

# Client Services Manual

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### REFERENCE MATERIALS

- Completing the Requisition Form
- Pap Test Results Explained – The 2001 Bethesda System
- Appropriate Use of Lubricant for Pap Collection - Hologic
- LINK to ASCCP Consensus Guidelines at [www.asccp.org/Consensus2012](http://www.asccp.org/Consensus2012)

### FORMS AND DOCUMENTS

- Supply Order Form
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- Surgical Requisition Form
- Advanced Beneficiary Notice – Medicare
  
- MSDS: CytoLyt
- MSDS: Formalin
- MSDS: BD Affirm Ambient Transport System
  
- CLIA License
- CAP License

## Collection Manual

# CONTACT INFORMATION



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### Main Laboratory

Monday - Friday, 7:30am - 5:00pm

**866.530.1860**

616.530.0575 fax

### Billing Department

Monday - Friday, 8:00am - 5:00pm

**888.208.6228**

616.532.8040 fax

### Email

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Correct billing minimizes the number of patient complaints and phone calls and makes us all more efficient. We require the complete patient demographic, billing insurance data and ICD coding (or reason for test) in order to properly submit a claim.

**Assignment** We participate with most carriers and accept assignment. As required by contract, co-pays, deductibles and non-covered tests, as applicable, are routinely billed to the patient after Explanation of Benefits is received.

**ICD Code** The ICD code (billing code) must be provided with the test requisition –or- signs / symptoms / reason for visit.

**Medicaid** Due to the increase in Medicaid HMO plans, it is imperative that you submit a copy of the patient Medicaid card

**Medicare** An **ABN (Advanced Beneficiary Notice)** is required by Medicare for Pap Test collection. It must be signed by the patient prior to the testing, then submitted to us with the specimen.

**Commercial Insurance Billing** We bill most commercial carriers directly when provided insurance card information. See the **Insurance Participation List**.

**Patient Payment Responsibility** We bill first to the insurances provided with the test requisition. We balance-bill patients for cash amounts owed. Please include patient address and phone number with all test requisitions.

CO-PAYS	We are obligated by our contracts with third-party payors to balance-bill each patient for any co-payment.
DEDUCTIBLES	We are obligated by our contracts with third-party payors to balance-bill each patient for any deductible.
NON-COVERED TEST	Some plans deny payment for certain tests even though the physician deemed the test advisable. We will bill the patient where their insurance excludes payment. Denials are sometimes successfully argued by the patient, but insurers do not hear arguments from the laboratory.
CASH-PAY (no insurance)	We will bill uninsured patients directly. Please include all patient demographic information requested on the test requisition.
DISCOUNTS	As a clinician you may occasionally offer a patient discounts. We can match your patient-bill discounts, up to 50% of our standard fee. To comply with Anti-kickback Regulations your request must be in writing and must attest to the percentage discount that you have applied.

# Client Manual

## INSURANCE PARTICIPATION LIST 8/1/13



<b>AARP</b>	<b>AETNA US Healthcare</b>	<b>ASR-Physician's Care</b>
<b>Beech Street US Health &amp; Life</b> (card copy front & back)	<b>Blue Choice</b>	<b>Blue Cross Blue Shield</b> all but BCN primary
<b>Blue Preferred</b>	<b>Blue Preferred Plus</b>	<b>Champus</b>
<b>Chandler Group</b>	<b>ChoiceCare Network</b>	<b>CIGNA</b>
<b>Cofinity</b>	<b>Community Blue</b>	<b>DirectCare America</b>
<b>Ethix Great Lakes</b>	<b>Federal Mogul</b>	<b>First Health</b>
<b>Great West</b>	<b>HAP</b> (card copy front & back)	<b>Healthscope</b>
<b>Health Plus</b>	<b>Humana</b>	<b>IBA</b>
<b>Integrated Health Plan (IHP)</b>	<b>McLaren Health Plan</b> all but Medicaid or healthcare employee plan	<b>Mail Handlers</b>
<b>Medicaid</b> all but CareSource, Midwest Health Plan, McLaren Medicaid	<b>Medicare</b> For Paps, patient must sign ABN	<b>MESSA</b>
<b>MultiPlan</b>	<b>OneHealth</b>	<b>PHCS</b>
<b>PHP</b> all but healthcare employee plan (card copy front & back)	<b>PPOM/Cofinity</b>	<b>Preferred Choices</b>
<b>Primary Health Services</b>	<b>Principal</b>	<b>Priority Health</b>
<b>Promerica</b> all but healthcare employee plan	<b>RealHealth Multiplan</b>	<b>SmartHealth Plans (HPO Network)</b>
<b>TRICARE</b>	<b>United Healthcare</b>	<b>UMR (United Medical Resource)</b>
<b>Cash Paying Patients</b> We understand that your practice may offer patient discounts on a case-by-case basis. We can match your patient-bill discounts, up to 50% of our standard fee. To comply with Anti-kickback Regulations your request must be in writing and must specify the percentage discount that you have applied.		

# Collection Manual

## BIOPSY / EXCISION - IN FORMALIN



### 1. Complete a requisition form - incomplete data may cause delay or rejection

- Clinician name, practice / location
- Patient name, address, phone, date of birth, MRN or Visit Number
- Date of service, time of collection
- Tissue site, position and laterality. Label multi-part specimens A, B, C etc with corresponding descriptions
- History, signs and symptoms
- Additional tests ie special stains, immunohistochemistry
- Include a billing face sheet and/or copy of the insurance card

### 2. Label each biopsy jar - 2 ID's and a specimen site on each jar

- Include two patient identifiers; Patient Name + (ie bar-code, MRN, Visit #, Date of Birth)
- Include the specimen collection site, labeled A, B, C etc corresponding to the requisition
- Apply the label to the jar

### 3. Submit the specimen in formalin

- **Small Specimen** - (ie breast core, skin, cervical biopsy, ECC, GI polyp, prostate core)
  - Immerse each discreet specimen in a separate 40ml formalin jar.
  - Mark relevant margins with suture. Indicate significance of suture on the requisition
- **Diathermy Loop Excision**
  - Cone - ink the squamo-columnar junction at the 12 o'clock position. Do not cut the specimen open
    - $\leq 1.5\text{cm}$  - place in a labeled white cassette, into a 60 ml formalin jar
    - $> 1.5\text{cm}$  - immerse directly into a 40 ml formalin jar
  - Tissue strips - ink the border nearest the cervical os and document it on the requisition. Place in a labeled lavender cassette, into a 40 ml formalin jar
- **Large specimen** - (ie appendix, breast reduction, colon, amputation, mastectomy, placenta, uterus)
  - Place specimen in the smallest container (1 qt, 2 qt, 1 gal) that allows full immersion
  - Carefully add bulk formalin, completely immersing the specimen

### 4. Package for transport

- Log the case on the Specimen Manifest
- Tighten the lid, and then seal the jar(s) in a bio-transport bag. Keep large containers upright
- Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
- Stable at room temperature
- Lockbox specimens - Place an activated hand-warmer in the lockbox at  $\leq 15^{\circ}\text{F}$ . See [Lockbox Instructions](#)

**Limitations:** Formalin fixation precludes chromosome studies, flow cytometry and frozen section. See [Biopsy - Fresh Tissue](#)

**Supplies:** Formalin pre-fill jar (40ml, 60ml), cassette, large container (1qt, 2 qt, 1 gal) + bulk formalin, ink, requisition form, bio-transport bag

**Formalin Caution:** Eye splash - rinse for 15 minutes, then seek immediate medical attention. Ingestion - Poison, do not induce vomiting, seek immediate medical attention. Carcinogen - avoid prolonged contact and inhalation. See [Formalin MSDS](#)

**Guideline Links:** [ASCCP Guidelines for Women's Health collections](#)

**Turn-around time:** 93% at 24 hours; ancillary stains may add 24 hours

1. **Call the laboratory to pre-arrange transport. These are RUSH specimens and must be scheduled.**
2. **Complete a requisition form - incomplete data may cause delay or rejection**
  - Clinician name, practice / location
  - Patient name, address, phone, date of birth, MRN or Visit Number
  - Date of service, time of collection
  - Tissue site, position and laterality. Label multi-part specimens A, B, C etc with corresponding descriptions
  - History, signs and symptoms
  - **Test(s) - specify chromosome study, flow cytometry or frozen section on the requisition**
  - Include a billing face sheet and/or copy of the insurance card
3. **Label each container - 2 ID's and a specimen site on each jar**
  - Include two patient identifiers; Patient Name + (ie bar-code, MRN, Visit #, Date of Birth)
  - Include the specimen collection site, labeled A, B, C etc corresponding to the requisition
  - Apply the label to the jar
4. **Submit the specimen as fresh tissue**
  - **Chromosome study** - submit in saline soaked gauze in a sterile container
  - **Flow cytometry** - submit in saline soaked gauze in a sterile container -or- flow transport media
  - **Frozen section** - submit in saline soaked gauze in a sterile container. Provide phone number for STAT result reporting.
5. **Package for transport**
  - Log the case on the Specimen Manifest
  - Tighten the lid, and then seal the container(s) in a bio-transport bag. Keep large containers upright.
  - Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
  - Refrigeration is required until transported.

