Title: Specimen Collection Manual

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PURPOSE/PRINCIPLE
The Specimen Collection Manual provides instructions for specimen collection and handling to assist clinicians and laboratory personnel in order to maintain the integrity of the sample.

POLICIES
N/A

APPLIES TO
All Arbor Diagnostics, Inc. employees, and clients

SPECIMEN
Approved Arbor collection devices

EQUIPMENT
The following equipment is required:
- Computer with access to the internet
- Centrifuge

FORMS
Arbor Quality Management 881: Blood Manual Requisition
Arbor Quality Management 882: Cytology, Histology, Molecular and Microbiology Manual Requisition

MATERIALS AND SUPPLIES
Required PPE for collection
Supplies necessary for collection
Patient labels
Glass slides, if applicable
Digital or physical copy of test requisition
Arbor Diagnostics, Inc. approved packaging:
- Large FedEx Clinical Box
- FedEx Clinical Pack
- 6X9 Specimen Bag (clear, yellow, red and/or green)
- 12X15 Specimen Transport Bag
- Johnny Plastic Ice XCB-24BR-24 Ice Pack
- Insulated Mailer
- Corrugated Box

PROCEDURE
For All Specimens:

I. Specimen Labels

A. All specimens should be labeled at the time of collection with at least two patient identifiers in addition to the date and time of collection.

1. The patient's name (full last name, then full first name or initial)

2. DOB

B. If glass slides are submitted, use a pencil for labeling the frosted end, with the patient's last name, first initial and DOB.

C. When submitting a specimen in a container other than the tube used to draw the sample (e.g., transfer vials), also indicate specimen type on the label (e.g., serum, plasma, urine, etc.).

D. When submitting specimens for microbiological testing (e.g., cultures, bacterial antigen, microscopic examination) and molecular testing, the nature and anatomic source of the sample and the specific organism(s) to be detected, if any, should be specified.

E. When submitting a clinical pathology timed tests with multiple tubes, the tube must be labeled with the time of collection and/or a method of indicating the order of the tubes. The method could be a labeled sticker or handwritten on the vial but is not all inclusive.

F. Adequate specimen identification is provided on specimen containers throughout all phases of testing, including, but not limited to aliquots, dilution, tubes, slides, blocks, culture plates, reaction units, nucleic acids and other extracts, and other secondary specimens created during the processing or testing of a specimen.

II. Test Requisition

A. Specimens should be accompanied by a paper requisition, prepared either by hand or printed from an electronic ordering system. The requisition, at a minimum should contain the following information:

1. Adequate patient identification information (e.g., name, registration number and location, or a unique confidential specimen code if an alternative audit trail exists)
2. Patient sex
3. Patient date of birth or age
4. Name and address (if different than the receiving laboratory) of the physician, legally authorized person ordering the test, or name and address of the laboratory referring the specimen
    i. Medical Assistants and Nurses are not authorized.
5. Tests requested
6. Last menstrual period (for gynecologic specimens)
7. Date of specimen collection, and if appropriate, time of collection
8. Source of specimen, when appropriate
9. Clinical information, when appropriate

B. Complete the “Patient Information” and “Insurance Information” sections on the requisition or attach appropriate information.

C. Select the test(s) to be performed.

D. Legibly print patient information and indicate with a check mark which party will be responsible for payment in the "Bill To" section of the requisition.

E. Enter the ICD diagnosis code that reflects the patient's symptoms, condition, or diagnosis and provide medical justification for the tests ordered.

F. EMR orders/requisitions will be considered source of truth when identifying discrepancies in patient name, demographics or DOB.

Improperly labeled specimens are considered suboptimal.

III. Packaging

A. The following are the minimum specimen packaging guidelines that should be followed when submitting specimens.
   1. Ensure that all specimen container caps and lids are properly tightened to prevent leakage.
   2. Properly complete the requisition.
   3. Collect the specimen(s) and transfer to a proper transport container, if needed. Verify the specimen container to ensure that the device is not beyond its stated expiration date.
   4. If using a manual test requisition, remove a self-stick label from the pre-printed paper test requisition and affix this label to the specimen transport container.
      i. Place on the container so that the label does not cover the handwritten patient name.
   5. The top copy (original) of the test requisition should be placed into the open pocket of the specimen transport bag. Retain the second copy for your files.
      i. Clear specimen transport bags are used for routine samples.
      ii. Green specimen transport bags are for SARS-CoV-2 Antibody and PCR samples.
      iii. Yellow bags denote priority, and are to be used for symptomatic patients, and time-sensitive results needed.
      iv. Red bags denote STAT testing.
   6. Place the specimen container(s) in the pocket that seals.

B. Refrigerated Specimens- Please refer to Attachment A in this document for Refrigerated Shipping Guides.
   1. Ensure the ice packs are properly stored and frozen prior to shipping.
   2. Horizontally place the ice pack in the bottom of the insulated mailer.
   3. Place the bagged blood specimens in the insulated mailer.
   4. Place one more ice pack on top of the bagged blood specimens.
   5. Once you have packaged your specimens in their individual specimen bags and placed them in a larger specimen bag, place the large specimen bag in the insulated mailer to be shipped, you will need to peel the adhesive cover strip to expose the adhesive.
   6. Fold the adhesive over and press to ensure a good seal.
   7. Place the insulated mailer in the Uline insulated foam shipping kit provided by Arbor.

