

CYTOLOGY DOCUMENT

PENNSYLVANIA DEPARTMENT OF HEALTH
BUREAU OF LABORATORIES
DIVISION OF LABORATORY IMPROVEMENT

CLIA #:		LABORATORY ID #:	
NAME OF LABORATORY:			
DATE OF SURVEY:	START TIME:	EXAMINER:	
PERSON(S) INTERVIEWED			
NAME:		TITLE:	
COMMENTS:			
REPEAT DEFICIENCIES:			
DIRECTOR PRESENT AT EXIT INTERVIEW: Y N			

DTAGS	REQUIREMENTS	QA	DOC	COMMENTS
ADMINISTRATIVE				
	<p>1. Hours of Work:</p> <p style="text-align: center;">Mon Tue Wed Thu Fri Sat Sun</p> <p>From</p> <p>_____</p> <p>To</p>			
	<p>2. Supervision:</p> <p style="text-align: center;">Director _____ Qualified _____ Functioning</p> <p style="text-align: center;">Technical Supervisor _____ Qualified _____ Functioning</p> <p style="text-align: center;">General Supervisor _____ Qualified _____ Functioning</p>			
D6029	<p>3. Are personnel appropriate for services offered? (1 CT or pathologist per 12,000-15,000 cases)</p>			
	<p>4. Personnel records are current and contain:</p>			
D6032	<p>A. Job description</p>			
D6029	<p>B. Education/training documents</p>			
D6030	<p>C. Evaluation/competency reports</p>			
	<p>5. If a computer system (LIS) is used in the lab:</p>			
D6029	<p>A. Individuals must be properly trained in the use of the system</p>			
D4062	<p>B. Procedures for computer use must be available</p>			

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D3054 D3063	C. There must be a mechanism in place to protect access codes and to prevent unauthorized access to patient sensitive data			
D4018	6. Safety procedures:			
	A. The lab must have a written plan to protect its employees from chemical hazards in the lab			
	B. The lab must notify its employees of the hazardous chemicals in the lab (MSDS sheets)			
	C. The lab must have a written plan to protect its employees from infectious agents and from those specimens generally considered to be infectious, such as those identified in the federal Bloodborne Pathogen Standard			
	D. Employees must be advised of their right to have the blood of a patient tested in the event they have a significant exposure to that blood (Act 148)			
	E. Basic electrical/fire/physical safety practices must be followed			
	F. Employees must be trained in appropriate procedures and practices prior to working with hazardous chemicals and/or infectious agents			
	1. Training must be documented			
	G. Infectious and hazardous waste must be handled and disposed of according to DER regulations			
FACILITIES				
D4318	1. All slides must be read on the premises of a certified cytology laboratory			

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D4012 D4016	2. The facility must have adequate space and proper ventilation			
PATIENT TEST MANAGEMENT				
D3016	1. Written instructions pertaining to the collection, labeling, preservation or fixation, transportation and processing or preparation of specimens must be made available to clients (Client Service Manual)			
	A. There must be written procedures for:			
D3001	1. Patient preparation			
D3004	2. Specimen collection and submission			
D3007	3. Labeling			
D3010	4. Preservation or fixation			
D3013	5. Transportation			
D3014	6. Processing			
	B. The request must include:			
D3022	1. Patient name or other identifier			
D3023	2. Name and address or other identifier of person ordering the test			
D3024	3. Test ordered			
D3025	4. Date of specimen collection			
D3026	5. For Pap smears, patient's last menstrual period, age or DOB and indication of whether patient had a previous abnormal report, treatment or biopsy			

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D3029	6. Any additional information relevant and necessary to assure accurate and timely testing and reporting of result (e.g. source, lesions)			
	C. Test Records (Accessioning Logs, Worksheets, Rejection Logs, Processing Logs, etc.) must contain:			
D3032	1. The laboratory must maintain a record system to ensure reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported			
	2. The record system must include:			
D3037	a. Patient ID #, accession #, or other unique ID			
D3038	b. Date specimen received in lab			
D3039	c. Time specimen received in lab			
D3040	d. Condition and disposition of specimens not meeting the lab's criteria for specimen acceptability			
D4166	e. Remedial action taken when specimens have been determined to be inadequately or improperly processed and identification of processing personnel			
D3041	f. The records and dates of all specimen testing:			
D3042	<ol style="list-style-type: none"> 1. Date CT screened case 2. Date pathologist reviewed case 3. Date 10% QC performed 4. Date of other QC procedures (5 yr retrospective review, tissue correlation) 			
D3073	2. The lab must refer specimens only to other labs approved for Cytology			