**Limitations:** Specimens submitted fresh (no formalin). Pre-schedule transport to coincide with surgery. Refrigerate until transported.

**Supplies:** Sterile urine container, requisition form, bio-transport bag

**Caution:** Fresh tissue should be handled observing Universal Precautions

**Turn-around time:** Chromosome study - preliminary report 48 hours; Flow cytometry - 72 hours; Frozen section - provisional diagnosis STAT

# Collection Manual

## BONE MARROW ASPIRATION & BIOPSY



### 1. Complete a requisition form - incomplete data may cause delay or rejection

- Clinician name, practice / location
- Patient name, address, phone, date of birth, MRN or Visit Number
- Date of service, time of collection
- Tissue site, position and laterality. Label multi-part specimens A, B, C etc with corresponding descriptions
- History, signs /symptoms and specify known cell type (ie B-cell, small cleaved cell).
- Attach most recent CBC and differential reports.
- Include a billing face sheet and/or copy of the insurance card

### 2. Label each biopsy jar - 2 ID's and a specimen site on each jar

- Include two patient identifiers; Patient Name + (ie bar-code, MRN, Visit #, Date of Birth)
- Include the specimen collection site, labeled A, B, C etc corresponding to the requisition
- Apply the label to the jar

### 3. Submit the specimen as bone marrow biopsy:

- **Aspirate clot** - submit in a 40 ml formalin jar labeled "A. Aspirate clot"
- **Core biopsy** - submit in a 40 ml formalin jar labeled "B. Core biopsy"
- **Prepared slides** - label each slide with patient name and site and secure in a plastic slide mailer
  - Peripheral smear, unstained, 1 - 2 slides
  - Touch prep slide, unstained, 2 slides
  - Bone marrow aspirate slides, unstained, 3 - 5 slides

### 4. Package for transport

- Log the case on the Specimen Manifest
- Tighten the lid, and then seal the jar(s) in a bio-transport bag.
- Submit slides in a separate bio-transport bag from the formalin containers
- Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
- Stable at room temperature
- Lockbox specimens - Place an activated hand-warmer in the lockbox at  $\leq 15^{\circ}\text{F}$ . See [Lockbox Instructions](#)

**Limitations:** Formalin fixation precludes chromosome studies, flow cytometry and frozen section. See [Biopsy - Fresh Tissue](#)

**Supplies:** Formalin pre-fill jar (40ml), microscope slides, slide mailers, requisition form, bio-transport bag

**Formalin Caution:** Eye splash - rinse for 15 minutes, then seek immediate medical attention. Ingestion - Poison, do not induce vomiting, seek immediate medical attention. Carcinogen - avoid prolonged contact and inhalation. See Formalin MSDS

**Turn-around time:** 48 hours

# Collection Manual

## FINE NEEDLE ASPIRATION (FNA)

### 1. Complete a requisition form - incomplete data may cause delay or rejection

- Clinician name, practice / location
- Patient name, address, phone, date of birth, MRN or Visit Number
- Date of service
- Include a billing face sheet and/or copy of the insurance card
- Provide site and clinical history on requisition or FNA Cytology Worksheet (included with FNA kit):
  - Organ / site, laterality or other position
  - Lesion features, i.e. hard, soft, size, duration, painful, attached, growth
  - History including prior diagnosis, clinical diagnosis, symptoms, treatment

### 2. Label each biopsy jar and slide - 2 ID's and a specimen site on each jar and slide

- Include two patient identifiers; Patient Name + (i.e. bar-code, MRN, Visit #, Date of Birth)
- Label the slides (not the mailers) in pencil. Ink will dissolve during processing

### 3. Evacuate prominent cysts, if present, prior to aspirating the solid mass.

- If < 1 ml of cystic fluid, prepare slides per instructions in section 5 below
- If  $\geq$  1 ml of cystic fluid, express the evacuated cyst fluid into a labeled CytoLyt™ vial

### 4. Aspirate solid mass lesions

- Collect multiple passes. Three passes are usually sufficient for the diagnosis of a solid lesion
- Use a new syringe and needle for each pass
- Insert the needle into the mass at a 90° angle
- Apply appropriate vacuum to the syringe:
  - Moderate vacuum for non-bloody lesions
  - Minimal vacuum for very bloody lesions, to avoid diluting the sample with copious amounts of blood
  - More vacuum or a larger gauge needle for fatty or fibrous lesions.
- Move the needle, within the mass, in a back and forth cutting motion. Keep the needle tip within the mass.
- Change the angle of the needle to aspirate different areas of the mass.
- Release the vacuum.
- Withdraw the needle at a 90° angle.

### 5. Prepare one fixed slide and one air-dried slide per pass

- Prepare 2 slides per pass by labeling one slide AD (air-dried) and one slide FX (fixed)
- Carefully, remove the needle from the syringe, apply vacuum to the syringe and reattach the needle
- Angle the needle-bevel flat against the FX slide and expel the entire needle contents
- Invert the AD slide over the FX slide, allow the sample to spread, and *gently* pull the slides apart, top to bottom.
- *Immediately* immerse the FX slide in the lavender-top alcohol slide vial
- Allow the AD slide to air-dry (fanning the slide to hasten drying will enhance the smear)
- Rinse the needle contents into the saline vial:
  - Open the saline vial and draw saline up through the needle into the syringe hub
  - Express the rinse back into the saline vial
  - Collect the needle rinses from all passes into the one saline vial
- For multiple passes, repeat step 5, using a new needle and syringe for each pass.

### 6. Package for transport

- Log the case on the Specimen Manifest
- Tighten the lid(s), and then seal the vial(s) in a bio-transport bag.
- Close the AD slides in the blue slide mailers and seal in the bio-transport bag
- Place the requisition form and FNA Cytology Worksheet in the outer sleeve of the bio-transport bag
- Stable at room temperature



**1. Complete a requisition form - incomplete data may cause delay or rejection**

- Clinician name, practice / location
- Patient name, address, phone, date of birth, MRN or Visit Number
- Method of specimen collection, for example; voided urine, catheter or wash, renal barbotage
- Relevant history i.e., hematuria, fever, history of UTI, history of bladder cancer, history of renal disease, CT scan findings and suspected diagnosis
- Related treatments including chemotherapy, radiation and surgery
- Include a billing face sheet and/or copy of the insurance card

**2. Label the CytoLyt jar - 2 ID's and a specimen site on each jar**

- Include two patient identifiers; Patient Name + (ie bar-code, MRN, Visit #, Date of Birth)
- Include the specimen collection site, labeled A, B, C etc corresponding to the requisition
- Apply the label to the jar

**3. Collect 20ml to 80ml of voided urine**

- Do not collect the first urine of the day. The second urine is preferred
- Provide the patient a moist towelette with instructions to wipe the area around the urethral opening
- Instruct the patient to collect a mid-stream specimen directly into the pre-filled CytoLyt jar

**4. Package for transport**

- Log the case on the Specimen Manifest
- Tighten the lid, and then seal the jar in a bio-transport bag
- Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
- Stable at room temperature

**Limitations:** Microbiology or culture & sensitivity are separate collections and must not be submitted in CytoLyt. Refer to your clinical laboratory collection procedures

**Supplies:** CytoLyt pre-filled jar, requisition form, bio-transport bag

**CytoLyt Caution:** Eye splash - rinse for 15 minutes, then seek immediate medical attention. Poison - ingestion of as little as 4 oz can cause blindness, do not induce vomiting; drink 2 glasses of water and seek immediate medical attention -. See CytoLyt MSDS

**Guideline Links:**

**Turn-around time:** 93% at 24 hours; ancillary stains may add 24 hours

**1. Instruct the patient**

- Avoid douching, intercourse and lubricants 24 hours prior to exam
- Schedule the exam for the non-menstrual portion of her cycle if possible

**2. Complete a requisition form - incomplete data may cause delay or rejection**

- Clinician name, practice / location
- Patient name, address, phone, date of birth, MRN or Visit Number
- Date of service
- Reason for Pap, specify: PAP screen low-risk, PAP screen high-risk or PAP diagnostic
- History, signs and symptoms, ICD9
- Menstrual status: LMP, pregnant, postpartum, postmenopausal, hysterectomy, hormones
- Medicare ABN submitted for all Medicare patients
- Include a billing face sheet and/or copy of the insurance card

**3. Label the vial - 2 ID's on the vial**

- Include two patient identifiers; Patient Name + (i.e. bar-code, MRN, Visit #, date of birth)

**4. Pre-collection procedures**

- Lubricate the *sides* of the speculum with minimal lubricant (avoid the speculum head); or use water. See reference 3.4, Appropriate Use of Lubricant for Pap Collection; Hologic Nov 2012
- Collect the Pap Test prior to all other gyn collections. Visualize the cervix and describe visible lesions
- Remove excess mucous, exudate and blood by gently dabbing with gauze

**5. Collect a cervical sample**

- Rotate the spatula 360° around the ectocervix. Include "erosion" borders
- Immediately swish the spatula 10 times in the vial to release the sample. Discard the spatula

