Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.
Hepatitis C Virus (HCV) is the causative agent of acute and chronic hepatitis infection. Globally, an estimated 71 million individuals are chronically infected, of whom approximately 399,000 die annually of hepatitis infection. Globally, an estimated 71 million individuals are chronically infected, of whom approximately 399,000 die annually of hepatitis infection. HCV belongs to the genus Hepacivirus in the family Flaviviridae and is characterized by the continued detection of both HCV RNA and antibodies to HCV, persisting for decades after initial infection.2,5 About 30% of infected individuals resolve their infection, which is characterized by the continued detection of antibodies to HCV, but with HCV RNA no longer being detectable.1,2

HCV is transmitted by exposure to blood or blood products, contaminated needle sticks, or unsterilized needles. It can also be transmitted through sexual or perinatal routes, or through contact with contaminated personal items, however these modes are less common. Because of effective blood screening using serological and nucleic acid testing (NAT) methods, the risk of transfusion-transmitted HCV infections has been reduced.4

Anti-HCV assays are used to identify individuals infected with HCV and to prevent transmission of the virus to recipients of blood or blood products. The Alinity’s Anti-HCV assay is designed to detect antibodies to recombinant antigens representing Core, NS3, and NS4 regions of the HCV genome.

**SUMMARY AND EXPLANATION OF THE TEST**

HCV belongs to the genus Hepacivirus in the family Flaviviridae and is a linear, single-stranded, positive-sense RNA virus. It is divided into at least 6 different genotypes (1-6) and several subtypes based on nucleotide sequence homology. Each HCV genotype can be present in at least 6 different genotypes (1-6) and several subtypes based on nucleotide sequence homology.1

The Alinity’s Anti-HCV assay is a two-step immunoassay for the qualitative detection of anti-HCV in human serum and plasma using chemiluminescent microparticle immunoassay (CMIA) technology.

The presence or absence of anti-HCV in the sample is determined by comparing the chemiluminescent RLU in the reaction to the cutoff RLU determined from an active calibration. For additional information on system and assay technology, refer to the Alinity’s System Operations Manual, Section 3.

**REAGENTS**

- **Kit Contents**
  - Alinity’s Anti-HCV Reagent Kit 06P04
  - Volumes (mL) listed in the table below indicate the volume per cartridge.

<table>
<thead>
<tr>
<th>REAGENTS</th>
<th>Volume (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tests per cartridge</td>
<td>500</td>
</tr>
<tr>
<td>Number of cartridges per kit</td>
<td>10</td>
</tr>
<tr>
<td>Tests per kit</td>
<td>5000</td>
</tr>
<tr>
<td><strong>MICROPARTICLES</strong></td>
<td>27.0 mL</td>
</tr>
<tr>
<td><strong>CONJUGATE</strong></td>
<td>26.5 mL</td>
</tr>
<tr>
<td><strong>ASSAY DILUENT</strong></td>
<td>47.1 mL</td>
</tr>
</tbody>
</table>

- **Test matrix**

Anti-HCV assays are used to identify individuals infected with HCV and to prevent transmission of the virus to recipients of blood or blood products. The Alinity’s Anti-HCV assay is designed to detect antibodies to recombinant antigens representing Core, NS3, and NS4 regions of the HCV genome.

**INTENDED USE**

The Alinity’s Anti-HCV assay is a chemiluminescent microparticle immunoassay (CMIA) used for the qualitative detection of antibodies to hepatitis C virus (HCV) in human serum and plasma specimens on the Alinity’s System.

The Alinity’s Anti-HCV assay is intended to screen individual human donors, including volunteer donors of whole blood and blood components, and other living donors for the presence of anti-HCV. The assay is also intended for use in testing serum and plasma specimens to screen organ donors when specimens are obtained while the donor’s heart is still beating, and in testing serum specimens to screen cadaveric (non-heart-beating) donors. It is not intended for use on cord blood specimens.

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HCV RNA can be detected within a few days of exposure to HCV, prior to the development of antibodies. This time period, referred to as the pre-seroconversion window period, often extends for several weeks after initial infection with HCV. In general, antibodies to HCV are absent in the early weeks of infection and are not detected until approximately 4–10 weeks after infection.5 In general, 75%–85% of HCV infected individuals develop chronic infection, which is characterized by the continued detection of both HCV RNA and antibodies to HCV, persisting for decades after initial infection.6

About 30% of infected individuals resolve their infection, which is characterized by the continued detection of antibodies to HCV, but with HCV RNA no longer being detectable.1,2

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About 30% of infected individuals resolve their infection, which is characterized by the continued detection of antibodies to HCV, but with HCV RNA no longer being detectable.1,2
Warnings and Precautions

- For In Vitro Diagnostic Use
- Performance characteristics of this product have not been established for laboratory diagnosis of HCV infection.

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. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.6-9

The following warnings and precautions apply to:

**WARNING**
Contains diethylenetriamine pentaacetic acid.

H361 Suspected of damaging fertility or the unborn child.

Prevention
P201 Obtain special instructions before use.
P280 Wear protective gloves / protective clothing / eye protection.

Response
P308+P313 IF exposed or concerned: Get medical advice / attention.

Disposal
P501 Dispose of contents / container in accordance with local regulations.

The following warnings and precautions apply to:

**DANGER**
Contains polyethylene glycol octylphenyl ether (Triton X-405) and sodium azide.

H318 Causes serious eye damage.
H412 Harmful to aquatic life with long lasting effects.
EUH032 Contact with acids liberates very toxic gas.

Prevention
P280 Wear protective gloves / protective clothing / eye protection.
P273 Avoid release to the environment.

Response
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER or doctor / physician.

Disposal
P501 Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.transfusion.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity s System Operations Manual, Section 8.

Reagent Handling

- Do not invert reagent cartridges.
- Upon receipt, reagent cartridges can be used immediately or stored in an upright position.
- If a reagent cartridge is dropped, place in an upright position for 1 hour before use to allow bubbles that may have formed to dissipate.
- Reagents are susceptible to the formation of foam and bubbles. Bubbles may interfere with the detection of the reagent level in the cartridge and cause insufficient reagent aspiration that may adversely affect results.

For a detailed discussion of reagent handling precautions during system operation, refer to the Alinity s System Operations Manual, Section 7.
Reagent Storage

- Do not freeze.

<table>
<thead>
<tr>
<th>Storage Temperature</th>
<th>Maximum Storage Time</th>
<th>Additional Storage Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unopened</td>
<td>2 to 8°C</td>
<td>Store in upright position.</td>
</tr>
<tr>
<td></td>
<td>Until expiration date</td>
<td></td>
</tr>
<tr>
<td>Opened</td>
<td>2 to 15°C</td>
<td>Store in upright position.</td>
</tr>
<tr>
<td></td>
<td>15 days after opening*</td>
<td>Discard after 15 days.</td>
</tr>
</tbody>
</table>

* Includes time on board the system.

