

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0680982	(X3) Date Survey Completed 07/22/2025
Name of Provider or Supplier Anderson Hills Pediatrics Inc	Street Address, City, State 1126 West Ohio Pike, Amelia, OH	
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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES 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 record review and interviews with Testing Personnel (TP) #4 and TP #11, the laboratory failed to enroll in a proficiency testing (PT) program for the sub-specialty of Bacteriology. This deficient practice had the potential to affect 461 out of 461 patients tested in the subspecialty of bacteriology from 08/17/2023 through 07/22/2025. Findings Include: 1. The laboratory failed to enroll in a proficiency testing (PT) program for Bacteriology specimens. (Refer to D2001)</p>
D2001	<p>ENROLLMENT CFR(s): 493.801(a)(1)(2)(i)</p> <p>The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; and</p>

This STANDARD is not met as evidenced by:

Based on record review and an interview with Testing Personnel (TP) #4 and TP #11, the laboratory failed to enroll in a proficiency testing (PT) program which contained five test specimens per event for moderate complexity urinalysis. This deficient practice had the potential to affect 461 out of 461 urinalysis tests under the subspecialty of Bacteriology from 06/17/2023 through 07/22/2025. Findings Include: 1. Review of the urinalysis procedure titled "Proficiency Testing Guidelines" signed and dated by the Laboratory Director on 08/31/2022, found the following statement: "Urine Colony Count - three times per year in March, June, October" 2. Further review of the urinalysis procedure did not find any mention of the number of challenges per event for PT. 3. The inspector reviewed the urine colony count American Proficiency Institute PT results from the 2023 third event through the 2025 second event which revealed the following: Year Event Test Samples 2023 Third Event UR-11, UR-12 2024 First Event UR-01, UR-02 2024 Second Event UR-06, UR-07 2024 Third Event UR-11, UR-12 2025 First Event UR-01, UR-02 2025 Second Event UR-06, UR-07 4. The inspector requested urine colony count PT results for the 2023 third event through the 2025 second event which included five test specimens from TP #4 and TP #11. TP #4 and TP #11 confirmed the laboratory only completed PT which included two test specimens per event and were unable to provide the requested documentation on the date of the inspection. The interview occurred on 07/22/2025 at 11:30 AM.