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Subject:	MOLECULAR DIAGNOSTICS				
Approved by: Laboratory Executive Director, Ed Hughes (electronic signature)					
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MOLECULAR DIAGNOSTICS SPECIMEN COLLECTION AND TRANSPORT

I. CHLAMYDIA TRACHOMATIS / NEISSERIA GONORRHEAE by COBAS AMPLICOR

SPECIMEN COLLECTION

Turnaround time goal for results 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 Dacron, rayon, or calcium alginate tipped collection swabs with plastic or non-aluminum shafts. Do not use cotton tipped wooden swabs.
2. Remove excess mucus from the endocervix with the large-tipped cleaning swab provided in the M4RT Swab Collection System and discard. The presence of mucus in cervical samples may inhibit PCR and cause false negatives.
3. Insert the second specimen swab into the endocervix and rotate the swab for 15-30 seconds.
4. Verify that all Swab Transport Buffer is at the bottom of the tube. Insert the swab into the transport tube, breaking off the plastic shaft or bending the wire shaft to fit into the tube, before securely replacing the cap. Any transport tube received without a swab will be rejected and a recollection will be required.
5. Label the transport tube with the patient's name, account number, and date of collection.

NOTE:

- Replens lubricant has been shown to inhibit PCR and yield false negative results with this test.
- Samples containing greater than 5% (V/V) blood may give false positive results.
- Other medias that can be used are:
 - 2SP Culture Transport Medium
 - Bartels Transport Medium

- *SPG Culture Transport Medium.*

Male Urethral Swab Specimen Collection:

1. Insert the small-tipped specimen swab 2-4 cm into the urethra and rotate the swab for 3-5 seconds to ensure adequate sampling.
2. Verify that all Swab Transport Buffer is at the bottom of the tube. Insert the swab into the transport tube, breaking off the plastic shaft or bending the wire shaft to fit into the tube, before securely replacing the cap. Any transport tube received without a swab will be rejected and a recollection will be required.
3. Label the transport tube with the patient's name, account number, and date of collection.

Urine Specimens (Male and Female):

1. Collect 10-50mL of first catch urine (the first part of the stream or "dirty catch") into a clean polypropylene container without preservatives.
2. Seal the specimen container. Label the container with the patient's name, account number, and date of collection.

***NOTE:** Patient must NOT have urinated during the previous 2 hours.*

CYTYC PreservCyt (Thin Prep PAP) Collection:

- Specimens in CYTYC PreservCyt Solution should be collected in the routine manner.
- Refer to the CYTYC PreservCyt package insert or Cytology for detailed instructions on Specimen Collection.

SPECIMEN TRANSPORT:

Swab specimens (Male and Female) collected in Culture Transport Media:

- Swab specimens may be transported to the test site at 18-25°C provided that transport time is less than 1 hour.
- Refrigerate swab specimens at 2-8°C if transport to the Lab is delayed for more than 1 hour from the time of collection.
- 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 to the test site at 18-25°C provided that transport time is less than 24 hours.
- Urine specimens that require shipment to off-site test centers must be shipped via overnight delivery with guaranteed arrival within 24 hours; shipment can be at 18-25°C.
- If urine specimens are shipped at 18-25°C, they should be stored at 2-8°C until time of shipment to ensure that the period of 18-25°C storage does not exceed 24 hours.

Specimens in CYTYC PreservCyt (Thin Prep Pap) Solution:

- May be transported and held up to three months at 2-30°C.

***NOTE:** DO NOT freeze these specimens.*

SPECIMEN STORAGE

Swab specimens (Male and Female) collected in Culture Transport Media:

- Store swab specimens that are not tested upon receipt at testing laboratory at 2-8°C and process within 7 days.
- Swab specimens that cannot be processed within 7 days of collection must be stored at -20°C or colder and tested within 30 days of collection.

Urine Specimens (Male and Female):

- Urine specimens that will not be processed within 24 hours of collection must be stored at 2-8°C and must be processed within 7 days of collection can be stored at -20°C or colder for up to 2 months.

Specimens in CYTYC PreservCyt (Thin Prep Pap) Solution:

- These specimens can be held up to three months at 2-30°C.
NOTE: Do not freeze these specimens.