**6. Collect an endocervical sample**

- Insert the cytobrush into the endocervical canal until only a few bristles remain exposed
- Rotate slowly 1/2 turn. Added rotation may cause bleeding
- Immediately rinse the brush in the vial, rotating 10 times while pressing against the vial wall.
- Swish the brush vigorously to further release sample. Discard the brush

**7. Collect cervical/endocervical sample utilizing the broom**

- Insert the broom into the endocervical canal, leaving a few of the broom bristles out of the canal
- Rotate the broom 360° four(4) times
- Immediately rinse the broom in the vial, rotating 10 times while pressing against the vial wall.
- Swish the broom vigorously to further release sample. Discard the broom

**8. A vaginal sample is not routinely collected**

- Collect a vaginal sample using a plastic spatula, for:
  - Hysterectomy patients - sample the lateral vaginal wall
  - Visualized vaginal lesions - scrape the lesion and follow with a biopsy
  - Suspected endometrial carcinoma - sample the vaginal pool
- Immediately swish the spatula 10 times in the vial to release the sample. Discard the spatula

**9. Package for transport**

- Log the case on the Specimen Manifest
- Tighten the vial lid, and then seal the vial in a bio-transport bag.
- Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
- Stable at room temperature

**Limitations:** The Pap Test is a screening test with irreducible false negative and false positive rates. Correlate with clinical findings. Management guidelines are recommendations and not a substitute for clinical judgment. High-yield collection is imperative. Lubricant can interfere with processing

**Supplies:** PreservCyt™ Solution, Cytobrush + Spatula, requisition form, bio-transport bag

**PreservCyt™ Caution:** Eye splash - rinse for 15 minutes, then seek immediate medical attention. Poison - ingestion of as little as 4 oz can cause blindness, do not induce vomiting; drink 2 glasses of water and seek immediate medical attention -. See PreservCyt MSDS

**Guideline Links:** ASCCP Guidelines for Women's Health collections

# Collection Manual

## HPV DNA - Human Papilloma Virus



1. **Complete a requisition form** - incomplete data may cause delay or rejection
  - Clinician name, practice / location
  - Patient name, address, phone, date of birth, MRN or Visit Number
  - Date of service, time of collection
  - History, signs and symptoms
  - Include a billing face sheet and/or copy of the insurance card
2. **Label a ThinPrep vial** - 2 ID's on each vial
  - Include two patient identifiers; Patient Name + (ie bar-code, MRN, Visit #, Date of Birth)
3. **Collect a ThinPrep cervical /endocervical sample. See [Collection Manual, PAP TEST](#)**
4. **Ordering HPV-HR (high-risk) probe options:**
  - On a current order - check "HPV high-risk probe" and check "any result"
  - On a current order / REFLEX - check "HPV high-risk probe" and check the applicable Pap diagnoses
  - Standing Order / REFLEX is available
5. **Ordering HPV 16/18 genotype - reflex if HPV-HR is Positive**
  - On a current order check "HPV16/18" and check the Pap diagnoses to REFLEX
  - Standing Order / REFLEX is available
6. **Ordering HPV expanded genotype - reflex if HPV-HR is Positive**
  - On a current order check "HPV expanded genotype" and check the Pap diagnoses to REFLEX
7. **Package for transport**
  - Log the case on the Specimen Manifest
  - Tighten the lid, and then seal the vial in a bio-transport bag.
  - Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
  - Stable at room temperature

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**HPV-HR:** Cervista™ HPV HR is a screen for 16, 18, 31, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68. Sensitivity 92.8%. Run daily

**HPV 16/18:** Cervista™ 16/18 is intended for use in conjunction with HPV-HR. TAT = ≤ 5 days / run weekly

**HPV expanded genotype** specifies 16, 18, 31, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68. Sensitivity, Specificity, methodology, TAT = ≤ 5 days / run weekly

**Standing Orders:** You will be prompted to renew your standing order annually. You may change a standing order at any time. You may override a Standing Order on any given test by changing the requisition order

**Supplies:** PreservCyt™ Solution, Cytobrush + Spatula, requisition form, bio-transport bag.

**Viability:** 6 weeks without refrigeration; tests may be ordered up to 6 weeks after collection.

**PreservCyt™ Caution:** Eye splash - rinse for 15 minutes, then seek immediate medical attention. Poison - ingestion of as little as 4 oz can cause blindness, do not induce vomiting; drink 2 glasses of water and seek immediate medical attention -. See PreservCyt MSDS

**Guideline Links:** [ASCCP Guidelines](#) for Women's Health collections

# Collection Manual

## HPV DNA - Human Papilloma Virus



1. **Complete a requisition form** - incomplete data may cause delay or rejection
  - Clinician name, practice / location
  - Patient name, address, phone, date of birth, MRN or Visit Number
  - Date of service, time of collection
  - History, signs and symptoms
  - Include a billing face sheet and/or copy of the insurance card
2. **Label a ThinPrep vial** - 2 ID's on each vial
  - Include two patient identifiers; Patient Name + (ie bar-code, MRN, Visit #, Date of Birth)
3. **Collect a ThinPrep cervical /endocervical sample. See [Collection Manual, PAP TEST](#)**
4. **Ordering HPV-HR (high-risk) probe options:**
  - On a current order - check "HPV high-risk probe" and check "any result"
  - On a current order / REFLEX - check "HPV high-risk probe" and check the applicable Pap diagnoses
  - Standing Order / REFLEX is available
5. **Ordering HPV 16/18 genotype - reflex if HPV-HR is Positive**
  - On a current order check "HPV16/18" and check the Pap diagnoses to REFLEX
  - Standing Order / REFLEX is available
6. **Ordering HPV expanded genotype - reflex if HPV-HR is Positive**
  - On a current order check "HPV expanded genotype" and check the Pap diagnoses to REFLEX
7. **Package for transport**
  - Log the case on the Specimen Manifest
  - Tighten the lid, and then seal the vial in a bio-transport bag.
  - Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
  - Stable at room temperature

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**HPV-HR:** Cervista™ HPV HR is a screen for 16, 18, 31, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68. Sensitivity 92.8%. Run daily

**HPV 16/18:** Cervista™ 16/18 is intended for use in conjunction with HPV-HR. TAT = ≤ 5 days / run weekly

**HPV expanded genotype** specifies 16, 18, 31, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68. Sensitivity, Specificity, methodology, TAT = ≤ 5 days / run weekly

**Standing Orders:** You will be prompted to renew your standing order annually. You may change a standing order at any time. You may override a Standing Order on any given test by changing the requisition order

**Supplies:** PreservCyt™ Solution, Cytobrush + Spatula, requisition form, bio-transport bag.

**Viability:** 6 weeks without refrigeration; tests may be ordered up to 6 weeks after collection.

**PreservCyt™ Caution:** Eye splash - rinse for 15 minutes, then seek immediate medical attention. Poison - ingestion of as little as 4 oz can cause blindness, do not induce vomiting; drink 2 glasses of water and seek immediate medical attention -. See PreservCyt MSDS

**Guideline Links:** [ASCCP Guidelines](#) for Women's Health collections

# Collection Manual

## CHLAMYDIA & GONORRHEA



### 1. Complete a requisition form - incomplete data may cause delay or rejection

- Clinician name, practice / location
- Patient name, address, phone, date of birth, MRN or Visit Number
- Date of service, time of collection
- History, signs and symptoms
- Include a billing face sheet and/or copy of the insurance card

### 2. Label the vial - 2 ID's on each vial

- Include two patient identifiers; Patient Name + (ie bar-code, MRN, Visit #, Date of Birth)

### 3. Collection

- **Collect a ThinPrep cervical /endocervical sample. See Collection Manual, PAP TEST**
- **Alternate female collection** - BD Collection Kit for Endocervical Specimens (**pink handle**)
  - Sample the endocervix with the pink swab
  - Insert the pink swab into the collection vial
  - Break of the swab handle by bending the pink handle until it snaps.
  - Seal the vial with only the pink swab inside
- **Male collection** - Use the BD Male Urethra Specimen Collection Kit (**blue handle**)
  - Insert the swab into the urethra and turn 1/2 turn
  - Insert the swab into the collection vial
  - Break of the swab handle by bending the blue handle until it snaps.
  - Seal the vial with the swab inside
- **Urine collection for female and male** - Use the BD Urine Preservative Transport (UPT)
  - Instruct the patient to collect 20ml to 60ml voided urine into a sterile urine cup
  - Pipette 2ml - 3ml urine into the UPT to the range of the Fill Window (do not overfill)
  - Securely cap the UPT tube and mix well. Discard the pipette

### 4. Package for transport

- Log the case on the Specimen Manifest
- Tighten the lid, and then seal the container in a bio-transport bag
- Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
- Stable at room temperature for 30 days

**Method:** BD Viper CT Qx and GC Qx. CT sensitivity = 94.1%, specificity = 99.8%. NG sensitivity = 95.3%, specificity = 99.9%