C. Ambient Specimens- Please refer to Attachment B in this document for Ambient Shipping Guides.
   1. Utilize the Large FedEx Clinical Box that Arbor has supplied.

2. Each specimen should be sealed properly, then packaged into a 6X9 specimen bag.
3. Place the requisition for the specimen in the outer pocket of the 6X9 specimen bag.
4. Place all individually packaged specimens into a larger 12X15 specimen transport bag.
5. Complete and place the specimen transport log into the outer pocket of the 12X15 specimen transport bag.
    i. Black pen should be used on the transport log.
6. Once you have packaged your specimens in their individual specimen bags and placed them in the larger specimen transport bag and that in the large FedEx clinical box, you will need to peel the adhesive cover strip to expose the adhesive at the top of the box and close the box.
7. Be sure to press firmly to ensure a proper seal.
8. Once the FedEx Clinical Box has been sealed properly, place the provided priority overnight shipping label in the designated area on the box.

D. Arbor Diagnostics, Inc. approved packaging:
1. Large FedEx Clinical Box
2. FedEx Clinical Pack
3. 6X9 Specimen Bag
4. 12 X 15 Specimen Transport Bag
5. Johnny Plastic Ice XCB-24BR-24 Ice Pack
6. Insulated Mailer
7. Corrugated Box

XVI. Supplies

A. Certain supplies necessary to draw and submit specimens for analysis by Arbor Diagnostics, Inc. are provided to customers as part of our testing services.
B. Type and quantity of items must correlate to the number of specimens submitted to Arbor Diagnostics, Inc. for testing.
C. Specimen collection devices supplied by Arbor Diagnostics, Inc. are to be used only for the collection of specimens for processing by Arbor Diagnostics, Inc.
D. Specimen collection supplies such as blood collection tubes and collection devices (e.g., culture swabs, and transport media) must be used within their expiration date and stored per manufacturer's instructions.

Department: Molecular

I. Copan E-Swab (GBS)

A. Preparation of the Patient:

1. Open the ESwab sample collection pouch and remove the tube and swab.
2. Collect the sample from the patient.
3. Unscrew and remove the cap from Eswab tube making sure not to spill the medium.
4. Insert the swab into the tube until the red marked breaking point is at the level of the tube opening end and break the swab at the red marked breaking point holding the tube away from your face.
5. Discard the broken handle part of the swab shaft into an approved medical waste disposal container.
6. Replace cap on the tube and secure tightly.
7. Write patient information on the tube label or apply patient identification label.

B. Type of Collection Container/Amount:

1. One Copan ESwab with one swab present inside transport tube.

C. Transport:

1. ESwab should be transported directly to the laboratory, preferably within 2 hours of collection to maintain optimum organism viability.
2. If immediate delivery or processing is delayed, then specimens should be refrigerated or stored at room temperature (2 – 50°C) and processed within 48 hours.

D. Clinical Data:

1. Penicillin allergic (Yes or No)
2. Weeks pregnant
3. Source: Vaginal/Rectal Only

II. Dry Flocked Swab (COVID-PCR)

A. Preparation of the Patient (Nasal):

1. For nasal swab specimens use flocked or polyester spun swab.
2. Peel open sterile pouch and remove swab.
3. Gently insert the sterile swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab a few times against the nasal wall and remove from nostril.
4. While holding the swab, remove cap from the tube. Insert the swab into the tube until the breakpoint is level with the tube opening then break the swab stem at that breakpoint.

5. Write patient information on the tube label or apply patient identification label.

B. Preparation of the Patient (Throat/Oropharyngeal):

1. Peel open sterile pouch and remove swab.
2. Touch the swab tip to the tonsil area. Rub the swab tip quickly and firmly over this area to obtain a good sample. Remove swab from mouth (without touching any surface). A gag reflex reaction is very common when a good sample is obtained.
3. While holding the swab, remove cap from the tube. Insert the swab into the tube until the breakpoint is level with the tube opening then break the swab stem at that breakpoint.
4. Write patient information on the tube label or apply patient identification label.

C. Type of Collection Container/Amount:

1. One dry flocked swab in a dry transport tube.

D. Transport:

1. Store patient swab(s) at room temperature for 24 hours or up to 72 hours at 2°C to 8°C until testing.
2. Routine SARS-CoV-2 samples are to be placed in Green specimen transport bags.

III. Saline and VTM Swabs (COVID-PCR)

A. Preparation of the Patient (Nasal):

1. For nasal swab specimens use flocked or polyester spun swab.
2. Peel open sterile pouch and remove swab.
3. Gently insert the sterile swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab a few times against the nasal wall and remove from nostril.
4. While holding the swab, remove cap from the tube. Insert the swab into the tube until the breakpoint is level with the tube opening then break the swab stem at that breakpoint.
5. Write patient information on the tube label or apply patient identification label.

