

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0508312	(X3) Date Survey Completed 09/05/2019
Name of Provider or Supplier Clinical Pathology Associates	Street Address, City, State 1150 N 18th Suite 102, Abilene, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Review of laboratory records for 2018 and 2019 and interview of facility personnel found no documentation available for review to ensure the negative and positive reactivity of Hematoxylin and Eosin staining was acceptable for each day of patient testing between January 1, 2018 through January 31, 2019. The findings included: 1. Review of quality control records for Hematoxylin and Eosin (H and E) staining found no documentation of staining acceptability between January 1, 2018 and January 31, 2019. 2. Interview of testing person 7 conducted on September 5, 2019 at 11:19 AM confirmed the H and E quality control records were not available available for review. She stated that the laboratory changed the format for documenting H and E quality control staining in February 2019, and misplaced previous records.</p>
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the College of American Pathologists (CAP) PAP proficiency testing records from 2018 and 2019 and interview of facility personnel, the laboratory failed to retain all proficiency testing records for at least 2 years in 1 of 2 reviewed events. The findings included: 1. PAP Proficiency testing (PT) records include all</p>

information regarding the PT event including the original submission forms, proctor examinations, testing records, signed attestation statements, PT results and scores from the provider and documentation of review and records of any corrective actions. 2. Based on review of the College of American Pathologists (CAP) proficiency testing records for 2018 and 2019, the laboratory failed to retain the original submission forms, proctor examinations, signed attestations and documentation of review of the laboratory's overall performance for the 2018 PAP testing event. 2. Interview of testing person 7 conducted on September 5, 2019 at 10:03 AM confirmed the records were not available for review. She stated she knew she had them, but cannot locate them.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:
Based on review of the College of American Pathologists(CAP) PAP proficiency testing records from 2018 and 2019, policies and procedures and staff interview, the laboratory failed to document the review of results received from the proficiency testing agency in two of two events reviewed. The findings included: 1. Review of CAP proficiency testing records from 2018 and 2019 found no documentation of review of proficiency testing results. 3. Interview of testing person 7 listed on the CMS report 209 Laboratory Personnel report conducted on September 5, 2019 confirmed that there were no other documentation of assessment of proficiency testing available for review.

D5311

SPECIMEN SUBMISSION, HANDLING, AND REFERRAL
CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, manufacturer's instructions, observations and interviews it was determined that the laboratory failed to ensure Hologic ThinPrep gynecologic specimens were transported according to the manufacturer's instructions. Findings included: 1. Review of the laboratory's policy (manufacturer's instructions) for the Aptima Combo 2 found under the heading Specimen Collection and Storage: Specimen transport and storage before testing: "1. Urogenital swab specimens: After Collection, transport and store the swab in the swab transport tube at 2 degrees C to 30 degrees C until tested. Specimens must be assayed with the Aptima Combo 2 Assay within 60 days of collection. If longer storage is needed, freeze at -20 degrees C to -70 degrees C for up to 12 months after collection. 2. Extragenital (throat and rectal) swab specimens: After Collection, transport and store the swab in the swab transport tube at 2 degrees C to 30 degrees C until tested. Specimens must be assayed with the Aptima Combo 2 Assay within 60 days of

collection. 3. Urine Specimens: Urine samples. that are still in the primary collection container must be transported to the lab at 2 degrees C to 30 degrees C. Transfer the urine sample into the Aptima urine specimen transport tube within 24 hours of collection. Store at 2 degrees to 30 degrees C and test within 30 days of collection 4. PreservCyt Solution liquid Pap Specimens: PreservCyt Solution liquid Pap specimens intended for CT and /or GC testing must be processed for cytology and/or transferred to an Aptima Specimen Transfer tube within 30 days of collection when stored at 2 degrees C to 30 degrees C." 2. Review of the Operator's manual for the ThinPrep 2000 (MAN-02624-001 Rev. 004) found on page 15 : "Store PreservCyt Solution with cytologic sample intended for ThinPrep Pap testing between 15C (59F) and 30C (86F) for up to 6 weeks." 3. Observations made during the delivery of specimens on September 4, 2019 at 1:10 PM found one PreservCyt Solution liquid Pap Specimen in the cooler with tissue specimens to be processed. There was no thermometer in the cooler to measure the temperature.. 4. Interview of testing person 7 on the CMS report 209 conducted on September 4, 2019 at 1:19 found that the laboratory used a contract courier service to transport specimens between clients and the laboratory. Interview of the courier found that they do not monitor the temperature of coolers used during the transport of patient specimens.