Cytopathology Regulations

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Cytology Divisions

Gynecologic

Cervix
Vaginal

Pap Test:

Screening test of asymptomatic individuals at potential risk for disease.

Diagnostic test performed on individuals suspected of having disease (previous abnormal Pap)

Non Gynecologic

- Fluids – pleural, pericardial, peritoneal, CSF, urine, sputum
- Washings- bronchial, pelvic
- Brushings – lung, GI
- FNA – superficial (thyroid, breast , LNs, salivary glands), deep(liver, lung, pancreas)
- Rapid On Site Evaluation (**ROSE**): Endo-Bronchial US **(EBUS)**/Endoscopic US **(EUS)** / Interventional Radiology **(IR)**

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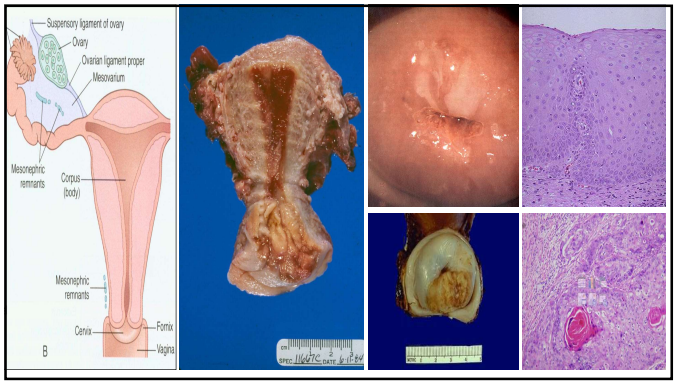

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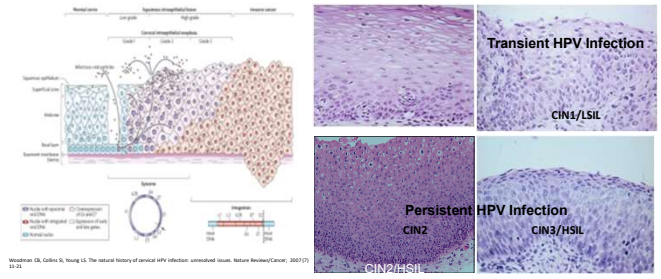
Dysplasia/CIN/ SIL: An abnormal cellular proliferation with nuclear atypia that includes enlargement, pleomorphism, change in chromatin texture, and irregular nuclear borders.



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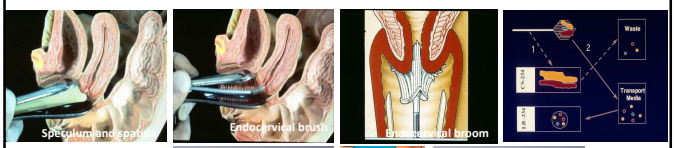
Pap Test



Both Pap and HPV tests addressed
21 years: begin screening
21-29 years: Pap test every 3 years
30-65 years: Cotest every 5 years (or Pap test every 3 years)
65 years: exit screening*

Saslow D., et al, Am J Clin Pathol. 2012; 516-42

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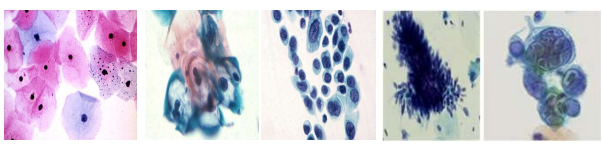
What is a Cytotechnologist?

- Laboratory professional that studies cells
- Uses a microscope to examine slides of human cells for any indication of abnormal or diseased cells (cancer, inflammatory processes, or infection)
- Works closely with the pathologist to determine a diagnosis and possible treatment paths



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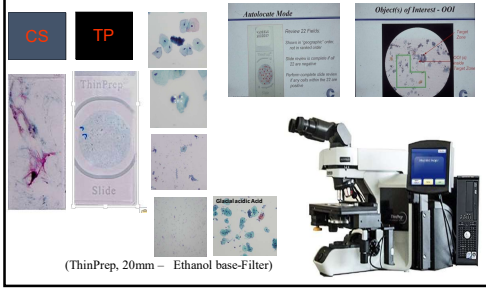
Hologic ThinPrep Imaging System



(ThinPrep, 20mm – Ethanol base-Filter)

Selects 22 fields of view for a Cytotechnologist to review. Following review of these fields, the Cytotechnologist will either complete the diagnosis if no abnormalities are identified or review the entire slide if any abnormalities are identified.

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PrepMate and PrepStain® System

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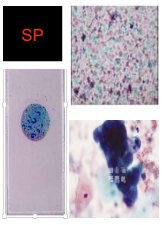
BD FocalPoint GS Imaging system



(SurePath, 13mm- Methanol based- Density gradient).

BD FocalPoint™ GS Imaging System
Imaging technology identifies and ranks microscopic fields for cytotechnologist review
Designates slides for QC
10 FOV
If no abnormalities, FOV review only
If abnormal, Full Manual Review performed (FMR)

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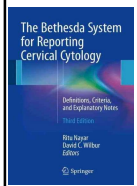
The Bethesda System



SPECIMEN TYPE
Indicate conventional smear (Pap smear) vs. liquid-based preparation vs. other

SPECIMEN ADEQUACY
- Satisfactory for evaluation *(describe presence or absence of endocervical/transformation zone component and any other quality indicators, e.g., partially obscuring blood, inflammation, etc.)*
- Unsatisfactory for evaluation … *(specify reason)*
  - Specimen rejected/not processed *(specify reason)*
  - Specimen processed and examined, but unsatisfactory for evaluation of epithelial abnormality because of *(specify reason)*

GENERAL CATEGORIZATION (optional)
- Negative for Intraepithelial Lesion or Malignancy
- Other: See Interpretation/Result (e.g., *endometrial cells in a woman ≥45 years of age*)
- Epithelial Cell Abnormality: See Interpretation/Result (*specify "squamous" or "glandular" as appropriate*)

