.
- Refrigerate at 2 to 10°C for a minimum of two hours before use on the instrument.
- Stable until the expiration date stated on the label when stored at 2 to 10°C (reagent pack unopened).
- Mix the new, unpunctured packs by gently inverting them until the particles are in solution and no longer adhere to the seal or sides of the well. Do not invert packs that have been punctured.
- Stable at 2 to 10°C for 28 days on board after initial use.
- Signs of possible deterioration are a broken elastomeric layer on the pack or control values out of range.
- If the reagent pack is damaged (i.e. broken elastomer), discard the pack.

5 Warnings and Precautions

- For *in vitro* diagnostic use. For healthcare professional use only.

5.1 Health and Safety Precautions

- This test kit should only be handled by qualified personnel trained in laboratory procedures and familiar with the potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately in accordance with Good Laboratory Practices.
- This test kit contains human blood components. No known test method can offer complete assurance that infectious agents are absent. Consequently, all human derivatives, reagents and human specimens should be handled as if capable of transmitting infectious disease, following recommended Universal Precautions for blood borne pathogens as defined by OSHA, the guidelines from the current CDC/NHI Biosafety in Microbiological and Biomedical Laboratories and/or local, regional or national regulations.
- Biological spills: human source material spills should be treated as potentially infectious. Spills not containing acid should be immediately decontaminated, including the spill area, material and any contaminated surfaces or equipment and with appropriate chemical disinfectant that is effective on the potential biohazards of the samples in question (commonly a 1:10 dilution of household bleach, 70-80% ethanol or isopropanol, an iodophor such as 0.5% Wescodyne™ Plus, etc.) and wiped dry. Spills containing acid should be appropriately absorbed (wiped up) or neutralized, the area flushed with water and wiped dry; materials used to absorb the spill may require hazardous waste disposal. The area should subsequently be decontaminated with one of the chemical disinfectants.
- Dispose of all specimens and material used to perform the test as though they contain an infectious agent. Laboratory, chemical or bio-hazardous waste must be handled and discarded in accordance with all local, regional and national regulations.

- For hazard and precaution recommendations related to any chemical components in this test kit, please refer to the pictogram(s) featured on the labels and the information supplied in the section 5.2. The Safety Data Sheet (SDS) is available at www.bio-rad.com.

5.2 Precautions Related to the Procedure

Warning:



H317: May cause an allergic skin reaction.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

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

P302+P352: If on skin: Wash with plenty of soap and water.

P501: Dispose of contents/container in accordance with local/regional/national/international regulations.

- This product contains human or animal components. Handle with care.

6 Specimens

1. Serum or plasma (heparin, EDTA or citrate) are the recommended samples.
2. Observe the following recommendations for handling, processing, and storing blood samples:⁽¹²⁾
 - Collect all blood samples observing routine precautions for venipuncture. Allow samples to clot completely before centrifugation.
 - Ensure that all residual fibrin and cellular matter has been removed prior to analysis.
 - Follow blood collection tube manufacturer's recommendations for centrifugation.
 - Keep tubes tightly stoppered at all times.
 - Store samples at room temperature (15 to 23°C) for no longer than 8 hours.
 - If the assay is not completed within 8 hours, refrigerate the samples at +2-10°C.
 - If the assay is not completed within 48 hours, or for shipment of samples, freeze at -20°C or below⁽¹²⁾.
 - Thaw samples once only - rapid thawing by heating for a few minutes in a 40°C water bath.
 - After thawing, the sample must be thoroughly mixed, centrifuged again at 3,000 g for 10 minutes and transferred into a cup in order to remove any suspended fibrin particles or aggregates liable to yield false-positive results.
3. Each laboratory should determine the acceptability of its own blood collection tubes and serum separation products. Variations in these products may exist between manufacturers and, occasionally, from lot to lot.

7 Procedure

7.1 Material Required

7.1.1 Materials Provided

R1 Access HCV Ab PLUS Reagent Packs

7.1.2 Materials Required but Not Provided

1. Access HCV Ab PLUS CALIBRATORS
Provided as one HCV-Ab negative serum and one anti-HCV Ab positive serum.
Cat. No. 34335
2. Quality control materials:
 - Access HCV Ab PLUS QC
Cat. No. 34339
 - Other commercial control sera
3. Access Substrate
Cat. No. 81906
4. Access 2:
Wash buffer: Access Wash Buffer II, Cat. No. A16792
5. UniCel[®] DxI[®]:
Wash buffer: UniCel DxI Wash Buffer II, Cat. No. 16793

6. Systems:
Access, Access 2, UniCel DxI (UniCel DxI 600, UniCel DxI 800, UniCel DxI 880i, UniCel DxI 860i, UniCel DxI 680i, UniCel DxI 660i).

