

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0185196	(X3) Date Survey Completed 08/19/2020
Name of Provider or Supplier Geisinger Mount Pocono	Street Address, City, State 126 Market Way, Mount Pocono, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manuals, personnel competency assessment records and interview with the technical supervisor (TS) and quality coordinator, the laboratory failed to follow their competency assessment program to assess the competency of 1 of 2 consultant/supervisors for their regulatory responsibilities in 2019 and 2020. Findings Include: 1. The Competency Assessment Program Policy #7 states, "The performance of delegated section directors/technical supervisors general supervisors and clinical and technical consultants must be assessed annual." 2. On the day of survey, 08/19/2020, the TS and quality coordinator could not provide documentation of competency assessments performed annually for 1 of 2 TS's (also listed as the technical consultant and general supervisor) for their regulatory responsibilities in 2019 and 2020. 3. The TS and quality coordinator confirmed the findings above on 08/19/2020 around 9:00 am.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities</p>

specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with the technical supervisor (TS) and quality coordinator, the laboratory failed to perform maintenance/function checks for 1 of 1 room humidity thermometer and 1 of 1 room temperature thermometer in 2019 and 2020. Findings Include: 1. On the day of survey, 08/19/2020, observation of the laboratory revealed, 1 of 1 room humidity thermometer was due for calibration on 09/26/2019 and 1 of 1 room temperature thermometer was due for inspection on 02/2019. 2. The TS and quality coordinator confirmed the findings above on 08/19/2020 around 1:00 pm.

D5449

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(ii)(g)

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.

This STANDARD is not met as evidenced by:

Based on review of quality control (QC) records, and interview with the technical supervisor (TS) and quality coordinator, the laboratory failed to document QC for urine sediment microscopic examinations and manual differentials each day of patient testing separately from 03/15/2018 to the day of survey. Findings Include: 1. On the day of survey, 08/19/2020, review of urine sediment microscopic examinations and manual differentials QC records revealed, visual QC's were performed for both tests on the same sheet each day of patient testing. 2. The TS could not differentiate which days QC's were performed for urine sediment microscopic examinations and or for manual differentials examination in 2018, 2019 and 2020. 3. In 2018 (03/15/2018 to 12/31/2018): - 1,411 Urine Sediment Microscopic examination were analyzed. - 341 Manual differentials examination were analyzed. 4. In 2019 (01/01/2019 to 12/31/2019): - 1527 Urine Sediment Microscopic Examination were analyzed. - 344 Manual differentials examination were analyzed. 5. In 2020 (01/01/2020 to 08/19/2020): - 417 Urine Sediment Microscopic Examination were analyzed. - 349 Manual differentials examination were analyzed. 6. The TS and quality coordinator confirmed on 08/19/2020 around 10:45 am.