This package insert must be read carefully prior to use. Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package insert.

Key to symbols used

- **REF**: List Number
- **IVD**: In Vitro Diagnostic Medical Device
- **LOT**: Lot Number
- **Ex**: Expiration Date
- **2-8°C**: Store at 2-8°C
- **i**: Consult instructions for use
- **Manufacturer**

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASSAY CD-ROM</td>
<td>Assay CD-ROM</td>
</tr>
<tr>
<td>REACTION VESSELS</td>
<td>Reaction Vessels</td>
</tr>
<tr>
<td>SAMPLE CUPS</td>
<td>Sample Cups</td>
</tr>
<tr>
<td>SEPTUM</td>
<td>Septum</td>
</tr>
<tr>
<td>REPLACEMENT CAPS</td>
<td>Replacement Caps</td>
</tr>
<tr>
<td>SN</td>
<td>Serial Number</td>
</tr>
<tr>
<td>CONTROL NO.</td>
<td>Control Number</td>
</tr>
<tr>
<td>CAL</td>
<td>Calibrator A-F</td>
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<tr>
<td>CONTROL -</td>
<td>Negative Control</td>
</tr>
<tr>
<td>CONTROL 1+</td>
<td>Positive Control 1</td>
</tr>
<tr>
<td>CONTROL 2+</td>
<td>Positive Control 2</td>
</tr>
<tr>
<td>REAGENT LOT</td>
<td>Reagent Lot</td>
</tr>
</tbody>
</table>

See **REAGENTS** section for a full explanation of symbols used in reagent component naming.
INTENDED USE

The ARCHITECT HCV Ag assay is a Chemiluminescent Microparticle Immunoassay (CMA) for the quantitative determination of core antigen to Hepatitis C virus in human serum and plasma.

SUMMARY AND EXPLANATION OF TEST

ARCHITECT HCV Ag is a Chemiluminescent Microparticle Immunoassay (CMA) technology, with flexible assay protocols referred to as Chemiflex, for the quantitative determination of core antigen of Hepatitis C virus.

In the Pre-Treatment step, sample, Pre-Treatment Reagent 1 and Pre-Treatment Reagent 2 are combined. An aliquot of the pre-treated sample is aspirated and dispensed into a new reaction vessel. The pre-treated sample, Assay Specific Diluent and anti-HCV coated microparticles are combined.

HCV Ag present in the pre-treated sample binds to the anti-HCV coated microparticles in the first step. After washing, acridinium-labeled anti-HCV conjugate is added in the second step.

Following another wash cycle, Pre-Trigger and Trigger Solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of HCV Ag in the sample and the RLUs detected by the ARCHITECT optical system.

The concentration of Hepatitis C core antigen in the specimen is determined using a previously generated ARCHITECT HCV Ag calibration curve. If the concentration of the specimen is greater than or equal to 3.00 fmol/L, the specimen is considered reactive for HCV Ag.

For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.

REAGENTS

Reagent Kit, 100 Tests

ARCHITECT HCV Ag Reagent Kit (6L47)

- **MICROPARTICLES** 1 Bottle (6.7 mL) Microparticles: murine anti-HCV antibody coated microparticles in 400 mM Bicine, 50 mM TRIS buffer with protein (bovine) stabilizer. Minimum concentration: 0.025% solids. Preservatives: sodium azide and antimicrobial agents.

- **CONJUGATE** 1 Bottle (6.1 mL) Conjugate: murine anti-HCV antibody acridinium-labeled conjugate in 80 mM BIS-TRIS with protein (bovine) stabilizer. Minimum concentration: 0.3 µg/mL. Preservatives: sodium azide and antimicrobial agents.

- **ASSAY SPECIFIC DILUENT** 1 Bottle (30.0 mL) HCV Ag Assay Specific Diluent containing 1.46 N NaOH.

- **PRE-TREATMENT REAGENT 1** 1 Bottle (14.5 mL) HCV Ag Pre-Treatment Reagent 1 containing 0.83 N HCl.

- **PRE-TREATMENT REAGENT 2** 1 Bottle (11.0 mL) HCV Ag Pre-Treatment Reagent 2 containing 0.83 N HCl.

