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MOLECULAR DIAGNOSTICS SPECIMEN COLLECTION AND TRANSPORT

I. CHLAMYDIA TRACHOMATIS / NEISSERIA GONORRHEAE by Panther Aptima Combo 2

SPECIMEN COLLECTION

Turn around time goal for result is 48 hours.

Note: All specimens should be properly labeled at the time of collection with the patient's name and at least one other unique identifying qualifier (example: Account number, Date of Birth, or Social Security Number). Refer to Specimen Rejection Criteria.

Endocervical Swab Specimen Collection:

1. Use only swabs with Unisex collection swab device kit.
2. Remove excess mucus from the endocervix with the cleaning swab (white shaft swab with red printing) provided in the unisex collection swab device kit and discard. The presence of mucus in cervical samples may inhibit PCR and cause false negatives.
3. Insert the collection swab (blue shaft swab with green printing) into the endocervix and rotate the swab for 10-30 seconds.
4. Unscrew the tube cap being careful not to spill the transport tube media. Verify that all swab transport media is at the bottom of the tube.
5. Insert the swab into the transport tube so that the tip of the swab is visible below tube label. Carefully break off the plastic shaft at the score line against the side of the tube. Discard broken top portion of swab shaft and re-cap transport tube tightly.
6. Any transport tube received without a swab or with both the cleaning and collection swabs will be rejected and a recollection will be required.
7. Label the transport tube with the patient's name, account number, and date of collection.

Male Urethral Swab Specimen Collection:

Note: Patient should not have urinated for at least 1 hour prior to specimen collection.

1. Discard the cleaning swab (white shaft swab with red printing).
2. Insert the collection swab (blue shaft swab with green printing) 2-4 cm into the urethra and rotate the swab clockwise for 2-3 seconds to ensure adequate sampling.
3. Unscrew the tube cap being careful not to spill the transport tube media. Verify that all swab transport media is at the bottom of the tube.
4. Insert the swab into the transport tube so that the tip of the swab is visible below tube label. Carefully break off the plastic shaft at the score line against the side of the tube. Discard broken top portion of swab shaft and re-cap transport tube tightly.
5. Any transport tube received without a swab will be rejected and a recollection will be required.
6. Label the transport tube with the patient's name, account number, and date of collection.

Urine Specimens (Male and Female): If transported within 24 hours.

Note: Patient should not have urinated for at least 1 hour prior to specimen collection.

1. Collect 20-30mL of first catch urine (the initial urine stream or "dirty catch") into a clean polypropylene container without preservatives. Note: Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity.
2. Female patients should NOT cleanse area prior to providing the specimen.
3. Seal the specimen container. Label the container with the patient's name, account number, and date of collection.

Urine Specimens (Male and Female): If delay in transport.

Note: Patient should not have urinated for at least 1 hour prior to specimen collection.

1. Collect 20-30mL of first catch urine (the initial urine stream or "dirty catch") into a clean polypropylene container without preservatives. Note: Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity.
2. Female patients should NOT cleanse area prior to providing the specimen.
3. Remove cap from urine specimen transport tube and transfer 2 mL of urine into the urine transport tube using the disposable pipette. Note: The correct volume of urine has been added when fluid level is between black fill lines on urine specimen transport tube label.
4. Seal the specimen container. Label the container with the patient's name, account number, and date of collection.

CYTYC PreservCyt (Thin Prep PAP) Collection:

1. Specimens in CYTYC PreserCyt Solution should be collected in the routine manner.
2. Refer to the CYTYC PreservCyt package insert or Cytology for detailed instructions on Specimen Collection.
3. On site, technical staff will vortex Thin Prep PAP sample and transfer 1 mL of fluid from PAP to Aptima specimen transfer tube.

SPECIMEN TRANSPORT:**Swab specimens (Male and Female) collected in Swab collection tube transport media:**

- Swab specimens may be transported to the test site at 2-30°C.
- Swab specimens that require shipment to off-site laboratories should be shipped at refrigerated temperature as soon as possible after collection. Follow the Lab's procedure for transport of Chlamydia culture specimens.

Urine Specimens (Male and Female):

- Urine specimens may be transported in sterile collection cup with no preservative to the test site at 2-30°C provided that transport time is less than 24 hours.
- Urine specimens that require shipment to off-site test centers (greater than 24 hour transport) must be transferred to a urine specimen transport tube. Urine specimen transport tube with specimen may be transported at 2-30°C.

Specimens in CYTYC PreservCyt (Thin Prep Pap) Solution:

- May be transported at 2-30°C.