INTERPRETATION/RESULT

NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY
(When there is no cellular evidence of neoplasia, state this in the General Categorization above and/or in the Interpretation/Result section of the report—whether or not there are organisms or other non-neoplastic findings)

NON-NEOPLASTIC FINDINGS *(optional to report; optional to report; list not inclusive)*
- Non-neoplastic cellular variations
  - Squamous metaplasia
  - Keratotic changes
  - Tubal metaplasia
  - Atrophy
  - Pregnancy-associated changes

Atypical squamous cells (ASC)
- Of undetermined significance (ASC-US)
- Cannot exclude HSIL (ASC-H)

Low-grade squamous intraepithelial lesion (LSIL) encompassing: human papillomavirus/mild dysplasia/cervical intraepithelial neoplasia (CIN) 1

High-grade squamous intraepithelial lesion (HSIL) encompassing: moderate and severe dysplasia, carcinoma in situ; CIN 2 and CIN 3

Squamous cell carcinoma

Atypical
- endocervical cells
- endometrial cells
- glandular cells

Atypical
- endocervical cells, favor neoplastic
- glandular cells, favor neoplastic

Endocervical adenocarcinoma in situ

Adenocarcinoma (endocervical, endometrial, extrauterine, or NOS)

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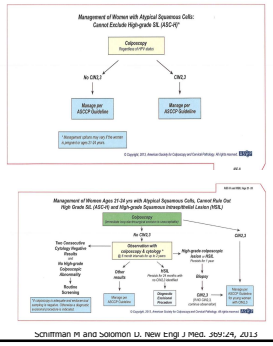
2012 ASCCP Guidelines

Cytology	HPV Testing	5 yr Risk CIN2+	Recommended Management
Negative	Negative	0.27	Repeat testing in 5 yrs
Negative	Positive	10	Repeat testing in 6-12 months
ASC	Negative	1.1	Repeat testing in 3 yrs
ASC	Positive	18	Immediate colposcopy if >25
LSIL	Negative	5.1	Repeat testing in 6-12 months
LSIL	Positive	19	Immediate colposcopy if >25
ASC-H	Negative	12	Immediate colposcopy
ASC-H	Positive	45	Immediate colposcopy
HSIL	Negative	49	Immediate colposcopy
HSIL	Positive	71	Immediate colposcopy
AGC	Negative	2.2	Immediate colposcopy
AGC	Positive	45	Immediate colposcopy



Schiffman M and Solomon D. New Engl J Med. 369:24, 2013

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Cytology is a highly regulated subspecialty

- Wall Street Journal article in 1987 exposes lack of standards in laboratory practices
  - Suboptimal training
  - Long hours
  - Too many Paps per day.
  - Unregulated laboratories.
  - Payment of techs on a per-slide basis.
  - Bonuses for exceeding daily numbers.
  - Taking slides home to screen
- **CLIA 88 (10% rescreen):** Clinical Laboratories Improvement Amendments of 1988, Final Rule 1992

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CLINICAL LABORATORY IMPROVEMENTS AMENDMENTS OF 1988 (CLIA 88)

Cytology is high complexity testing- mandated quality standards:

- Location of cytology testing.
- Methods of slide preparation and staining.
- Retention of records
- Personnel requirements and duties
- Established workload limits based on performance evaluations
- Hierarchical review of gynecological cases reactive or higher and all non-gynecological cases
- Quality control and quality assurance practices
- Statistical reports
- Proficiency testing

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A good QI program encompasses all aspects of the testing process:

QC: A system for verifying and maintaining a desired level of quality in a test or process: Span the entire testing process- collection and submission of the specimen, specimen preparation and staining, microscopic evaluation, and reporting.

QA: is defined by CAP as a systematic monitoring of QC results and quality practice parameters to assure that all systems are functioning appropriately: A coordinated effort of the various designed to detect, control and prevent the occurrence of errors.

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Which Division of the Department of Health & Human Services is responsible for overseeing implementation of CLIA '88?

1. CDC
2. CMS
3. FDA
4. HCFA
5. NIH

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Which Division of the Department of Health & Human Services is responsible for overseeing implementation of CLIA '88?

- Centers for Medicare and Medicaid Services (CMS) oversees implementation of CLIA '88 regulations

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To bill for and receive Medicare and Medicaid payments, a laboratory must have a CLIA certificate from which of the following 2 approved accrediting organizations?

1. ASCP or CAP
2. ASCP or JCAHO
3. ASCP or OSHA
4. CAP or CAAHEP
5. CAP or JCAHO

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Laboratory payment

- To receive payments from Medicare and Medicaid:
  - Labs must maintain a CLIA certificate
  - Adhere to CLIA '88 regulations
  - Re-accredited by CAP or JCAHO every 2 years

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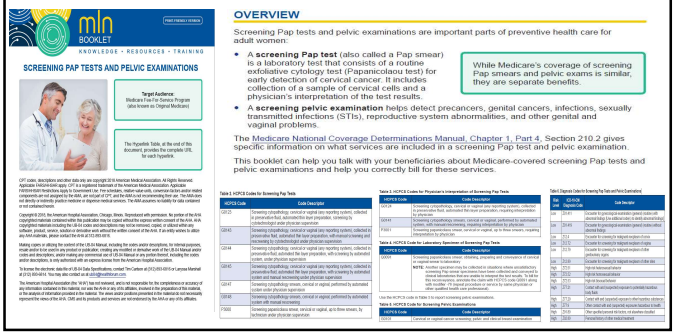
CMS: Medicare Billing


mln BOOKLET
KNOWLEDGE ▪ RESOURCES ▪ TRAINING
SCREENING PAP TESTS AND PELVIC EXAMINATIONS
OVERVIEW
Screening Pap tests and pelvic examinations are important parts of preventive health care for adult women:
• A **screening Pap test** (also called a Pap smear) is a laboratory test that consists of a routine exfoliative cytology test (Papanicolaou test) for early detection of cervical cancer. It includes collection of a sample of cervical cells and a physician's interpretation of the test results.
• A **screening pelvic examination** helps detect precancers, genital cancers, infections, sexually transmitted infections (STIs), reproductive system abnormalities, and other genital and vaginal problems.
While Medicare's coverage of screening Pap smears and pelvic exams is similar, they are separate benefits.
The Medicare National Coverage Determinations Manual, Chapter 1, Part 4, Section 210.2 gives specific information on what services are included in a screening Pap test and pelvic examination.
This booklet can help you talk with your beneficiaries about Medicare-covered screening Pap tests and pelvic examinations and help you correctly bill for these services.