- **SPECIMEN DILUENT** 1 Bottle (5.9 mL) HCV Ag Specimen Diluent containing phosphate buffer with protein (horse serum) stabilizer. Preservatives: sodium azide and antimicrobial agents.

Other Reagents

ARCHITECT / Pre-Trigger Solution
- Pre-Trigger Solution containing 1.32% (w/v) hydrogen peroxide.

ARCHITECT / Trigger Solution
- Trigger Solution containing 0.35 N sodium hydroxide.

ARCHITECT / Wash Buffer
- Wash Buffer containing phosphate buffered saline solution. Preservative: antimicrobial agent.

SAFETY PRECAUTIONS

- **IVD**

Safety Precautions

**CAUTION:** This product requires the handling of human specimens. It is recommended that all human sourced materials be considered potentially infectious and handled in accordance with the OSHA Standard on Bloodborne Pathogens, especially practice^5^6 should be used for materials that contain or are suspected of containing infectious agents.

- The ARCHITECT HCV Ag Assay Specific Diluent (6L47J) contains sodium hydroxide and is classified per applicable European Community (EC) Directives as: Corrosive (C). The following are the appropriate Risk (R) and Safety (S) phrases.

  - **R35** Causes severe burns.
  - **S26** In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
  - **S35** This material and its container must be disposed of in a safe way.
  - **S36/37/39** Wear suitable protective clothing, gloves and eye/face protection.
  - **S45** In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

- **R32** Contact with acids liberates very toxic gas.

- **S26** In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

- **S35** This material and its container must be disposed of in a safe way.

- **S36/37/39** Wear suitable protective clothing, gloves and eye/face protection.

- **S45** In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

- **R2** Contact with acids liberates very toxic gas.

- **S35** This material and its container must be disposed of in a safe way.

- **S46** If swallowed, seek medical advice immediately and show its container or label.

- **R35** Causes severe burns.

- **S26** In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

- **S35** This material and its container must be disposed of in a safe way.

- **S36/37/39** Wear suitable protective clothing, gloves and eye/face protection.

- **S45** In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

- **R32** Contact with acids liberates very toxic gas.

- **S35** This material and its container must be disposed of in a safe way.

- **S46** If swallowed, seek medical advice immediately and show its container or label.

- **R32** Contact with acids liberates very toxic gas.

- **S35** This material and its container must be disposed of in a safe way.

- **S46** If swallowed, seek medical advice immediately and show its container or label.

For information on the safe disposal of sodium azide and a detailed discussion of safety precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 8.

For product not classified as dangerous per European Directive 1999/45/EC as amended - Safety data sheet available for professional user on request.
Handling Precautions

- Do not use reagent kits beyond the expiration date.
- Do not open the ASSAY SPECIFIC DILUENT plastic bag until ready to use.
- If leaking is observed with the Assay Specific Diluent bottle, the reagent kit cannot be used due to a lack of homogeneity which may impact results. The Assay Specific Diluent contains sodium hydroxide, and can cause severe skin and eye burns. Leaking bottles should be handled with appropriate safety precautions.
- Do not pool reagents within a reagent kit or between reagent kits.
- Prior to loading the ARCHITECT HCV Ag Reagent Kit on the system for the first time, the reagents shipped on dry ice must be completely thawed and mixed thoroughly. For mixing instructions, refer to the PROCEDURE, Assay Procedure section of this package insert.
- A septum MUST be used to prevent reagent evaporation and contamination, and to ensure reagent integrity. Reliability of assay results cannot be guaranteed if a septum is not used according to the instructions in this package insert.
- To avoid contamination, wear clean gloves when placing a septum on an uncapped reagent bottle.
- Once a septum has been placed on an open reagent bottle, do not invert the bottle as this will result in reagent leakage and may compromise assay results.
- Over time, residual liquids may dry on the septum surface. These are typically dried salts and have no effect on assay efficacy.
- For a detailed discussion of handling precautions during system operation, refer to the ARCHITECT System Operations Manual, Section 7.