SPECIMEN STORAGE**Swab specimens (Male and Female) collected in swab collection tube transport media:**

- Swab specimens in swab collection transport tube may be stored at 2-30°C for up to 60 days.
- Swab specimens that cannot be processed within 60 days of collection must be stored at 20°C or colder and tested within 12 months of collection.
- Swab specimens that have been tested will be stored at 15-30°C for 7 days if negative and at -20°C or colder for up to three months if positive.

Urine Specimens (Male and Female):

- Urine specimens that have been processed (transferred into the urine specimen transport tube) may be stored at 2-30°C for up to 30 days.
- Urine specimens in urine specimen transport tubes may be stored for up to 12 months after collection if stored at -20°C or colder.
- Urine specimens that have been tested will be stored at 15-30°C for 7 days if negative and at -20°C or colder for up to three months if positive.

Specimens in CYTYC PreservCyt (Thin Prep Pap) Solution:

- PAP specimens transferred into the Aptima specimen transport tube may be stored at 2-30°C for up to 30 days.
- PAP specimens in Aptima specimen transport tubes may be stored for up to 12 months after collection if stored at -20°C or colder.
- PAP specimens that have been tested will be stored at 15-30°C for 7 days if negative and at -20°C or colder for up to three months if positive.

SPECIMEN REJECTION CRITERIA

It is the Laboratory General Rejection Criteria not to accept improperly labeled specimens, such as wrong name or account number. Those specimens received unlabeled are also unacceptable unless it can be relabeled by the collecting personnel and an affidavit completed with the physician accepting full responsibility that the specimen belongs to that patient.

- Swab specimens not received in appropriate media and collection device.
- Swab transport tubes with no visible swab specimen or both cleaning and collection swabs in swab transport tube.
- Swab specimens that have been processed for testing in Microbiology are unacceptable.
- Unacceptable sources for this test method include: throat, rectal, eye drainage, or other types of specimens not indicated in the list under specimen collection.
- Urines that have been collected and stored in containers with preservative, such as Boric Acid.
- Urine samples that are greater than 24 hours and have not been transferred into the urine specimen transport tube.
- Urines and swab specimens not stored at appropriate temperatures for transport time.

II. HPV (Human Papillomavirus) by Panther Aptima HPV Assay

Turnaround time goal for results is 2 days.

Note: All specimens should be properly labeled at the time of collection with the patient's name and at least one other unique identifying qualifier (example: Account number, Date of Birth, or Social Security Number). Refer to Specimen Rejection Criteria.

SPECIMEN COLLECTION:

Specimens that are accepted for use with this testing system are:

- Specimens in CYTYC PreservCyt Solution should be collected in the routine manner. There must be at least 1 mL of PreservCyt solution remaining for testing analysis.

SPECIMEN TRANSPORT:

Specimens in CYTYC PreservCyt (Thin Prep Pap) Solution:

- May be transported and held up to thirty days at 2-30°C.

SPECIMEN STORAGE:

Specimens in CYTYC PreservCyt (Thin Prep Pap) Solution:

- These specimens can be held up to three months at 2-8°C in original vial.
- Thirty days at room temperature (up to 30°C) in original vial.
- PAP specimens transferred into the Aptima specimen transport tube may be stored at 2-30°C for up to 30 days.
- PAP specimens in Aptima specimen transport tubes may be stored for up to 12 months after collection if stored at -20°C or colder.
- PAP specimens that have been tested will be stored at 2-30°C for 30 days if negative and at -20°C or colder for up to three months if positive.

SPECIMEN REJECTION CRITERIA

It is the Laboratory General Rejection Criteria not to accept improperly labeled specimens, such as wrong name or account number. Those specimens received unlabeled are also unacceptable unless it can be relabeled by the collecting personnel and an affidavit completed with the physician accepting full responsibility that the specimen belongs to that patient.

- Specimen sources or collection/transport devices not listed in specimen collection for Aptima HPV testing.
- PreservCyt solution that is less than 1 mL.
- Specimens not stored at appropriate temperatures or time frame for transport time.

III. FACTOR V LEIDEN

Turnaround time goal for results is 7 days.

Note: All specimens should be properly labeled at the time of collection with the patient's name and at least one other unique identifying qualifier (example: Account number, Date of Birth, or Social Security Number). Refer to Specimen Rejection Criteria.

SPECIMEN COLLECTION

- Whole blood should be collected in one sterile EDTA (purple top) tube.
- Minimum blood sample volume is 50uL, 100uL recommended.
- ACD tubes are not the specimen of choice but will be accepted upon supervisor approval.
Note: High concentrations of Heparin might interfere with PCR testing.