Reagents may be stored on or off the system. If removed from the system, store reagents with new replacement caps in an upright position at 2 to 15°C. For reagents stored off the system, it is recommended that they be stored in their original trays or boxes to ensure they remain upright.

For information on unloading reagents, refer to the Alinity s System Operations Manual, Section 5.

**Indications of Reagent Deterioration**

Deterioration of the reagents may be indicated when a calibration error occurs or a control value is out of the specified range. Associated test results are invalid, and samples must be retested. Assay recalibration may be necessary.

For troubleshooting information, refer to the Alinity s System Operations Manual, Section 10.

**INSTRUMENT PROCEDURE**

The Alinity s Anti-HCV Assay File must be installed on the Alinity s System prior to performing the assay.

For detailed information on assay file installation and viewing and editing assay parameters, refer to the Alinity s System Operations Manual, Section 2.

For information on printing assay parameters, refer to the Alinity s System Operations Manual, Section 5.

For a detailed description of system procedures, refer to the Alinity s System Operations Manual.

**SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS**

**Specimen Types**

The specimen types listed below were verified for use with this assay. Other specimen types and anticoagulants have not been verified with this assay.

<table>
<thead>
<tr>
<th>Specimen Types</th>
<th>Anticoagulants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum (including serum separator tubes)</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Plasma</td>
<td>Dipotassium EDTA (including plasma preparation tubes)</td>
</tr>
<tr>
<td></td>
<td>Tripotassium EDTA</td>
</tr>
<tr>
<td></td>
<td>Lithium heparin (including plasma separator tubes)</td>
</tr>
<tr>
<td></td>
<td>Sodium citrate</td>
</tr>
<tr>
<td></td>
<td>Sodium heparin</td>
</tr>
<tr>
<td></td>
<td>ACD-A</td>
</tr>
<tr>
<td></td>
<td>ACD-B</td>
</tr>
<tr>
<td></td>
<td>CP2D</td>
</tr>
<tr>
<td></td>
<td>CPD</td>
</tr>
<tr>
<td></td>
<td>CPDA-1</td>
</tr>
</tbody>
</table>

- Liquid anticoagulants may have a dilution effect resulting in lower S/CO values for individual specimens.
- Performance has not been established for the use of umbilical cord blood or bodily fluids such as urine, saliva, semen, amniotic fluid, cerebrospinal fluid, or pleural fluid.
- Performance has been established for the use of cadaveric serum specimens (including specimens collected post-mortem, non-heart-beating) that have been collected up to 24 hours after death. Follow general standards and/or regulations for collection, storage, and handling.
- Performance has not been established for the use of cadaveric plasma specimens.
- Testing of cadaveric serum specimens from patients with plasma dilution due to transfusions of > 2000 mL of blood or colloids within 48 hours, or > 2000 mL of crystalloids within 1 hour (or any combination thereof) prior to collection of the specimens has not been verified.
- The system does not provide the capability to verify specimen types. It is the responsibility of the operator to verify that the correct specimen types are used with the assay.

**Specimen Conditions**

- Do not use:
  - heat-inactivated specimens
  - pooled specimens
  - grossly hemolyzed specimens
  - specimens with obvious microbial contamination
  - specimens with fungal growth
- For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter.
- To prevent cross contamination, use of disposable pipettes or pipette tips is recommended.

**Preparation for Analysis**

Failure to follow the specified centrifugation procedure may give erroneous or inconsistent test results.

- Clear, nonhemolyzed specimens should be used when possible. Specimens containing visible particulate matter may give erroneous or inconsistent test results.
- Specimens should be free of bubbles. Remove bubbles with an applicator stick before analysis. Use a new applicator stick for each specimen to prevent cross contamination.
- Prior to centrifugation, previously frozen specimens (including previously frozen plasmapheresis specimens) must be mixed gently and thoroughly after thawing.
- Specimens collected by plasmapheresis, which have not been frozen, do not require centrifugation. All other specimens (including previously frozen plasmapheresis specimens) must be centrifuged between 30,000 - 75,000 g-minutes.
- All specimens must be tested or restested within 48 hours of initial centrifugation. After 48 hours, these specimens need to be recentlyrifuged between 30,000 - 75,000 g-minutes.

The acceptable time and force ranges that meet this criterion are listed in the table below.

<table>
<thead>
<tr>
<th>Centrifugation Time</th>
<th>RCF (x g)</th>
<th>g-Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
<td>3000</td>
<td>30,000</td>
</tr>
<tr>
<td>15</td>
<td>2000 – 3000</td>
<td>30,000 – 45,000</td>
</tr>
<tr>
<td>20</td>
<td>1500 – 3000</td>
<td>30,000 – 60,000</td>
</tr>
<tr>
<td>25</td>
<td>1300 – 3000</td>
<td>32,500 – 75,000</td>
</tr>
</tbody>
</table>

Convert rpm to RCF as follows: RCF = 1.12 × f_{max} (rpm/1000)^2
Convert rpm to RCF as follows:

\[ \text{rpm} = 1000 \times \sqrt{\frac{\text{RCF}}{1.12 \times f_{max}}} \]

RCF - The relative centrifugal force generated during centrifugation.

rpm - The revolutions per minute of the rotor on which the specimens are being spun (usually the digital readout on the centrifuge will indicate the rpm).

Centrifugation Time - The time should be measured from the time the rotor reaches the required RCF or rpm to the time it begins decelerating.

f_{max} - Radius of the rotor in millimeters. The radius measured is dependent on whether the rotor is a fixed angle rotor or a swinging bucket rotor. This value is typically provided with the rotor by the manufacturer. For the fixed angle rotor, f_{max} is the measure of the distance from the rotor axis (center) to the bottom of the specimen tube in the rotor or rotor adapter. For the swinging bucket rotor, f_{max} is the measure of the distance from the rotor axis (center) to the bottom of the specimen tube in the rotor adapter or bucket at full extension.

NOTE: If custom tube adapters (i.e., adapters not defined by the centrifuge manufacturer) are used, then the radius (f_{max}) should be manually measured in millimeters and the RCF calculated.

g-minutes - The unit of measure for the product of RCF (x g) and centrifugation time (minutes).

