

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0260856	<b>(X3) Date Survey Completed</b>  01/21/2021
<b>Name of Provider or Supplier</b>  Associated Pathologists, Llc	<b>Street Address, City, State</b>  1901 Phoenix Blvd, Suite 210, Atlanta, GA	
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>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 21, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of laboratory records and an interview with the Laboratory Manager (LM), the laboratory failed to enroll in a CMS-approved proficiency test (PT) as required by Clinical Laboratory Improvement Amendments (CLIA) for the specialty of Histopathology for 2019 and 2020. The findings include: 1. Review of laboratory records revealed the laboratory was not enrolled in a PT program for the specialty of Histopathology for 2019 and 2020. 2. The LM confirmed on January 21, 2021 at 1:30 P.M. in an office, inside of the laboratory, that the facility was not enrolled in a CMS-approved PT as required by CLIA for the specialty of Histopathology for 2019 and 2020.</p>
<b>D5781</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(1)</p>

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of temperature records and staff interview, the lab failed to document corrective actions when temperatures exceeded acceptable limits. Findings include: 1. Review of water bath #1 temperature records: January 2019 & July 2019 revealed one or more days the temperature was out of range without corrective actions documented. 2. Interview with the lab manager on 01/21/2021 at approximately 12:44 PM in an office, inside of the laboratory, confirmed the corrective actions were not documented.