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.
- M4RT transport tubes with no visible swab specimen.
- 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 of specimen collection.
- Urines that have been collected and stored in containers with preservative, such as Boric Acid.
- Urines and swab specimens not stored at appropriate temperatures for transport time.

II. HIV QUANTITATIVE VIRAL LOAD by COBAS AMPLIPREP/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 plasma only.)

1. Blood should be collected in two sterile tubes using EDTA (purple top) **only**. Separate plasma from whole blood within 6 hours of collection by centrifugation at 800-1600 x g for 20 minutes at room temperature.

2. Transfer plasma to a sterile polypropylene tube.
3. Minimum sample volume is 1.5 mL or 1500 uL.

NOTE: Specimens collected using Heparin or ACD as an anticoagulant are not acceptable.

SPECIMEN TRANSPORT:

- Whole blood or plasma must be transported at 2-25°C and processed within 6 hours of collection.
- Plasma may be transported at 2-8°C or frozen at -20 to -70°C or colder.
- Plasma specimens may be kept frozen at -70°C or colder for delay in transport of specimen.
- Plasma 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:

- Plasma specimens may be stored at 2-8°C for up to 5 days, or frozen at -20 to -70°C or colder.
- It is recommended that specimens be stored in 1200 uL aliquots in sterile, 2.0 mL polypropylene screw-cap tubes.
- Studies have shown that specimens can be frozen and thawed up to five times without loss of HIV-1 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 the anticoagulant **HEPARIN or ACD**.
- Plasma samples that have **NOT** been centrifuged and separated within 6 hours after collection.
- Plasma samples that have **NOT** been frozen after collection beyond five days storage.
- Plasma samples that have been frozen and thawed greater than five times before testing.
- Plasma specimens not stored at appropriate temperatures for transport time.

III. HPV (Human Papillomavirus) by DIGENE HYBRID CAPTURE 2

Turnaround time goal for results is 3-4 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:

- The HC Cervical Sampler (cervical brush and STM) or hc2 DNA Collection Device. (Refer to package insert for additional specimen collection information).
- Cervical Biopsies –
 - Must be freshly collected fresh and immediately placed into 1.0 mL of STM and stored frozen at -20°C
 - Optimally, biopsy should be between 2-5 mm in cross-section size.
NOTE: Biopsies <2 mm in diameter should not be used.
- Specimens in CYTYC PreservCyt Solution should be collected in the routine manner. There must be at least 4 mL of PreservCyt solution remaining for testing analysis.

SPECIMEN TRANSPORT:

The HC Cervical Sampler:

- Good for two weeks at room temperature.
- Specimens may be shipped without refrigeration to a testing laboratory; however specimens should be shipped in an insulated container using either an overnight or 2-day delivery vendor.

Cervical Biopsies:

- Biopsy specimens may be shipped at 2-30°C for overnight delivery to the testing laboratory.

Specimens in CYTYC PreservCyt (Thin Prep Pap) Solution:

- May be transported and held up to three months at 2-30°C.
NOTE: These specimens cannot be frozen.

SPECIMEN STORAGE:

The HC Cervical Sampler:

- Two weeks at room temperature.
- Three weeks at 2-8°C.
- Three months at -20°C.

Cervical Biopsies:

- Frozen at -20°C until processed.

Specimens in CYTYC PreservCyt (Thin Prep Pap) Solution:

- These specimens can be held up to three months at 2-30°C.
NOTE: Do not freeze these specimens.

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 Digene testing.
- Cervical brush collected on a pregnant female.
- Cervical sample that has been collected after the application of acetic acid or iodine.
- Consult with pathologist for cervical biopsies less than 2 mm in diameter.
- PreservCyt solution that is less than 4 mL.
- PreservCyt solution that has been stored frozen.
- Specimens not stored at appropriate temperatures for transport time.

IV. 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) tubes.
 - 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.

V. 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) tubes.
- 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.

VI. 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 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.
- It is recommended that specimens be stored in 1200 uL aliquots in sterile, 2.0 mL polypropylene screw-cap tubes.
- 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.
- Plasma 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.

VIII. MRSA BY REAL-TIME PCR

Turnaround time goal for results is 12 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 2-30°C.
- Avoid freezing or excessive heat exposure.

SPECIMEN STORAGE:

- Specimens may be stored at 15-30°C for up to 36 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.