

HPV HR AND HPV 16/18: SPECIMEN TYPE, COLLECTION, TRANSPORT, STORAGE AND PROCESSING

Specimen Type and Collection

Cervical specimens should be collected in PreservCyt® Solution, the ThinPrep® Pap Test preservation system, using a broom-type device, or Endocervical Brush/ Spatula. For Cervista™ HPV HR testing, cervical specimens can be stored at room temperature (20-30°C) in PreservCyt® Solution for up to 18 weeks prior to performing the test. Solution specimens cannot be frozen.

All necessary patient information is provided in Cerner. Labels are generated upon ordering and all specimen is transported to the Cytology Laboratory. See details on the Ordering Primer. Insure proper specimen barcode label(s) are on collected specimen.

Transport of Specimen

Collected specimen will be transported in containers containing PreservCyt solution at room temperature by courier from the Cytology Laboratory after Pap smear slides have been prepared for patients 30 years and over and after diagnosis of ASCUS in patients less than 30 years old but more than 21 years old. See details on the Test Ordering Primer. Samples are then routed to the Molecular Pathology Laboratory located at the 4th floor of the BSB, Room 4-128.

Sample Accessioning, Storage and Processing at the Molecular Pathology Laboratory

It is essential that each sample be received and identified, verified, and processed correctly.

1. Patient and specimen information, including name, age, clinical information, physician's name and date of collection are to be verified. Follow LIS Accessioning instructions on separate binder.
2. Evaluate specimen according to criteria enumerated below.
3. If specimen is acceptable, it is then placed in a box at room temperature that is strictly for incoming specimens in Room 4-125 (Sample Preparation Room) for HPV HR and HPV 16/18 testing.
4. Notify the Supervisor or the Director immediately if there is any confusion or if an error is suspected.
5. Store cervical samples in designated box at room temperature until processed.
6. Using the three-rack system, take 2.0 mL of the sample to be processed for DNA extraction, the rest is saved as back-up until the report is issued. **NO ALIQUOT IS EVER RETURNED TO THE ORIGINAL CONTAINER!!!**
7. The remainder of the sample will be kept at room temperature for the duration of testing or up to a period of 18 weeks, if necessary. Extracted DNA may be kept at 4°C for a period of 6 weeks.
8. Turn around time for most nucleic acid-based tests is 2-3 weeks from receipt of specimen in the Molecular Pathology Laboratory.

9. Retention of records and materials/specimen will be according to LAB Policies (LAB-35).

Evaluation of Specimen

To avoid contamination, specimen receiving and processing will be done in Room BSB 4-127B. The criteria in rejecting specimen and action to be taken that are enumerated under the General Lab-11 Policy will be implemented. The following criteria are specific to Molecular Pathology Laboratory specimen for HPV HR and HPV 16/18:

Acceptance Criteria

1. Cervical specimen collected into proper PreservCyt collection solution using prescribed collection device(s).
2. At least 5 mL of sample and placed in a properly capped container.
3. Uncontaminated, unfrozen, and not outdated sample

Rejection Criteria

1. Inappropriately ordered test
2. Unlabeled and/or mislabeled containers
3. Duplicate samples
4. Empty collection tube or insufficient quantity
5. Grossly bloody
6. Soiled tube or evidence of leakage
7. Contaminated with contraceptive jelly and/or anti-fungal creams
8. Outdated specimen (beyond 18 weeks at room temperature)
9. Frozen specimen

If a sample is rejected, the laboratory notifies the physician/location and request repeat collection with corrective action depending on the reason for rejection. Proper documentation is necessary.