**Supplies:** PreservCyt™ Solution, Cytobrush + Spatula, requisition form, bio-transport bag; Male - BD Male Urethra Collection Kit. Alternate collections: BD Collection Kit for Endocervical Specimens -or- BD Male Urethra Specimen Collection Kit -or- BD Urine Preservative Transport (UPT)

**Caution: PreservCyt™:** Eye splash - rinse for 15 minutes, then seek immediate medical attention. Poison - ingestion of as little as 4 oz can cause blindness, do not induce vomiting; drink 2 glasses of water and seek immediate medical attention -. See PreservCyt MSDS

**Standing Orders:** You will be prompted to renew your standing order annually. You may change a standing order at any time. You may override a Standing Order on any given test by changing the requisition order

**Guideline:** CDC recommends annual chlamydia screening for all sexually active females 25 and under and for women older than 25 with risk factors such as a new sex partner or multiple partners

**Turn-around time:** 93% at 24 hours

**1. Complete a requisition form - incomplete data may cause delay or rejection**

- Clinician name, practice / location
- Patient name, address, phone, date of birth, MRN or Visit Number
- Date of service, time of collection
- History, signs and symptoms
- Include a billing face sheet and/or copy of the insurance card

**2. Label the vial - 2 ID's on each vial**

- Include two patient identifiers; Patient Name + (ie bar-code, MRN, Visit #, Date of Birth)
- Label the vial as "HSV" or "Lesion"

**3. Collection utilizing the BD Collection Kit for Endocervical Specimens (pink handle)**

- Discard the white swab immediately
- Sample the visible ano-genital lesion with the pink-handled swab
- Insert the swab into the collection vial
- Break off the swab handle by bending the pink handle until it snaps.
- Seal the vial with only the pink swab inside

**4. Package for transport**

- Log the case on the Specimen Manifest
- Tighten the lid, and then seal the vial in a bio-transport bag. Keep large containers upright
- Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
- Stable at room temperature for 14 days

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**Method:** BD Viper. HSV I sensitivity = 96.7%, specificity = 95.1. HSV II sensitivity = 98.4%, specificity = 80.6%

**Supplies:** BD Collection Kit for Endocervical Specimens (pink handle), requisition form, bio-transport bag

**Guideline:** Sample visible ano-genital lesions

**Turn-around time:** run once per week

# Collection Manual

## ORAL OR CUTANEOUS HERPES SIMPLEX I & II



### 1. Complete a requisition form - incomplete data may cause delay or rejection

- Clinician name, practice / location
- Patient name, address, phone, date of birth, MRN or Visit Number
- Date of service, time of collection
- History, signs and symptoms
- Include a billing face sheet and/or copy of the insurance card
- Indicate site (oral, skin and anogenital)

### 2. Label the vial - 2 ID's on each vial

- Include two patient identifiers; Patient Name + (i.e. bar-code, MRN, Visit #, Date of Birth)
- Label the vial as "HSV" or "Lesion"

### 3. Collection utilizing the BD Collection Kit for Endocervical Specimens (pink handle)

- Discard the white swab immediately
- Sample the visible oral or cutaneous lesion with the pink-handled swab
- Insert the swab into the collection vial
- Break off the swab handle by bending the pink handle until it snaps.
- Seal the vial with only the pink swab inside

### 4. Package for transport

- Log the case on the Specimen Manifest
- Tighten the lid, and then seal the vial in a bio-transport bag. Keep large containers upright
- Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
- Stable at room temperature for 14 days

\*\* Note: This test is not FDA approved. It has been validated at Pathology Laboratory; CLIA ID 23D0380021.

**Method:** BD Viper.

**Supplies:** BD Collection Kit for Endocervical Specimens (pink handle), requisition form, bio-transport bag

**Guideline:** Sample visible oral or cutaneous lesions

**Turn-around time:** run once per week

# Collection Manual

## VAGINITIS SCREEN - Candida, Gardnerella, Trichomonas



### 1. Complete a requisition form - incomplete data may cause delay or rejection

- Clinician name, practice / location
- Patient name, address, phone, date of birth, MRN or Visit Number
- Date of service, time of collection
- History, signs and symptoms
- Include a billing face sheet and/or copy of the insurance card

### 2. Label the vial - 2 ID's per vial

- Include two patient identifiers; Patient Name + (ie bar-code, MRN, Visit #, Date of Birth)
- Include date and time of collection on the vial (time-sensitive specimen)

### 3. Collect the specimen - using BD Affirm Collection Device

- Break the ampule and dispense the Transport Media into the Sample Collection Tube
- Use the swab to obtain a sample from the posterior vaginal fornix. Twist the swab against the vaginal wall 3 times. Swab the lateral vaginal wall while removing the swab
- Immediately place the swab in the Sample Collection Tube (SCT)
- Break the swab at the pre-scored mark by bending the handle until it breaks. Leave the swab in the Tube and discard the handle into the bio-waste
- Press the cap onto the Tube (with the Swab inside). The cap will "snap" when properly sealed

### 4. Package for transport

- Log the case on the Specimen Manifest
- Assure the cap is firmly sealed, and then seal the vial in a bio-transport bag.
- Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
- Stable for 3 days at room temperature. **Must be received by the lab within 72 hours**

**Limitations:** Source is limited to vaginal samples using the only materials from the BD kit. Swab must be submitted in the Tube with Transport Media. Test must be received at the lab within 72 hours. Candida sensitivity = 82.3%, specificity = 98.4%. Gardnerella sensitivity = 95.2%, specificity = 100%. Trichomonas sensitivity = 92.8%, specificity = 99.9%.

**Supplies:** BD Affirm VPIII Ambient Temperature Transport System, requisition form, bio-transport bag

**Guideline Links:** [ASCCP Guidelines](#) for Women's Health collections

**Transport Media™ Caution:** Poison – avoid ingestion, inhalation and skin contact. Flammable - See BD Affirm Transport System MSDS

**Turn-around time:** 93% at 24 hours



**1. Complete a requisition form - incomplete data may cause delay or rejection**

- Clinician name, practice / location
- Patient name, address, phone, date of birth, MRN or Visit Number
- Date of service, time of collection
- History, signs and symptoms
- Include a billing face sheet and/or copy of the insurance card

**2. Label the vial - 2 ID's on each vial**

- Include two patient identifiers; Patient Name + (ie bar-code, MRN, Visit #, Date of Birth)

**3. Collection**

- Collect a ThinPrep cervical /endocervical sample. See Collection Manual, PAP TEST

**4. Package for transport**

- Log the case on the Specimen Manifest
- Tighten the lid, and then seal the jar(s) in a bio-transport bag
- Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
- Stable at room temperature

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**Method:** Autogenomics Spot On; sensitivity = 100%, specificity = 82.4%

**Supplies:** PreservCyt™ Solution, Cytobrush + Spatula, requisition form, bio-transport bag

**Caution:** PreservCyt™: Eye splash - rinse for 15 minutes, then seek immediate medical attention. Poison - ingestion of as little as 4 oz can cause blindness, do not induce vomiting; drink 2 glasses of water and seek immediate medical attention. See PreservCyt MSDS

**Guideline:** Symptomatic patients or *REFLEX* if vaginitis screen (BD Affirm) is Negative or *REFLEX* if Pap indicates a shift in vaginal flora

**Turn-around time:** 4 days from order or after Reflexed test is complete

# Collection Manual

## CANDIDA PANEL -

**Candida albicans, parapsilosis, tropicalis, glabrata and krusei**



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### 1. Complete a requisition form - incomplete data may cause delay or rejection

- Clinician name, practice / location
- Patient name, address, phone, date of birth, MRN or Visit Number
- Date of service, time of collection
- History, signs and symptoms
- Include a billing face sheet and/or copy of the insurance card

### 2. Label the vial - 2 ID's on each vial

- Include two patient identifiers; Patient Name + (ie bar-code, MRN, Visit #, Date of Birth)

### 3. Collection

- Collect a ThinPrep cervical /endocervical sample. See Collection Manual, PAP TEST

### 4. Package for transport

- Log the case on the Specimen Manifest
- Tighten the lid, and then seal the jar(s) in a bio-transport bag
- Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
- Stable at room temperature

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**Method:** Autogenomics Spot On; sensitivity 97.1%, specificity 84.2%

**Supplies:** PreservCyt™ Solution, Cytobrush + Spatula, requisition form, bio-transport bag

**Caution:** PreservCyt™: Eye splash - rinse for 15 minutes, then seek immediate medical attention. Poison - ingestion of as little as 4 oz can cause blindness, do not induce vomiting; drink 2 glasses of water and seek immediate medical attention. See PreservCyt MSDS

**Guideline:** Symptomatic patient or *REFLEX* if vaginitis screen (BD Affirm) is Positive for Candida or *REFLEX* if Pap indicates Candida sp.