B. Preparation of the Patient (Throat/Oropharyngeal):

1. Peel open sterile pouch and remove swab.
2. Touch the swab tip to the tonsil area. Rub the swab tip quickly and firmly over this area to obtain a good sample. Remove swab from mouth (without touching any surface). A gag reflex reaction is very common when a good sample is obtained.

3. While holding the swab, remove cap from the tube. Insert the swab into the tube until the breakpoint is level with the tube opening then break the swab stem at that breakpoint.

4. Write patient information on the tube label or apply patient identification label.

C. Type of Collection Container/Amount:

1. The swab placed in a 3mL pre-filled tube of Teknova 0.85% saline or Hardy Diagnostics Viral Transport Medium.

D. Transport:

1. Store patient swab(s) at room temperature for 24 hours or up to 72 hours at 2°C to 8°C until testing.

2. Routine SARS-CoV-2 samples are to be placed in Green specimen transport bags.

IV. Aptima Multitest Swab

A. Vaginal (CT/NG/Trich) and Vaginal Panels include a combination of the following targets:

1. *Candida krusei*
2. *Candida albicans*
3. *Candida parapsilosis/Candida tropicalis*
4. *Candida glabrata*
5. *Gardnerella vaginalis*
6. *Mycoplasma genitalium*
7. *Mycoplasma hominis*
8. *Ureaplasma urealyticum*
9. *Atopobium vaginae*
10. *Mobiluncus curtisii*
11. *Mobiluncus mulieris*
12. *Prevotella bivia*
13. *Bacteroides fragilis*

B. Preparation of the Patient- Vaginal Swab Specimens

1. Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection Kit.
2. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
3. Carefully insert the swab into the vagina about 2 inches (5 cm) past the introitus and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin.
4. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection Kit.
5. Immediately place the swab into the transport tube so that the score line is at the top of the tube.

6. Carefully break the swab shaft at the score line against the side of the tube.
7. Immediately discard the top portion of the swab shaft.
8. Tightly screw the cap onto the tube.

C. Preparation of the Patient – Lesions (HSV- 1 & -2)

1. Partially peel open the swab package. Remove the swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new Aptima Multitest Swab Specimen Collection kit.
2. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaf.t below the score line.
3. If needed, expose the base of the lesion to access fluid.
4. Vigorously swab the base of the lesion to absorb fluid, being careful not to draw blood. Withdraw the swab without touching any other site outside the lesion.
5. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new Aptima Multitest Swab Specimen Collection kit.
6. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
7. Carefully break the swab shaft at the score line against the side of the tube.
8. Discard the top portion of the swab shaft.
9. Tightly screw the cap onto the tube.

NOTE: Do not use disinfectant or cleaners on the lesion before the specimen is collected.

D. Type of Collection Container/Amount:

1. One Aptima Multitest Swab with one swab present inside transport tube.

E. Transport:

1. After collection, transport and store the swab in the swab specimen transport tube at 2°C to 30°C.
2. Routine SARS-CoV-2 samples are to be placed in Green specimen transport bags.

F. Clinical Data:

1. Source (HSV ONLY): Lesion Only
2. Source (vaginal panels): Vaginal Only

V. Aptima Urine

A. Preparation of the Patient (CT/NG/Trich):
FEMALE:

1. The patient should not have urinated for at least 1 hour prior to specimen collection.
2. Direct patient to provide a first-catch urine (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in rRNA target dilution that may reduce test sensitivity.
    a. Female patients should not cleanse the labial area prior to providing the specimen.
3. Remove the cap and transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine specimen transport tube label.
4. Re-cap the urine specimen transport tube tightly.

MALE:

1. Clean the head of the penis with a sterile wipe. If patient is not circumcised, pullback (retract) the foreskin first.
2. Urinate a small amount into the toilet bowl, and then stop the flow of urine.
3. Then collect a sample of urine into the clean or sterile cup, until it is half full. Remove the cap and transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine specimen transport tube label.
4. Re-cap the urine specimen transport tube tightly.

B. Type of Collection Container/Amount:

1. One Aptima Urine tube between black fill lines
    a. If urine is over the max fill line or under the minimum fill line, the specimen will be rejected.

C. Transport:

1. After collection, transport the processed urine specimens in the Aptima urine specimen transport tube at 2°C to 30°C and store at 2°C to 30°C.
2. Urine samples that are still in the primary collection container must be transported to the lab at 2°C to 30°C. Transfer the urine sample into the Aptima urine specimen transport tube within 24 hours of collection. Store at 2°C to 30°C.

