| **Hepatitis C Antibody Screen (Anti-HCV)** | |
| --- | --- |
| **Purpose** | This procedure provides instructions for performing ARCHITECT Anti-HCV on the Abbott Architect i1000SR. |
| **Policy Statements** | This procedure applies to all personnel responsible for performing testing on the Abbott Architect i1000SR. |
| **Principle** | The ARCHITECT Anti-HCV assay is a two-step immunoassay, using chemiluminescent microparticle immunoassay (CMIA) technology, for the qualitative detection of anti-HCV in human serum and plasma.  In the first step, sample, recombinant HCV antigen coated paramagnetic microparticles and Assay Diluent are combined. Anti-HCV present in the sample binds to the HCV coated microparticles. After washing, anti-human acridinium-labeled 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 anti-HCV in the sample and the RLUs detected by the ARCHITECT i\* System optics.  The presence or absence of anti-HCV in the specimen is determined by comparing the chemiluminescent signal in the reaction to the cutoff signal determined from a previous ARCHITECT Anti-HCV calibration. If the chemiluminescent signal in the specimen is greater than or equal to the cutoff signal, the specimen is considered reactive for anti-HCV.  For additional information on system and assay technology, refer to the ARCHITECT System Operations Manual, Section 3.  \* i = immunoassay |
| **Clinical Significance** | The ARCHITECT Anti-HCV assay is a chemiluminescent microparticle immunoassay (CMIA) for the qualitative detection of antibody to hepatitis C virus (anti-HCV) in human serum and plasma including specimens collected post-mortem (non-heart-beating). The HCV assay is intended to be used as an aid in the diagnosis of Hepatitis C infection.  HCV is a bloodborne virus. Serological studies employing EIAs for detection of antibodies to recombinant antigens of HCV have established HCV as the cause of most bloodborne as well as community-acquired10 non-A, non-B hepatitis. The presence of anti-HCV indicates that an individual may have been infected with HCV, may harbor infectious HCV, and/or may be capable of transmitting HCV infection. Although the majority of infected individuals may be asymptomatic, HCV infection may develop into chronic hepatitis, cirrhosis, and/or increased risk of hepatocellular carcinoma. The implementation of blood donation screening for anti-HCV by EIAs has led to a marked decline in the risk of transfusion-transmitted hepatitis. |
| **Instrument** | **PRIMARY METHOD:** Abbott Architect i1000SR  Backup Method**:** Mayo Medical Laboratories |
| **Sunquest Test Code** | AHCV |
| **Specimen** | **Preferred Container:** SST (gold, marble) or Red no gel  **Preferred Draw Volume:** 4.5 mL blood  **Minimum Processed Volume:** 1.1 mL serum  Note: Minimum volume does not permit repeat analysis  **Stability:** 7 days refrigerated at 2-8°C  2 years frozen at -20°C  **Transport:** Ship refrigerated to Minneapolis laboratory.  **Rejection:**Specimens not removed from red cells within two hours of collection, mislabeled or unlabeled specimens**,** or grossly hemolyzed specimens.  **Preparation:**   1. Serum specimens should be centrifuged following complete clot formation, according to Specimen Processing procedures prior to analysis. **For accurate results, serum and plasma specimens should be free of fibrin, red blood cells, and other particulate matter.** (Serum specimens from patients receiving anticoagulant or thrombolytic therapy may contain fibrin due to incomplete clot formation.) 2. Serum or plasma should be physically separated from cells as soon as possible with a maximum limit of two hours from the time of collection. 3. Lipemic samples should be ultrafuged. 4. Specimens should be free of particulate matter. 5. Transfer serum or plasma to a properly labeled sendout tube. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time. |