Storage Instructions

- $-20^\circ C$ The ARCHITECT HCV Ag Reagent Kit is shipped on dry ice and must be stored at $-2$–$8^\circ C$ in an upright position after receipt.
- When stored and handled as directed, reagents are stable until the expiration date.
- The ARCHITECT HCV Ag Reagent Kit may be stored on board the ARCHITECT / System for a maximum of 15 days. After 15 days, the reagent kit must be discarded. For information on tracking onboard time, refer to the ARCHITECT System Operations Manual, Section 5.
- Reagents may be stored or off the ARCHITECT / System. If reagents are removed from the system, store them at $2$–$8^\circ C$ (with septums and replacement caps) in an upright position. For reagents stored off the system, it is recommended that they be stored in their original trays and boxes to ensure they remain upright. If the microparticle bottle does not remain upright (with a septum installed) while in refrigerated storage off the system, the reagent kit must be discarded. After reagents are removed from the system, a scan must be initiated to update the onboard stability timer.

Indications of Reagent Deterioration

When a control value is out of the specified range, it may indicate deterioration of the reagents or errors in technique. Associated test results may be invalid and may require retesting. Assay recalibration may be necessary. For troubleshooting information, refer to the ARCHITECT System Operations Manual, Section 10.

INSTRUMENT PROCEDURE

- The ARCHITECT HCV Ag assay file (801_002.iae or higher) must be installed on the ARCHITECT / System from the ARCHITECT / Assay CD-ROM (Addition C) prior to performing the assay. For detailed instructions on assay file installation and on viewing and editing assay parameters, refer to the ARCHITECT System Operations Manual, Section 2.
- The ARCHITECT HCV Ag assay requires ARCHITECT System Software Version 5.00 or higher and ARCHITECT / Assay CD-ROM (Addition C) Version 6.0 (LN 8K30-06) or higher.
- If the ARCHITECT Anti-HCV assay and the ARCHITECT HCV Ag assay are run on the same ARCHITECT / System, the Anti-HCV assay file (161_020.iae or higher) must be installed from ARCHITECT / Assay CD-ROM -WW (excluding US) - Version 27.0 (LN 6E59-27) or higher, prior to the installation of the HCV Ag assay file.
- For information on printing assay parameters, refer to the ARCHITECT System Operations Manual, Section 5.
- For a detailed description of system procedures, refer to the ARCHITECT System Operations Manual.
- The default result unit for the ARCHITECT HCV Ag assay is fmol/L. An alternate result unit, pg/mL, may be selected for reporting results by editing assay parameter "Result concentration units", to pg/mL. The conversion factor used by the system is 0.02.

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Specimen Types

The specimen collection tubes listed below were verified to be used with the ARCHITECT HCV Ag assay. Other specimen collection tubes have not been tested with this assay.

- Human serum (included serum collected in serum separator tubes)
- Human plasma collected in:
  - Sodium EDTA
  - Potassium EDTA
  - Lithium Heparin
  - Sodium Heparin
  - Sodium Citrate
  - CPD
- Liquid anticoagulants may have a dilution effect resulting in lower concentrations for individual patient specimens.
- The ARCHITECT / System does not provide the capability to verify specimen type. It is the responsibility of the operator to verify that the correct specimen types are used in the ARCHITECT HCV Ag assay.

Specimen Conditions

- Do not use specimens with the following conditions:
  - heat-inactivated
  - pooled
  - grossly hemolyzed
  - obvious microbial contamination
  - cadaver specimens or any other body fluids
- For optimal results, serum and plasma specimens should be free of fibrin, red blood cells, or other particulate matter. Such specimens may give inconsistent results and must be transferred to a centrifuge tube and centrifuged at 3000 x g for 10 minutes. Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.
- When using plasma primary tubes, samples must be priority loaded immediately after centrifugation to minimize disturbance of the red blood cells.
- Use caution when handling patient specimens to prevent cross contamination. Use of disposable pipettes or pipette tips is recommended.
- For optimal results, inspect all samples for bubbles. Remove bubbles with an applicator stick prior to analysis. Use a new applicator stick for each sample to prevent cross contamination.

