



State of Utah
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Utah Department of Health

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Executive Director

Division of Disease Control and Prevention

Robyn M. Atkinson-Dunn, Ph.D, HCLD/PHLD
Director, Utah Public Health Laboratory

Date: March 1, 2019

Subject: In house HCV viral load testing at UPHL

Dear Clients of the Utah Public Health Laboratory,

We are pleased to announce that beginning March 15, 2019, UPHL will offer a nucleic acid amplification test (NAAT) for detection of the Hepatitis C virus (HCV) and quantitation of viral loads. We have validated and implemented the Aptima HCV Quant Dx assay by Hologic. This is an FDA approved NAAT based on transcription mediated amplification with a lower limit of quantification of 10 IU/mL. The implementation of this test at UPHL will allow us to verify positive serological results and perform the CDC-recommended algorithm entirely in house. UPHL will also be able to assist in Pre-treatment and On-treatment monitoring. Please note that the Aptima HCV Quant Dx assay is not approved for use as a screening test for the presence of HCV in blood products.

The test is performed once a week on Fridays and results will be provided between 1 to 7 days from receipt of the specimen. The cost of this test is \$75.

- Clients submitting specimens for HCV primary diagnosis will need to mark both the "Hepatitis C Antibody" and "HCV RNA testing if Positive" box on our requisition (<https://uphl.utah.gov/wp-content/uploads/ID-test-request-form-2018.pdf>).
- Clients ordering the NAAT for a patient already diagnosed with HCV must specify that in the "comments" section at the bottom of the form.
- The Aptima HCV Quant Dx assay requires a minimum of 1.2 mL of plasma or serum.
- Whole blood can be collected in tubes for the preparation of plasma or serum and submitted to the lab prior to centrifugation. However, it must reach the UPHL within 6 hours of collection. If centrifuged at the collection site, plasma and serum samples have a stability of 5 days when kept refrigerated in their primary collection tube. Separated plasma and serum can be transferred to a secondary tube following centrifugation and be stored frozen for maximal stability (60 days).

Please review the attached specimen collection guidelines to help evaluate your process and transport times. Laboratory staff can help answer any specimen-related questions (jharbour@utah.gov).

As a reminder, UPHL has a FREE courier service available to clients. Any requests for specimen transport should be directed to Nancy Arbon (narbon@utah.gov).

We look forward to assisting you in caring for HCV infected individuals and improving surveillance for this disease in our community.

Sincerely,

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Specimen Collection and Storage

Note: Handle all specimens as if they contain potentially infectious agents. Use Universal Precautions.

Note: Take care to avoid cross-contamination during sample handling steps. For example, discard used material without passing over open tubes.

Note: Only plastic secondary tubes are recommended for storage.

Whole blood specimens collected in the following glass or plastic tubes may be used:

- Tubes containing ethylenediaminetetraacetic acid (EDTA) or acid citrate dextrose (ACD) anticoagulants or
- Plasma preparation tubes (PPTs)
- Serum tubes
- Serum separator tubes (SSTs)

For serum, allow the clot to form before further processing.

A. Specimen Collection

Whole blood can be stored at 2°C to 30°C and must be centrifuged within 6 hours of specimen collection. Separate the plasma or serum from the pelleted red blood cells following the manufacturer's instructions for the tube used. Plasma or serum can be tested on the Panther system in a primary tube or transferred to a secondary tube such as the Aptima Specimen Aliquot Tube. To obtain the 500 µL reaction volume, the minimum volume of plasma or serum for primary collection tubes is up to 1200 µL and for secondary tubes, the minimum volume is 700 µL. The following table identifies dead volume requirements for each primary and secondary tube type.

Tube (Size and Type)	Dead Volume on Panther
Aptima Sample Aliquot Tube (SAT)	0.2 mL
12x75 mm	0.5 mL
13x100 mm	0.5 mL
13x100 mm with Gel	0.3 mL
16x100 mm with Gel	0.7 mL

If not tested immediately, plasma and serum can be stored in accordance with the specifications below. If transferred to a secondary tube, plasma or serum may be frozen at -20°C. Do not exceed 3 freeze–thaw cycles. Do not freeze specimens in EDTA, ACD, or serum primary collection tubes.