7.2 Assay Procedure

1. Refer to the appropriate system manuals and/or Help system for a detailed description of installation, start-up, principles of operation, system performance characteristics, operating instructions, calibration procedures, operational limitations and precautions, hazards, maintenance, and troubleshooting.
2. Mix contents of new (unpunctured) reagent packs by gently inverting pack several times before loading on the instrument. Do not invert open (punctured) packs.
3. Twenty five (25) μL of sample is used for each determination (in addition to dead volume).
4. Time to first result is approximately 55 minutes.
5. The system default unit of measure for sample results is the Signal/Cut-off (S/CO) ratio.

7.3 Calibration

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, entering calibrator test requests and reviewing calibration data.

7.4 Quality Control

Quality control materials simulate the characteristics of patient samples and are essential for monitoring the system performance of immunochemical assays. Quality control is recommended, at least, every 24 hours⁽¹³⁾ and on system start-up prior to running patient samples. Include Access HCV Ab PLUS QC or other commercially available quality control materials that cover at least two levels of analyte. More frequent use of these controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws. Follow the manufacturer's instructions for reconstitution and storage. Each laboratory should establish mean values and acceptable ranges to ensure proper performance. Quality control results that do not fall within acceptable ranges may indicate invalid test results. Examine all test results generated since the last acceptable quality control test point for this analyte.

The Access HCV Ab PLUS assay has been evaluated at a room temperature range of 18-32°C. 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.

All manufactured and commercialized reagents are subject to a comprehensive quality system starting from the reception of raw materials right up to the ultimate commercialization of the product.

Each lot is submitted to a quality control and is only released onto the market if it conforms to the acceptance criteria.

7.5 Calculation / Interpretation of the Results

Patient test results are calculated automatically by the system software using the cut-off value 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). However, results ~10% lower than the "cut-off value" should be cautiously 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 will be automatically reported, enabling 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.

First result analysis:

- Any sample with a ratio (S/CO) lower than 0.9 is considered to be non-reactive with the Access HCV Ab PLUS test.
- Samples with a ratio (S/CO) ≥ 0.9 and < 1 are in the gray zone and should be retested in duplicate before final interpretation.

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

Second result analysis:

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

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

However, in accordance with local regulations, it is necessary to analyze any “reactive” sample by supplementary tests to clearly establish the positive result.

Table 1: Access HCV Ab PLUS result interpretation

Result Ratio: Signal/Cut-Off		Interpretation	Supplementary tests	
First Result Analysis	S/CO < 0.9	Non-reactive	HCV Ab not detected	NA
	S/CO ≥ 1.0	Reactive	“Initial Reactive”	Retest in duplicate
	$0.9 \leq$ S/CO < 1.0	Gray zone	“Initial Reactive”	Retest in duplicate
Second Result Analysis	Retest in duplicate: if the 2 results are < 1.0	Non-reactive	HCV Ab not detected	NA
	Retest in duplicate: if one of the 2 results is ≥ 1.0	Reactive	HCV Ab detected “Repeat Reactive”	Supplementary test

8 Test Limitations

1. The Access HCV Ab PLUS assay is strictly limited to the detection of anti-HCV antibodies in human serum or plasma (Heparin, EDTA or citrate). The performance characteristics using other sample types have not been established or are limited.
2. The Access HCV Ab PLUS results should be interpreted in light of the total clinical presentation of the patient, including: clinical history, data from additional tests and other appropriate information.
3. The magnitude of the measured result, above the cut-off, is not indicative of the total amount of antibody and/or antigen present.
4. Given the diversity of the immunological reactions of patients infected 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 exposure to or infection by Hepatitis C Virus.
5. For an infection to be declared, a reactive result obtained with the Access HCV Ab PLUS assay should be confirmed by an appropriate method.
6. 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.
7. Immunocompromised individuals and conditions such as severe infection and immunosuppressive drug therapy can result in the suppression of antibody levels below the detection threshold of the assay. Results obtained with such samples should be interpreted with caution.

9 Performance Characteristics

9.1 Precision Measurement

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 tables below:

9.1.1 Repeatability

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. less than 5%.

9.1.2 Intermediate Precision

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. less than 10%.