Preparation for Analysis

- Follow the tube manufacturer’s processing instructions for serum and plasma collection tubes. Gravity separation is not sufficient for specimen preparation.
- Mix thawed specimens thoroughly by low speed vortexing or by inverting 10 times. Visually inspect the specimens. If layering or stratification is observed, continue mixing until specimens are visibly homogeneous.
- To ensure consistency in results, specimens must be transferred to a centrifuge tube and centrifuged at 3000 x g for 10 minutes before testing if:
  - they contain fibrin, red blood cells, or other particulate matter,
  - they require repeat testing, or
  - they were frozen and thawed.
- Transfer clarified specimen to a sample cup or secondary tube for testing.
- Centrifuged specimens with a lipid layer on the top must be transferred to a sample cup or secondary tube. Care must be taken to transfer only the clarified specimen without the lipemic material.
Storage

- Specimen may be stored on or off the clot, red blood cells, or separator gel for up to 5 days refrigerated at 2-8°C.
- If testing will be delayed more than 5 days, remove serum or plasma from the clot, red blood cells, or separator gel and store frozen at -20°C or colder.
- Avoid more than two freeze/thaw cycles.

Shipping

- Before shipping specimens, it is recommended that specimens be removed from the clot, serum separator, or red blood cells.
- When shipping specimens, package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.
- Specimens may be shipped at 2-8°C (wet ice), or -20°C or colder. Do not exceed the storage time limitations listed above.

PROCEDURE

Materials Provided

- 6L47 ARCHITECT HCV Ag Reagent Kit
- 6L47-02 ARCHITECT HCV Ag Calibrators
- 6L47-11 ARCHITECT HCV Ag Controls
- ARCHITECT / PRO-TRIGGER SOLUTION
- ARCHITECT / WASH BUFFER
- ARCHITECT / REACTION VESSELS
- ARCHITECT / SAMPLE CUPS
- ARCHITECT / SEPTUM
- ARCHITECT / REPLACEMENT CAPS
- Pipettes or pipette tips (optional)

For information on materials required for maintenance procedures, refer to the ARCHITECT System Operations Manual, Section 9.

Assay Procedure

- Before loading the ARCHITECT HCV Ag Reagent Kit on the system for the first time, the reagents shipped on dry ice must be completely thawed and mixed thoroughly. After the first time the reagents have been loaded, no further mixing is required.
  - Tear open the ASSAY SPECIFIC DILUENT plastic bag.
  - Invert all the reagent bottles 30 times.
  - Visually inspect the bottle to ensure microparticles are resuspended. If microparticles are still adhered to the bottle, continue to invert the bottle until the microparticles have been completely resuspended.
  - If the microparticles do not resuspend, DO NOT USE. Contact your local Abbott representative.
  - Once the microparticles have been resuspended, place a septum on the bottle. For instructions on placing septums on bottles, refer to the Handling Precautions section of this package insert.

- Load the ARCHITECT HCV Ag Reagent Kit on the ARCHITECT System.
  - Verify that all necessary reagents are present.
  - Ensure that septums are present on all reagent bottles. Refer to ARCHITECT Operations Manual, Section 5 for details on how to load reagents.
  - Order calibration, if necessary.
  - For information on ordering calibrations, refer to the ARCHITECT System Operations Manual, Section 6.

- Order test.
  - For information on ordering patient specimens and controls and for general operating procedures, refer to the ARCHITECT System Operations Manual, Section 5.

- The minimum sample cup volume is calculated by the system and is printed on the Orderlist report. No more than 10 replicates may be sampled from the same sample cup. To minimize the effects of evaporation, verify adequate sample cup volume is present before running the test.
  - Priority: 158 μL for the first HCV Ag test plus 108 μL for each additional HCV Ag test from the same sample cup.
  - ≤ 3 hours on board: 158 μL for the first HCV Ag test plus 108 μL for each additional HCV Ag test from the same sample cup.
  - > 3 hours on board: replace with fresh sample (patient specimens, controls, and calibrators).
  - If using primary or aliquot tubes, use the sample gauge to ensure sufficient patient specimen is present.
  - To obtain the recommended volume requirements for the ARCHITECT HCV Ag Calibrators and Controls, hold the bottles vertically and dispense 12 drops of each calibrator or 7 drops of each control into each respective sample cup.

- Load samples.
  - For information on loading samples, refer to the ARCHITECT System Operations Manual, Section 5.
  - Press RUN.
  - For additional information on principles of operation, refer to the ARCHITECT Operations Manual, Section 3.
  - For optimal performance, it is important to perform routine maintenance as described in the ARCHITECT System Operations Manual, Section 9.

  When a laboratory requires more frequent maintenance, follow these procedures.

Specimen Dilution Procedures

Specimens with an HCV Ag concentration of > 20,000 fmol/L will be flagged as “>20,000” and may be diluted with either the Automated Dilution Protocol or the Manual Dilution Procedure.

