

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0505003	<b>(X3) Date Survey Completed</b> 05/25/2018
<b>Name of Provider or Supplier</b> Clinical Pathology Labs Inc	<b>Street Address, City, State</b> 9200 Wall Street Attn Karen Pruett, Austin, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records, and interview it was determined that the laboratory failed to establish written policies and procedures to assess the competency of nineteen of nineteen Technical Supervisors in 2016, 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for assessing the competency of nineteen of nineteen Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for nineteen of nineteen Technical Supervisors who performed microscopic evaluations during 2016, 2017 and to the date of the survey in 2018. Technical Supervisors include: - Technical Supervisor A - Technical Supervisor B - Technical Supervisor C - Technical Supervisor D - Technical Supervisor E - Technical Supervisor F - Technical Supervisor G - Technical Supervisor H - Technical Supervisor I - Technical Supervisor J - Technical Supervisor K - Technical Supervisor L - Technical Supervisor M - Technical Supervisor N - Technical Supervisor O - Technical Supervisor P - Technical Supervisor Q - Technical Supervisor R - Technical Supervisor S 3. During an interview on 5/25/18 at 9:40 AM, the Laboratory Director/Technical Supervisor A and Technical Supervisor B confirmed these findings.</p>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p>

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on review of one hundred and five written laboratory procedures and interviews it was determined that the laboratory failed to ensure that thirty-six written procedures were approved, signed, and dated by the Laboratory Director prior to the start of the survey on 5/21/18. Findings include: 1. The Laboratory Director/Technical Supervisor A failed to sign and date thirty-six of one hundred and five laboratory procedures. Procedures include: - AUS250575SOP QUALITY MANAGEMENT PROGRAM PROCEDURE - AUS250576SOP HIERARCHY OF REVIEW & CLINICAL CORRELATION PROCEDURE - AUS250577SOP PROFICIENCY TESTING PROCEDURE (CYTOLOGY) - AUS250580SOP ASSESSMENT OF PERSONNEL COMPETENCY PROCEDURE - AUS250587SOP TEST NOT PERFORMED (TNP) PROCEDURE - AUS250588SOP MISSING PAP SMEAR PROCEDURE - AUS250590SOPA BIOPSY CORRELATION PROCEDURE - AUS250592SOPA PRIORITIZING CASES PROCEDURE - AUS250593SOP CONVENTIONAL PAP SMEAR PROCEDURE - AUS250594SOP THINPREP COLLECTION & PREPARATION PROCEDURE - AUS250596SOP SUREPATH COLLECTION & PREPARATION PROCEDURE - AUS250598SOP REPROCESSING THINPREP (CYTYC) PROCEDURE - AUS250929SOP REPROCESSING SUREPATH (THINLAYER/AUTOCYTE) PROCEDURE - AUS250600SOP AUTOMATED COVERSLIPPING PROCEDURE - AUS250601SOP MANUAL COVERSLIPPING PROCEDURE - AUS250605SOP EQUIPMENT MAINTENANCE PROCEDURE - AUS250606SOP INSTRUMENT FAILURE & DOWNTIME PROCEDURE - AUS250609SOP TEST & EQUIPMENT VALIDATION PROCEDURE - AUS250930SOP THINPREP ARCHIVING PROCEDURE - AUS250612SOPA FOCALPOINT IMAGING SYSTEM PROCEDURE - AUS250613SOP SUREPATH ARCHIVING PROCEDURE - AUS250649SOP PREVENTIVE MAINTENANCE PROCEDURE - AUS250685SOP ABNORMAL RATES PROCEDURE - AUS250650SOP MICROSCOPIC EVALUATION PROCEDURE - AUS250651SOP ERGONOMIC ASSESSMENT PROCEDURE - AUS250652SOP GYN DIAGNOSTIC CRITERIA PROCEDURE - AUS250655SOP CRITERIA FOR SPECIMEN ADEQUACY PROCEDURE - AUS250692SOP XYLENE MONITORING PROCEDURE - AUS251460SOP REPROCESSING UNSATISFACTORY THINPREP SMEARS USING THE SUREPATH PROCESSING METHOD - AUS251461SOP GYN SLIDE TRACKING AND DISTRIBUTION PROCEDURE - AUS250619SOP URINE CYTOLOGY PROCEDURE - AUS250623SOP BODY CAVITY FLUID PROCEDURE (PLEURA, PERICARDIAL, AND PERITONEAL) - AUS250626SOP BREAST /NIPPLE DISCHARGE CYTOLOGY PROCEDURE - AUS250639SOP SYNOVIAL (KNEE/JOINT) FLUID CYTOLOGY PROCEDURE - AUS250640SOP SMEAR PREPARATION PROCEDURE - AUS250642SOP CENTRIFUGATION PROCEDURE 2. During an interview on 5/22/18 at 10:50 AM, the Laboratory Manager confirmed that the Laboratory Director did not approve the procedures. 3. During an interview on 5/23/18 at 1:30 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.