B. Specimen Storage Conditions

1. EDTA and ACD Plasma Specimens

Whole blood can be stored at 2°C to 30°C and must be centrifuged within 6 hours of specimen collection. Plasma may then be stored under one of the following conditions:

- In the primary collection tube or secondary tube at 2°C to 25°C for up to 24 hours,
- In the primary collection tube or secondary tube at 2°C to 8°C for up to 5 days, or
- In the secondary tube at -20°C for up to 60 days.

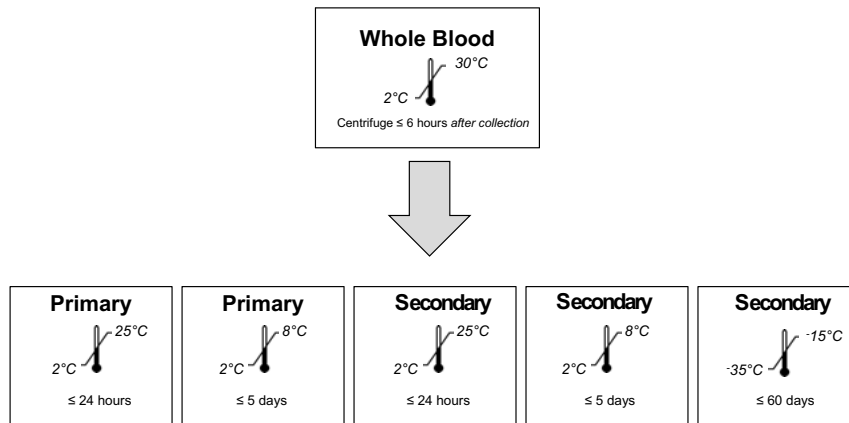


Figure 1. Storage Conditions for EDTA/ACD Tubes

2. PPT Specimens

Whole blood can be stored at 2°C to 30°C and must be centrifuged within 6 hours of specimen collection. Plasma may then be stored under one of the following conditions:

- In the primary collection tube or secondary tube at 2°C to 25°C for up to 24 hours,
- In the primary collection tube or secondary tube at 2°C to 8°C for up to 5 days, or
- In the primary collection tube or secondary tube at -20°C for up to 60 days.

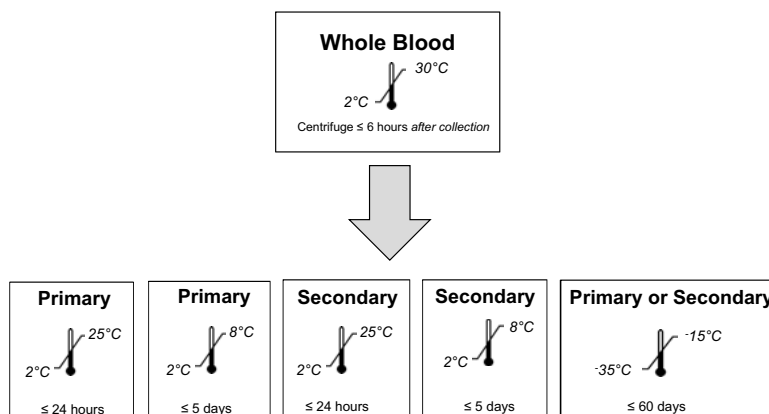


Figure 2. Storage Conditions for PPTs

3. Serum Tube Specimens

Whole blood can be stored at 2°C to 30°C and must be centrifuged within 6 hours of specimen collection. Serum may then be stored under one of the following conditions:

- In the primary collection tube or secondary tube at 2°C to 30°C for up to 24 hours,
- In the primary collection tube or secondary tube at 2°C to 8°C for up to 5 days, or
- In the secondary tube at -20°C for up to 60 days.