VI. ThinPrep (CT/NG/Trich/HR HPV/HPV GT/ All Vaginal Panels)

A. Please see Cytology ThinPrep Pap Test for detailed information

1. Transportation: After collection, transport the specimen at 2°C to 50°C.

B. ThinPrep vials submitted with unapproved collection devices will be rejected. (ex: flocked or Aptima swabs).

C. Vaginal Panels include a combination of the following targets:

1. *Candida krusei*
2. *Candida albicans*
3. *Candida parapsilosis/Candida tropicalis*
4. *Candida glabrata*
5. *Gardnerella vaginalis*
6. *Mycoplasma genitalium*
7. *Mycoplasma hominis*
8. *Ureaplasma urealyticum*
9. *Atopobium vaginae*
10. *Mobiluncus curtisii*
11. *Mobiluncus mulieris*
12. *Prevotella bivia*
13. *Bacteroides fragilis*

VII. Analyte specific limitations for Aptima assays

A. HPV (Reference Hologic package insert AW-14517-001 Rev. 003)

1. The performance of the Aptima HPV assay has not been evaluated for HPV vaccinated individuals.
2. The effects of other potential variables such as vaginal discharge, use of tampons, douching, etc. and specimen collection variables have not been evaluated.

B. HPV 16 18/45 Genotype (Reference Hologic package insert 503653-REG Rev 6)
    1. The performance of the Aptima HPV 16 18/45 Genotype assay has not been evaluated for HPV vaccinated individuals.
    2. The effects of other potential variables such as vaginal discharge, use of tampons, douching, etc. and specimen collection variables have not been evaluated.
C. Trichomonas vaginalis (Reference Hologic package insert 503797 Rev 002)
    1. The effects of tampon use, douching, and specimen collection variables have not been assessed for their impact on the detection of *Trichomonas vaginalis*.
    2. Performance of the vaginal swab specimen has not been evaluated in pregnant women.
    3. Performance of urine, vaginal swab, and PreservCyt Solution liquid Pap specimens has not been evaluated in women less than 14 years of age.
D. CT/GC (Reference Hologic package insert 502487 Rev 001)
    1. The effects of tampon use, douching, and specimen collection variables have not been assessed for their impact on the detection of CT or GC.
    2. The performance of the vaginal swab specimen has not been evaluated in pregnant women.

I. ThinPrep Pap Test

A. Sample Collection Technique using Brush/Spatula Collection Devices:

1. Sample ectocervix with a plastic spatula.
2. Rinse spatula in the PreservCyt Solution vial by swirling vigorously 10 times. Place cap on vial until Step 4. Discard collection device.
3. Sample endocervix with an endocervical brush.
4. Rinse the brush in the PreservCyt Solution by rotating the device in the solution 10 times while pushing against the PreservCyt vial wall. Swirl the brush vigorously to further release the material. Discard the collection device.
5. Tighten the PreservCyt sample vial cap so that the torque line on the cap passes the torque line on the vial.

B. Sample Collection Technique using Broom-Like Collection Device:

1. Obtain a sample from the cervix using a broom-like device.
2. Rinse the collection device into a PreservCyt Solution vial by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to further release cellular material. Discard the collection device.
3. Cap the PreservCyt sample vial tightly. Tighten the cap of the vial so that the black torque line on the cap passes the black torque line on the vial.

C. Type of Collection Container/Amount:

1. ThinPrep PAP test vial exclusively. (No slide smears, SurePath and non-Gyn and Anals are not acceptable)
    a. Do not pour solution out of vial ~ 20mL of PreservCyt Solution

D. Transport:

1. Transport at 2°C to 50°C

E. Clinical Data:

1. Source
2. Last Menstrual Period (LMP)
3. Pertinent Clinical History

F. Restrictions:

1. Ideally collect Pap smear two weeks after the first day of the last menstrual period.
2. The patient should be instructed not to use vaginal medications, lubricants, spermicides, or douches 48 hours prior to the collection of the Pap smear.
3. The patient should also refrain from intercourse 24 hours prior to the collection of the Pap smear.

Department: Microbiology

I. Copan ESwab (Vaginal, GBS, Wound, Lesion and Throat Cultures)

A. Preparation of the Patient:

1. Peel open the kit package and remove the tube of medium and inner pouch containing the sterile swab applicator.

2. Remove the swab applicator from its peel pouch and use to collect the specimen. During sample collection when handling the swab applicator, the operator must not touch the area below the breakpoint indication line; that is the area from the line to the tip of the nylon flocked swab, as this will lead to contamination of the applicator shaft and the culture thus invaliding the test results.

a. Vaginal:

i. Wipe away old secretions/discharge.

ii. Obtain secretions from the mucosal membrane of the vaginal wall with a sterile swab/

b. Vaginal/rectal (For GBS):

i. Insert sterile swab 2cm into vagina, rotate swab.

ii. Insert the same swab 1cm into anus and rotate swab.

c. Wound:

i. Remove surface exudate by wiping with sterile saline or 70% alcohol.

ii. Using a sterile swab pass deep into the wound to firmly sample the wound's "fresh border."

d. Lesion:

i. While pressing the base of the lesion, firmly rub base with a sterile swab to collect fluid.

e. Throat:

i. Depress tongue with a tongue depressor.

ii. Sample the posterior pharynx, tonsils, and inflamed areas with a sterile swab.

3. After the swab sample is taken from the patient, break the swab off into the tube as follows:

- With the other hand grasp the swab shaft at the very end with the thumb and first finger
- Lean the part of the shaft with the breaking point against the rim of the tube

- Bend the swab shaft at a 180 degrees angle to break if off at the colored ink breakpoint mark.
- Discard the broken handle part of the swab shaft into an approved medical waste disposal container.

