

# Lab Testing Update

## HCV RIBA Testing No Longer Available

St Elizabeth Healthcare  
1 Medical Village Drive  
Edgewood KY 41017  
Lab - 859-301-2170

Attention: Medical Staff

From: SEH Laboratory  
Jackson Pemberton, MD  
Medical Director SEH Laboratories

**Effective immediately, St. Elizabeth Healthcare Laboratory cannot offer reflex testing to HCV RIBA supplemental/confirmatory on reported Positive HCV Antibody testing.**

St. Elizabeth Healthcare Laboratory has provided reflex testing to HCV RIBA supplemental assay for Low Positive (<5 serum/cutoff ratio- Abbott Architect Platform) Hepatitis C Antibody. Due to a nationwide shortage of material, HCV RIBA testing is no longer available. Currently, no resolution to the material shortage has been provided.

The suggested protocol for reported Low Positive HCV Antibody (<5 S/CO ratio) is to consider an alternative test for supplemental/confirmatory testing. Please consider ordering an alternate method of supplemental/confirmatory testing such as Quantitative PCR for HCV RNA.

Unfortunately, this supplemental/confirmatory testing will require that patients be redrawn as this test cannot be added-on to existing specimens in the laboratory.

Please see the attached document from our reference Laboratory (ARUP) where testing is performed.

If you have any questions, please contact Dr. Jay Pemberton at (859) 301-2357.

We will update you on any status change or return to reflex testing with HCV RIBA should it occur.

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### Hepatitis C Virus Antibody (RIBA), Supplemental (ARUP test code 0020104) and Related Tests

As previously communicated on 2/19/2011, ARUP Laboratories was notified of a nationwide backorder of the reagent for Hepatitis C Virus (HCV) Antibody (RIBA), Supplemental (ARUP test code 0020104). The vendor has provided no plan for resolution of the backorder in the near future.

ARUP is experiencing no test delays at this time; however, the current supply will be exhausted on or before 4/4/2011. Effective April 4, 2011, as described in the accompanying Immediate Hot Line, ARUP will inactivate the test codes that include the Hepatitis C Virus (HCV) Antibody (RIBA). Any orders received for this testing, subsequent to use of the last reagent, will be managed through the ARUP exception handling process.

As described in the original communication on 2/19/2011, ARUP recommends ordering Hepatitis C Virus RNA Quantitative, Real-Time PCR (ARUP Test Code 0098268) for follow up to a low positive Hepatitis C Virus Antibody by CIA and in lieu of the inactivated HCV RIBA. **Please note that due to stringent specimen integrity requirements for testing by PCR, this test may not be performed on a specimen previously submitted for antibody testing.**

### Hepatitis C Virus RNA Quantitative, Real-Time PCR (ARUP test code 0098268)

**Specimen Required:** **Collect:** Two 6 mL serum separator tubes, two plasma preparation tubes, or two 5 mL lavender (EDTA) or pink (K<sub>2</sub>EDTA).

**Specimen Preparation:** Separate from cells within 6 hours.

**Storage/Transport Temperature:** 3 mL serum or plasma, frozen. (Min: 1.5 mL) Submit specimen in an ARUP Standard Transport Tube. Specimens collected in a PPT should be submitted in original container. Submit specimen according to Biological Substance, Category B, shipping guidelines.

**Remarks:** **Separate specimens must be submitted when multiple tests are ordered.** Separate serum or plasma from cells within six hours.

**Unacceptable Conditions:** Heparinized specimens.

**Stability (collection to initiation of testing):** Ambient: 6 hours (on cells); Plasma or serum removed from cells: Refrigerated: 72 hours; Frozen: 6 weeks