- Storage at a combination of 15 to 30°C and 2 to 8°C may not exceed 14 days (inclusive of shipping time) and cannot exceed the maximum durations listed in the table above.
- Performance has not been established for cadaveric specimens that have undergone more than 6 freeze/thaw cycles.
- Performance has not been established using cadaveric specimens stored at –20°C or colder for greater than 3 months.
- Storage at a combination of 15 to 30°C and 2 to 8°C may not exceed 14 days (inclusive of shipping time) and cannot exceed the maximum durations listed in the table above.
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### Specimen Storage

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Maximum Storage Time</th>
<th>Special Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Living Donor Serum/Plasma</td>
<td>Room temperature (15 to 30°C)</td>
<td>7 days</td>
<td>Specimens may be stored on or off the clot, red blood cells, or separator gel.</td>
</tr>
<tr>
<td></td>
<td>2 to 8°C</td>
<td>14 days</td>
<td>Specimens may be stored on or off the clot, red blood cells, or separator gel.</td>
</tr>
<tr>
<td></td>
<td>-20°C or colder</td>
<td>3 months</td>
<td>Remove serum or plasma from the clot, red blood cells, or separator gel.</td>
</tr>
</tbody>
</table>

- Living donor specimens stored at ~20°C or colder for greater than 3 months may be used for informational purposes. (e.g., lookback testing, discordant sample testing, clinical and validation testing).

### Specimen Shipping

Package and label specimens in compliance with applicable state, federal, and international regulations covering the transport of clinical specimens and infectious substances.

### PROCEDURE

#### Materials Provided

- 06P04 Alinity s Anti-HCV Reagent Kit
- 06P0403 Alinity s Anti-HCV Calibrator Kit
- 06P0420 Alinity s Anti-HCV Assay Control Kit
- 06P0424 Alinity s Anti-HCV Release Control Kit
- Alinity Trigger Solution
- Alinity Pre-Trigger Solution
- Alinity s Concentrated Wash Buffer

For information on materials required for operation of the system, refer to the Alinity s System Operations Manual, Section 1.

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

#### Assay Procedure

For a detailed description of how to run an assay, refer to the Alinity s System Operations Manual, Section 5.

- Primary tubes may be on board the system for up to 10 hours.
- If using primary or aliquot tubes, refer to the Alinity s System Operations Manual, Section 4 to ensure sufficient specimen is present.
- To minimize the effects of evaporation, verify adequate sample cup volume is present prior to running the test.
- Maximum number of replicates sampled from the same sample cup: 10
Invalid controls: Additional controls may be tested anywhere within a run as an invalidate control. Specifications may be assigned to invalidating controls. If an invalidate control fails to meet assigned specifications, no sample results are calculated or provided by the system. When an invalidate control meets assigned specifications, sample processing continues, and a valid release control result is required to release test results.

Non-validating controls: Additional controls may be tested anywhere within a run as a non-validating control. Specifications may be assigned to non-validating controls. A valid release control result is required to release test results. If the user-assigned specifications for the non-validating control(s) are not met and the release control specifications are met, there will be no effect on sample processing. In this case, reactive sample results must not be considered invalid.

Quality Control Guidance
Refer to “Basic QC Practices” by James O Westgard, Ph.D. for guidance on laboratory quality control practices.

RESULTS
Calculation
The Alinity s System calculates results for the Alinity s Anti-HCV assay using the ratio of the sample RLU to the cutoff RLU (S/CO) for each specimen and control.

\[
\text{Cutoff RLU} = \text{Calibrator 1 Mean RLU} \times 0.35
\]

The cutoff RLU is stored for each reagent lot calibration.

\[
S/CO = \frac{\text{Sample RLU}}{\text{Cutoff RLU}}
\]

The cutoff is 1.00 S/CO.

\[
\text{If } S/CO > 1.00 \text{ then specimen is considered reactive to HCV.}
\]

\[
\text{If } S/CO \leq 1.00 \text{ then specimen is considered nonreactive.}
\]

Quality Control Procedures
Assay Controls
The Alinity s Anti-HCV Assay Controls must be tested once every 24 hours when the system is being used.

Assay control values must be within the ranges specified in the Alinity s Anti-HCV Assay Control Kit package insert. 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 the Alinity s System Operations Manual, Section 10.

Release Controls
The Alinity s Anti-HCV Release Control must be tested in order to release test results.

The release control is tested at user-defined intervals. For configuring the release control, refer to the Alinity s System Operations Manual, Section 2. For manually ordering the release control, refer to the Alinity s System Operations Manual, Section 5.

The release control must meet specifications defined in the Alinity s Anti-HCV Release Control Kit package insert. If the release control does not meet specifications, refer to the Alinity s System Operations Manual, Section 10, for additional information.

Other Controls
Additional controls may be tested at operator’s discretion in accordance with local, state, and/or federal regulations or accreditation requirements and your laboratory’s quality control policy. For additional information on configuring customer controls, refer to the Alinity s System Operations Manual, Section 2.

<table>
<thead>
<tr>
<th>Initial Result (S/CO)</th>
<th>Interpretation</th>
<th>Retest Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 1.00</td>
<td>Nonreactive</td>
<td>No retest required. Specimen considered negative for antibodies to HCV.</td>
</tr>
<tr>
<td>≥ 1.00</td>
<td>Reactive</td>
<td>Retest in duplicate.</td>
</tr>
</tbody>
</table>

Final Interpretation

<table>
<thead>
<tr>
<th>Retest Result (S/CO)</th>
<th>Final Result</th>
<th>Final Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Both results &lt; 1.00</td>
<td>Nonreactive</td>
<td>Specimen considered negative for antibodies to HCV.</td>
</tr>
<tr>
<td>One or both results ≥ 1.00</td>
<td>Repeatedly Reactive</td>
<td>Specimen should be further tested by supplemental methods.</td>
</tr>
</tbody>
</table>

Supplemental methods should follow appropriate FDA recommendations and regulations for specimens found to be repeatedly reactive.

Customers outside the US must follow their country’s government recommendations and regulations for specimens found to be repeatedly reactive.

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 Alinity s System Operations Manual, Section 5.

LIMITATIONS OF THE PROCEDURE

- Potential interference has not been evaluated for substances other than those described in the SPECIFIC PERFORMANCE CHARACTERISTICS - Interference section of this package insert.
- False reactive results can be expected with any test kit. Falsely elevated results may be observed due to non-specific interactions (refer to the SPECIFIC PERFORMANCE CHARACTERISTICS section of this package insert).
• Although the association of infectivity and the presence of antibodies to HCV is strong, it is recognized that presently available methods for HCV antibody detection are not sensitive enough to detect all potentially infectious units of blood or possible cases of HCV infection. A nonreactive test result does not exclude infection. Refer to the SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS section of this package insert for specimen limitations.

## SPECIFIC PERFORMANCE CHARACTERISTICS

Representative performance data are provided in this section. Results obtained in individual laboratories may vary.

### Reproducibility

A study was performed based on guidance from CLSI EP15-A2. Testing was conducted using 3 lots of the Alinity s Anti-HCV Reagent Kit, Calibrator Kit, Assay Control Kit, and Release Control Kit. Panel members and controls were tested twice a day for 5 days in replicates of 4 at 3 sites.

