

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0685699	(X3) Date Survey Completed 01/28/2021
Name of Provider or Supplier Upmc Yorktowne Urology	Street Address, City, State 2350 Freedom Way Suite 102, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory record review and interview with the Practice Manager on (01/28/2021), the laboratory failed to verify twice annually the accuracy of Urine Sediment examination tests performed from 07/31/2021 through the date of survey. Findings include: 1.The Laboratory could not provide documentation of twice annual accuracy, for Urine Sediment examination tests, from 07/31/2021 through the date of the survey 2. During the survey, the Practice Manager confirmed that twice annual accuracy, for Urine Sediment examination tests, was not documented.</p>
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on quality control record review and interview with the Practice Manager on (01/29/2021), the laboratory failed to document all Quality Control procedures performed for Urine Sediment examination. Findings include: 1.The Laboratory could not provide Quality Control documentation for Urine Sediment Examination tests</p>

performed from 07/31/ 2021 through the date of survey. 2. During the survey, the Practice Manager confirmed that Quality Control was not documented each day of patient testing for Urine Sediment Examination.

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 laboratory personnel interview and review of the laboratory Testing Personnel records on the date of the survey (01/28/2021), the Technical Consultant failed to evaluate the competency for 4 of 5 testing personnel. Findings include: 1. Review of the laboratory Testing Personnel records revealed no competency records for 4 of 5 Testing Personnel who performed Urine Sediment examination tests, from 07/31/2018 through the date of the survey. 2. The Laboratory Director acted as the Technical Consultant and Testing Person from 07/31/2018 the date of the survey. 3. During the survey at 11:30 pm, the Practice Manager confirmed the above findings.