SPECIMEN TRANSPORT

- Refrigerate specimens at 2-8°C if transport to the Lab is delayed for more than 1 hour from the time of collection.
- Specimens should be placed on ice for courier transport to MCL.

SPECIMEN STORAGE

- Store whole blood specimens at 2-8°C if not tested upon receipt at testing laboratory.
- Specimens must be processed within 7 days.
- Whole blood specimens that cannot be processed within 7 days of collection must be stored at <-20°C or colder and tested within 12 months of collection with one freeze thaw.

SPECIMEN REJECTION CRITERIA

It is the Laboratory General Rejection Criteria not to accept improperly labeled specimens, such as wrong name or account number. Those specimens received unlabeled are also unacceptable unless it can be relabeled by the collecting personnel and an affidavit completed with the physician accepting full responsibility that the specimen belongs to that patient.

- Whole blood samples not collected in EDTA anticoagulant or ACD.
- Whole blood samples not stored at appropriate temperature for transport time.
- Whole blood samples that have been frozen and thawed more than one time before testing.
- Whole blood sample less than minimum volume required to perform testing.

IV. PROTHROMBIN MUTATION G20210A

Turnaround time goal for results is 7 days.

Note: All specimens should be properly labeled at the time of collection with the patient's name and at least one other unique identifying qualifier (example: Account number, Date of Birth, or Social Security Number). Refer to Specimen Rejection Criteria.

SPECIMEN COLLECTION

- Whole blood should be collected in one sterile EDTA (purple top) tube.
- Minimum blood sample volume is 50uL, 100uL recommended.
- ACD tubes are not the specimen of choice but will be accepted upon supervisor approval.
Note: High concentrations of Heparin might interfere with PCR testing.

SPECIMEN TRANSPORT

- Refrigerate specimens at 2-8°C if transport to the Lab is delayed for more than 1 hour from the time of collection.
- Specimens should be placed on ice for courier transport to MCL.

SPECIMEN STORAGE

- Store whole blood specimens at 2-8°C if not tested upon receipt at testing laboratory.
- Specimens must be processed within 7 days.
- Whole blood specimens that cannot be processed within 7 days of collection must be stored at <-20°C or colder and tested within 12 months of collection with one freeze thaw.

SPECIMEN REJECTION CRITERIA

It is the Laboratory General Rejection Criteria not to accept improperly labeled specimens, such as wrong name or account number. Those specimens received unlabeled are also unacceptable unless it can be relabeled by the collecting personnel and an affidavit completed with the physician accepting full responsibility that the specimen belongs to that patient.

- Whole blood samples not collected in EDTA anticoagulant or ACD.
- Whole blood samples not stored at appropriate temperature for transport time.
- Whole blood samples that have been frozen and thawed more than one time before testing.
- Whole blood sample less than minimum volume required to perform testing.

V. HCV RNA QUANTITATIVE VIRAL LOAD by COBAS TAQMAN48

Turnaround time goal for results is 7 days.

Note: All specimens should be properly labeled at the time of collection with the patient's name and at least one other unique identifying qualifier (example: Account number, Date of Birth, or Social Security Number). Refer to Specimen Rejection Criteria.

SPECIMEN COLLECTION: (For use with serum only.)

- Blood should be collected in two, preferably three, sterile serum gel tubes.
- Separate serum within 6 hours of collection by centrifugation at 800-1600 x g for 20 minutes at room temperature.
- Transfer serum to a sterile polypropylene tube.

- Minimum sample volume is 1.5 mL of serum.

NOTE: Specimens collected using an anticoagulant are not acceptable.

SPECIMEN TRANSPORT:

- Whole blood or serum must be transported at 2-25°C and processed within 6 hours of collection.
- Serum may be transported at 2-8°C or frozen at -20 to -70°C or colder.
- Serum specimens may be kept frozen at -70°C or colder for delay in transport of specimen.
- Serum specimens that require shipment to off-site laboratories should be shipped frozen as soon as possible after collection. Follow the Lab's procedure for transport of blood specimens.

SPECIMEN STORAGE:

- Serum specimens may be stored at 2-8°C for up to 3 days, or frozen at -20 to -70°C or colder.
- Studies have shown that specimens can be frozen and thawed up to five times without significant loss of HCV RNA.

SPECIMEN REJECTION CRITERIA

It is the Laboratory General Rejection Criteria not to accept improperly labeled specimens, such as wrong name or account number. Those specimens received unlabeled are also unacceptable unless it can be relabeled by the collecting personnel and an affidavit completed with the physician accepting full responsibility that the specimen belongs to that patient.