### Specificity

A total of 7347 fresh serum specimens and 6514 fresh plasma specimens from volunteer whole blood donors were collected at 3 distinct blood centers. A total of 3138 specimens from plasmapheresis donors were collected at one additional blood center. The initial and repeat reactive rates for the serum specimens were 0.19% (14/7347) and 0.18% (13/7347), respectively. The initial and repeat reactive rates for the plasma specimens were 0.08% (5/6514) and 0.08% (5/6514), respectively. The initial and repeat reactive rates for the plasmapheresis donor specimens were 0.06% (2/3138) and 0.06% (2/3138), respectively. Repeatedly reactive specimens were further tested using an HCV qualitative RNA assay and a research-use only line immunosassay for anti-HCV. Based on supplemental test results for the repeatedly reactive specimens, 4 specimens were positive, 14 specimens were negative, and 2 specimens were indeterminate.

Specificity based on assumed zero prevalence of antibody to HCV in whole blood and plasmapheresis donors was estimated in this study to be 99.92% (16 975/16 989) with a 95% confidence interval of 99.86% to 99.95%.

<table>
<thead>
<tr>
<th>Specimen Category</th>
<th>Number Tested</th>
<th>IR (%) of Total (95% CI)</th>
<th>RR (%) of Total (95% CI)</th>
<th>Number Positive by Supplemental Testing (%) of RR</th>
<th>Specificity (%) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volunteer Blood Donors - Serum</td>
<td>7347</td>
<td>14 (0.19) (0.09 – 0.30)</td>
<td>13 (0.18) (0.09 – 0.30)</td>
<td>0 (0.00)</td>
<td>99.85 (73/7347 / 7431) (99.73 – 99.93)</td>
</tr>
<tr>
<td>Volunteer Blood Donors - Plasma</td>
<td>6514</td>
<td>5 (0.08) (0.02 – 0.18)</td>
<td>5 (0.08) (0.02 – 0.18)</td>
<td>4 (0.06)</td>
<td>99.98 (6507 / 6508) (99.91 – 100.00)</td>
</tr>
<tr>
<td>Total Volunteer Blood Donors</td>
<td>13 961</td>
<td>19 (0.14) (0.08 – 0.21)</td>
<td>18 (0.13) (0.08 – 0.21)</td>
<td>14 (0.22) (0.13 – 0.34)</td>
<td>99.91 (13 893 / 13 951) (99.85 – 99.96)</td>
</tr>
<tr>
<td>Plasmapheresis Donors</td>
<td>3138</td>
<td>2 (0.06) (0.01 – 0.13)</td>
<td>2 (0.06) (0.01 – 0.13)</td>
<td>0 (0.00)</td>
<td>99.94 (3136 / 3138) (99.77 – 99.99)</td>
</tr>
<tr>
<td>Total Donors</td>
<td>16 999</td>
<td>21 (0.12) (0.08 – 0.19)</td>
<td>20 (0.12) (0.08 – 0.19)</td>
<td>4 (0.06)</td>
<td>99.92 (16 975 / 16 999) (99.86 – 99.95)</td>
</tr>
</tbody>
</table>

IR = Initially Reactive; RR = Repeatedly Reactive; CI = Confidence Interval

<table>
<thead>
<tr>
<th>Specimen Category</th>
<th>Number Tested</th>
<th>Number Positive</th>
<th>Number RR (%) of Total</th>
<th>Number RR Positive by Supplemental Testing (%) of RR</th>
<th>Sensitivity (%) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preselected Anti-HCV Positive</td>
<td>281</td>
<td>281</td>
<td>281 (100.00)</td>
<td>281 (100.00)</td>
<td>100.00 (281/281) (98.70 – 100.00)</td>
</tr>
<tr>
<td>Preselected Anti-HCV Positive – Chronic Infection</td>
<td>121</td>
<td>121</td>
<td>121 (100.00)</td>
<td>121 (100.00)</td>
<td>100.00 (121/121) (97.00 – 100.00)</td>
</tr>
<tr>
<td>Individuals at Increased Risk of HCV Infection</td>
<td>402</td>
<td>402</td>
<td>402 (100.00)</td>
<td>402 (100.00)</td>
<td>100.00 (402/402) (99.99 – 100.00)</td>
</tr>
<tr>
<td>Total</td>
<td>809</td>
<td>492</td>
<td>493 (60.94)</td>
<td>492 (99.80)</td>
<td>100.00 (492/492) (99.25 – 100.00)</td>
</tr>
</tbody>
</table>

RR = Repeatedly Reactive; CI = Confidence Interval

a Preselected anti-HCV positive specimens were positive by an FDA-licensed HCV recombinant immunoblot assay (RIBA).
b Preselected anti-HCV positive specimens (chronic infection) were from individuals identified with chronic infection based on medical diagnoses and HCV RNA and/or anti-HCV results.

c The following risk factors were included: current or past residence in a Hepatitis C endemic region, diagnosed or treated for a sexually transmitted disease, hemodialysis patient, history of incarceration, household contact with HCV infected individual, intranasal cocaine user, intravenous drug user, multiple sex partners, recipient of blood or blood components, including clotting factors, and transplant recipients.
Genotype Detection
A total of 105 preselected HCV positive specimens of known genotype (genotypes 1-6) obtained from commercial vendors were tested using the Alinity s Anti-HCV assay. The results were compared to a commercially available anti-HCV assay. All 105 specimens were repeatedly reactive using the Alinity s Anti-HCV assay. Of the 105 specimens, 103 were repeatedly reactive using the commercially available anti-HCV assay; results from 2 specimens were not obtained due to insufficient sample volume.

Seroconversion Sensitivity
To determine the seroconversion sensitivity, 22 seroconversion panels obtained from commercial vendors were tested on the Alinity s System using the Alinity s Anti-HCV assay. The results were compared to a commercially available anti-HCV assay and representative data obtained from commercial vendors were tested on the Alinity s System using the Alinity s Anti-HCV assay. The results were compared from 5 panels are summarized in the following table.