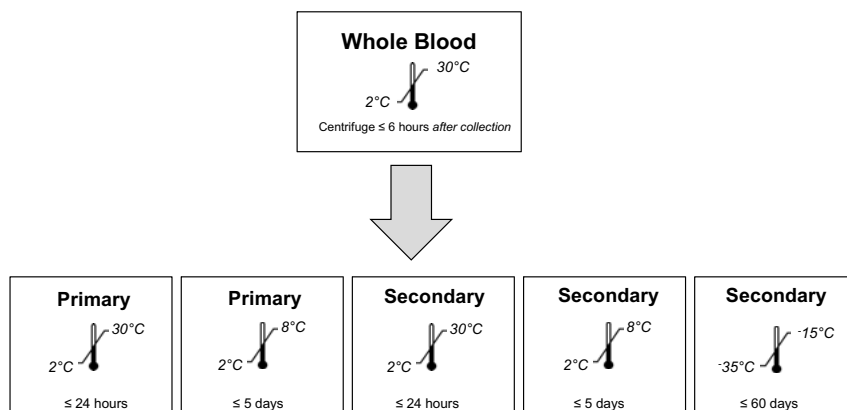


Figure 3. Storage Conditions for Serum Tubes

4. SST Specimens

Whole blood can be stored at 2°C to 30°C and must be centrifuged within 6 hours of specimen collection. Serum may then be stored under one of the following conditions:

- In the primary collection tube or secondary tube at 2°C to 30°C for up to 24 hours,
- In the primary collection tube or secondary tube at 2°C to 8°C for up to 5 days, or
- In the primary collection tube or secondary tube at -20°C for up to 60 days.

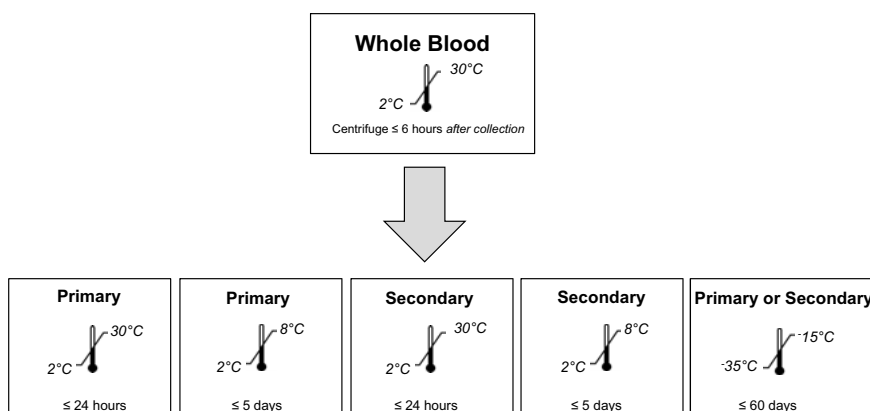


Figure 4. Storage Conditions SSTs

C. Long Term Frozen Storage

Plasma or serum samples may be stored at -65°C to -85°C for up to 60 days in SATs.

D. Dilution of Plasma and Serum Specimens

Plasma and serum specimens may be diluted in the SAT or secondary tube for testing on the Panther system. See *Panther System Test Procedure*, step E.6 below for more information.

⚠ *A diagnostic interpretation should not be made from a "Not Detected" result for serum or plasma specimens that have been diluted. Obtain a new, undiluted specimen and retest.*

Note: *If a specimen is diluted, it should be tested immediately after dilution. Do not freeze a diluted specimen.*

Samples Onboard the Panther System

Samples may be left on the Panther system uncapped for up to 8 hours. Samples may be removed from the Panther system and tested as long as the total time onboard does not exceed 8 hours prior to the pipetting of the sample by the Panther system.

Specimen Transport

Maintain sample storage conditions as described in *Specimen Collection and Storage*.

Note: *Specimens must be shipped in accordance with applicable national, international, and regional transportation regulations.*