- If using the Automated Dilution Protocol, the system performs a 1:9 dilution of the specimen and automatically calculates the concentration of the specimen before dilution and reports the result.

  Manual dilutions should be performed as follows:
  - The suggested dilution for the ARCHITECT HCV Ag assay is 1:20.
  - Add 20 μL of the patient specimen to 380 μL of ARCHITECT HCV Ag Negative Control.
  - The operator must enter the dilution factor in the Patient or Control order screen. The system will use this dilution factor to automatically calculate the concentration of the sample before dilution and report the result. The result (before the dilution factor is applied) should be greater than 3.00 fmol/L.

  For detailed information on ordering dilutions, refer to the ARCHITECT System Operations Manual, Section 5.

Calibration

- To perform an ARCHITECT HCV Ag calibration, test Calibrators A through F in duplicate. A single sample of each control level must be tested to evaluate the assay calibration. Ensure that assay control values are within the concentration ranges specified in the control package insert. Calibrators should be priority loaded.

  - Calibration Range: 0 – 20,000 fmol/L
  - Once an ARCHITECT HCV Ag calibration is accepted and stored, all subsequent samples may be tested without further calibration unless:
    - A reagent kit with a new lot number is used.
    - Controls are out of range.

  For detailed information on how to perform an assay calibration, refer to the ARCHITECT System Operations Manual, Section 6.
QUALITY CONTROL PROCEDURES
The recommended control requirement for the ARCHITECT HCV Ag assay is that a single sample of all control levels be tested once every 24 hours each day of use. If laboratory quality control procedures require more frequent use of controls to verify test results, follow those procedures.

Verification of Assay Claims
The ARCHITECT HCV Ag Control values must be within the acceptable ranges specified in the control package insert. If a control is out of its specified range, the associated test results are invalid and samples must be retested. Recalibration may be indicated.
For protocols to verify package insert claims, refer to the ARCHITECT System Operations Manual, Appendix B.
The ARCHITECT HCV Ag assay belongs to method group 5.

RESULTS
The ARCHITECT HCV Ag assay uses a 4 Parameter Logistic Curve fit (4PLC, Y-weighted) data reduction method to generate a calibration curve.

Flags
- Some results may contain information in the Flags field. For a description of the flags that may appear in this field, refer to the ARCHITECT System Operations Manual, Section 5.

Interpretation of Results
- Specimens with concentration values < 3.00 fmol/L are considered nonreactive for HCV Ag.
- Specimens with concentration values ≥ 3.00 fmol/L are considered reactive for HCV Ag.
- Specimens with concentration values ≥ 3.00 fmol/L to < 10.00 fmol/L should be retested in duplicate.
  - If both retest values are nonreactive, the specimen must be considered nonreactive for HCV Ag.
  - If one or both of the duplicates is (are) ≥ 3.00 fmol/L, the specimen must be considered repeatedly reactive for HCV Ag, and the initial value is used as the final reported value.

NOTE: For details on configuring the ARCHITECT i System to use gray zone interpretations, refer to the ARCHITECT System Operations Manual, Section 2.

LIMITATIONS OF THE PROCEDURE
- For diagnostic purposes, results should be used in conjunction with other data; e.g., symptoms, results of other tests, clinical impressions, etc.
- Specimens from patients who have received preparations of mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies (HAMA). Such specimens may show either falsely elevated or depressed values when tested with assay kits which employ mouse monoclonal antibodies.
  - The ARCHITECT HCV Ag reagents contain a component that reduces the effect of HAMA reactive specimens. Additional clinical or diagnostic information may be required to determine patient status.
  - If the ARCHITECT HCV Ag results are inconsistent with clinical evidence, additional testing is suggested to confirm the result.
- Samples containing particulate matter or red blood cells must be centrifuged prior to running the assay. Insufficiently separated plasma specimens from clots or red blood cells must not be used.
- Specimens from patients with high levels of IgM, e.g., specimens from patients with multiple myeloma, may generate "3350 Unable to process test-aspiration error for (Sample Pipetter) at (RV 24)".

