

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0508312	(X3) Date Survey Completed 07/30/2025
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
D0000	An announced routine recertification survey of the laboratory was conducted from 07/29/2025 to 07/30/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties /subspecialties for which it was surveyed. Standard level deficiencies were cited.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, review of the laboratory's proficiency testing (PT) records, and confirmed in interview, the laboratory failed to attest to the routine integration of PT samples into the patient workload for one of three American Proficiency Institute (API) PT events and one of two College of American Pathologists (CAP) PT events in 2024. Findings include: 1. Review of the laboratory's policy titled "PROFICIENCY TESTING AND ACCURACY VERIFICATION -QA" stated: " ...i. The individual testing the samples must sign the attestation statement section of the results sheet to attest to the routine integration of the samples into the patient workload using routine methodsj. The Medical Director must also sign the attestation form ..." 2. Review of the laboratory's PT records in 2024 determined the laboratory failed to ensure PT attestation pages were signed for one of three API PT events and one of two CAP PT events in 2024: a. PT Provider: API Event: 2024 Microbiology - 1st event Person performing test: no signature b. PT Provider: CAP Event: MGEN-B 2024 Mycoplasma genitalium, Molecular Survey Director (or Designee): no signature 3. The general supervisor-2 (as listed on the CMS-209) form confirmed the findings in an interview on 07/29/2025 at 1110 hours in the office. Key: CMS: Centers for Medicare and Medicaid Services</p>

TEST REQUEST

CFR(s): 493.1241(b)

(b) The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy, review of the laboratory's patient order forms and confirmed in interview, the laboratory failed to ensure patient test requisitions included information necessary for proper interpretation of results for Papanicolaou (PAP) smear testing for 12 of 13 patients randomly reviewed from August 2023 to July 2025. Findings include: 1. Review of the laboratory's policy titled "GENERAL LABORATORY POLICY - REQUISITION", approved by the laboratory director on 01/08/2024 stated: "PROCEDURE: A. GYN Cytology Specimen Demographic Information: ...2. Clinical Information a. Last menstrual period b. Hormonal status (e.g., pregnant, post-menopausal) c. Exogenous hormone therapy (birth control pills, estrogen cream) d. Use of IUD e. History of previous abnormal report, treatment or biopsy f. Patient's risk factors for cervical cancer g. Any other patient history" 2. Review of the laboratory's patient order forms determined the laboratory failed to ensure patient test requisitions included information necessary for proper interpretation of results for PAP smear testing for 12 of 13 patients randomly reviewed from August 2023 to July 2025. a. Patient ID: 470430 Patient date of birth: 07/01/1972 Requisition Number: 3725437CE23308 Date: 08/03/2023 3:33pm b. Patient ID: 628777 Patient date of birth: 11/29/1975 Requisition Number: 5974363CE21794 Date: 10/10/2023 2:48pm c. Patient ID: 284223 Patient date of birth: 03/15/1961 Requisition Number: 3715013CE23308 Date: 11/01/2023 1:48pm d. Patient ID: 506132 Patient date of birth: 11/13/1988 Requisition Number: 3988927CE23308 Date: 02/20/2024 8:59am e. Patient ID: 464319 Patient date of birth: 06/04/1983 Requisition Number: 4041813CE23308 Date: 05/13/2024 1:47pm f. Patient ID: 547922 Patient date of birth: 08/01/2000 Requisition Number: 4089356CE23308 Date: 07/30/2024 3:10pm g. Patient ID: 235295 Patient date of birth: 03/26/2002 Requisition Number: 6784899CE21794 Date: 09/09/2024 4:16pm h. Patient ID: 11937119 Patient date of birth: 08/13/1989 Requisition Number: 6916769CE21794 Date: 10/30/2024 4:26pm i. Patient ID: 649705 Patient date of birth: 08/27/1992 Requisition Number: 7038554CE21794 Date: 01/02/2025 8:41am j. Patient ID: 707419 Patient date of birth: 11/15/1990 Requisition Number: 7306014CE21794 Date: 04/07/2025 3:59pm k. Patient ID: 478020 Patient date of birth: 09/10/1976 Requisition Number: 7371892CE21794 Date: 05/02/2025 10:27am l. Patient ID: 11918579 Patient date of birth: 03/24/1998 Requisition Number: 7482745CE21794 Date: 07/02/2025 1:07pm 3. The general supervisor-2 (as listed on the CMS-209 form) confirmed the findings in an interview on 07/29/2025 at 1325 hours in the office. Key: CMS: Centers for Medicare and Medicaid Services