4. Replace cap on the tube and secure tightly

B. Type of Collection Container/Amount:

1. One Copan ESwab with one swab present inside transport tube.

NOTE: Neisseria gonorrhoeae cannot be detected using the Eswab method, an approved molecular collection device (i.e., Aptima Multitest Swab, Aptima Urine, or ThinPrep) is the preferred method of collection for Neisseria gonorrhoeae confirmation testing.

C. Transport:

1. ESwab should be transported directly to the laboratory, preferably within 2 hours of collection to maintain optimum organism viability.
2. If immediate delivery or processing is delayed, then specimens should be stored at 2 – 45°C and processed within 48 hours.

D. Clinical Data:

1. Source
2. Pertinent Clinical History
3. (GBS Only) Penicillin allergic (Yes or No)
4. (GBS Only) Weeks pregnant

II. C&S tube (grey top) (Urine Cultures)

A. Preparation of the Patient:

1. Patients should be directed by clinic staff to provide a midstream urine specimen.
    a. While holding the labia apart, begin voiding.
    b. After several milliliters has passed, collect a midstream portion without stopping the flow of urine.
    c. The midstream portion is used for bacterial culture.
2. A clinic staff member will obtain the urine cup from patient.
3. Submerge tip of the transfer straw in specimen.
    a. Push C&S Preservative tube (grey top) into the transfer straw.
        i. Hold in position until flow stops.
        ii. Remove tube, leaving transfer straw in specimen container.
        iii. Shake tube vigorously

Note: The tube must be filled to the minimum fill line and not exceed the maximum fill line, in order to maintain the proper additive to urine ratio.

4. Dispose of transfer straw in sharps container and urine cup in trash.

B. Type of Collection Container/Amount:

1. C&S tube (grey top) – 4mL

C. Transport:

1. C&S Preservative tube (grey top)

    1. C&S Preservative tube is to be sent to the laboratory within 48 hours. Specimen can be kept at 2-40°C for 48 hours.

B. Clinical Data:

1. Source
2. Pertinent Clinical History

Department: Clinical Pathology

A. Preparation of the Patient:

1. Identify the patient using two identifiers such as their name and date of birth. This information must match the requisition.
2. Reassure the patient that the minimum amount of blood required for testing will be drawn.
3. Assemble the necessary equipment. Check for expired tubes at this time.
4. When submitting a clinical pathology timed tests with multiple tubes, the tube must be labeled with the time of collection and/or a method of indicating the order of the tubes. The method could be a labeled sticker or handwritten on the vial but is not all inclusive.

5. Wash hands or sanitize and put on gloves.
6. Position the patient with the arm extended to form a straight-line from shoulder to wrist.
7. Select the appropriate vein for venipuncture.
    a. At no time may phlebotomists perform venipuncture on an artery.
    b. At no time will blood be drawn from non-arm/hand areas unless there is a specific order allowing such.
    c. Factors to consider in site selection:
        1. Extensive scarring or healed burn areas should be avoided.
        2. Specimens should not be obtained from the same side as a mastectomy.
        3. Avoid areas of hematoma.
        4. If an IV is in place, samples may be obtained below but never above the IV site.
        5. Do not obtain specimens from an arm having a cannula, fistula, or vascular graft.
8. Apply the tourniquet 3-4 inches above the collection site.
    a. Never leave the tourniquet on for over 1 minute.
    b. If a tourniquet is used for preliminary vein selection, release it and reapply after two minutes.
9. Clean the puncture site by making a back and forth pass over the site with the 70% alcohol pad. Allow the skin to dry before proceeding.
    a. Do not touch the puncture site after cleaning.

- <u>Perform the venipuncture with a hub and needle</u>.
    1. Attach the appropriate needle to the hub by removing the plastic cap over the small end of the needle and inserting into the hub, twisting it tight.
    2. Remove plastic cap over needle and hold bevel up.
    3. Pull the skin tight with your thumb or index finger just below the puncture site.
    4. Holding the needle in line with the vein, use a quick, small thrust to penetrate the skin and enter the vein in one smooth motion.
    5. Holding the hub securely, insert the first vacutainer tube following proper order of draw into the large end of the hub penetrating the stopper. Blood should flow into the evacuated tube. (**Use order of draw job aide**)
    6. After blood starts to flow, release the tourniquet and ask the patient to open his or her hand.

7. When blood flow stops, remove the tube by holding the hub securely and pulling the tube off the needle.
8. If multiple tubes are needed, follow the proper order of draw.
    - DO NOT SHAKE OR MIX VIGOROUSLY.
9. Gently invert tube to allow proper mixing. (**Use tube guide job aide** to **determine the number of inversions.)**
10. Place a gauze pad over the puncture site and remove the needle.
11. Immediately apply slight pressure immediately after the needle is removed.
12. Apply a fresh bandage, gauze or tape.
13. One phlebotomist may attempt to obtain a blood specimen twice. If no blood has been obtained, a second phlebotomist, if available, may make a third attempt, with patient consent. If a second phlebotomist is not available, the maximum number of attempts is 2 for 1 phlebotomist.
14. The requisition should have a patient label attached to the top of the page that includes this information in this format:
    Pt Last Name, First Name
    DOB: MM/DD/YYYY
    DOC: MM/DD/YYYY Time:HH:MM
    Below the label, the phlebotomist should initial and record the tube types and quantities being sent.