9.2 Diagnostic Performance

9.2.1 Diagnostic 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 as low positive with Access HCV Ab PLUS.

9.2.2 Diagnostic Sensitivity

Confirmed HCV Ab positive samples

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

- 101 PCR positive serums collected from HCV chronic patient 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 composed 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 and no apparent difference was evidenced in detection of the various HCV genotypes tested.

Specimens from commercial seroconversion panels

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 performed or in a very short period later (a few days).
- Among the 45 panels tested by the experts, Access HCV Ab PLUS test was positive at the same time (i.e. positive with the same bleed) as 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.

Fresh samples

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

9.3 Analytical Specificity

9.3.1. Cross reactivity Study

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.

9.3.2. Interference Study

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.



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1 Intended Use

The Access HCV Ab PLUS CALIBRATORS are intended to calibrate the Access HCV Ab PLUS assay for the qualitative detection of antibodies to HCV in human serum and plasma, using the Access Immunoassay Systems.

2 Summary and Explanation of the Test

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.

3 Product Information

3.1 Description

Access HCV Ab PLUS CALIBRATORS

Identification on label	Description	Presentation/ preparation 34335
C0 Negative Calibrator	Negative Calibrator: negative (non-reactive) human serum for anti-HCV antibodies, with < 0.1% sodium azide.	1 x 1 mL Ready to use
C1 Positive Calibrator	Positive Calibrator: positive (reactive) human serum for anti-HCV antibodies, inactivated, with < 0.1% sodium azide.	1 x 1 mL Ready to use
Calibration card	1	

3.2 Storage and Handling Conditions

- Store upright and refrigerate at 2 to 10°C.
- Mix contents by gently inverting before use. Avoid bubble formation.
- The contents of opened vials will remain stable until the expiration date stated on the vial label when stored at + 2-10°C.
- Out-of-range control values are a possible sign of deterioration.

4 Warnings and Precautions

- For *in vitro* diagnostic use. For healthcare professional use only.
- This product contains human or animal components. Handle with care.
- This test kit should only be handled by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately in accordance with Good Laboratory Practices.
- 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 antibodies.
- This test kit contains human blood components. No known test method can offer complete assurance that infectious agents are absent. Consequently, all human derivatives, reagents and human specimens should be handled as if capable of transmitting infectious disease, following recommended Universal Precautions for bloodborne pathogens as defined by OSHA, the guidelines from the current CDC/NHI Biosafety in Microbiological and Biomedical Laboratories and/or local, regional or national regulations.
- Biological spills: human source material spills should be treated as potentially infectious. Spills not containing acid should be immediately decontaminated, including the spill area, materials and any contaminated surfaces or equipment and with appropriate chemical disinfectant that is effective on the potential biohazards of the samples in question (commonly a 1:10 dilution of household bleach, 70-80% ethanol or isopropanol, an iodophor such as 0.5% Wescodyne™ Plus, etc.) and wiped dry. Spills containing acid should be appropriately absorbed (wiped up) or neutralized, the area flushed with water and wiped dry; materials used to absorb the spill may require hazardous waste disposal. The area should subsequently be decontaminated with one of the chemical disinfectants.

- Dispose of all specimens and material used to perform the test as though they contain an infectious agent. Laboratory, chemical or biohazardous waste must be handled and discarded in accordance with all local, regional and national regulations.
The Safety Data Sheet (SDS) is available at www.bio-rad.com.

5 Procedure

Refer to the appropriate system manuals and/or Help system for information on calibration theory, configuring calibrators, entering calibrator test requests and reviewing calibration data.

Calibration

The Access HCV Ab PLUS CALIBRATORS are provided as negative calibrator C0 and positive calibrator C1.

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.

Each calibration requires at least 75 μ L of each calibrator (determination in triplicate) in addition to the sample container and system dead volume. One drop is equal to approximately 40 μ L.

6 Test Limitation

If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.



ACCESS[®]
Immunoassay System

HCV Ab PLUS QC

REF 34339

For monitoring system performance of the HCV Ab PLUS assay.



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1 Intended Use

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

2 Summary and Explanation of the Test

Quality control materials simulate the characteristics of patient samples and are essential for monitoring the system performance of the Access HCV Ab PLUS assay. In addition, they are an integral part of good laboratory practices^(13,14,15,16,19,20). When performing assays with Access reagents for anti-HCV antibodies, include quality control materials to validate the integrity of the assays. The assayed values should fall within the acceptable range if the test system is working properly.