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How often must laboratories be surveyed to maintain accreditation?

1. Every 2 years
2. Every 3 years
3. Every 5 years
4. Every 7 years
5. Every 10 years

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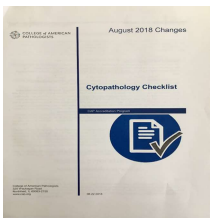
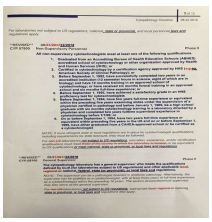
Accreditation process

- On-site surveys of laboratories to ensure they meet the necessary requirements to be compliant with regulations
- Must be conducted **every 2 years** to maintain CLIA compliance
- CAP checklists:


August 2018 Changes
Cytopathology Checklist



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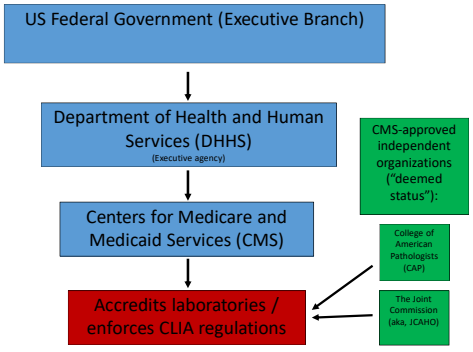

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CLIA 88: Cytology-specific mandates

- 1. Personnel standards
  - Hierarchical review of slides
- 2. Pre-analytics: Cytopreperatory
  - Staining
- 3. Analytics
  - Rescreening
  - Workload limits
- 4. Post Analytics
  - Cytology-histology correlation
  - Proficiency testing
  - Slide retention
  - Performance evaluations

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1. Personnel standards:

Cytotechnologists

- Bachelors degree
- Must graduate from an accredited cytotechnology school, and pass board exam (ASCP)
- Screen and sign out negative GYN, except reactive/repair/inflammatory specimens (Herpes; Follicular cervicitis)
- Assist in FNA and ROSE

General supervisor

- CT with ≥ 3 years full time experience.
- Can participate in prospective Q/C rescreen and 5 year retrospective review for HSIL/malignancy.
- Assist with day-to-day running of lab

Technical supervisor/Medical director

- Licensed M.D. or D.O. with board certification in anatomic pathology (or AP/CP) from ABP
  - Sign out abnormal GYN including reactive/repair and all non-GYN cases
  - Evaluate and set workload limits/other medical director duties
- Technical supervisor/Medical director– BC/BE in Anatomical pathology
  - Confirms all non-negative gyn
  - Reviews/Reports all non-gyn including negatives

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Six Elements for Evaluating Competency

1. **Direct observations** of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing
2. **Monitoring** the recording and reporting of test results
3. **Review** of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records
4. **Direct observations** of performance of instrument maintenance and function checks
5. **Assessment of test performance** through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples
6. Assessment of **problem solving skills**

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Assessors of Competency

- Testing personnel performing high complexity testing must be assessed by an individual who:
  - meets qualification of general supervisor in Cytology
  - be delegated by lab director in writing

General supervisors in Cytology must be assessed and deemed competent to assess competency.

- Be qualified as a technical supervisor
  or
- Be qualified as a cytotechnologist and have at least 3 years of full-time (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years.

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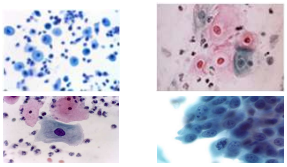
Hierarchical review of slides: In gynecologic cytology, a cytotechnologist must refer which of the following interpretations for pathologist review?

1. NILM – atrophy
2. NILM – Candida
3. NILM – reactive or repair
4. NILM – Trichomonas
5. Unsatisfactory



- Cytotechnologists screen and send the following to the pathologist for sign out:
  - GYN: reactive/repair and all epithelial cell abnormalities

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Hierarchical review of slides

- All non-GYN cases including anal cytology.
- Selected gyn cases are reviewed, either by a second cytotechnologist (who qualifies as a general supervisor), or by a cytopathologist.
- **These are Lab Dependent- No Specific CLIA Guidelines address this:** The general cytology supervisor reviews all cases screened by a new employee during the first two weeks of employment. Cytotechnologists with less than three years screening experience or PRN employees will require the general supervisor to "review 150 negative gynecological cases" for recent graduates or Board-eligible.
- NILM/positive HPV cases are included in the QC review by a second cytotechnologist

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Hierarchical review of slides: GYN cytology

Send to pathologist for review all cases specified below:

a. showing endometrial cells in a woman postmenopausal or patient age 45 or older

c. with cellular evidence of Herpes virus cytopathic effect, Actinomyces

d. with laboratory record of history of exposure to DES

e. showing significant reactive or reparative cellular changes

f. showing atypical cells of undetermined significance, or more severe changes

g. with a significant disagreement in diagnosis between the first and second cytotechnologist

h. about which there is some question

i. any described cervical abnormality stated in the clinical diagnosis area of requisition: bleeding cervix, erosion, ulcer, cervical mass, friable cervix (as examples).