**Turn-around time:** 4 days from order or after Reflexed test is complete

**1. Complete a requisition form** - incomplete data may cause delay or rejection

- Clinician name, practice / location
- Patient name, address, phone, date of birth, MRN or Visit Number
- Date of service, time of collection
- History, signs and symptoms
- Include a billing face sheet and/or copy of the insurance card

**2. Label the vial** - 2 ID's on each vial

- Include two patient identifiers; Patient Name + (ie bar-code, MRN, Visit #, Date of Birth)

**3. Collection**

- Collect a ThinPrep cervical /endocervical sample. See Collection Manual, PAP TEST

**4. Package for transport**

- Log the case on the Specimen Manifest
- Tighten the lid, and then seal the jar(s) in a bio-transport bag
- Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
- Stable at room temperature

---

**Method:** Autogenomics Spot On; sensitivity 100%, specificity 100% - to reference samples

**Supplies:** PreservCyt™ Solution, Cytobrush + Spatula, requisition form, bio-transport bag

**Caution:** PreservCyt™: Eye splash - rinse for 15 minutes, then seek immediate medical attention. Poison - ingestion of as little as 4 oz can cause blindness, do not induce vomiting; drink 2 glasses of water and seek immediate medical attention. See PreservCyt MSDS

**Guideline:** Symptomatic patient

**Turn-around time:** 72 hours

Consultation specimens may be submitted to Aurora Diagnostics Pathology Laboratory for formal pathologist review and reporting. Specimens may be submitted as completed cases, with prepared slides and reports, or as cases requiring further testing including immunohistochemical stains. Consults are accepted from attending physicians and from pathologists. Consult reports are sent to the requesting physician and the original laboratory.

### 1. Complete a requisition form - incomplete data may cause delay or rejection

- Clinician name, practice / location
- Patient name, address, phone, date of birth, MRN or Visit Number
- Date of service, time of collection
- Relevant clinical history, signs and symptoms
- Requests for special stains, immunohistochemistry, etc
- List of submitted specimens and the intent of the review
- Include a billing face sheet and/or copy of the insurance card

### 2. Submit materials for review

- Include two patient identifiers; Patient Name + (ie bar-code, MRN, Visit #, Date of Birth)
- Provide the original slides representing all aspects of all cases to be reviewed. Provide the tissue block if additional testing is to be performed
- Provide copies of all test requisition forms and final report results

### 3. Package for transport

- Submit slides in slide mailers
- Use padded envelopes or a box with cushioning filler

### 4. Delivery options

- Fedex to:  
*Aurora Diagnostics Pathology Laboratory, 2620 Horizon Drive SE, Suite 100, Grand Rapids, MI 49546*
- Delivery via pre-established courier
- For assistance in selecting the most appropriate option call, (866) 530-1860

**1. Complete a requisition form - incomplete data may cause delay or rejection**

- Clinician name, practice / location
- Patient name, address, phone, date of birth, MRN or Visit Number
- Date of service, time of collection
- Tissue site, position and laterality. Label multi-part specimens A, B, C etc with corresponding descriptions
- History, signs and symptoms
- Additional tests ie special stains, immunohistochemistry
- Include a billing face sheet and/or copy of the insurance card

**2. Label each biopsy jar - 2 ID's and a specimen site on each jar**

- Include two patient identifiers; Patient Name + (ie bar-code, MRN, Visit #, Date of Birth)
- Include the specimen collection site, labeled A, B, C etc corresponding to the requisition
- Apply the label to the jar

**3. Obtain an adequate tissue sample**

- **Carefully and slowly** insert the tapered device head into the endocervical canal until the **Kylon®** fabric is not visible, or as deeply as can comfortably fit.
- While pressing the **Kylon®** pad against the inner canal, rotate the **Soft-ECC®** device at least 3 rotations clockwise and 3 rotations counter-clockwise while pressing the fabric against the endocervical canal firmly. The marker notches on the shaft and near the head of the device can be used to count the number rotations.
- **DO NOT FORCE THE DEVICE INTO A STENOTIC OS, OR INSERT THE DEVICE PAST THE INTERNAL ENDOCERVICAL OS.**
- **The Kylon® (fabric) device head will be abundantly covered with a blood-tinged mucoid sample.** Inspect the fabric and if it does not appear sample is sufficient, repeat the biopsy with a second device and send two samples in one vial.

**4. Transfer sample to biopsy jar**

- Place your index and thumb on the handle/shaft of the device with the scored mark between the fingers of the right and left hand.
- The **Soft-ECC®** head will separate from the handle by bending firmly.
- Discard the acrylic handle.
- Place the head of the **Soft-ECC®** device into formalin in a secure manner.

**5. Package for transport**

- Log the case on the Specimen Manifest
- Tighten the lid, and then seal the jar(s) in a bio-transport bag. Keep large containers upright
- Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
- Stable at room temperature
- Lockbox specimens - Place an activated hand-warmer in the lockbox at ≤15°F. See [Lockbox Instructions](#)

**Limitations:** Formalin fixation precludes chromosome studies, flow cytometry and frozen section. See [Biopsy - Fresh Tissue](#)

**Supplies:** Formalin pre-fill jar (40ml, 60ml), cassette, large container (1qt, 2 at, 1 gal) + bulk formalin, ink, requisition form, bio-transport bag

**Formalin Caution:** Eye splash - rinse for 15 minutes, then seek immediate medical attention. Ingestion - Poison, do not induce vomiting, seek immediate medical attention. Carcinogen - avoid prolonged contact and inhalation. See Formalin MSDS

**Guideline Links:** [ASCCP Guidelines](#) for Women's Health collections

**Turn-around time:** 93% at 24 hours; ancillary stains may add 24 hours

**1. Complete a requisition form - incomplete data may cause delay or rejection**

- Clinician name, practice / location
- Patient name, address, phone, date of birth, MRN or Visit Number
- Date of service, time of collection
- Tissue site, position and laterality. Label multi-part specimens A, B, C etc with corresponding descriptions
- History, signs and symptoms
- Additional tests ie special stains, immunohistochemistry
- Include a billing face sheet and/or copy of the insurance card

**2. Label each biopsy jar - 2 ID's and a specimen site on each jar**

- Include two patient identifiers; Patient Name + (ie bar-code, MRN, Visit #, Date of Birth)
- Include the specimen collection site, labeled A, B, C etc corresponding to the requisition
- Apply the label to the jar

**3. Obtain an adequate tissue sample**

- For the best yield and placement, dry the lesion area with a cotton applicator or gauze prior to obtaining biopsy.
- Gently press the round tip on to the center of the lesion or cervical quadrant involved. Use pressure similar to tooth brushing. A one or two handed technique may be utilized.
- Once the fabric pad is pressed firmly against the cervix target area, rotate the device 360° clockwise for three to five rotations. Alternatively 6-10 half (180°) rotations (like key turning) in each direction may be used.
- Remove and inspect the **Kylon®** fabric pad. The **Kylon®** (fabric) device head will be filled with tissue and mucous.

**4. Transfer sample to biopsy jar**

- Snap the tip of the **SoftBiopsy®** device and place the tip into formalin in a secure manner.
- Discard the acrylic handle.

**5. Package for transport**

- Log the case on the Specimen Manifest
- Tighten the lid, and then seal the jar(s) in a bio-transport bag. Keep large containers upright
- Fold the requisition form and place in the outer sleeve of the bio-transport bag, name visible
- Stable at room temperature
- Lockbox specimens - Place an activated hand-warmer in the lockbox at  $\leq 15^{\circ}\text{F}$ . See [Lockbox Instructions](#)

**Limitations:** Formalin fixation precludes chromosome studies, flow cytometry and frozen section. See [Biopsy - Fresh Tissue](#)












**Supplies:** Formalin pre-fill jar (40ml, 60ml), cassette, large container (1qt, 2 at, 1 gal) + bulk formalin, ink, requisition form, bio-transport bag

**Formalin Caution:** Eye splash - rinse for 15 minutes, then seek immediate medical attention. Ingestion - Poison, do not induce vomiting, seek immediate medical attention. Carcinogen - avoid prolonged contact and inhalation. See Formalin MSDS

**Guideline Links:** [ASCCP Guidelines](#) for Women's Health collections

**Turn-around time:** 93% at 24 hours; ancillary stains may add 24 hours

\*\*\*All labels for collection vials MUST include at least 2 patient identifiers (Patient Name and DOB)  
or (Patient Name & Reg Form Sticker)

