

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0187591	(X3) Date Survey Completed 05/04/2022
Name of Provider or Supplier Upmc Security Family Medicine	Street Address, City, State 1930 Security Drive, York, PA	
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 review of the Urine Culture test records and interview with the Laboratory Coordinator (LC), the laboratory failed to enroll in an approved proficiency testing (PT) program for Bacteriology from 01/27/2020 to 05/04/2022. Refer to Dtag: D6015</p>
D6015	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <p>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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the Laboratory</p>

Coordinator (LC), the laboratory director failed to ensure that the laboratory was enrolled in a proficiency testing (PT) program that is approved by HHS for Bacteriology testing performed from January 27, 2020 to May 04, 2022. Findings include: 1. On the day of survey 05/04/2022 at 10:50 a.m., review of the laboratory records revealed that the laboratory was not enrolled in an approved PT program for Urine Cultures positive and negative identification from 01/27/2020 to 05/04/2022. 2. No documented proof of PT enrollment was available at the time of inspection. Interview with the LC at the time of inspection confirmed that the laboratory did not enroll in an approved PT program for Urine Cultures. 3. According to the laboratory's CMS 116 records the laboratory performed 35 urine cultures patient testing annually. 4. The LC on 05/04/2022 at 11:30 a.m confirmed the findings above.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on lack of competency assessment (CA) records and interview with the Laboratory Coordinator (LC), the Technical Consultant (TC) failed to assess the competency of 1 of 2 Testing Personnel (TP) who performed urine culture examinations in 2020 and 2021. Finding Include: 1. On the day of survey, 05/04/2022 at 10:10 a.m., The LC could not provide CA records for 1 of 2 (CMS 209 Personnel #2) who performed urine culture examinations from 1/1/2020 to 12/31/2022 2. The laboratory performed 35 urine cultures annually. 3. The LC confirmed the findings above on 05/04/2022 at 11:30 a.m.