- Specimens that have been collected with an anticoagulant.
- Serum samples that have **NOT** been centrifuged and separated within 6 hours after collection.
- Serum samples that have **NOT** been frozen after collection beyond three days storage.
- Serum samples that have been frozen and thawed greater than five times before testing.
- Serum specimens not stored at appropriate temperatures for transport time.

VI. MRSA BY REAL-TIME PCR

Turnaround time goal for results is 18 hours.

Note: All specimens should be properly labeled at the time of collection with the patient's name and at least one other unique identifying qualifier (example: Account number, Date of Birth, or Social Security Number). Refer to Specimen Rejection Criteria.

SPECIMEN COLLECTION: (For use with Nasal swabs only)

- Recommended sample is a nasal swab collection with Liquid Stuart Medium.
- Moisten swab with 2 drops of sterile saline or use dry.
- Carefully insert swab into patient's nostril (insert up to 1 inch from edge of nares).
- Gently press nostril closed around swab and roll 5 times.
- Insert swab into second nostril and repeat. Place swab in its container.

SPECIMEN TRANSPORT:

- Transport at 2-25°C.
- Avoid freezing or excessive heat exposure.

SPECIMEN STORAGE:

- Specimens may be stored at 15-25°C for up to 48 hrs or 2-8°C for up to 5 days.
- **DO NOT** store specimens in freezer.

SPECIMEN REJECTION CRITERIA

It is the Laboratory General Rejection Criteria not to accept improperly labeled specimens, such as wrong name or account number. Those specimens received unlabeled are also unacceptable unless it can be relabeled by the collecting personnel and an affidavit completed with the physician accepting full responsibility that the specimen belongs to that patient.

- Specimens that have been collected utilizing a swab collection device other than the one specified for test analysis.
- Specimens that do not meet the specified source requirement.
- Specimens not stored at appropriate temperatures for transport time.
- Specimens received on patients who have prior positive MRSA test results from the nares within four weeks of current collection.
- Specimens from neonatal patients submitted for repeat testing less than 72 hours of initial test result.
- Specimens submitted for repeat testing less than 7 days of initial test result.

VII. CDIFF BY REAL-TIME PCR

Turnaround time goal for results is 18-24 hours.

Note: All specimens should be properly labeled at the time of collection with the patient's name and at least one other unique identifying qualifier (example: Account number, Date of Birth, or Social Security Number). Refer to Specimen Rejection Criteria.

SPECIMEN COLLECTION: (For use with liquid stools only)

- Specimen should be stored and transported in a dry sterile container that is free of preservatives.

SPECIMEN TRANSPORT:

- Transport at 2-25°C.
- Avoid freezing or excessive heat exposure.

SPECIMEN STORAGE:

- Specimens may be stored at 2-25°C for up to 48 hrs or 2-8°C for up to 5 days.

SPECIMEN REJECTION CRITERIA

It is the Laboratory General Rejection Criteria not to accept improperly labeled specimens, such as wrong name or account number. Those specimens received unlabeled are also unacceptable unless it can be relabeled by the collecting personnel and an affidavit completed with the physician accepting full responsibility that the specimen belongs to that patient.

- Specimens that have been collected utilizing a collection device other than the one specified for test analysis.

- Specimens that do not meet the specified source requirement (only liquid or unformed stool).
NOTE: This will be reviewed on a case by case basis.
- Specimens not stored at appropriate temperatures for transport time.
- Patients that test negative will not be retested within a seven day time frame.
- Patients that test positive will not be retested for that hospital admission.
- Patients from outreach clients will not be retested within 14 days of initial result.

VIII. GROUP B STREP BY REAL-TIME PCR

Turnaround time goal for results is < 48 hrs

Note: All specimens should be properly labeled at the time of collection with the patient's name and at least one other unique identifying qualifier (example: Account number, Date of Birth, or Social Security Number). Refer to Specimen Rejection Criteria.

SPECIMEN COLLECTION:

- Collect the vaginal and/or rectal swab specimen using the CDC recommended clinical procedure. Use a swab collection device with non-nutritive transport medium such as Amies or Stuart.
- If vaginal-rectal swabs are collected separately from the same patient, both swabs can be placed in the same transport container.
- Label specimen clearly for GBS testing.

SPECIMEN TRANSPORT:

- Transport at 2-30°C.
- Avoid freezing or excessive heat exposure.

SPECIMEN STORAGE:

- Specimens may be stored at 2-8°C in Lim broth for up to 7 days.