<table>
<thead>
<tr>
<th>Panel ID</th>
<th>Days Since 1st Bleed</th>
<th>Alinity s Anti-HCV Reactive &gt; 1.00 S/CO</th>
<th>Commercially-Available Anti-HCV Reactive &gt; 1.00 S/CO</th>
</tr>
</thead>
<tbody>
<tr>
<td>6229</td>
<td>0</td>
<td>0.17</td>
<td>0.37</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>0.17</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>0.16</td>
<td>0.32</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>0.20</td>
<td>0.43</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>1.17</td>
<td>1.37</td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>1.83</td>
<td>1.72</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>2.90</td>
<td>2.58</td>
</tr>
<tr>
<td></td>
<td>28</td>
<td>6.57</td>
<td>4.27</td>
</tr>
<tr>
<td>9047</td>
<td>0</td>
<td>0.05</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>0.05</td>
<td>0.12</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>0.05</td>
<td>0.12</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>0.05</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>0.05</td>
<td>0.12</td>
</tr>
<tr>
<td></td>
<td>21</td>
<td>0.05</td>
<td>0.14</td>
</tr>
<tr>
<td></td>
<td>28</td>
<td>3.16</td>
<td>2.55</td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>7.27</td>
<td>3.45</td>
</tr>
<tr>
<td></td>
<td>35</td>
<td>7.97</td>
<td>3.78</td>
</tr>
<tr>
<td></td>
<td>37</td>
<td>8.23</td>
<td>4.38</td>
</tr>
<tr>
<td>PHV914</td>
<td>0</td>
<td>0.05</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>0.05</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>0.04</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>0.09</td>
<td>0.12</td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>0.89</td>
<td>0.35</td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>1.15</td>
<td>0.54</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>3.36</td>
<td>1.71</td>
</tr>
<tr>
<td></td>
<td>30</td>
<td>4.74</td>
<td>3.28</td>
</tr>
<tr>
<td></td>
<td>33</td>
<td>6.12</td>
<td>4.10</td>
</tr>
<tr>
<td>PHV915</td>
<td>0</td>
<td>0.11</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>0.53</td>
<td>0.36</td>
</tr>
<tr>
<td></td>
<td>12</td>
<td>1.94</td>
<td>1.02</td>
</tr>
<tr>
<td></td>
<td>14</td>
<td>3.69</td>
<td>2.32</td>
</tr>
<tr>
<td>PHV920(M)</td>
<td>0</td>
<td>0.05</td>
<td>0.06</td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>0.09</td>
<td>0.09</td>
</tr>
<tr>
<td></td>
<td>13</td>
<td>1.12</td>
<td>0.89</td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>4.26</td>
<td>2.84</td>
</tr>
<tr>
<td></td>
<td>20</td>
<td>5.10</td>
<td>2.94</td>
</tr>
<tr>
<td></td>
<td>26</td>
<td>6.49</td>
<td>3.14</td>
</tr>
<tr>
<td></td>
<td>28</td>
<td>7.33</td>
<td>4.23</td>
</tr>
<tr>
<td></td>
<td>33</td>
<td>9.31</td>
<td>4.62</td>
</tr>
<tr>
<td></td>
<td>35</td>
<td>9.39</td>
<td>4.35</td>
</tr>
</tbody>
</table>

Seroconversion Sensitivity Table

<table>
<thead>
<tr>
<th>Specimen Category</th>
<th>Number Tested</th>
<th>IR (% of Total)</th>
<th>RR (% of Total)</th>
<th>% of Repeatedly Reactive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other Specimen Conditions or Disease Statesa</td>
<td>192</td>
<td>1 (0.52)</td>
<td>1 (0.52)</td>
<td>1 (100.00)b</td>
</tr>
</tbody>
</table>

IR = Initially Reactive; RR = Repeatedly Reactive

a The specimens included the following: Anti-HIV-1/HIV-2 Positive (10), Anti-HTLV I/II Positive (10), HBV Positive (10), Anti-HAV Positive (10), Anti-HDV Positive (9), Co-infected CMV/EBV/HSV (10), Anti-T pallidum Positive (10), Non-viral Hepatitis (10), Rheumatoid Factor Positive (10), Anti-ds DNA Positive (10), Pregnant Females (14), Multiparous Females (10), Hyper IgG/IgM (10), Influenza Vaccine Recipient (10), Hemodialysis Patients (10), HAMA Positive (10), E coli Infection (10), Heterophilic Antibody Positive (9), and Fungal (yeast) Infection (10).
b One influenza vaccine recipient specimen was positive by supplemental testing.

Interference
Potentially Interfering Endogenous Substances
A study was performed based on guidance from CLSI EP07-A2.13
No interference was observed using the Alinity s Anti-HCV assay from potentially interfering substances at the levels shown below.

<table>
<thead>
<tr>
<th>Potentially Interfering Substance</th>
<th>Interferent Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conjugated Bilirubin</td>
<td>≤ 20 mg/dL</td>
</tr>
<tr>
<td>Unconjugated Bilirubin</td>
<td>≤ 20 mg/dL</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>≤ 500 mg/dL</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>≤ 3000 mg/dL</td>
</tr>
<tr>
<td>Total Protein</td>
<td>≤ 12 g/dL</td>
</tr>
</tbody>
</table>

In addition, a negative and positive control were spiked with biotin to a concentration of 4250 ng/mL. No interference was observed using the Alinity s Anti-HCV assay.

The effect of potentially interfering substances has only been evaluated for those listed in this package insert.

Performance Characteristics of Cadaveric Specimen Testing
Reproducibility
Twenty-three cadaveric donor serum specimens and 23 living donor serum specimens were spiked with human plasma reactive for anti-HCV to create low-level reactive specimens. Each specimen was tested once per day for 6 days using each of 3 lots of the Alinity s Anti-HCV Reagent Kit. Total %CV values were determined.

<table>
<thead>
<tr>
<th>Specimen Category</th>
<th>Number of Replicates</th>
<th>Mean S/CO</th>
<th>SD</th>
<th>%CV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cadaverica</td>
<td>414</td>
<td>3.45</td>
<td>0.130</td>
<td>3.8</td>
</tr>
<tr>
<td>Living Donora</td>
<td>414</td>
<td>3.47</td>
<td>0.121</td>
<td>3.5</td>
</tr>
</tbody>
</table>

a Total variability contains within-specimen, between-lot and lot-specimen interaction variance components.
b Cadaveric serum specimens were collected up to 14.6 hours after death.
**Specificity**

Specificity was determined by testing 55 cadaveric serum specimens and 55 living donor serum specimens. Each specimen was tested using each of 3 lots of the Alinity s Anti-HCV Reagent Kit.

<table>
<thead>
<tr>
<th>Specimen Category</th>
<th>Lot</th>
<th>Nonreactive</th>
<th>Repeatedly Reactive</th>
<th>Sensitivity (%) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cadaveric</td>
<td>Lot 1</td>
<td>55</td>
<td>0</td>
<td>100.00 (93.51 – 100.00)</td>
</tr>
<tr>
<td></td>
<td>Lot 2</td>
<td>55</td>
<td>0</td>
<td>100.00 (93.51 – 100.00)</td>
</tr>
<tr>
<td></td>
<td>Lot 3</td>
<td>55</td>
<td>0</td>
<td>100.00 (93.51 – 100.00)</td>
</tr>
<tr>
<td>Living Donor</td>
<td>Lot 1</td>
<td>55</td>
<td>0</td>
<td>100.00 (93.51 – 100.00)</td>
</tr>
<tr>
<td></td>
<td>Lot 2</td>
<td>55</td>
<td>0</td>
<td>100.00 (93.51 – 100.00)</td>
</tr>
<tr>
<td></td>
<td>Lot 3</td>
<td>55</td>
<td>0</td>
<td>100.00 (93.51 – 100.00)</td>
</tr>
</tbody>
</table>

CI = Confidence Interval

analytical sensitivity

Cadaveric serum specimens and living donor serum specimens were spiked with human plasma reactive for anti-HCV to create low-level reactive specimens. Each specimen was tested once, within 24 hours of spiking, using each of 3 lots of the Alinity s Anti-HCV Reagent Kit. All specimens were reactive on all 3 reagent lots.