| **Reagents** | |  |  |  |  | | --- | --- | --- | --- | | ***Product Description*** | ***Product Code*** | ***Stability*** | | | Anti-HCV reagent | 01L7925 | **Store at:** 2 – 8 °C  **Unopened/Opened:** Manufacturer expiration date.  **On-board:** 30 Days | | Anti-HCV calibrator | 01L7901 | **Store at:**  2-8°C  **Unopened**: Manufacturer expiration date.  **Opened**: Store at 2 – 8 °C, stable until expiration date when stored and handled as directed. | | Pre-Trigger Solution | 06E23-65 | Refer to Supply Status on Analyzer | | Trigger Solution | 06C55-60 | Refer to Supply Status on Analyzer | | Wash Buffer | 06C54-58 | Refer to Supply Status on Analyzer | | Reaction Vessels | 07C15 (-02 or -03) | N/A | |
| **Risk and Safety:** | Contains sodium azide. Avoid contact with skin and eye. Causes serious eye irritation. Wear gloves. Contact with acids liberates very toxic gas. Recap and dispose of in appropriate Hazardous Waste Container, unless reagent bottles are empty, in which case they may be disposed of in regular trash. |
| Calibration/ Verification/AMR | |  |  | | --- | --- | | Analytical Measuring Range: | 0-999999.0 S/CO | | Reference Material: | Abbott Architect HCV 2.0 Calibrator 01L7901 | | Suggested Calibration Levels | See Calibrator Package insert | | Verification Scheme: | n=6 | | Verification Frequency: | * For each new lot of reagent * After major maintenance or service, if indicated by quality control results * As indicated in laboratory quality control procedures | | AMR | Verification of AMR is accomplished with each calibration.   * Cal Verification and AMR verification are performed at least once every six (6) months | |  | | | |
| **Quality Control** | Bio-Rad Viroclear Control, and Bio-Rad Virotrol 2  **Frequency:** Run both controls each day of use.  **Stability:** 60 Days at 2-8°C.  **Sunquest Control name:** C-VIROC (Viroclear) C-VIRO2 (Virotrol 2)  **Acceptable ranges:**   * Ranges are current in Sunquest and the instrument. Refer to the Quality Control in Chemistry procedure for QC exception codes. * If a control value is outside the confidence interval, the determination must be repeated. If the repeat determination confirms the deviation, a new reference curve should be established. * Do not release patient results until the cause of deviation has been identified and corrected * When a new lot of assayed control is received, validate the manufacturer’s insert range by running the new lot in parallel with the current lot, and confirming that the results obtained are within the stated range * When a new lot of unassayed control is received, verify new ranges by running the new lot in parallel with the current lot 30 times, and calculate a new range using the method mean ± 3 SD. Ranges are current in Sunquest and the instrument. Refer to the Quality Control Procedure for QC exception codes. |
| **Reference Range** | 0.00-0.79 S/CO Nonreactive  0.80-0.99 S/CO Equivocal  >1.00 S/CO Reactive |
| **Critical Values** | None specified |
| **Limitations** | Technical Range 0-99999999 S/CO   * The instrument reporting system contains error messages to warn the operator of specific malfunctions. Refer to Operator’s Manual for troubleshooting specific error messages. * Heterophile antibodies may interfere with immunoassay testing. * For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute or chronic infection. * If antibodies to HCV are not detected this does not exclude the possibility of exposure to HCV. * A reactive Anti-HCV does not exclude co-infection by another hepatitis virus. * Antibody levels below the detection of this assay or antibodies not reacting to the recombinant antigens used in this assay will yield nonreactive results. * Immunocompromised patients who have HCV may produce levels of antibodies below the sensitivity of this assay and may not be detected as reactive. * Results obtained from the architect Anti-HCV assay may not be used interchangeably with values obtained with different manufacturer’s assay methods. * No common interferents were recognized in testing by Abbott Laboratories. |
| **Dilutions** | Do not dilute |