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PROCEDURE MANUAL				
D4043 to D4069	1. A procedure manual must be available and have procedures for: <ul style="list-style-type: none"> A. Submission of specimens B. Referral of specimens C. Accessioning D. Criteria for rejection (no patient ID on slide or requisition, broken slide that cannot be repaired) E. Processing [gyn vs. non-gyn (cytocentrifugation, membrane filtration, Saccamono's Technique)] F. Staining (Pap, concentrations, diptimes and number of dips, changing and filtering solutions) G. Coverslipping H. Quality control I. Reading of slides (vertical vs. horizontal, method for noting abnormalities) J. Method of reporting K. Written criteria for categorizing slide preparations as Unsatisfactory 			

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D4056	2. The laboratory must have written procedures for remedial action when staining characteristics are less than optimal (should include destaining and restaining procedures)			
D4055	3. Procedures for control requirements: A. 10% rescreen B. Statistical evaluations C. Personnel evaluations D. 5 yr retrospective review E. Tissue correlation activities (Including time frames for completion) F. Turn-around-times			
EQUIPMENT MAINTENANCE & FUNCTION CHECKS				
D4084	1. The following equipment maintenance and function checks must be performed in order to insure proper test performance and reporting:			
D4022 D4089	A. Equipment: (Centrifuge, microscope, coverslipping and staining instruments, autoreaders, LIS system)			
D4017	B. Utilities necessary for conducting all phases of patient testing (preanalytical, analytical, postanalytical)			
D4025	C. Temperature monitoring			
D4030	D. Labeling of reagents			
D4038	E. Reagents exceeding expiration date			
STAINING				
D4154	1. Each day of use staining materials must be tested to ensure predictable staining characteristics			

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D4182	A. Stain checks must be documented			
D4313	2. All gyn smears must be stained using a Papanicolaou or a modified Papanicolaou staining method			
D4314	3. Effective measures must be taken to prevent cross-contamination between gyn and non-gyn specimens during staining			
D4315	4. Non-gyn specimens that have a high potential for cross-contamination must be stained separately from other non-gyn specimens			
D4316	A. Stains must be filtered or changed following staining			
D4182	B. This must be documented			
D4317	5. Diagnostic interpretations must not be reported for unsatisfactory smears (e.g. squamous epithelial cells covering less than 10% of the slide, obscuring blood, poor fixation)			
QUALITY CONTROL				
D6162	1. Slides must be screened by appropriately qualified personnel			
D4319 D6166	<p>2. Each person evaluating cytology preparations by non-automated microscopic techniques may examine no more than 100 slides (gyn, non-gyn or both) in a 24 hour period irrespective of the site of the laboratory.</p> <p style="padding-left: 40px;">This is an absolute maximum number of slides and is <u>not</u> to be used as a performance target for each person</p> <p style="padding-left: 40px;">Non-gyn slides, gyn slides, QC slides, PT slides, and any slide screened for QA purposes must be included in workload records and counted toward the maximum 100 slides/24 hr period</p>			

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D4320	A. Previously examined non-negative gyn cases and previously examined non-gyn cytology slides and tissue pathology slides examined by a technical supervisor qualified under 493.1449 (b) or (k) are not included in the 100 slide limit			
D4321	B. Automated preparations count as half slides when cell dispersion is one-half or less of the total slide area			
D4322 D6167 D4182	C. Records must be kept of the total number of slides examined by each person during each 24 hour period (irrespective of the site of the laboratory) and the number of hours each person spends examining slides in the 24 hour period			
D4324	D. The maximum number of 100 slides (described in D4319 and D4320) must be examined in no less than 8 hours			
D4325	<p>E. For purposes of establishing workload limits for persons examining slides by non-automated microscopic techniques on other than an 8 hour workday basis (e.g. part-time employees and full-time employees with other duties) a period of 8 hours must be used to prorate the number of slides that may be examined</p> <p>Use the formula:</p> $\frac{\text{\# of hrs examining slides} \times 100}{8}$ <p>(or 12.5 slides/hour)</p> <p>To determine maximum slide volume permitted</p>			

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	3. Technical Supervisor Responsibilities:			
D6109	A. The laboratory must employ a person who qualifies as a Technical Supervisor (TS) under 493.1449 (b) or (k)			
D6133	B. If the TS is responsible for screening cytology slide preparations, the TS must document the number of cytology slides he/she screened in a 24 hour period and the number of hours devoted to screening slides			
	C. The TS must ensure that:			
D4326	1. All gyn smears interpreted to be non-negative are confirmed by a TS in cytology			
D4327	a. The report must be signed to reflect the review by the TS (actual or electronic signature)			
D4318	2. All non-gyn smears are reviewed by the cytology TS and reports signed as per D4327			
D4330	3. The performance of each CT is evaluated (through reexamination of normal and negative cases as well as feedback on non-negative cases) and review is documented			
D6117	a. Criteria for what constitutes a diagnostic discrepancy must be in writing			
D4166	b. There must be written criteria for remedial action to be taken as a result of a diagnostic discrepancy			
D4333	4. A maximum number of slides (not to exceed the maximum allowable workload limit) is established for each person examining slides by non-automated microscopic techniques			