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Hierarchical review of slides

If the current Pap is **negative**, send to a second cytotechnologist (who qualifies as a general supervisor in cytology according to CLIA '88 Standard 493.1469) all cases:

a. with a previous **history of an abnormal Pap** (either designated on the requisition or in the laboratory information system data base).

b. with a **previous abnormal biopsy** (as above).

c. with a history of **endometrial cells if patient is 45 years or older**

d. with a laboratory **record of previous ASC-US** (if ≥2 Dr 3 negative then not high risk) **, ASC-H, AGUS, SIL, or carcinoma**

e. designated **abnormal bleeding** per requisition

f. with a laboratory record of **any type of malignancy**

g. history of **DES exposure**

h. **Unsatisfactory** interpretation

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CLIA 88: Cytology-specific mandates

- **1. Personnel standards**
  - **Hierarchical review of slides**
- **2. Pre-analytics: Cytopreperatory**
  - **Staining**
- **3. Analytics**
  - **Rescreening**
  - **Workload limits**
- **4. Post Analytics**
  - **Cytology-histology correlation**
  - **Proficiency testing**
  - **Slide retention**
  - **Performance evaluations**

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2. Preanalytic- Cytopreparatory: Cytopreparatory technician

- A. Stain Assessment ("done by qualified Cytotechnologist")
- B. Cross-contamination
- C. Reagents/Labeling
- D. Equipment
- E. Temperature Control
- F. Numbering Cytology Samples
- G. Specimen Receipt Acceptance and Rejection Policy

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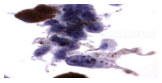
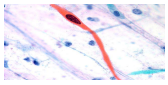
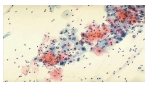
2. Preanalytic: A. Staining Assessment:

- Gyn and Non-Gyn: Papanicolaou(Pap) or modified Pap
- Non-Gyn: Romanowsky stain (DQ) for air dried slides and hematoxylin and eosin on cell blocks. Histochemical stains (GMS) and Immunohistochemistry.
- Daily review of all stains for nuclear and cytoplasmic clarity is performed after the first morning staining run. At the time of screening, the quality of both the stain and coverslip is recorded. ("done by qualified Cytotechnologist")

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2. Preanalytic:
B. Cross-contamination: CLIA- Effective measures to prevent cross contamination between GYN/Non-GYN during staining must be used .

- Non-gynecologic specimens are stained separately from gynecologic samples.
- The non-GYN automated stainer is cleaned daily, and stains are filtered and the other solutions are discarded, dishes rinsed and refilled with fresh solutions. At lesser volume labs; stains are filtered and the other solutions discarded, dishes rinsed and refilled with fresh solutions based on volume and on an as needed basis.
- All specimens containing "floaters" are recorded as a Specimen/Requisition deficiency.

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2. Preanalytic:
C. Reagents/Labeling and D. Equipment.

C. Reagents/Labelling

- All reagents are stored as recommended by the manufacturer.
- Reagents are dated with received date to allow for proper usage of inventory.
- Working solutions will be labeled with the contents, concentration (where required), preparation date, expiration date, lot number, hazards warnings and the initials of the person who made it.

D. Equipment

- All the equipment in Pathology and Laboratory Medicine has a control number issued by Clinical Engineering upon receipt.
- Each cytotechnologist is responsible for upkeep and maintenance of his/her own microscope.
- All equipment is entered by control number for inventory purposes.

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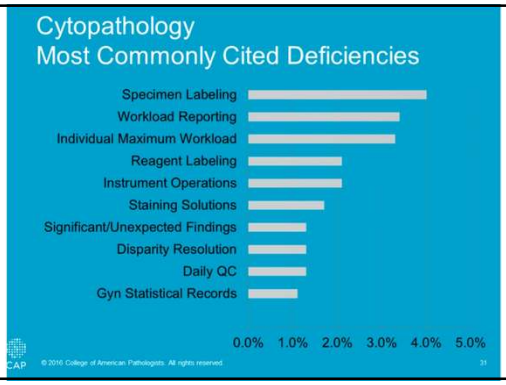

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2. Preanalytic:
F. Numbering Cytology Samples

- Specimens must be properly labeled
  - Two patient identifiers required on specimen containers
  - Two patient identifier required on slides
  - Slides and containers labeled **at time** of FNA procedures (no pre-labeling)
- The prep personnel match the requisition to the slides verifying patient and sample identification.
- The prep personnel and cytotechnologists match preprinted labels to corresponding slides and paperwork.

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2. Preanalytic:
G. Specimen Receipt Acceptance and Rejection Policy

Specimen requirements include:

- Patient's name, DOB, and medical record number
- Source of material submitted
- Ordering physician's name and telephone number.
- Last menstrual period (LMP) and/or hormonal status (Paps only).
- Exogenous hormone therapy
- Use of intrauterine device (IUD)
- DES exposure
- Histories of abnormal cytology, systemic chemotherapy, gynecologic surgery, cryosurgery, electrocautery or laser surgery.
- Date of last Pap test
- Any other pertinent history.

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2. Preanalytic:
G: Quality Control – Accepted Specimens

- Specimen Rejection Criteria
  - Patient information not clear or not included on specimen, slides, or requisition
  - Patient information on specimen, slides, and requisition does not match
  - Slide(s) broken beyond repair
  - Specimen leaked beyond recovery
  - Specimen source not included

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2. Preanalytic:
G. To accept or not to accept?