B. Pediatric Draw Volume Limits

1. This procedure is a guideline for blood drawing. If test requests require greater amounts of blood drawn that indicated in the guidelines, laboratory staff should call the ordering provider to determine if all tests are to be drawn or to prioritize testing.
2. A Pediatric draw volume worksheet is a required document that needs to be sent with the order.
3. Conversions
    a. Lbs/2.2 = kg
    b. Kg x 1.7 = mLs

Pounds (lbs)	Kilograms (kg)	(mLs) Volume which can be safely drawn per day
6 - 8	2.7 - 3.6	4.6 - 6.1
9- 10	4.1 – 4.6	7.0 – 7.8
11 - 14	5.0 – 6.4	8.5 – 10.8
15 - 17	6.8 – 7.7	11.6 – 13.1
18 - 20	8.2 – 9.1	13.9 – 15.5
21 - 23	9.6 – 10.5	16.3 – 17.9
24 - 26	10.9 – 11.8	18.5 – 20.1
27 - 29	12.3 – 13.2	20.8 – 22.4
30 - 32	13.6 – 14.5	23.2 – 24.7
33 - 35	15.0 – 15.9	25.5 – 27.1
36 - 38	16.4 – 17.3	27.8 – 29.4
39 - 41	17.7 – 18.6	30.1 – 31.7
42 - 44	19.1 - 20	32.5 – 34.0
45 - 47	20.5 – 21.4	34.8 – 36.3
48 - 50	21.8 – 22.7	37.1 – 38.6

C. Centrifugation

1. The SST must properly clot prior to centrifugation in an upright position for at least **30 minutes.**
2. Red top tubes must properly clot prior to centrifugation in an upright position for at least **60 minutes.**
3. Centrifugation is required within **2 hours**.
4. Centrifugation should achieve a clear separation of cells and plasma/serum.
5. Centrifuge tubes for **15 minutes** at 3280-3480 rpm.
6. If centrifuge does not have a timer, watch time carefully to avoid over or under centrifuging.

D. Aliquoting:

1. To prevent cross contamination of specimens and aliquots, please label all tubes prior to aliquoting with two patient identifiers.

E. Transport:

1. Refrigerated- Please refer to Attachment A in this document for Refrigerated Shipping Guides.
2. Frozen: Dry ice can be utilized. Frozen specimens should not be more than ¾ full and only plastic vials should be used.

F. Clinical Data:

1. Source
2. Pertinent Clinical History
3. (ABO/Rh) Blood type if known
4. (ABO/Rh) Transfusion, if applicable
5. (ABO/Rh) Date of last RhoGAM shot

I. K2 and/or K3 Lavender - Contains EDTA anti-coagulant. (Used for CBC, ESR, Abo/Rh, and Antibody Screens)

- Whole blood – send filled tube.
    1. If Antibody Screen is ordered, draw two separate EDTA tubes.
- Plasma – transfer to plastic vial and label with patient's name and date of birth.
    a. Only EDTA plasma is acceptable for PTH.

II. Serum Separator tube (SST) - Contains gel-barrier. (RPR, Toxo IgG and IgM, Anti HBc IgM, CMV IgG and IgM, Rubella IgG, Rubeola, VZV IgG, Syphilis IgG, HIV Combo Ag/Ab, HSV-1 and HSV-2 IgG, HCG+beta, Anti-HCV, Anti-HBS, HBC IgM, HAV IgM, SARS-Cov-2 Total Antibody, HBsAg, and Progesterone.)

- Serum – allow blood to clot and centrifuge tube. If needed draw multiple tubes, depending on number or tests ordered.
- Please draw an extra tube if submitting a SARS-CoV-2 Total Antibody order.

1. SARS-CoV-2 samples are to be placed in Green specimen transport bags.

III. Light Blue - Contains sodium citrate anticoagulant. (PT/INR, PTT)

- PT/INR (whole blood): must be received within 24 hours.
- PTT (whole blood): must be received within 4 hours.
- Processing the sample (platelet poor plasma)
    - Centrifuge the sample 15 minutes at 3280-3480 rpm.
    - Aliquot the plasma into a transfer tube. Be careful to not disturb the platelet layer. Label the tube with appropriate identifiers.
    - To prevent cross contamination of specimens and aliquots, please label all tubes prior to aliquoting with two patient identifiers.
    - Centrifuge the aliquot tube 15 minutes at 3280-3480 rpm.
    - Aliquot the platelet poor plasma into a second transfer polypropylene #5 tube leaving a small amount at the bottom of the tube. Use care to not aspirate the pellet of Platelets/RBC's at the bottom of the tube. This is the second aliquot tube. Label the transfer tube with appropriate identifiers.
    - Freeze the sample (in a non-frost-free freezer). **The sample MUST be frozen first and sent frozen on dry ice.**

Department: Histology

I. Preparation of the Patient:

A. Biopsy site should be cleaned and prepared as appropriate for the site. Click on the links below for additional collection and handling information pertaining to the individual biopsy types.