Tests	What It Tests For	Collection Device	Notes
Pap Test	Screening or Diagnostic	 ThinPrep Vial	Mark <u>one</u> type of Pap test (either screening or diagnostic - <u>select</u> only <u>one</u> option)
HPV	HPV High Risk & HPV 16/18 Genotyping	 ThinPrep Vial	We do have standing orders upon request
CT/GC	Chlamydia and Gonorrhoeae (There are 3 different collection options to choose from - <u>select</u> only <u>one</u> option)	 1. ThinPrep Vial	We do have standing orders (for pts. 25 and younger) upon request
		 2. BD Swab (Pink Swab) Endocervical/Lesion	Collect with Pink Swab Only, Keep Swab in Vial, Breaking at Scored Location on Stick
		 3. Pipette Urine to UPT from Sterile Container	Voided Urine (pt. must not have urinated 1 hr. prior) 20-60 ml. Fill UPT tube no more or no less than indicated within window on the container.
Vaginitis Screen	Candida, Gardnerella & Trichomonas (test will indicate "negative" or "positive" for each.)	 BD Affirm (Little Affirm tube & solution)	Time sensitive. Lab must process specimens <u>within 72 hours</u> . Because of this, we need the date and time on both the req form and on the label of the vial. Keep swab in vial.
Candida Panel	C. albicans, parapsilosis, tropicalis, glabrata and krusei (test will specify which of the 5 Candida species are identified)	 ThinPrep Vial	1. Can request this as a reflex test if Pap results indicate Candida species identified. 2. Or may reflex this test (if we have Thin Prep vial on hand) if the Vaginitis Screen (from BD Affirm) indicates that test is positive for Candida.
Bacterial Vaginosis Panel	B. fragilis, G. vaginalis, M. mulleris, M. curtisi, A. vaginalis, P. bivia (test will specify which of the 6 species are identified)	 ThinPrep Vial	1. Can request this as a reflex test if results indicate shift in flora suggestive of B. Vaginosis. 2. Or may reflex this test (if we have Thin Prep vial on hand) if the Vaginitis Screen (from BD Affirm) indicates that test is negative for all: Candida, Gardnerella and Trichomonas.
UroGen Panel	Ureaplasma, Mycoplasma (U. urealyticum, M. genitalium, M. hominis)	 ThinPrep Vial	
Herpes	Herpes Simplex I, II (result will specify Type I or II)	 2. BD Swab (Pink Swab) Endocervical/Lesion	Collect with Pink Swab Only, Keep Swab in Vial, Breaking at Scored Location on Stick
Cystic Fibrosys	Cystic Fibrosis Testing	 ThinPrep Vial	

# Collection Manual

## COMPLETING THE REQUISITION



### DHHS and other requirements for test requisitions

The Department of Health and Human Services / Federal Register, Vol. 55, No.50 has mandated standards regarding receipt of patient information to ensure patient safety. Note that on each test container DHHS has specified TWO test IDs; first/last name + (ie MRN, date of birth, requisition bar code number, SSN last 4 digits). Additionally, we require complete insurance and patient information to properly bill for our services. Each test submitted must include the following:

- Clinician name, practice / location
- Patient name, address, phone
- Patient gender
- Patient date of birth or age
- Patient MRN or Visit Number when for locations with an emr
- Date of service
- Relevant clinical history, signs and symptoms
- Requests for special stains, immunohistochemistry, etc
- List of submitted specimens and the intent of the review
- Include a billing face sheet or copy of the insurance card(s)

To ensure that all necessary information is being provided to the laboratory, we have designed a Laboratory Requisition Form prompting capture of the necessary information. Our Requisition Forms are bar-coded with corresponding bar-coded labels to satisfy one of the two test IDs required by the DHHS. An example Requisition Form follows. Please note that lack of all the data items will result in delay of testing.



# Pap Test Results Explained - The 2001 Bethesda System

## What is the 2001 Bethesda System?

Prior to 1988 there were several reporting formats in use for cervical cytology (Pap tests). A 1988 meeting in Bethesda, Maryland brought together representatives from over three dozen national and international health agencies, including the American Cancer Society, American College of Obstetricians and Gynecologists, American Society of Clinical Pathologists, American Society for Colposcopy and Cervical Pathology and the American Society of Cytopathology. The result was the standardization of cervical cytology reporting, known as Bethesda '88. The Bethesda Workshops reconvened in 1991 and again in 2001. The 2001 workshop was a yearlong iterative review, resulting in the current system of reporting. The 2001 Bethesda System reflects important advances in biological understanding of cervical neoplasia and cervical screening technologies.

## The 2001 Bethesda System Nomenclature

### **GENERAL CATEGORY & DESCRIPTIVE DIAGNOSIS**

NEGATIVE for Intraepithelial Lesion or Malignancy

EPITHELIAL CELL ABNORMALITY – SQUAMOUS:

- ASC-US, atypical squamous cells, uncertain significance
- ASC-H, atypical squamous cells, exclude a high-grade lesion
- LSIL, low-grade squamous intraepithelial lesion (*encompasses HPV, CIN1 and VAIN1*)
- HSIL, high-grade squamous intraepithelial lesion (*encompasses CIN2, CIN3, CIS, and VAIN 2/3*)
- SQUAMOUS CELL CARCINOMA

EPITHELIAL CELL ABNORMALITY – GLANDULAR:

- ATYPICAL GLANDULAR CELLS (*will specify endocervical, endometrial or NOS. A comment may be included to indicate a high degree of suspicion if applicable*)
- ADENOCARCINOMA IN SITU, ENDOCERVICAL (*consistent with*)
- ADENOCARCINOMA (*will specify endocervical, endometrial or other*)
- MALIGNANT CELLS PRESENT (*for undifferentiated or non-epithelial lesions, a description will be provided*).

DESCRIPTIVE FINDINGS:

- Endometrial cells present. Benign-appearing endometrial cells in a woman  $\geq 40$  years of age. No evidence of squamous intraepithelial lesion. (*Comment: Endometrial cells after age 40, particularly out of phase or after menopause, may be associated with benign endometrium, hormonal alterations and, less commonly, endometrial / uterine abnormalities. Clinical correlation is recommended*)

### **OTHER FINDINGS**

ORGANISMS:

- Fungal organisms morphologically consistent with *Candida* spp.
- *Trichomonas vaginalis*
- Bacteria morphologically consistent with *Actinomyces* spp.
- Shift in flora suggestive of bacterial vaginosis.
- Cellular changes consistent with Herpes simplex virus.

OTHER NON-NEOPLASTIC FINDINGS:

- Acute inflammatory response.
- Reactive epithelial changes consistent with repair and/or benign epithelial reaction.
- Reactive cellular changes consistent with radiation effect.

### **SPECIMEN ADEQUACY:**

SATISFACTORY FOR EVALUATION

- The presence or lack of an endocervical component will be noted (*if there is a cervical sample*).
- Incomplete clinical history, ie missing menstrual status, birth date or specimen source.
- Technical limitations, ie partially obscuring blood or inflammation, incomplete fixation.

UNSATISFACTORY - processed & examined but not suitable for diagnosis (*specify reason*).

UNSATISFACTORY - rejected & not processed (*specify reason*).

### **COMMENTS:**

As applicable, includes recommendations, verification of reflex testing, explanations or further descriptions of the findings.

November 1, 2012

**Re: Lubricant use during Pap sample collection**

Dear Colleague,

On occasion, Hologic personnel are asked to provide information concerning the use of lubricants when collecting a Pap sample using the ThinPrep® Pap Test. As part of Hologic's continuing education for clinicians and laboratorians, this bulletin addresses the proper preparation of the cervix for an adequate Pap sample collection pertaining to the ThinPrep Pap Test and the use of lubricants on the speculum. Steps taken by the clinician, from patient education to improved sampling technique, may ensure that the sample collected maximizes the potential of the Pap test.<sup>1,2</sup>

**Patient Education:**

Women should be counseled to refrain from intercourse, douching, using tampons, or using intravaginal medication for at least 48 hours before the examination to decrease the possibility that the number of exfoliated cells will be diminished or obscured by personal lubricants or spermicides.<sup>1,2</sup> In addition, the patient should avoid scheduling her appointment during heavy menstrual bleeding.<sup>1</sup> If you would like Hologic patient education materials for your office, please visit [www.hologiccustomersolutions.com](http://www.hologiccustomersolutions.com).

**Sample Collection Options for Lubricating the Speculum:**

1. **Lukewarm Water:** For a patient without physical or physiologic reasons for needing lubricant, lukewarm water may be used to warm and lubricate the speculum. This protocol has the least risk to the quality of the Pap sample collected.<sup>1,3</sup> Professional organizations including ACOG and CLSI recognize that excessive use of lubricant may contaminate or obscure the Pap sample.
2. **Lubricant Gels:** If lubricant must be used due to patient discomfort or other circumstances, lubricant should be used sparingly and applied *only* to the exterior sides of the speculum blades, *avoiding contact with the tip of the speculum*.<sup>1,2,3,4</sup> (see pictures below) When a lubricant is used sparingly and appropriately, it poses little risk to the quality of the Pap sample. However, when a lubricant is used in excess, it can adversely affect the Pap sample. Hologic evaluated a variety of popular lubricants and found those containing carbomer or carbopol polymers (thickening agents) interfere with the ThinPrep Pap test when found in the sample vial.<sup>5</sup> Hologic recognizes the varying availability of different types of lubricants and recommends that, if used, any lubricant should be applied sparingly as described below.