<table>
<thead>
<tr>
<th>Specimen Category</th>
<th>Number of Specimens</th>
<th>Mean S/CO</th>
<th>Sensitivity (%) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cadaveric</td>
<td>Lot 1</td>
<td>55</td>
<td>3.17 (93.51 – 100.00)</td>
</tr>
<tr>
<td></td>
<td>Lot 2</td>
<td>55</td>
<td>3.45 (93.51 – 100.00)</td>
</tr>
<tr>
<td></td>
<td>Lot 3</td>
<td>55</td>
<td>3.36 (93.51 – 100.00)</td>
</tr>
<tr>
<td>Living Donor</td>
<td>Lot 1</td>
<td>55</td>
<td>3.20 (93.51 – 100.00)</td>
</tr>
<tr>
<td></td>
<td>Lot 2</td>
<td>55</td>
<td>3.43 (93.51 – 100.00)</td>
</tr>
<tr>
<td></td>
<td>Lot 3</td>
<td>55</td>
<td>3.34 (93.51 – 100.00)</td>
</tr>
</tbody>
</table>

CI = Confidence Interval

Cadaveric Specimen Storage

Cadaveric specimen storage was determined by testing a minimum of 12 low-level reactive specimens, prepared by spiking nonreactive cadaveric serum specimens to a target S/CO value near the cutoff with human plasma reactive for anti-HCV, and a minimum of 12 nonreactive cadaveric serum specimens. Each specimen was tested at Day 0, and then subjected to either 2 to 8°C storage for 14 days, room temperature (15 to 30°C) storage for 3 days, −20°C or colder storage for 3 months, or 6 freeze/thaw cycles. Nonreactive specimens were evaluated by calculating the differences between the mean S/CO of Day 0 and the mean S/CO of each storage condition and related timepoint. Reactive specimens were evaluated by calculating the percent differences between the mean S/CO of Day 0 and the mean S/CO of each storage condition and related timepoint. There were no changes to the interpretation; the data demonstrate that cadaveric serum specimens can be stored at the following conditions when tested using the Alinity s Anti-HCV assay.

- **Room Temperature (15 to 30°C)**: 3 days, 0.00 S/CO
- **2 to 8°C**: 14 days, 0.01 S/CO
- **−20°C or colder**: 3 months, 0.00 S/CO
- ** Freeze/Thaw**: 6 cycles, 0.00 S/CO

**BIBLIOGRAPHY**

Note for number formatting:
• A space is used as thousands separator (example: 10 000 specimens).
• A period is used to separate the integer part from the fractional part of a number written in decimal form (example: 3.12%).

### Key to Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>![image]</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>![image]</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>![image]</td>
<td>Sufficient for</td>
</tr>
<tr>
<td>![image]</td>
<td>Temperature limitation</td>
</tr>
<tr>
<td>![image]</td>
<td>Use by/Expiration date</td>
</tr>
<tr>
<td>![image]</td>
<td>Assay Diluent</td>
</tr>
<tr>
<td>![image]</td>
<td>Conjugate</td>
</tr>
<tr>
<td>![image]</td>
<td>Contains Sodium Azide. Contact with acids liberates very toxic gas.</td>
</tr>
<tr>
<td>![image]</td>
<td>Distributed in the USA by</td>
</tr>
<tr>
<td>![image]</td>
<td>Information needed for United States of America Only</td>
</tr>
<tr>
<td>![image]</td>
<td>In Vitro Diagnostic Medical Device</td>
</tr>
<tr>
<td>![image]</td>
<td>Lot Number</td>
</tr>
<tr>
<td>![image]</td>
<td>Microparticles</td>
</tr>
<tr>
<td>![image]</td>
<td>Product of Germany</td>
</tr>
<tr>
<td>![image]</td>
<td>List Number</td>
</tr>
<tr>
<td>![image]</td>
<td>Serial Number</td>
</tr>
</tbody>
</table>

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Customer Service: Contact your local representative or find country-specific contact information at www.transfusion.abbott

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Revised July 2019
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Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

NAME
Alinity® Anti-HCV Calibrator Kit

INTENDED USE
The Alinity® Anti-HCV Calibrator is used to calibrate the Alinity® System when it is used for the qualitative detection of antibodies to hepatitis C virus (HCV) in human serum and plasma.

REAGENTS
Kit Contents
2 bottles of Anti-HCV Calibrator 1 contain recalcified, heat-inactivated, human plasma reactive for anti-HCV. Preservatives: ProClin 950 and sodium azide.

<table>
<thead>
<tr>
<th>Calibrator</th>
<th>Quantity</th>
<th>Color</th>
<th>Target Value (S/CO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAL 1</td>
<td>2 x 0.7 mL Green</td>
<td></td>
<td>2.86</td>
</tr>
</tbody>
</table>

S/CO = Sample to Cutoff
* Dyes: Acid Yellow No. 23 and Acid Blue No. 9

Standardization
The Anti-HCV Calibrator 1 is standardized to an Abbott internal reference standard.

Warnings and Precautions
For In Vitro Diagnostic Use

CAUTION: This product contains human-sourced and/or potentially infectious components. Refer to the REAGENTS section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.1-4

The human plasma used in the calibrator is reactive for anti-HCV and nonreactive for HBsAg, anti-HIV-1/HIV-2, and HIV-1 RNA or HIV-1 Ag.

The following warnings and precautions apply to: CAL 1

<table>
<thead>
<tr>
<th>WARNING</th>
<th>CAUTION</th>
<th>Contact with acids liberates very toxic gas.</th>
</tr>
</thead>
<tbody>
<tr>
<td>H317</td>
<td>May cause an allergic skin reaction.</td>
<td></td>
</tr>
<tr>
<td>EUH032</td>
<td>Contact with acids liberates very toxic gas.</td>
<td></td>
</tr>
</tbody>
</table>

Prevention
P281 Avoid breathing mist / vapors / spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves / protective clothing / eye protection.