SPECIMEN REJECTION CRITERIA

It is the Laboratory General Rejection Criteria not to accept improperly labeled specimens, such as wrong name or account number. Those specimens received unlabeled are also unacceptable unless it can be relabeled by the collecting personnel and an affidavit completed with the physician accepting full responsibility that the specimen belongs to that patient.

- Specimens that have been collected utilizing a collection device other than the one specified for test analysis.
- Specimens that do not meet the specified source requirement (only vaginal or rectal).
- Specimens not stored at appropriate temperatures for transport time.

NOTE: The presence of feces and body powder can potentially inhibit the detection of GBS at low organism levels.

IX. STOOL PATHOGEN PANEL BY PCR

Turnaround time goal for results is 18-24 hours.

Note: All specimens should be properly labeled at the time of collection with the patient's name and at least one other unique identifying qualifier (example: Account number, Date of Birth, or Social Security Number). Refer to Specimen Rejection Criteria.

SPECIMEN COLLECTION:

- Specimen should be stored and transported in a dry sterile container that is free of preservatives or in Carey Blair transport media.

SPECIMEN TRANSPORT:

- Transport at 2-25°C.
- Avoid freezing or excessive heat exposure.

SPECIMEN STORAGE:

- Specimens may be stored at 2-25°C for up to 48 hrs or 2-8°C for up to 5 days.

SPECIMEN REJECTION CRITERIA

It is the Laboratory General Rejection Criteria not to accept improperly labeled specimens, such as wrong name or account number. Those specimens received unlabeled are also unacceptable unless it can be relabeled by the collecting personnel and an affidavit completed with the physician accepting full responsibility that the specimen belongs to that patient.

- Specimens that have been collected utilizing a collection device other than the one specified for test analysis.
- Specimens that do not meet the specified source requirement.
- Specimens not stored at appropriate temperatures for transport time.
- Patients that test positive will not be retested within 21 days of initial result.
- Patients that test negative will not be retested within 7 days of initial result.

X. SHIGA-TOXIN DNA BY PCR

NOTE: It is recommended to order Stool Pathogen Panel instead which includes Shiga-Toxin producing E. coli.

Turnaround time goal for results is 18-24 hours.

Note: All specimens should be properly labeled at the time of collection with the patient's name and at least one other unique identifying qualifier (example: Account number, Date of Birth, or Social Security Number). Refer to Specimen Rejection Criteria.

SPECIMEN COLLECTION:

- Specimen should be stored and transported in a dry sterile container that is free of preservatives or in Carey Blair transport media.

SPECIMEN TRANSPORT:

- Transport at 2-25°C.
- Avoid freezing or excessive heat exposure.

SPECIMEN STORAGE:

- Specimens may be stored at 2-25°C for up to 48 hrs or 2-8°C for up to 5 days.

SPECIMEN REJECTION CRITERIA

It is the Laboratory General Rejection Criteria not to accept improperly labeled specimens, such as wrong name or account number. Those specimens received unlabeled are also unacceptable unless it can be relabeled by the collecting personnel and an affidavit completed with the physician accepting full responsibility that the specimen belongs to that patient.

- Specimens that have been collected utilizing a collection device other than the one specified for test analysis.
- Specimens that do not meet the specified source requirement.
- Specimens not stored at appropriate temperatures for transport time.
- Patients that test positive will not be retested within 21 days of initial result.
- Patients that test negative will not be retested within 7 days of initial result.

XI. HERPES SIMPLEX VIRUS PCR, CSF

Turnaround time goal for results is 2 hours during staffed hours.

Note: All specimens should be properly labeled at the time of collection with the patient's name and at least one other unique identifying qualifier (example: Account number, Date of Birth, or Social Security Number). Refer to Specimen Rejection Criteria.

SPECIMEN COLLECTION:

- Specimen should be collected in a sterile container per standard operating procedures.
- CSF is the only acceptable sample for this test.
- Minimum sample volume is 55uL, recommended is 110uL.

SPECIMEN TRANSPORT:

- Transport at 2-8°C.
NOTE: It is recommended to transport on ice.

SPECIMEN STORAGE:

- Specimens may be stored at 2-8°C for up to 7 days or -70°C for delays beyond 7 days.

SPECIMEN REJECTION CRITERIA

It is the Laboratory General Rejection Criteria not to accept improperly labeled specimens, such as wrong name or account number. Those specimens received unlabeled are also unacceptable unless it can be relabeled by the collecting personnel and an affidavit completed with the physician accepting full responsibility that the specimen belongs to that patient.

- Specimens that have been collected utilizing a collection device other than the one specified for test analysis.
- Specimens that do not meet the specified source requirement.
- Specimens not stored at appropriate temperatures for transport time.