

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0657610	(X3) Date Survey Completed 04/20/2021
Name of Provider or Supplier Endless Mountains Health Systems	Street Address, City, State 100 Hospital Drive, Montrose, 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's procedures and interview with the technical supervisor (TS) #1, the laboratory failed to establish a complete competency assessment procedure from 2019 to the day of survey. Findings include: 1. On the day of survey, 04/20/2021, the laboratory's could not provide a complete competency assessment procedure in use from 04/20/2019 to 04/20/2021. 2. The TS #3 confirmed the finding above on 04/20/2021 around 2:00 pm. ** Repeat Deficiency</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical consultant (TS) #1, the laboratory failed to verify the performance specifications for the BioFire</p>

FilmArray Torch System Respiratory 2.1 (RP2.1) Panel before reporting patient results from June 2020 to the day of survey. Findings include: 1. On the day of survey, 04/21/2021, the TS #1 was unable to provide performance specifications performed for the BioFire FilmArray Torch System Respiratory 2.1 (RP2.1) Panel before reporting patient results from June 2020 to April 20, 2021. 2. 1183 - RP2.1 panels were analyzed on the BioFire FilmArray Torch System in 2020 (01/01/2020 to 12/31/2020). 3. 1352 - RP2.1 panels were analyzed on the BioFire FilmArray Torch System in 2021 (01/01/2020 to 04/20/2021). 4. The TC confirmed the finding above on 04/20/2021 around 12:30 pm.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:
Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with testing personnel (TP) #7, the laboratory director failed to ensure that all proficiency testing reports received and identified problems that require corrective action in 2019. Findings include: 1. On the day of survey, 04/20/2021, review of API PT records revealed, the laboratory did not document corrective actions for the API 2019 Event 2, Chemistry score of 80% for pCO₂. 2. TP#7 confirmed the finding above on 04/20/2021 around 9:50 am.

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 review of testing personnel (TP) competency assessment records, API proficiency testing (PT) records, interview with technical supervisor (TS) #1 and testing personnel #7, the laboratory failed to evaluate the competency assessment for 4 of 4 TP performing blood gases on the OPTI CCA-TS2 Blood Gas and Electrolyte Analyzer and 6 of 6 TP performing the Respiratory 2.1 (RP2.1) Panel on the BioFire FilmArray Torch System from 2019 to the day of survey. Findings include: 1. On the date of survey, 04/20/2021, review of TP competency records revealed, 4 of 4 TP performing blood gases on the OPTI CCA-TS2 Blood Gas and Electrolyte Analyzer were not assessed for the following procedures of competency in 2019, 2020 and 2021: - Monitoring the recording and reporting of test results. - Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. - Direct observation of performance of instrument maintenance and function checks. - Assessment of test performance

through testing previously analyzed specimens, internal blind testing samples or external proficiency testing (PT) samples. - Assessment of problem solving skills. 2. 1 of 4 TP performed all API blood gases PT events in 2019, 2020 and 2021. TP#7 could not provide documentation of internal blind testing samples or PT samples analyzed for 3 of 4 TP. 3. 6 of 6 TP performing the Respiratory 2.1 (RP2.1) Panel on the BioFire FilmArray Torch System were not assessed for the following procedures of competency in 2020 and 2021: - Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. - Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. - Direct observation of performance of instrument maintenance and function checks. - Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external PT samples. - Assessment of problem solving skills. 4. The TS #1 confirmed the findings above on 04/20/2021 around 2:10 pm.