Response
P302+P352 IF ON SKIN: Wash with plenty of water.
P333+P313 IF skin irritation or rash occurs: Get medical advice / attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

Disposal
P501 Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.transfusion.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity® System Operations Manual, Section 8.

Reagent Handling
• Do not pool the calibrators.
• Do not freeze.
• For a detailed discussion of handling calibrators during system operation, refer to the Alinity® System Operations Manual, Section 7.

Reagent Storage

<table>
<thead>
<tr>
<th>Storage Temperature</th>
<th>Maximum Storage Time</th>
<th>Additional Storage Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unopened</td>
<td>2 to 8°C</td>
<td>Until expiration date</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Store in an upright position.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>May be used immediately after</td>
</tr>
<tr>
<td></td>
<td></td>
<td>removal from 2 to 8°C storage.</td>
</tr>
</tbody>
</table>

Onboard

<table>
<thead>
<tr>
<th>System Temperature</th>
<th>5 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opened</td>
<td>2 to 8°C</td>
</tr>
<tr>
<td></td>
<td>Store tightly capped.</td>
</tr>
<tr>
<td></td>
<td>Store in an upright position. Do not invert calibrators prior to loading them on the system.</td>
</tr>
</tbody>
</table>
Indications of Deterioration

- Instability or deterioration should be suspected if there are precipitates, visible signs of leakage, turbidity, if calibration does not meet the appropriate package insert and/or Alinity System Operations Manual criteria, or if controls do not meet the appropriate criteria.
- For troubleshooting information, refer to the Alinity System Operations Manual, Section 10.

PROCEDURE

Materials Provided

- 06P0403 Alinity Anti-HCV Calibrator Kit

Instructions for Use

- Calibrator bottles are one-time use.
- For information on ordering calibrations and loading calibrators, refer to the Alinity System Operations Manual, Section 5.

QUALITY CONTROL PROCEDURES

- Three replicates of Calibrator 1 are automatically tested by the system. The calibrator must be priority loaded.
- Once a calibration is accepted and stored, it may be used for 14 days. During this time, all subsequent samples may be tested without further calibration unless:
  - A reagent kit with a new lot number is used.
  - Daily quality control results are outside of quality control limits used to monitor and control system performance.
- This assay may require recalibration after maintenance to critical parts or subsystems or after service procedures have been performed.
- Refer to the Alinity Anti-HCV Reagent Kit package insert and the Alinity System Operations Manual for additional information.
- A single sample of each assay control must be tested to evaluate the calibration. For information on ordering controls, refer to the Alinity System Operations Manual, Section 5.
  - Ensure that assay control values are within the ranges specified in the RESULTS section of the Alinity Anti-HCV Assay Control Kit package insert.

BIBLIOGRAPHY


Key to Symbols

- Caution
- Consult instructions for use
- Manufacturer
- Temperature limitation
- Use by/Expiration date
- Calibrator 1
- Control Number
- Contains sodium azide. Contact with acids liberates very toxic gas.
- Distributed in the USA by
- Information needed for United States of America only
- In vitro Diagnostic Medical Device
- Lot Number
- Product of Germany
- List Number
- Serial Number

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Abbott Park, IL 60064 USA

Customer Service: Contact your local representative or find country-specific contact information on www.transfusion.abbott

Revised April 2019.

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Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

**NAME**
Alinity s Anti-HCV Assay Control Kit

**INTENDED USE**
The Alinity s Anti-HCV Assay Controls are used to verify the calibration of the Alinity s System when it is used for the qualitative detection of antibodies to hepatitis C virus (HCV) in human serum and plasma.

**REAGENTS**

**Kit Contents**
- 1 x 30 tests
- CONTROL + 1 bottle of Anti-HCV Positive Control contains recalcified, heat-inactivated, human plasma reactive for anti-HCV. Preservatives: ProClin 950 and sodium azide.

<table>
<thead>
<tr>
<th>Control</th>
<th>Quantity</th>
<th>Color</th>
<th>Minimum Activity (S/CO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONTROL -</td>
<td>1 x 1.3 mL</td>
<td>None</td>
<td>Not applicable</td>
</tr>
<tr>
<td>CONTROL +</td>
<td>1 x 1.3 mL</td>
<td>Blue*</td>
<td>1.34</td>
</tr>
</tbody>
</table>

*S/CO = Sample to Cutoff
* Dye: Acid Blue No. 9

**Warnings and Precautions**

**In Vitro Diagnostic Use**

**CAUTION:** This product contains human-sourced and/or potentially infectious components. Refer to the REAGENTS section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.1-4

The human plasma used in the negative control is nonreactive for anti-HCV, HBsAg, anti-HIV-1/HIV-2, and HIV-1 RNA or HIV-1 Ag.

The human plasma used in the positive control is reactive for anti-HCV and nonreactive for HBsAg, anti-HIV-1/HIV-2, and HIV-1 RNA or HIV-1 Ag.

The following warnings and precautions apply to:

**CONTROL -** and **CONTROL +**

**WARNING:** Contains methylisothiazolone and sodium azide.

**H317** May cause an allergic skin reaction.

**ELM32** Contact with acids liberates very toxic gas.

**Prevention**
- P261 Avoid breathing mist / vapors / spray.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P280 Wear protective gloves / protective clothing / eye protection.

**Response**
- P302+P352 IF ON SKIN: Wash with plenty of water.
- P333+P313 If skin irritation or rash occurs: Get medical advice / attention.
- P362+P364 Take off contaminated clothing and wash it before reuse.

**Disposal**
- P501 Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.transfusion.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity s System Operations Manual, Section 8.

**Reagent Handling**
- Do not pool the assay controls.
- Do not freeze.

For a detailed discussion of handling assay controls during system operation, refer to the Alinity s System Operations Manual, Section 7.

**Reagent Storage**

<table>
<thead>
<tr>
<th>Storage Temperature</th>
<th>Maximum Storage Time</th>
<th>Additional Storage Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unopened</td>
<td>2 to 8°C</td>
<td>Until expiration date</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Store in an upright position.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>May be used immediately after</td>
</tr>
<tr>
<td></td>
<td></td>
<td>removal from 2 to 8°C storage.</td>
</tr>
</tbody>
</table>

**Onboard System Temperature**

| System Temperature | 15 hours | Store tightly capped. Return to refrigerated storage after use. Do not invert controls prior to loading on the system. |

Alinity s Anti-HCV
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Indications of Deterioration

• Instability or deterioration should be suspected if there are precipitates, visible signs of leakage, turbidity, or if assay controls do not meet the appropriate package insert criteria.
• For troubleshooting information, refer to the Alinity s System Operations Manual, Section 10.

PROCEDURE

Materials Provided

• 06P0420 Alinity s Anti-HCV Assay Control Kit

Instructions for Use

For troubleshooting information, refer to the Alinity s System Operations Manual, Section 10.