3 Product Information

3.1 Description

Access HCV Ab PLUS QC

Identification on label	Description	Presentation/ preparation 34339
QC1 Negative QC	Negative Quality Control: Human serum with < 0.1% sodium azide. Negative (non-reactive) for anti-HCV antibodies.	3 x 2.5 mL Ready to use
QC2 Positive QC	Positive Quality Control, Anti-HCV: Human serum with < 0.1% sodium azide. Positive (reactive) for anti-HCV antibodies, inactivated.	3 x 2.5 mL Ready to use
QC card	1	

3.2 Storage and Handling Conditions

- Store upright and refrigerate at 2 to 10°C.
- Mix contents by gently inverting before use. Avoid bubble formation.
- QC are stable until the expiration date stated on the label when stored at 2 to 10°C.
- Vial is stable at 2 to 10°C for 30 days after initial use.
- Out-of-range quality control values are a possible sign of deterioration.
- Refer to the QC value card for mean values and standard deviations (SDs).

4 Warnings and Precautions

- For *in vitro* diagnostic use. For healthcare professional use only.
- This product contains human or animal components. Handle with care.
- This test kit should only be handled by qualified personnel trained in laboratory procedures and familiar with their potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately in accordance with Good Laboratory Practices.
- Human source material used in the preparation of the reagent has been tested and found to be non-reactive for hepatitis B surface antigen (HBs Ag), for antibodies to human immunodeficiency virus (HIV-1 and HIV-2) and for antibodies to hepatitis C virus (HCV), except for the positive quality control QC2 which is positive for anti-HCV antibodies.
- This test kit contains human blood components. No known test method can offer complete assurance that infectious agents are absent. Consequently, all human derivatives, reagents and human specimens should be handled as if capable of transmitting infectious disease, following recommended Universal Precautions for blood-borne pathogens as defined by OSHA, the guidelines from the current CDC/NHI Biosafety in Microbiological and Biomedical Laboratories and/or local, regional or national regulations.
- Biological spills: human source material spills should be treated as potentially infectious. Spills not containing acid should be immediately decontaminated, including the spill area, materials and any contaminated surfaces or equipment and with appropriate chemical disinfectant that is effective on the potential biohazards of the samples in question (commonly a 1:10 dilution of household bleach, 70-80% ethanol or isopropanol, an iodophor such as 0.5% Wescodyne™ Plus, etc.) and wiped dry. Spills containing acid should be appropriately absorbed (wiped up) or neutralized, the area flushed with water and wiped dry; materials used to absorb the spill may require hazardous waste disposal.

The area should subsequently be decontaminated with one of the chemical disinfectants.

- Dispose of all specimens and material used to perform the test as though they contain an infectious agent. Laboratory, chemical or bio-hazardous waste must be handled and discarded in accordance with all local, regional and national regulations.

The Safety Data Sheet (SDS) is available at www.bio-rad.com.

5 Procedure

The Access HCV Ab PLUS QC should be treated in the same way as patient specimens and run in accordance with the instructions accompanying the instrument and/or method being used.

To process the Access HCV Ab PLUS QC, a minimum of 25 μL of sample is required for each of the 2 levels of quality controls (single determination) in addition to the sample container and system dead volume. One drop is equal to approximately 40 μL .

Quality control is recommended at least, every 24 hours^(13,16) and on system start-up prior to running patient samples.

More frequent use of controls or the use of additional controls is left to the discretion of the user based on good laboratory practices or laboratory accreditation requirements and applicable laws.

Refer to the appropriate system manuals and/or Help system for information on quality control theory, on configuring controls, entering QC sample test requests and reviewing quality control data.

6 Test Limitations

1. The use of the Access HCV Ab PLUS QC has not been established with assays other than the Access HCV Ab PLUS assay.
2. Quality control results that do not fall within acceptable ranges may indicate invalid test results. Examine all test results generated since obtaining the last acceptable quality control test point for this analyte.
3. If there is evidence of microbial contamination or excessive turbidity in a reagent, discard the vial.

7 Expected Values

The expected means (\bar{x}) and SDs (σ) for the Access HCV Ab PLUS QC are provided on the QC value card contained in the kit for initial quality control system configuration. Each laboratory should establish its own acceptability criteria by selecting the QC rules to be applied to the control results. Individual control results should fall within the initial acceptance range. However, each laboratory should update the mean and SD once sufficient data has been collected^(13,17,21).

Given that specific levels of reactivity may vary by assay manufacturer, by procedure, by lot number and by laboratory, each laboratory should determine the specific level of reactivity and establish its own range of acceptable values^(13,17,18,19). The acceptable range might include all values within ± 2 SD of the mean of 20 data points out of 20 determinations over a period of 30 days⁽²¹⁾.

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