1. Soft Biopsy: Exocervix or lower genital tract biopsy

a. https://histologics.com/softbiopsy.html
b. The SoftBiopsy® design is a special device used to non-surgically acquire an exocervical biopsy.
c. The tip is snapped free of the handle and submitted in the formalin vial.
d. Please thoroughly read the instructions for the SoftBiopsy® kit to ensure accurate specimen collection.

2. Soft ECC: Endocervical curettage

a. https://histologics.com/soft-ecc.html
b. https://histologics.com/soft-ecc-s.html
c. The SoftECC® design is a special device used to non-surgically acquire an endocervical biopsy.
d. The tip is snapped free of the handle and submitted in 10% Neutral Buffered Formalin (NBF) or Carson Millonig' formalin.
e. Please thoroughly read the manufacturer's instructions for the SoftECC® kit to ensure accurate specimen collection.

3. Loop Electrosurgical Excision procedure: LEEP

a. The transformation zone and/or lesional area of cervix is removed with a heated wire loop.
b. Place into 10% Neutral Buffered Formalin (NBF).
c. Use 40 mL or 60 mL size vial, depending on the size of the excision.

4. Cervical Punch: Punch biopsy

a. A small tissue sample is punched from the cervix and placed into 10% Neutral buffered formalin or Carson Millonig' formalin.

5. Cervical Conization: Cone Biopsy

a. The transformation zone is surgically removed and placed into 10% Neutral Buffered Formalin (NBF).
b. Use 60 mL size vial for adequate fixation.

6. Endometrial Biopsy: Endometrium

a. A sample of the endometrium is taken using a Pipelle, curette, or other biopsy device, and is placed into 10% Neutral Buffered Formalin (NBF).
b. Use a 40 mL or 60 mL size vial (20x volume of formalin to volume of the biopsy required for proper fixation).

7. Tissue Biopsy, NOS

a. Biopsy sample submitted in 10% Neutral Buffered Formalin (NBF).

8. Endocervical Curettage

a. A curette is used to scrape the lining of the endocervical canal.
b. Place tissue is placed in 10% Neutral Buffered Formalin (NBF) or Carson Millonig' formalin.

9. Vulva Biopsy

a. A small area of the vulva is removed and placed into 10% Neutral Buffered Formalin (NBF) or Carson Millonig' formalin.
b. Sample will be sent out to reference lab.

10. Vaginal Biopsy

a. A small area of the vagina is removed and placed in 10% Neutral Buffered Formalin (NBF) or Carson Millonig' formalin.

II. Transport:

A. Transport at 2°C to 50°C

III. Clinical Data:

A. Source
B. (LEEP) Orientation
C. Pertinent Clinical History

IV. Restrictions:

A. Hemostatic solutions, such as Monsel's solution, should NOT be applied until after all biopsies are taken, as these chemicals cause a coagulative artifact that severely limits microscopic evaluation of the tissue.
B. Specimens are occasionally delivered in CytoRich Red. If this happens, the sample needs to be transferred to formalin immediately.
C. Any sample not listed above is an excluded source.
D. If the source submitted is incorrect and discovered at time of pathologist review, a note will be added to the patient report and/or an amended report will be issued.

ATTACHMENTS

ATTACHMENT A

National Air Carrier Refrigerated Shipping Guide

This is a brief guide that will detail how to properly package and ship your blood specimens to ensure specimen stability through transit. NOTE: **The insulated mailer is for blood specimens only.**

Step 1

Ice packs have been provided by Arbor Diagnostics to keep the blood specimens at a stable temperature while in transit.

- Ensure the ice packs are properly stored and frozen prior to shipping. The ice packs should be thoroughly frozen while lying flat in the freezer. Please note that the ice packs should be rock solid when completely frozen. If they are soft and malleable, they are not ready to be shipped.

Step 2

- After the ice packs have completely frozen, horizontally place 1 ice pack in the bottom of the insulated mailer.
- Place the bagged blood specimens in the insulated mailer.
- Place 1 more ice pack on top of the blood specimens.
- **Please note** that only one ice pack should be used if there are less than 30 blood specimens in one insulated mailer

Step 3

Once you have packaged your specimens in their individual specimen bags and placed them in the insulated mailer to be shipped, you will need to:

- Peel off the adhesive cover strip to expose the adhesive.
- Fold the adhesive over and press to ensure a good seal.
- Place the insulated mailer in the Uline insulated foam shipping kit provided by Arbor.

NOTE: **Please ensure the Uline shipping kit is sealed with tape before shipping**

National Overnight Air Carrier Refrigerated Shipping Guide

This is a brief guide that will detail how to properly package and ship your blood specimens to ensure specimen stability through transit. NOTE: **The Uline insulated foam shipping kit is for blood specimens only.**

Step 1

Ice packs and Uline insulated foam shipping kits have been provided by Arbor Diagnostics to keep the blood specimens at a stable temperature while in transit.