**HOLOGIC**®

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[www.hologic.com](http://www.hologic.com)



**LABORATORY SUPPLY ORDER FORM - Please fax to 616.530.0575**

Today's Date \_\_\_\_\_ Office/Practice Name \_\_\_\_\_  
 Address \_\_\_\_\_ City, State, Zip Code \_\_\_\_\_  
 Contact Name \_\_\_\_\_ Phone number (ext.) \_\_\_\_\_

**SPECIMEN COLLECTION**

Histology	UNITS/PKG	QUANTITY
Biopsy jars, pre-filled formalin, 40ml (CASE)	96/Case	
Biopsy jars, pre-filled formalin, 40ml (BOX)	24/Box	
Biopsy jars, pre-filled formalin, 60ml (CASE)	96/Case	
Biopsy jars, pre-filled formalin, 60ml (BOX)	24/Box	
Biopsy buckets, small, 1 qt.	Each	
Biopsy buckets, medium, 1/2 gal.	Each	
Biopsy buckets, large, 1 gal.	Each	
Specimen jar, empty, 40ml	Each	
Prostate biopsy kit, 12-part	Each	
Michel's media (vial for immunofluorescence)	Each	
Formalin, bulk	Each	
Biopsy container labels	30/Sheet	
Soft-ECC®	Each	
Soft-Biopsy®	Each	

Cytology	UNITS/PKG	QUANTITY
ThinPrep™ kits - w/brush & scraper	25/Pkg	
ThinPrep™ kits - w/Cervex™ broom	25/Pkg	
CytoLyt™, 120ml fixative jars	Each	
UroVysion™ FISH kits	Each	
FNA kits	Each	
Slide mailers, plastic 2-slide	Each	
Microscope slides	72/Box	
ARC (Anal-rectal Cytology) kits	Each	

Molecular	UNITS/PKG	QUANTITY
BD Urine Preservative Transport Kit (BX)	10/Box	
BD Urine Preservative Transport Kit (CS)	100/Case	
Sterile Urine Cup (120ml), Empty	Each	
Endocervical/Lesion Swab (PINK)	Each	
Male Urethral Swab (BLUE)	Each	
BD Affirm™ VPIII transport kits	10/Box	
Buccal Swab for CF testing	Each	

**FORMS AND TRANSPORT BAGS**

	UNITS/PKG	QUANTITY
Requisition forms	75/Pkg.	
Medicare ABN forms	50/Pad	
Supply order forms	Each	
Bio-hazard transport bags, 6"x9"	100/Pkg.	
Multi-specimen bags, 12"x15", clear	Each	

Notes, Comments, Special Requests:

Date filled MM / DD / YYYY Filled by First Initial Last name

Delivered on MM / DD / YYYY Via route(circle choice(s)): A B LOCAL HOLL LATE ML FEDEX UPS SALES: INITIALS



2620 Horizon Drive SE, Suite 100, Grand Rapids, MI 49546  
616.530.1860 fax 616.530.0575 tollfree 866.530.1860  
www.pathlab.ws

LAST NAME		FIRST NAME	
ADDRESS			
CITY, STATE		ZIP	
PHONE		SOCIAL SECURITY #	
BIRTH DATE		SEX <input type="checkbox"/> M <input type="checkbox"/> F	
BIRTH DATE		MEDICAL ID	
Copy to: _____			
Address: _____			
Attach the patient's complete demographic and insurance information			
LMP: mm / dd / yy			
<input type="checkbox"/> Pregnant: weeks <input type="checkbox"/> IUD <input type="checkbox"/> ASCUS: mm/yy <input type="checkbox"/> Vaginitis			
<input type="checkbox"/> Postpartum: weeks <input type="checkbox"/> HRT <input type="checkbox"/> ASCH: mm/yy <input type="checkbox"/> Cervicitis			
<input type="checkbox"/> Postmenopausal <input type="checkbox"/> BCP <input type="checkbox"/> LSIL: mm/yy <input type="checkbox"/> AEN Bleeding			
<input type="checkbox"/> Hysterectomy <input type="checkbox"/> Depo-Pro <input type="checkbox"/> HSIL: mm/yy <input type="checkbox"/> Gyn Cancer: type & mm/yy			
<input type="checkbox"/> Hysterectomy - partial <input type="checkbox"/> Hx + HPV: mm/yy <input type="checkbox"/> Gyn Rct: type & mm/yy			
Date of Service: mm / dd / yy			
Time Collected: _____ am pm			
ICD9s (see back)			
PAP Screen low-risk routine V762: AGN if Medicare		<input type="checkbox"/> CYTOLOGY <input type="checkbox"/> FNA: _____	
PAP Screen high-risk V1589		Other: _____	
PAP Diagnostic: Signs, symptoms or ICD9 (see back):		<input type="checkbox"/> Anal-rectal Cytology	
<input type="checkbox"/> Cervix / Endocervix <input type="checkbox"/> Vaginal <input type="checkbox"/> Other: _____			
HPV High-risk probe REFLEX if Pap: <input type="checkbox"/> any result <input type="checkbox"/> NEG <input type="checkbox"/> ASCUS <input type="checkbox"/> ASCH <input type="checkbox"/> LSIL			
HPV 16/18 genotype REFLEX if HPV+ and Pap is: <input type="checkbox"/> NEG <input type="checkbox"/> ASCUS <input type="checkbox"/> ASCH <input type="checkbox"/> LSIL		AS, AB	
HPV expanded genotype REFLEX if HPV+ and Pap is: <input type="checkbox"/> NEG <input type="checkbox"/> ASCUS <input type="checkbox"/> ASCH <input type="checkbox"/> LSIL		AS, AB, 31, 33, 35, 39, 45, 51, 52, 54, 56, 58, 66, 68	
CTING <input type="checkbox"/> Screen <input type="checkbox"/> Pregnant <input type="checkbox"/> History STD <input type="checkbox"/> Rx Check <input type="checkbox"/> Other: _____		C. trachomatis and N. gonorrhoeae	
CT ONLY <input type="checkbox"/> Screen <input type="checkbox"/> Pregnant <input type="checkbox"/> History STD <input type="checkbox"/> Rx Check <input type="checkbox"/> Other: _____		C. trachomatis only	
NG ONLY <input type="checkbox"/> Screen <input type="checkbox"/> Pregnant <input type="checkbox"/> History STD <input type="checkbox"/> Rx Check <input type="checkbox"/> Other: _____		N. gonorrhoeae only	
VAGINITIS screen <input type="checkbox"/> Reflex to Candida panel of ThinPrep if positive for Candida		Candida, Gardnerella, Trichomonas	
Reflex to B. Vaginosis panel of ThinPrep if negative for Gardnerella		To Laboratory within 72 hours	
CANDIDA panel REFLEX if Pap suggests Candida species		C. albicans, parapsilosis, tropicalis, glabrata, krusei	
B. VAGINOSIS panel REFLEX if Pap suggests Bacterial Vaginosis		B. fragilis, C. vaginialis, M. mulieris, M. curtisi, A. vaginas, P. bivia	
UROGEN panel <input type="checkbox"/> Cervicitis <input type="checkbox"/> Pregnant <input type="checkbox"/> History STD <input type="checkbox"/> Symptoms		U. urealyticum, M. genitalium, M. hominis	
CYSTIC FIBROSIS Testing <input type="checkbox"/> Screening / Carrier Testing <input type="checkbox"/> Pregnancy			
HERPES Source: _____		H simplex 1&2	
TISSUE		Other Tests / History:	
A. _____ R L			
B. _____ R L			
C. _____ R L			
D. _____ R L			
E. _____ R L			
F. _____ R L			















LAST NAME		FIRST NAME		Copy to: _____  Address: _____
ADDRESS				
CITY/STATE		ZIP		
PHONE		SOCIAL SECURITY #		
BIRTH DATE		<input type="checkbox"/> M <input type="checkbox"/> F	MINI-CHART ID:	
Attach the patient's complete demographic and insurance information				

**Date of Review:** \_\_\_\_\_

Time Collected: \_\_\_\_\_

<input type="checkbox"/> Biopsy (Slide Prep & Read) <input type="checkbox"/> Slide Prep Only <input type="checkbox"/> Slide Consult Only <input type="checkbox"/> Direct Immunofluorescence <input type="checkbox"/> Check Margins				
Time/step	Procedure			Diagnoses/Symptoms/History/Special Instructions
A.	<input type="checkbox"/> Curettage <input type="checkbox"/> Punch	<input type="checkbox"/> Excision <input type="checkbox"/> Re-Excision	<input type="checkbox"/> Shave	
B.	<input type="checkbox"/> Curettage <input type="checkbox"/> Punch	<input type="checkbox"/> Excision <input type="checkbox"/> Re-Excision	<input type="checkbox"/> Shave	
C.	<input type="checkbox"/> Curettage <input type="checkbox"/> Punch	<input type="checkbox"/> Excision <input type="checkbox"/> Re-Excision	<input type="checkbox"/> Shave	
D.	<input type="checkbox"/> Curettage <input type="checkbox"/> Punch	<input type="checkbox"/> Excision <input type="checkbox"/> Re-Excision	<input type="checkbox"/> Shave	
E.	<input type="checkbox"/> Curettage <input type="checkbox"/> Punch	<input type="checkbox"/> Excision <input type="checkbox"/> Re-Excision	<input type="checkbox"/> Shave	
F.	<input type="checkbox"/> Curettage <input type="checkbox"/> Punch	<input type="checkbox"/> Excision <input type="checkbox"/> Re-Excision	<input type="checkbox"/> Shave	

**Delivery Times**

INTEGRATED LABEL		LAB ONLY	
	\$15200		88804 ×
	\$15200		88805 ×
	\$15200		88812 ×
	\$15200		88813 ×
	\$15200		88821 ×
	\$15200		88842 ×
	\$15200		88846 ×
	\$15200		88860 ×

### 1. Product and company identification

**Product name** ThinPrep CytoLyt Solution  
**Product code**  
**Address** 4 Fisher Crescent, Mount Wellington  
 Auckland, New Zealand  
**Telephone number:** +64 9 377 3336  
**Emergency Telephone Number:** 3E Hotline: +64 800 451719  
**E-mail:** sds@hologic.com  
**Manufacturer** Hologic, Inc.  
**Address** 250 Campus Drive  
**Supplier** Pharmaco (NZ) Ltd.  
 Marlborough, Massachusetts 01752  
 USA  
**Telephone number:** +1-800-442-9892  
**Emergency Telephone Number:** 3E Hotline: +1-866-519-4752  
**Access code** 333605  
**E-mail:** sds@hologic.com

### Recommended use and Limitations on use

**Recommended use** A methanol based, buffered preservative solution used to support cells during transport and slide preparation.