| **Result Reporting**  **Result Reporting (cont.)** | The result that will cross over in OEM will be Reactive, Nonreactive or Equivocal. Each result will have the comment “Check procedure for repeat and interpretation protocol.” Use the interpretation chart on page 5 of this procedure to determine if a retest is required. If a repeat test is not needed (specimen is nonreactive), manually accept the Sunquest result.  **If retesting is required** :   1. Reject the cup in OEM. 2. Take specimen off the analyzer and check for clots, red cells, or other particulate matter. **Recentrifuge if any are seen or suspected.** 3. Manually order the specimen **in duplicate** (two replicates) with an ‘R’ in front of the accession number to signify the accession number that crosses OEM is a retest. For example, accession number “H111” would be manually ordered in the Architect as “RH111” with 2 replicates. 4. When testing is complete, both results will cross into Sunquest in two different cups. 5. To accept results in Sunquest, you will have to manually retype the correct accession number without the (R) for the result you wish to report in OEM. Sunquest will ask CHANGE EXISTING ACCESSION NUMBER (Y/<N>). Type Y then press ENTER to enter the accession number for the cup you wish to report. 6. **\*Go to the analyzer and check results**\* 7. If both repeat tests are <0.8 (non reactive), then manually accept the Sunquest result of nonreactive. 8. If both of the repeat tests are ≥0.8 to <0.99 (equivocal), then manually accept the Sunquest result of equivocal. 9. If one of the repeat tests are <0.8 **or** >1 and the other test is ≥0.8 or < 1 equivocal, then you must (M) modify the result in Sunquest. When modifying results, you must enter the equivocal **numeric result** from the analyzer. Sunquest will append an equivocal comment. **Do not free text the result in Sunquest because the correct interpretation will not append**. 10. If both repeat tests are >1 (reactive), accept one of the numeric reactive results. Mayo Medical Laboratories test HCVQN will automatically reflex for confirmation and a label will print. Place label on sample and place in the Send outs freezer for transport to MML.      |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Initial Result** | **Retest Result** | **Result** | **Interpretation** | **What to enter into Sunquest** | | <0.79 S/CO | No Retest Required | Nonreactive | Antibodies to HCV are not detected: does not exclude the possibility of exposure to HCV | Accept Result | | ≥0.8 S/CO to < 1 S/CO | Both of the duplicate retests are <0.8 S/CO | Nonreactive | Antibodies to HCV are not detected: does not exclude the possibility of exposure to HCV | Accept Result of Nonreactive | | One or both of the duplicate retest results are ≥0.8 S/CO to <1 S/CO | Equivocal | “Antibodies to HCV may or may not be present: recommend repeat testing with another specimen.” | Modify the Result and **enter the Numerical Value** from the Architect **(result should be ≥0.80 and <1)** | | Both of the duplicate retests are >1.0 S/CO | Reactive | “Presumptive evidence of antibodies to HCV. Confirmatory testing reflexed.” Send to MML (HCVQN)  **Freeze 0.8mL Serum immediately** | Accept Result of Reactive. | | ≥1.0 S/CO | No Retest Required | Reactive | “Presumptive evidence of antibodies to HCV. Confirmatory testing reflexed.” Send to MML (HCVQN)  **Freeze 0.8mL Serum immediately** | Accept Result of Reactive. | |
| **Specimen Storage** | Promptly stopper tested specimen and store upright in specimen rack. Every 8 hours remove specimens to refrigerator/freezer storage. Samples are retained 14 days in specimen storage freezer. |
| **References** | 1. Abbott Architect HCV 2.0 Package insert, Abbott Diagnostics, Abbott Park, IL 60064. Revised November 2015 2. Bio-Rad Viroclear Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618 July 2017. 3. Bio-Rad Virotrol II Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618 October 2017. |
| **Historical Record** | |  |  |  |  | | --- | --- | --- | --- | | **Version** | **Written/Revised By** | **Effective Date** | **Summary of Revisions** | | 1 | Stephen Gripentrog/Erin Bartos | May 15, 2018 | New Procedure | |  |  |  |  | |  |  |  |  | |