QUALITY CONTROL PROCEDURES

• The Alinity s Anti-HCV Assay Controls must be tested once every 24 hours when the system is being used.
• Assay control values must be within the ranges specified in the RESULTS section of this package insert. 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 the Alinity s System Operations Manual, Section 10.
• Refer to the Alinity s Anti-HCV Reagent Kit package insert and the Alinity s System Operations Manual for additional information.

RESULTS

The following table details the acceptable Sample to Cutoff ratio (S/CO) specifications for the Alinity s Anti-HCV Assay Controls.

<table>
<thead>
<tr>
<th>Assay Control</th>
<th>S/CO Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>CONTROL -</td>
<td>≤ 0.58</td>
</tr>
<tr>
<td>CONTROL +</td>
<td>1.34 - 6.86</td>
</tr>
</tbody>
</table>

BIBLIOGRAPHY


Key to Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>☢️</td>
<td>Caution</td>
</tr>
<tr>
<td>📚</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>🛠️</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>🌡️</td>
<td>Sufficient for</td>
</tr>
<tr>
<td>🌡️</td>
<td>Temperature limitation</td>
</tr>
<tr>
<td>🕒</td>
<td>Use by/Expiration date</td>
</tr>
<tr>
<td>🌡️</td>
<td>Control Number</td>
</tr>
<tr>
<td>🌡️</td>
<td>Contains sodium azide. Contact with acids liberates very toxic gas.</td>
</tr>
<tr>
<td>☢️</td>
<td>Negative Control</td>
</tr>
<tr>
<td>🌡️</td>
<td>Positive Control</td>
</tr>
<tr>
<td>🌡️</td>
<td>Distributed in the USA by</td>
</tr>
<tr>
<td>🌡️</td>
<td>Information needed for United States of America only</td>
</tr>
<tr>
<td>🌡️</td>
<td>In vitro Diagnostic Medical Device</td>
</tr>
<tr>
<td>🌡️</td>
<td>Lot Number</td>
</tr>
<tr>
<td>🌡️</td>
<td>Product of Germany</td>
</tr>
<tr>
<td>🌡️</td>
<td>List Number</td>
</tr>
<tr>
<td>🌡️</td>
<td>Serial Number</td>
</tr>
</tbody>
</table>

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Instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from these instructions.

**NAME**

Alinity s Anti-HCV Release Control Kit

**INTENDED USE**

The Alinity s Anti-HCV Release Control is used to validate the Alinity s System functionality and release sample results when it is used for the qualitative detection of antibodies to hepatitis C virus (HCV) in human serum and plasma.

**REAGENTS**

**Kit Contents**

25 x 20 tests

<table>
<thead>
<tr>
<th>Control</th>
<th>Quantity</th>
<th>Color</th>
<th>Minimum Activity (S/CO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>S/CO = Sample to Cutoff</td>
<td>25 x 1.1 mL</td>
<td>Blue</td>
<td>1.34</td>
</tr>
</tbody>
</table>

*a Dye: Acid Blue No. 9

**Warnings and Precautions**

**In Vitro** Diagnostic Use

**CAUTION:** This product contains human-sourced and/or potentially infectious components. Refer to the REAGENTS section of this package insert. No known test method can offer complete assurance that products derived from human sources or inactivated microorganisms will not transmit infection. Therefore, all human-sourced materials should be considered potentially infectious. It is recommended that these reagents and human specimens be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.1-4

The human plasma used in the release control is reactive for anti-HCV and nonreactive for HBsAg, anti-HIV-1/HIV-2, and HIV-1 RNA or HIV-1 Ag.

The following warnings and precautions apply to:

**RELEAS CONTROL**

- **WARNING:** Contains methylisothiazolone and sodium azide.
- **H317** May cause an allergic skin reaction.
- **EUH032** Contact with acids liberates very toxic gas.

**Prevention**

- **P261** Avoid breathing mist / vapors / spray.
- **P272** Contaminated work clothing should not be allowed out of the workplace.
- **P280** Wear protective gloves / protective clothing / eye protection.

**Response**

- **P302+P352** IF ON SKIN: Wash with plenty of water.
- **P333+P313** If skin irritation or rash occurs: Get medical advice / attention.
- **P362+P364** Take off contaminated clothing and wash it before reuse.

**Disposal**

- **P501** Dispose of contents / container in accordance with local regulations.

Safety Data Sheets are available at www.transfusion.abbott or contact your local representative.

For a detailed discussion of safety precautions during system operation, refer to the Alinity s System Operations Manual, Section 8.

**Reagent Handling**

- Do not pool the release controls.
- Do not freeze.
- For a detailed discussion of handling release controls during system operation, refer to the Alinity s System Operations Manual, Section 7.

**Reagent Storage**

<table>
<thead>
<tr>
<th>Storage Temperature</th>
<th>Maximum Storage Time</th>
<th>Additional Storage Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 to 8°C</td>
<td>Until expiration date</td>
<td>Store in an upright position. May be used immediately after removal from 2 to 8°C storage.</td>
</tr>
</tbody>
</table>

| System Temperature | 24 hours | 14 days | Store tightly capped. Return to refrigerated storage after use. Do not invert controls prior to loading on the system. |

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Part 3 Other Labeling Page 6
Indications of Deterioration

- Instability or deterioration should be suspected if there are precipitates, visible signs of leakage, turbidity, or if the release control does not meet the appropriate package insert criteria.
- For troubleshooting information, refer to the Alinity’s System Operations Manual, Section 10.

PROCEDURE

Materials Provided

- 06P0424 Alinity’s Anti-HCV Release Control Kit

Instructions for Use

For information on ordering release controls, refer to the Alinity’s System Operations Manual, Section 5.

QUALITY CONTROL PROCEDURES

- The Alinity’s Anti-HCV Release Control must be tested in order to release test results. The release control is tested at user-defined intervals. For configuring the release control, refer to the Alinity’s System Operations Manual, Section 2. For manually ordering the release control, refer to the Alinity’s System Operations Manual, Section 10.
- The release control must meet the specifications defined in the RESULTS section of this package insert in order to validate the system functionality and release test results. If the release control does not meet specifications, refer to the Alinity’s System Operations Manual, Section 10, for additional information.
- Refer to the Alinity’s Anti-HCV Reagent Kit package insert and the Alinity’s System Operations Manual for additional information.

RESULTS

The acceptable Sample to Cutoff ratio (S/CO) specification for the Alinity’s Anti-HCV Release Control is shown below.

\[
\text{RELEASE CONTROL, S/CO Range: 1.34 - 6.86}
\]

BIBLIOGRAPHY


Key to Symbols

- Caution
- Consult instructions for use
- Manufacturer
- Sufficient for
- Temperature limitation
- Use by/Expiration date
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