**D5411**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed

following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on review of the HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL, review of certification records for the Hologic ThinPrep Pap Test and interviews it was determined that the laboratory failed to ensure that one of nineteen Technical Supervisors had received the appropriate training to evaluate gynecologic specimens using the Hologic ThinPrep Pap Test, according to the manufacturer's instructions. Findings include: 1. The HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL, CYTYC Part Number 70354-001, states "the evaluation of microscopic slides produced with the THINPREP 2000 System should be performed only by cytotechnologists and pathologists who have been trained to evaluate THINPREP prepared slides by CYTYC Corporation or by organizations or individuals designated by CYTYC Corporation." a. The Survey Team requested and the laboratory failed to provide the training records for one of nineteen Technical Supervisors who performed diagnostic interpretations on Hologic ThinPrep Pap Tests. Technical Supervisor includes: - Technical Supervisor O 2. During an interview on 5/22/18 at 3:15 PM, the Cytology Supervisor stated that there were no training records for Technical Supervisor O. 3. During an interview on 5/23/18 at 1:30 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.

**D5625**

CYTOLOGY

CFR(s): 493.1274(c)(3)

(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, review of laboratory records and review of gynecologic specimen slides it was determined that the laboratory failed to follow written policies and procedures for the review of prior negative gynecologic specimens from current HSIL cases. The laboratory failed to identify one of thirty-one prior negative specimens as having a more significant lesion than initially reported. Findings include: 1. The laboratory failed to follow the procedure AUS250689SOP titled RETROSPECTIVE RESCREEN PROCEDURE (signed and dated by the Laboratory Director on 4/15/14) which stated: "All the cases are screened by a qualified Senior Cytotechnologist and any discrepancy is documented on the log (Appendix A)." "The Technical Supervisor reviews all discrepancies and issues a follow up letter (Appendix B) to the original Cytotechnologist who signed out the case with an appropriate feedback comment." "The technical supervisor documents all discrepancies in the Five Year Retrospective Rescreen Summary report (Appendix C)." 2. The Survey Team reviewed thirty-one prior negative cases from twenty-four current HSIL's and the Survey Team Pathologist confirmed that the laboratory did not

identify one of thirty-one prior negative specimens as having a more significant lesion than was originally reported. Case includes: ZH478856

**D5629**

CYTOLOGY  
CFR(s): 493.1274(c)(5)

(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures for the evaluation and comparison of six of six laboratory statistics, and failed to document six of six required annual statistics for 2016 and 2017. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for an annual statistical evaluation of six of six required annual statistics. 2. The Survey Team requested and the laboratory failed to provide records of the six of six required annual statistics for 2016 and 2017 for this facility. 3. During an interview on 5/21/18 at 10:40 AM, the Laboratory Manager stated the statistics the laboratory compiled included cases reported at other facilities. 4. During an interview on 5/23/18 at 1:30 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.

**D5645**

CYTOLOGY  
CFR(s): 493.1274(d)(3)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policies and procedure, laboratory records and interviews it was determined that the laboratory failed to follow written policies and procedures to ensure that the laboratory would maintain accurate records for seven of thirty-five Cytotechnologists of the total number of slides examined. The laboratory failed to maintain accurate records of the number of slides examined for eleven of twenty-one random days from February through April 2018. Findings include: 1. The laboratory failed to follow the laboratory procedure AUS250673SOP titled CYTOTECHNOLOGIST WORKLOAD PROCEDURE (signed and dated by the

Laboratory Director on 7/7/15) which stated: "The daily workload form is completed by each cytotechnologist as a backup documentation procedure (Exhibit A). The Team leaders are responsible to collect, review, and sign the forms for each of their team members." "The cytology department assistant is responsible for entering all data on a monthly basis. 2. The Survey Team reviewed twenty-one random daily workload forms. Eleven of twenty-one forms did not indicate the number of field of view (FOV) and full review slides when imaged slides were screened. The eleven workload forms were signed by a team leader to indicate review. Dates include: Cytotechnologist A: 3/27/18 Cytotechnologist B: 2/3/18, 3/15/18 Cytotechnologist C: 4/23/18 Cytotechnologist D: 3/5/18, 4/24/18 Cytotechnologist E: 2/20/18, 3/16/18 Cytotechnologist F: 2/1/18 Cytotechnologist G: 2/6/18, 2/8/18 3. During an interview on 5/22/18 at 4:00 PM, Technical Supervisor B, the Laboratory Manager, and the Cytology Supervisor confirmed these findings. 4. During an interview on 5/23/18 at 1: 30 PM, the Laboratory Director/Technical Supervisor A confirmed these findings.