- If specimen rejected, ordering physician notified
- Specimens may be labeled post-receipt by ordering physician or designated staff
  - Misidentification form completed, sent to QA department
- If specimen cannot be salvaged, recollection may be necessary
  - Physician must be notified
  - Reported to QA, possibly risk management

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2. Preanalytic:
Summary: Specimen Preparation and Staining Quality management plan – Prep Lab

- Cytotechnologist Prep Competency Evaluation
- Daily Technical Quality Reviews and Quality Assurance/Improvement Monitors
  - Stain quality monitors: Record of stain evaluation for quality
  - Date and number of times the stains are filtered and changed
  - Temperature monitors
  - Strict specimen acceptance and rejection policy
  - Equipment monitors/ maintenance logs
- A log of quality control staining procedures should be maintained
  - Any problems noted with appropriate follow-up and corrective action

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3. Analytic

- **A. Procedure for Re-screen of negative GYN cases**
- **B. The QA rescreen percent**
- **C. Discrepant QC**
- D. Reclassified
- **E. Cytotechnologist workload**
- **F. Workload policy**
- G. Ten percent (10%) check on accessions.
- H. Internal check
- I. Safety reporting system (SERS)
- J. Consultation
- K. Hematology correlation
- L. Mandatory review

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3. Analytic:
A. Slide Rescreen: Mandated Quality Control Practices:

- Designed to reduce laboratory component of errors contributing to false negatives
- Mandatory **10% rescreening** of normal gynecologic specimens-Before the cases is reported.
  - Randomly selected cases (can include high risk patients)
  - "High-risk" patients (can added to 10%- no history- to an additional % that can total approximately of 18-25% negative cases reviewed)
- **5-year review**: If new HSIL or malignancy detected on Pap test, mandatory review of all NILM cases within **5** years prior.
  - If discrepancies found that affect current clinical management, must issue amended report and notify clinician

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3. Analytic
A. Procedure for Re-screen of Negative GYN Cases

- Computer randomly picks a percent of the daily negative gynecologic samples for prospective re-screening by the QC cytotechnologist.
- There are also negative cases that are targeted for QC rescreen: clinical history as well as concurrent HPV status when known.
- Rescreen is not done by the same person and are signed out after the 2nd cytotechnologist has reviewed the slide.
- Rescreen percent is reviewed monthly by the Cytology supervisor or designee to ensure all cytotechnologists have 10% rescreened.

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3. Analytic
C. Discrepant QC

- Each month discrepant QC pap tests are identified.
- All QC discrepant cases with a final interpretation of AEC, ASC-H, LSIL and HSIL and above are reviewed on a review scope by a supervisor or designee.
- ? If missed by the cytotechnologist or imager.
- There must be an annual statistical evaluation of the number of reviews of any NILM cases reclassified as LISL+ (No consensus upgrades to ASCUS)
- Reviews are compared as individuals against the laboratories' overall statistics, and are used to determine workload limits

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E. Cytotechnologist workload

- Maximum 100 slides in an 8-hour workday (12.5 slides/hr)

GYN	Non-GYN
Imaged slide without manual review = 0.5 slide Imaged slide + manual review = 1.0 = 0.5 = 1.5 slides	Liquid-based (ThinPrep, cytospin, SurePath) = 1 slide Smear = 1 slide Cell block = 0.5 slide

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E. Cytotechnologist workload: Maximum workload limits

- Required manufacturers to revise their product labeling and send customer bulletins
- Published laboratorian safety tip

- The value of slides screened is as follows:
  - GYN manual review= 1 slide
  - GYN FOV only= .5 slide
  - GYN FOV + manual review= 1.5 slides
  - All non-GYN slides= 1 slide
  - Outside slides with a previous review/diagnosis=.5

- The exceptions to this are outside slide reviews that have been screened and resulted at another institution. The cases that contain IHC and cell block slides can be counted as .5 (many labs count them as 1 slide).
- **Upper limit is NOT for everyday productivity or a performance target**
- CLIA '88 requires *individual* maximum workload limits to be established by the technical supervisor

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm220292.htm

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3. Analytic F. Workload Policy

- Cytotechnologists are to screen all NON-GYN specimens assigned to them on a given day, and then to screen as many GYN slides as reasonably possible. The total number of slides screened is not to exceed 100 per 24 hour time period, or the individual workload limit determined for that cytotechnologist. Each Cytotechnologist has individually established workload limits that they are not to exceed. If a cytotechnologist screens less than 8 hours a day there is a formula to determine how many slides they can screen.
- The formula follows:

$$\frac{\text{number of hours spent screening X100= daily slides screened}}{8}$$

- i.e. 4 hours screened would mean the cytotechnologist could not exceed 50 slides for that day.

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E. Workload limits

- Workload limits evaluated and assigned every 6 months by Technical supervisor.
- Monthly workload tally sheets
  - Cases screened
  - Slides screened
  - Time spent screening, time spent not screening
- Workload includes slides, not cases
  - Gyn
  - Non-gyn
  - QC
  - Prof testing
  - Rescreen new hire

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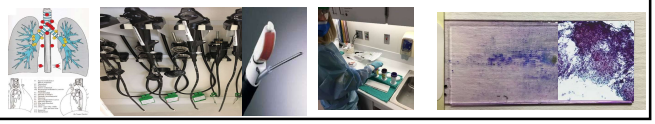
ROSE workload – New 2018

- The letter basically states that slides for rapid on-site evaluation for adequacy would only need to have the amount of time spent on those slides (52 min.) recorded and not the number of slides. However, the time spent determining adequacy would need to be subtracted from the total amount allowable for the day.
- The 2018 edition of the CAP Cytopathology Checklist reflects this new interpretation by CMS.



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3. Analytic E. Cytotechnologist Workload

- Each cytotechnologist records in their **logbook** the cytology case number, the number of slides screened for that case, and the case interpretation.
- Each Cytotechnologist, prints their monthly screening log, signs it and gives it to the supervisor for review.
- Every six months, a workload worksheet is completed by the cytology supervisor. The cytotechnologist meets with the laboratory director who reviews the form and establishes the workload limit for each individual.