**SDS number** RD-01529 Rev.001

### 2. Hazards identification

#### GHS classification

<b>Physical hazards</b>	Flammable liquids	Category 3
<b>Health hazards</b>	Acute toxicity, oral	Category 3
	Acute toxicity, dermal	Category 3
	Acute toxicity, inhalation	Category 3
	Specific target organ toxicity, single exposure	Category 1
<b>Environmental hazards</b>	Not classified.	

\*Hazards not stated here are "Not classified", "Not applicable" or "Classification not possible".

#### Label elements

##### Symbols



**Signal word** None.

**Hazard statement** Flammable liquid and vapor. Toxic if swallowed. Toxic in contact with skin. Toxic if inhaled. Causes damage to organs (Central nervous system, liver, and kidneys).

#### Precautionary statement

**Prevention** Avoid breathing dust/fume/gas/mist/vapors/spray. Use only outdoors or in a well-ventilated area. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.

**Response** In case of fire: Use alcohol-resistant foam, carbon dioxide, dry powder or water fog for extinction. IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth. Wash contaminated clothing before reuse. IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician. IF exposed: Call a POISON CENTER or doctor/physician.

**Disposal** Dispose of waste and residues in accordance with local authority requirements.

**Other hazards** None known.

## Material Safety Data Sheet

### 10% Neutral buffered formalin

ACC# 88082

#### Section 1 - Chemical Product and Company Identification

**MSDS Name:** 10% Neutral buffered formalin

**Catalog Numbers:** NC9638612, NC9638613, 023-798, 027-274, 028-866, 032-039, 032-060, 032-067, 032-069, 035-159, 037-238, 037-239, 038-528, 045-112, 23-005-155, 23-005-193, 23-005-500, 23-011-120, 23-111-114, 23-111-123, 23011112, 23023798, 23027274, 23028866, 23032059, 23032060, 23032067, 23032069, 23035199, 23037238, 23037239, 23038528, 23045111, 23045112, 23245684, 23245685, 23253998, 23266200, 23305510, 23314028, 23314029, 23314033, 23314034, 23314035, 23314036, 23314037, 23314038, 23314039, 23314040, 23316154, 23316155, 23316156, 23426796, 23426797, 23427998, 245-684, 245-685, 253-998, 286-208, 305-510, 314-025, 314-026, 314-028, 314-029, 314-030, 314-033, 314-034, 314-035, 314-038, 316-154, 316-155, 316-156, 316154, 316155, 316156, 426-796, 426-797, 427-098, 57011, 57011-16, 57011 GA, 57011A, 59001-20

**Synonyms:** None.**Company Identification:**

Fisher Scientific  
1 Reagent Lane  
Fair Lawn, NJ 07410

**For information, call:** 201-796-7100**Emergency Number:** 201-796-7100**For CHEMTREC assistance, call:** 800-424-9300**For International CHEMTREC assistance, call:** 703-527-3887

#### Section 2 - Composition, Information on Ingredients

CAS#	Chemical Name	Percent	EINECS/ELINCS
50-00-0	Formaldehyde	3.7	200-001-8
67-56-1	Methyl alcohol	1.5	200-659-6
7558-19-4	Sodium phosphate dibasic	<1.0	231-448-7
7558-60-7	Sodium phosphate monobasic	<1.0	231-449-2
7732-18-5	Deionized Water	Balance	231-791-2

#### Section 3 - Hazards Identification

##### EMERGENCY OVERVIEW

Appearance: colorless liquid. Flash Point: &gt; 200 deg F.

**Warning!** Harmful if inhaled. Harmful if absorbed through the skin. Contains formaldehyde which can cause cancer. May cause severe skin irritation. May cause allergic respiratory and skin reaction. May cause respiratory tract irritation. May cause eye irritation and transient injury. May cause lung damage. May cause pulmonary edema. May cause reproductive and fetal effects.

**Target Organs:** Lungs, respiratory system, eyes, skin.



Date Prepared: 03/01/2011

Reviewed On: 02/11/2011

### 1 Identification of the substance/mixture and of the company/undertaking

- Product Identifier
- Product Name: Transport Reagent  
(Affirm RT Transport System)
- Catalog Number: 446255
- Details of the supplier of the safety data sheet
- Manufacturer/Supplier:  
BD Diagnostic Systems  
7 Loveton Circle  
Sparks, MD 21152  
Telephone: (410) 771 - 0100 or (800) 638 - 8663
- Information Department: Technical Service
- Emergency telephone number:  
In case of a chemical emergency, spill, fire, exposure, or accident contact BD Diagnostic Systems (410) 771-0100 or (800)-638-8663, or ChemTrec at (800) 424-9300.



### 2 Composition/information on ingredients

- Chemical characterization: Mixture
- Description: Mixture consisting of the following components.

#### Dangerous Components:

67-56-1	methanol	50.0%
67-68-5	dimethyl sulfoxide	50.0%

### 3 Hazards identification

- Classification of the substance or mixture
- Classification according to Directive 67/548/EEC or Directive 1999/45/EC  
 **T: Toxic**  
R23/24/25: Toxic by inhalation, in contact with skin and if swallowed.
-  **F: Highly flammable**  
R11: Highly flammable.
- Information concerning particular hazards for human and environment:  
This product contains dimethylsulfoxide freely penetrates the skin and may carry dissolved chemicals into the body.
- Classification system:  
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
- Label elements
- Labelling according to EU guidelines:  
The product has been classified and marked in accordance with regulations on hazardous materials.
- Code letter and hazard designation of product:  
T Toxic  
F Highly flammable
- Hazard-determining components of labelling:  
methanol  
dimethyl sulfoxide

(Contd. on page 2)

125A



**CENTERS FOR MEDICARE & MEDICAID SERVICES  
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS  
CERTIFICATE OF ACCREDITATION**

**LABORATORY NAME AND ADDRESS**

**PATHOLOGY LABORATORY PC  
2620 HORIZON DR SE SUITE 100  
GRAND RAPIDS, MI 49548-1222**

**LABORATORY DIRECTOR**

**TIMOTHY J PELKLY**

**CLIA ID NUMBER**

**23D0380021**

**EFFECTIVE DATE**

**02/28/2013**

**EXPIRATION DATE**

**02/27/2015**

Pursuant to Section 558 of the Public Health Service Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved location) may accept human specimens for the purpose of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date shown, but is subject to revocation, suspension, limitation, or other action for violation of the Act or the regulatory promulgated thereunder.



*Judith A. Nash*  
Judith A. Nash, Director  
Division of Laboratory Services  
Survey and Certification Group  
Center for Medicare and State Operations

764 - Core22\_010713

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the Laboratory specialties/specialties you are certified to perform and their effective date:

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>	<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
BACTERIOLOGY (110)	08/23/2002		
MYCOLOGY (120)	04/22/2011		
PARASITOLOGY (130)	03/25/2011		
VIROLOGY (140)	06/18/2006		
URICOPATHOLOGY (610)	07/26/1995		
CYTOLOGY (630)	04/19/2003		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT [WWW.CMS.HHS.GOV/CLIA](http://WWW.CMS.HHS.GOV/CLIA)  
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE LISTING FOR  
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.  
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.



*Pathology Laboratory*

**Accredited  
Laboratory**



**The College of American Pathologists**  
*certifies that the laboratory named below*

**Pathology Laboratory  
Grand Rapids, Michigan  
Timothy J. Pelkey, MD**

LAP Number: 31449H1  
AU-ID: 1189708  
CLIA Number: 23D0380021

*has met all applicable standards for accreditation and  
is hereby accredited by the College of American Pathologists'  
Laboratory Accreditation Program. Reinspection should occur prior  
to December 10, 2014 to maintain accreditation.*

Accreditation does not automatically survive a change in director, ownership,  
or location and assumes that all interim requirements are met.

*Frank R. Rudy*

Chair, Commission on Laboratory Accreditation

*Stanley H. Hing*

President, College of American Pathologists



*Pathology Accredited*

**Accredited  
Laboratory**



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**Pathology Laboratory  
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President, College of American Pathologists