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	2. Records of initial examination and rescreen results must be available			
	3. The review must be completed before reporting patient results on cases selected			
D4347	5. The laboratory must compare clinical information, when available, with cytology reports and must compare all malignant and premalignant gyn reports with histology reports, if available, and determine the cause of any discrepancies			
D4350	6. For each patient with a current high grade intra epithelial lesion (moderate dysplasia or CIN-2 or above), the laboratory must review all normal or negative gyn specimens received within the previous 5 years (if available to the laboratory)			
D7062	a. If significant discrepancies are found that would affect patient care, the laboratory must notify the patient's physician and issue an amended report			
D7065	b. The individual who originally screened the negative case must be given the opportunity to review the diagnostic			

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D4354	<p>7. The laboratory must establish and document an annual statistical evaluation of the following:</p> <ul style="list-style-type: none"> A. The number of cytology cases examined B. The number of specimens processed by specimen type C. The number of cases reported by diagnosis (Abnormals should be > 1%) D. The number of cases reported as unsatisfactory for diagnostic interpretation E. The number of gyn cases where cytology and available histology results are discrepant F. The number of gyn cases where rescreen of a normal or negative results in a reclassification as malignant or premalignant G. The number of gyn cases for which histology results were unavailable to compare with malignant and premalignant cytology cases 			
D4360	8. The laboratory must evaluate the case reviews of each person examining slides against the laboratory's overall statistical values			
D4182	A. Any discrepancies must be documented and include reasons for deviations			
D7065	C. Corrective actions must be taken to prevent recurrences			
REPORTS AND RECORDS				
D3019	1. Test records (requisitions, accessioning logs, worksheets, etc.) must be retained for a minimum of 2 years			
D3049 D3071	2. Test reports must be kept for 10 years and maintained in a manner that permits ready identification and timely accessibility			
D3056	3. The test report must indicate the name and address of the screening location and the test result			

DTAGS	REQUIREMENTS	QA	DOC	COMMENTS
	4. The laboratory report must:			
D4363	A. Clearly distinguish specimens or smears, or both, that are unsatisfactory for diagnostic interpretation			
D4364	B. Contain narrative descriptive nomenclature for all results			
D4062	1. The procedure manual must include the lab's system for reporting patient results Gyn reporting system: PAP WHO CIN/Richart Bethesda			
D4365	5. Corrected reports issued by the laboratory must indicate the basis for the correction			
D4366	6. The laboratory must retain all slide preparations for 5 years from the date of examination			
D4367	7. Slides may be loaned to proficiency testing programs in lieu of maintaining them for 5 years if written acknowledgement of such loan is maintained by the laboratory			
D4369	8. Documentation for slides loaned or referred for purposes other than proficiency testing must be maintained			
D4370	9. All slides must be retrievable upon request			
QUALITY ASSURANCE				
D7001	1. Laboratories must have a written Quality Assurance policy and conduct periodic quality assurance reviews			
D7019 D7066	A. The lab must identify clients in need of remedial training for collection techniques and/or submitting required patient information			

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D7033	B. The laboratory must utilize the data obtained from the annual statistical evaluations to identify trends and improve lab performance				
	C. There must be ongoing modifications to the Quality Assurance policy which address correction and evaluation of newly encountered problems and situations				
PROFICIENCY TESTING					
	1. If the laboratory has a license from the state of Maryland for gyn cytology, each CT and pathologist must participate in the Maryland Cytology PT program				
	2. If the laboratory has a license from New York state, the lab must participate in the New York state PT program				
	3. If the laboratory is accredited by CAP, the lab must participate in PAP Interlaboratory Comparison Program or another approved glass slide program				

GYNECOLOGIC CYTOLOGY REPORTING SYSTEMS

PAPANICOLAOU	WHO	CIN/RICHART	BETHESDA
Class 0	Unsatisfactory	Unsatisfactory	Unsatisfactory
Class I	Negative	Negative	Within Normal Limits
Class I or Class II	Negative or Reactive	Negative or Reactive	Benign Cellular Changes Infection Reactive Cellular Changes
Class II or Class II or Class III	Atypia Mild Dysplasia	Atypia CIN 1 (Cervical intraepithelial Neoplasia 1)	Epithelial Cell Abnormalities Squamous Cell