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision
The ARCHITECT HCV Ag assay precision is <$10\%$ total CV. A study was performed as described in the National Committee for Clinical Laboratory Standards (NCCLS) Protocol EP5-A2. Five samples consisting of two buffer protein based HCV Ag positive controls and three serum based panels were assayed in replicates of two at two separate times per day for twenty days ($n=80$ for each sample), using three lots of reagents. Data from this study are summarized in the following table.*

<table>
<thead>
<tr>
<th>Table I</th>
<th>ARCHITECT HCV Ag Precision</th>
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<tr>
<td>Sample</td>
<td>Reagent Lot</td>
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<tr>
<td>1 1 80</td>
<td>52.41</td>
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<tr>
<td>1 2 80</td>
<td>50.08</td>
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<td>1 3 80</td>
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<td>1 2 80</td>
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<td>1 3 80</td>
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<td>2 3 80</td>
<td>7516.93</td>
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</table>
* Representative data; results in individual laboratories may vary from these data.

Specificty
The ARCHITECT HCV Ag assay demonstrated a specificity of $\geq 99.5\%$ in a study where specimens from a blood donor population, hospitalized patients and specimens containing potentially interfering substances were tested. This study includes the specimens from individuals with medical conditions unrelated to HCV infection (Table II). A total of 5027 serum and plasma specimens from blood donors were evaluated. The initial and repeat reactive rates were 0.24% (12/5027) and 0.02% (1/5027), respectively. Four of 250 specimens obtained from hospital patients were repeatedly reactive and confirmed positive for HCV infection. In 126 specimens from individuals with medical conditions unrelated to HCV infection and specimens containing potentially interfering substances, five specimens were repeatedly reactive and confirmed positive for HCV infection.
Reactivity of the ARCHITECT HCV Ag Assay in Specimens from Blood Donors, Hospital Patients, Individuals with Medical Conditions Unrelated to HCV Infection, and in Specimens Containing Potentially Interfering Substances

<table>
<thead>
<tr>
<th>Category</th>
<th>Number Tested</th>
<th>IR (% of Total)</th>
<th>RR (% of Total)</th>
<th>Number of Positive by Supplemental Testinga (% of RR)</th>
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<tr>
<td><strong>Blood Donors</strong></td>
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<tr>
<td>Serum</td>
<td>2256</td>
<td>7 (0.31)</td>
<td>1 (0.04)</td>
<td>0 (0.00)</td>
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<td>EDTA Plasma</td>
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<td>Na Citrate Plasma</td>
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<td>3 (0.25)</td>
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<td><strong>Total Donors</strong></td>
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<td>12 (0.24)</td>
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<td><strong>Hospital Patients</strong></td>
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<td>4 (1.60)</td>
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<td><strong>Individuals with Medical Conditions Unrelated to</strong></td>
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<tr>
<td>HCV Infection and Specimens Containing Potentially Interfering Substancesb</td>
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<tr>
<td>Sensitivity</td>
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</table>

The ARCHITECT HCV Ag assay has a sensitivity of ≤ 3.00 fmol/L. A total of 452 serum and plasma specimens known to be positive for HCV RNA including genotypes 1a, 1b, 2a, 2b, 3a, 3k, 4a, 5a, 5b, 6a, and 6i, were tested. Of the 452 specimens, 97.8% (442/452) were reactive.

Seroconversion

Sensitivity of the ARCHITECT HCV Ag assay was evaluated utilizing 10 commercially available panels of sequential specimens from patients who seroconverted for the detection of anti-HCV antibodies. In each panel, a positive result in the ARCHITECT HCV Ag assay was obtained prior to detection of anti-HCV antibody, resulting in an average reduction between the times of infection and detection of 35.8 days.

Interference

The ARCHITECT HCV Ag assay is designed to have a mean interference of ≤ 10% difference in concentration for patient samples with triglycerides (3000 mg/dL), bilirubin (20 mg/dL), hemoglobin (500 mg/dL), and protein (9.2 g/dL).

In a representative study, the interference from hemoglobin, bilirubin, triglycerides, and protein was evaluated in the ARCHITECT HCV Ag assay. The following interferences were obtained:

- Hemoglobin < 10% at 500 mg/dL
- Bilirubin < 10% at 20 mg/dL
- Triglycerides < 10% at 3000 mg/dL
- Protein < 10% at 9.2 g/dL

**BIBLIOGRAPHY**