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3. Analytic F. Workload Policy

- Individual workload limits are reviewed semiannually and readjusted if warranted. Cytotechnologist performance is evaluated for Pap Tests by comparing the number of disagrees on:
  - Five year reviews,
  - Post biopsy reviews,
  - QC discrepancies to laboratory disagree rates.
  - Each cytotechnologists abnormality and unsatisfactory rates are also compared to laboratory rates.
  - For non GYN performance each cytotechnologist is compared to final sign out and disagrees are reported on their six month workload evaluation.

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4. Post Analytic

- **A. Adequacy Assessment Billing Audit**
- **B. Billing Report**
- C. Pending Urovision Report
- D. QA parameters
- **E. Cytology- Histology Correlation**
- F. Personnel Standards and Responsibilities
- G. Error Policy
- **H. Retrospective Review**
- **I. External Audits (Proficiency Testing/Educational Events)**
- **J. Final Reports**
- **K. Statistical Analysis**
- **L. Slide and Record Retention**
- **M. HR HPV results**

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4. Post Analytics
Billing Report: CPT codes in cytopathology

- 88108 (Cytospin) and 88112 (Thin Prep) cannot be billed together
- 88112 (Thin Prep) and 88173 (FNA Interpretation & Report) cannot be billed together
- Ex. Pleural Fluid
  - 2 Cytospins, 1 Thin Prep, 1 Cell Block prepared
  - Billing: 88112 (Thin Prep) and 88305 (CB)
- Ex. Thyroid FNA
  - 4 Direct smears, 1 Thin Prep prepared
  - Billing: 88173 (FNA Interpretation & Report)

- CPT codes assigned based on type of evaluation episode; different for FNA vs TP
  - 88172: Initial evaluation episode during on-site FNA evaluations
  - 88177: Additional evaluation episodes during on-site FNA evaluations (not used for Pathologist performed FNAs)
  - 88333: Touch Prep Evaluation, Initial Site
  - 88334: Touch Prep Evaluation, Additional Site

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4. Post Analytic:
E. Gynecologic Cytologic- Histologic Correlation

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires "Laboratory comparison of clinical information, when available, with cytology reports and comparison of all gynecologic cytology reports with a diagnosis of high-grade squamous intraepithelial lesion (HSIL), adenocarcinoma, or other malignant neoplasms with the histopathology report, if available in the laboratory (either on-site or in storage), and determination of the causes of any discrepancies." This requirement is generally referred to as cytologic-histologic correlation (CHC).

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4. Post Analytic
H. 5-year retrospective review of cases diagnosed as HSIL or higher

- CLIA mandates documented retrospective review of all negative gynecological specimens received in the preceding 5 years for patients with documented HSIL or above.
- If significant discrepancies are found, which affect current patient care, an amended report must be issued.
- Post Biopsy Review (PBR): Many laboratories perform 5 year review of negative Pap slides, triggered by a biopsy finding of HSIL, AIS, and above.

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Prospective and Retrospective Review of Gynecologic Cytopathology

- *Conclusions:*
  - The number of Pap tests from high-risk patients should be maximized in prospective and retrospective rescreening.
  - Unsatisfactory Pap tests should also be included.
  - All readily identifiable HPV cases with in interpretation of negative for SIL or malignancy should be prospectively rescreened.
  - Cervical biopsy results with HSIL+/CIN 2+ should trigger retrospective rescreening. Regular feedback should be provided to cytotechnologists and cytopathologists.
  - Upgraded diagnoses from negative for SIL /malignancy to ASC-H, should be monitored.

Refs: (Arch Pathol Lab Med. 2013;137:175–182;Jennifer A. Brainard, MD; George C. Birdsong, MD; Tarik M. Elsheikh, MD; David A. Hartley, CT(ASCP);Kalyani Naik, MS, SCT(ASCP); Margaret H. Neal, MD; Rhona J. Souers, MS; Michael R. Henry, MD

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4. Post Analytic:
I. External Audits- Proficiency testing (PT)

- Implemented in 2005, for GYN cytology only
- Each lab involved in GYN cytology must enroll in a CMS-approved PT program
- Each individual (pathologist and cytotechnologist) engaged in examination of *gynecologic* preparations must be *tested annually*.
- Lab director responsible for compliance

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4. Post Analytic:
I. External Audits-Proficiency testing (PT)

Each test set must contain at least one challenge representing each regulatory diagnostic category

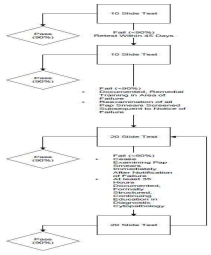
- A – Unsatisfactory
- B - Normal or benign
- C - Low grade SIL
- D - High grade SIL or cancer

Cytotechnologists:

Participant Diagnosis	A	B	C	D
Correct Diagnosis				
A	10	0	**5**	**5**
B	5	10	**5**	**5**
C	5	0	10	**10**
D	0	-5	**10**	10

Technical Supervisors:

Participant Diagnosis	A	B	C	D
Correct Diagnosis				
A	10	0	**0**	**0**
B	5	10	**0**	**0**
C	5	0	10	**5**
D	0	-5	**5**	10



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4. Post Analytic:
I. External Audits- Educational events

In-house continuing education some of which may include:

- GYN and non-GYN assessment programs
- Lecture by intra and interdepartmental staff, residents, cytotechnologists and visitors
- Grand Rounds
- Sessions at multi-headed microscope
- Mini continuing education sessions involving peer discussion of a difficult case which has been shown to other cytotechnologists yielding an oral exchange of information often supplemented by research through the extensive Cytology Library
- Participation in CAP PAP inter-laboratory comparison program
- Participation in CAP non-GYN and FNA inter-laboratory comparison programs
- Teleconferences
- Research Projects
- Attendance at monthly Pathology QA meeting during which current cytology issues are discussed.
- Attendance at Institute continuing education lectures.
- Journal Club

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4. Post Analytic:
J. Final Report-Quality: Components of the Report