**D5655**

CYTOLOGY  
CFR(s): 493.1274(e)(4)

(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policies and procedures, gynecologic cytology slides and interview it was determined that the laboratory failed to follow written policies and procedures to ensure that unsatisfactory gynecologic cytology slide preparations were identified and reported as unsatisfactory. The laboratory failed to identify and report five of five gynecologic cytology cases from February 2018 as being "Unsatisfactory for Evaluation." Findings include: 1. The laboratory failed to follow the procedure AUS250SOP titled CRITERIA FOR SPECIMEN ADEQUACY PROCEDURE (not signed and dated by the Laboratory Director) which stated: "Adequate preparation requires at least 5,000 well visualized squamous epithelial cells." 2. The laboratory failed to identify and report five of five gynecologic cytology cases from February 2018 as being "Unsatisfactory for Evaluation." Cases include: ZH447279 ZJ882977 ZJ881183 ZJ882931 ZG737009 3. During an interview on 5/25 /18 at 9:40 AM, the Laboratory Director/Technical Supervisor A confirmed these findings.

**D5659**

CYTOLOGY  
CFR(s): 493.1274(e)(6)

(e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to follow written policies and procedures to ensure that corrected reports indicated the basis for the correction on the report. Five of five corrected reports from February through April 2018 did not indicate the basis for the correction. Findings include: 1. The laboratory failed to

follow the procedure AUS250663SOP titled CHANGE AFTER RELEASE: CORRECTED AND ADENDUM REPORTS PROCEDURE (signed and dated by the Laboratory Director on 5/22/18) which stated: "When a new diagnosis is entered into a LabIS report, the reason for the correction must be included, and the previously reported diagnosis entered into the comment section." 2. The Survey Team reviewed five corrected reports from February through April 2018. Five of five reports did not include the basis for the correction. Reports include: ZJ506576 ZJ942940 ZK470651 ZK533878 ZK533958 3. During an interview on 5/22/18 at 4:00 PM, Technical Supervisor B, the Laboratory Manager, and Cytology Supervisor confirmed these findings. 4. During an interview on 5/23/18 at 1:30 PM, the Laboratory Director /Technical Supervisor A confirmed these findings.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:  
Based on record review, surveyor interviews, and slide review it was determined that the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations (refer to D6079); failed to ensure that one of nineteen Technical Supervisors had received the training required by the manufacturer (refer to D6102); and failed to ensure the competency of nineteen of nineteen Technical Supervisors performing cytology test procedures (refer to D6103). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.

**D6079**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(a)(b)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policies and procedures, laboratory records, slide review and interviews it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory including assuring compliance with applicable regulations by having cytology procedures and

programs established and followed. Cross Refer to D5407, D5411, D5625, D5629, D5645, D5655, D5659

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on review of the HOLOGIC THINPREP 2000 SYSTEM OPERATOR'S MANUAL, review of certification records for the Hologic ThinPrep Pap Test and interviews it was determined that the laboratory failed to ensure that one of nineteen Technical Supervisors had received the appropriate training to evaluate gynecologic specimens using the Hologic ThinPrep Pap Test, according to the manufacturer's instructions. Cross Refer to D5411

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the Laboratory Director failed to ensure written policies and procedures were established to assess, monitor and maintain competency of nineteen of nineteen Technical Supervisors performing cytology test procedures. Cross refer to D5209

**D6115**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on review of 1119 random negative gynecologic cases (1163 slides) from February through April 2018 and confirmation by the Survey Team Pathologist on May 25, 2018 it was determined that the Technical Supervisor failed to verify the accuracy of seven gynecologic tests. 1. ZH482090 3/8/18 Imaged ThinPrep Pap Test (I-TPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion

SURVEY TEAM PATHOLOGIST DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 2. ZJ890530 2/13/18 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Atypical Glandular Cells 3. ZH447279 2/9/18 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation - Insufficient Cellularity 4. ZJ882977 2/10/18 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation - Insufficient Cellularity 5. ZJ881183 2/10/18 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation - Insufficient Cellularity 6. ZJ882931 2/10/18 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation - Insufficient Cellularity 7. ZG737009 2/13/18 I-TPPT LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM PATHOLOGIST DIAGNOSIS: Unsatisfactory for Interpretation - Insufficient Cellularity

**D9999**

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