- Ensure the ice packs are properly stored and frozen prior to shipping. The ice packs should be thoroughly frozen while lying flat in the freezer. Please note that the ice packs should be rock solid when completely frozen. If they are soft and malleable, they are not ready to be shipped.

Step 2

- After the ice packs have completely frozen, place 2 ice packs in the bottom of the 9x9x7 insulated foam shipping kit.
- Place the bagged blood specimens in the shipping kit.

Step 3

Once you have packaged your specimens in their individual specimen bags and then into a specimen transport bag and placed them in the insulated foam shipping kit to be shipped, you will need to:

- Ensure the foam lid is put on the foam box and seated properly.
- Ensure the foam box has a corrugated outer box.
- Seal the corrugated outer box with boxing tape.

NOTE: **Please ensure the Uline shipping kit is sealed with tape before shipping**

ATTACHMENT B

National Air Carrier Ambient Shipping Guide

This is a brief guide that will detail how to properly package and ship your ambient specimens to ensure specimen stability through transit.

Step 1

A Uline insulated foam shipping kit has been provided by Arbor Diagnostics to ship ambient specimens.

- Each specimen should be sealed properly and then packaged in a 6x9 specimen bag.
- Place the requisition for the specimen in the outer pocket of the 6x9 specimen bag.

Step 2

- Place all individually packaged specimens into a larger 12x15 specimen transport bag.
- Complete and place the specimen transport log in the outer pocket of the 12x15 specimen transport bag.

Step 3

Once you have packaged your specimens in their individual specimen bags and placed them in the transport bag to be shipped, you will need to:

- Place all sealed 12x15 specimen transport bag in the Uline insulated foam shipping kit.
- Put the lid on the insulated foam shipping kit and seal the outer box with tape.

National Overnight Air Carrier Ambient Shipping Guide

This is a brief guide that will detail how to properly package and ship your ambient specimens to ensure specimen stability through transit.

Step 1

FedEx Large Clinical Boxes have been provided by Arbor Diagnostics to ship your ambient specimens.

- Each specimen should be sealed properly and then packaged in a 6x9 specimen bag.
- Place the requisition for the specimen in the outer pocket of the 6x9 specimen bag.

Step 2

- Place all individually packaged specimens into a larger 12x15 specimen transport bag.
- Complete and place the specimen transport log in the outer pocket of the 12x15 specimen transport bag.

Step 3

Once you have packaged your specimens in their individual specimen bags and placed them in the insulated mailer to be shipped, you will need to:

- Place the sealed 12x15 specimen transport bag in the FedEx Large Clinical Box.
- Remove the adhesive cover from the adhesive strip at the top of the box and fold to close the box
- Be sure to press firmly to ensure a proper seal.
- Once the FedEx Clinical Box is sealed properly, place the provided priority overnight label in the designated area on the Box.

ATTACHMENT C

BD

Helping all people live healthy lives

BD Vacutainer® Order of Draw for Multiple Tube Collections

Designed for Your Safety

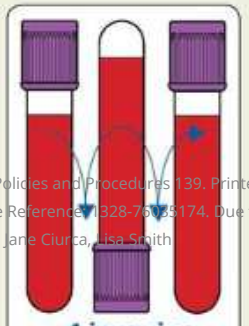
Reflects change in CLSI recommended Order of Draw (H3-A5, Vol 23, No 32, 8.10.2)

Closure Color	Collection Tube	Mix by Inverting
BD Vacutainer® Blood Collection Tubes *(glass or plastic)*		
	• Blood Cultures - SPS	8 to 10 times
	• Citrate Tube*	3 to 4 times
or	• BD Vacutainer® SST™ Gel Separator Tube	5 times
	• Serum Tube *(glass or plastic)*	5 times (plastic) none (glass)
	• BD Vacutainer® Rapid Serum Tube (RST)	5 to 6 times
or	• BD Vacutainer® PST™ Gel Separator Tube With Heparin	8 to 10 times
	• Heparin Tube	8 to 10 times
or	• EDTA Tube	8 to 10 times
	• BD Vacutainer® PPT™ Separator Tube K_2EDTA with Gel	8 to 10 times
	• Fluoride (glucose) Tube	8 to 10 times

* When using a winged blood collection set for venipuncture and a coagulation (citrate) tube is the first specimen tube to be drawn, a discard tube should be drawn first. The discard tube must be used to fill the blood collection set tubing's "dead space" with blood but the discard tube does not need to be completely filled. This important step will ensure proper blood-to-additive ratio. The discard tube should be a nonadditive or coagulation tube.

Note: Always follow your facility's protocol for order of draw

Handle all biologic samples and blood collection "sharps" (lancets, needles, luer adapters and blood collection sets) according to the policies and procedures of your facility. Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury) since they may transmit viral hepatitis, HIV (AIDS), or other infectious diseases. Utilize any built-in used needle protector if the blood collection device provides one. BD does not recommend reshielding used needles, but the policies and procedures of your facility may differ and must always be followed. Discard any



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