- Name & sex of patient
- Date of birth &/or age
- Unique patient number
- Patient location
- Attending physician
- Dates of collection, receipt & reporting
- Source of material
- Accession number
- Lab name and address
- Condition of specimen on receipt
- Diagnosis
- Comments & recommendations
- Pathologist's signature
- Basis of correction, if corrected report issued

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4. Post Analytic:
J. Final Report- Quality

- "User friendly"
- Readable format
- Typed with correct spelling & grammar
- Use clear, concise descriptive nomenclature
- Accurate
- Clearly distinguish specimens that are unsatisfactory for diagnostic interpretation
- Contain narrative descriptive nomenclature for all results
- Corrected reports must include the basis for the correction

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4. Post Analytic:
J/K. Final Report and Statistics
-Quality Assurance/Improvement Monitors

- Turnaround Time Monitoring
  - 90% in 2 working days (simple cases). For gynecologic cytology, a mean collection-to-reporting TAT of 6 or fewer days, with 90% of cases reported in 8 or fewer days will place the lab in the top 50%
- Incidents of Misidentification
- Tissue Lost Post Receipt
- Employee Safety Incidents/Issues
- Number of Serious Events.
  - An event, occurrence or situation involving the clinical care of a patient in a medical facility that *results in death or compromised patient safety and results in an unanticipated injury requiring the delivery of additional healthcare services* to the patient

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4. Post Analytic:
J/K. Final Report and Statistics Requirements - Annual Statistics

- Number of Cases Examined
- Specimens by Specimen Type
- Volume of Cases by Diagnosis
- Number of Unsatisfactory cases
- Results from 10% QC
- 5 year retrospective review
- Cytology/histology correlation by tech
- Premalig/malig Paps without bx
- **Report by Dx category for gyn/non-gyn**
- **Abnormal submission rate by tech**
- Negative Conversion Rate

<u>Individual vs. Lab Statistics</u>

- CLIA requirement
- **Report generated from LIS monthly**
  - **% of cases per diagnostic category**
- **CAP provides laboratory statistical benchmarks**

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Reporting of interpretation categories for each individual and for the entire lab along with HPV results for ASC-US/ASC-H

CAP: Cytopathology Checklist –Revised 8/22/2018

*ThinPrep***
Laboratory Percentile-Reporting Rate

CATEGORY	5th	10th	25th	Median	75th	90th	95th
Unsatisfactory (%)	0.3	0.4	0.8	1.3	2.4	4.3	6.2
LSIL (%)	1.0	1.0	2.0	2.7	3.6	4.7	6.6
HSIL (%)	0.4	0.3	0.3	0.4	0.7	1.4	1.4
ASC-US (%)	2	2.7	3.9	5.4	7.6	10.3	13.3
ASC-H (%)	0.0	0.1	0.2	0.3	0.5	0.8	1.0
AGC (%)	0.0	0.0	0.1	0.2	0.3	0.6	1.0
ASC/SIL	0.8	0.9	1.4	1.8	2.6	3.2	3.9

*SurePath******
Laboratory Percentile-Reporting Rate

CATEGORY	5th	10th	25th	Median	75th	90th	95th
Unsatisfactory (%)	0.0	0.1	0.1	0.3	0.5	0.7	1.0
LSIL (%)	1.0	1.4	2.0	2.8	3.5	4.7	6.2
HSIL (%)	0.4	0.1	0.2	0.4	0.6	1.0	1.2
ASC-US (%)	1.9	2.4	3.7	5.0	6.9	9.8.2	11.5
ASC-H (%)	0.0	0.1	0.1	0.3	0.4	0.6	0.9
AGC (%)	0.0	0.1	0.1	0.2	0.3	0.6	0.7
ASC/SIL	0.7	0.9	1.3	1.7	2.2	2.7	3.3

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4. Post Analytic:
L. Slide and Record Retention

- Specific regulations regarding length of time that cytology laboratories must retain:
  - Accessioning records: 2 years
  - Test reports: 10 years
  - Gynecologic glass slides: 5 years
  - FNA glass slides: 10 years

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Competency Assessment in the Cytology Laboratory
Definition Pertaining to Laboratories

Competency is the ability of testing personnel to apply their skill, knowledge, and experience to perform their laboratory duties correctly.

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Six Elements for Evaluating Competency

1. **Direct observations** of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

2. **Monitoring the recording and reporting of test results.**
   - Result entry discrepancy rates with pathologist review.
   - Amended Reports
   - Proper use of terminology
   - Review of patient test reports
   - HSIL/Positive reporting to submitting clinicians

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Six Elements for Evaluating Competency

3**. Review** of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records:
- QC forms- Daily stain assessment, ROSE stain forms, equipment maintenance forms
- Cyto/Surgical correlation, HSIL follow up reviews, Cyto-Hem correlation

4. Direct observations of performance of instrument maintenance and function checks (Dependent on roles cytotechnologist)
- fulfills
- Equipment verification forms
- Performs Cyto prep duties-can do direct observation

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Six Elements for Evaluating Competency

5. **Assessment of test performance** through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.
- Pap Proficiency Test
- Non Gyn and FNA inter laboratory comparison educational programs
- 10% QC Review records

6. Assessment of problem solving skills
- Problem logs and documentation
- Quizzes

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CAP Phase II Requirement

GEN.55500 Competency Assessment

Non waived Testing

- CAP most common deficiency cited in Lab General checklist
- Competency is not training, but rather ongoing assessment
- Each test system needs defined and assessed for all phases (pre analytic, analytic, post analytic) as described in testing SOP

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Competency Assessment

- Competency assessment must be done 6 months and 12 months after initial training, then annually thereafter
- All 6 elements (as applicable) are used to assess each test system
- Delegated supervisory responsibilities (ongoing assessment)
- Checklist (s) with supporting documentation

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Cytology General Supervisor

- Be qualified as a technical supervisor

  or
- Be qualified as a cytotechnologist and have at least 3 years of full-time

  (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years.

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Cytotechnologist Report Cards

- Establish scoring criteria for each parameter
- Be specific to allow objective evaluation
- Each lab may have different criteria to define the scores
- Parameters
  - Review discrepancies (QC and QA)
  - Conciliations
  - Referral rates
  - Workloads
  - Error rates
  - ASCUS to SIL ratios
  - Work ethic indicators

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CLIA 88: Cytology-specific mandates

- 1. Personnel standards
  - Hierarchical review of slides
- 2. Pre-analytics: Cytopreperatory
  - Staining
- 3. Analytics
  - Rescreening
  - Workload limits
- 4. Post Analytics
  - Cytology-histology correlation
  - Proficiency testing
  - Slide retention
  - Performance evaluations

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Cytotechnology as a career

- Potential pathologist shortages
- Reimbursement changes
- Healthcare structural changes
- Organizational efforts
- Expansion of high complexity testing
- Declining Pap test volume
- Primary HPV screening
- HPV vaccination
- Declining CT school enrollment
- School closures
- Declining traditional roles for the CT.
- Rise of CT-based advanced practice models
  - Molecular procedures
  - Digital pathology
  - Laboratory administration

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Cytology

- The vacancy rate for cytology is 4.75%.
- Total staff and supervisor vacancy rates are 5.08% and 2.53%, respectively.
- Survey results show that 17.65% of cytology personnel are expected to retire in the next 5 years. The staff retirement rate is 14.26%, and the rate for supervisors is 32.26%.
- Respondents from the cytology department prefer CT and specialist in cytotechnology certifications when hiring employees.
- Also, 86.10% of the respondents indicated that certification is a prerequisite for all candidates for hire. This is the department that has the highest rate of respondents reporting they require certification for candidates they hire. Survey results show that 70.33% of staff and 86.43% of supervisors are certified.
- Nights, evening, weekends, holidays, and double shifts are the most difficult to fill in this department.

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Voices from the field: supporting the educational needs of cytotechnologists

- Results Research findings reveal CT education needs to align with emerging practice areas as reported in other Workgroup data collection efforts. The incorporation of new entry-level competencies in cytotechnology training programs prepares new CT graduates, but there is no standardized mechanism for formal, robust, and recognized ongoing education for other practicing CTs.

Friedlander MA et al. JASC 2018, 7, 250-260

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A "Mid-level Pathology Practitioner" is a:

1) highly trained health professional;

2) who uses morphologic skill,

- understanding of neoplasia/disease

- ability to synthesize clinical and laboratory data

- to assist the pathologist

- in providing the highest quality diagnostic services.

"Mid-level Pathology Practitioners" expand the team-based model of the pathologist and cytotechnologist to include other, more advanced functions in the clinical laboratory arena.

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"Mid-level Pathology Practitioners"

- Requires changes in federal and state regulations
- Medical legal liability; insurance premiums for MLPP
- Loss of reimbursement for pathologists
- Hospital privileges would be required for FNA performance and independent non-gynecologic sign out

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Table 3 Perceived usefulness of education in various cytopathology-related practice areas.

Practice area category	Practice activity surveyed	Useful, %	Not useful, %
Cell Block	Cell block preparation*	81.5	18.5
	Cell block - Interpretation*	76.1	23.9
FNA Adequacy Assessment	Working as part of a clinical team with a cytopathologist and/or radiologist/clinician/surgeon*	78.6	24.4
	Determination of appropriate specimen triage for ancillary testing*	78.3	21.7
	Potential challenges and/or pitfalls in performing ROSE*	78.1	21.9
Immunocytochemistry	ICC/IHC - Interpretation*	75.4	24.6
	Selection of appropriate IHC stains*	73.2	26.8
	ICC/IHC - - Theory and validation protocols	70.9	29.1
	ICC/IHC - - Laboratory Process/Specimen processing	68.1	31.9
Procedurally FNA techniques	Triage of specimens (IHC/flow/molecular)*	74.8	25.2
	Endobronchial ultrasound—guided FNA*	74.4	25.6
	Endoscopic ultrasound—guided FNA*	74.3	25.7
	Clinico-radiologic-pathologic correlation*	68.9	31.1
	Transcutaneous FNA	59.8	40.2
Molecular Diagnostics	Molecular diagnostics - Theory & application to practice*	76.7	23.3
	Molecular diagnostics - Laboratory process/Specimen Processing	74.2	25.8
	New test integration	74.4	25.6
	Molecular diagnostics - QA/QC	73.2	26.8
	Interpretation (eg, ER/PR/HER2)	73.2	26.8

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Lab Management & Operations	Inspection readiness*	78.8	21.2
	Competencies/Competency Assessment*	78.3	21.7
	Regulatory compliance*	77.7	22.3
	QA non-GYN*	76.0	24.0
	Quality essentials, LEAN concepts, process improvement concepts; Quality Management*	74.3	25.7
	QA-GYN	73.1	26.9
	Document development and control	73.0	27.3
	Workload recording	69.7	30.3
	Personnel Management	65.4	34.5
	Performance/QI (LEAN, Six Sigma)	64.4	35.6
	Billing and coding	64.4	35.6
FISH/CISH	FISH/CISH - Morphologic assessment and	63.5	36.5
	FISH/CISH - New test integration	60.9	39.1
	FISH/CISH - Laboratory process	59.7	40.3
Circulating Tumor Cells	Circulating tumor cells - Interpretation	58.5	41.5
	Circulating tumor cells - Laboratory Process	59.3	40.7
Use of Computer-Assisted Devices	ThinPrep imaging system	55.2	44.8
	BD Focal Point GS imaging system	41.6	58.5
	GYN screening	49.3	50.7

*Topic incorporated as part of ACE conference agenda.

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Summary

- Engaged CTs, with the assistance of their professional societies, have an opportunity to design education and training to prepare an appropriately skilled and sustainable workforce to meet changing practice and patient care needs.

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