Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0657610	05/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Endless Mountains Health Systems	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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with technical supervisor #1 (TS), the laboratory failed to ensure that the verifications of accuracy for serum acetone examinations were performed at least twice annually, as required for tests not included in subpart I from 04/20/2021 to the date of the survey. Findings include: 1. On the day of the survey, 05/17/2022 at 09:10 am, the laboratory could not provide documentation that the verification of accuracy for serum acetone examinations was performed at least twice annually from 04/20/2021 to 05/17/2023. 2. TS #1 confirmed the findings above on 05/17/2023 around 03:00 pm.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of the Siemens Dimension EXL validation records and interview

	with technical supervisor #1 (TS), the laboratory failed to provide complete validation records for the required performance specifications for 3 of 3 analytes tested on the Siemens Dimension EXL chemistry analyzer before reporting patient results from 06 /17/2022 to the date of the survey. Findings Include: 1. On the day of the survey, 05/17 /2023 at 02:15 pm, the laboratory was unable to provide complete validation records verifying the following performance specifications for 3 of 3 chemistry analytes introduced on the Siemens Dimension EXL before patient testing from 06/17/2022 to 05/17/2023:: - C-Reactive protein (CRP) performed 11/3/2022: missing acceptable criteria and reference range/ normal value study - Salicylate performed 12/16/2022: missing accuracy, acceptance criteria and reference range/normal value study - Troponin performed 06/17/2022: missing acceptance criteria and reference range /normal value study 2. The laboratory could not provide documentation that the validation studies were reviewed and evaluated by the appropriate staff before patient testing was performed. 3. TS # 1 confirmed the findings above on 05/17/2023 around 03:00 pm.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with technical supervisor #1 (TS), the laboratory failed to perform calibration verification at least once every six months for 1 of 1 Siemens Dimension EXL chemistry analyzer from 04/20/2021 to the date of the survey. Findings include: 1. On the date of the survey, 05/17/2023 at 01:19 pm, the laboratory could not provide calibration verification records for the required analytes tested on 1 of 1 Siemens Dimension EXL chemistry analyzers from 04/20/2021 to 05 /17/2023. 2. TS #1 confirmed the findings above on 05/17/2023 around 03:00 pm.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or

	instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with technical supervisor #1 (TS), the laboratory failed to have a system that twice a year evaluates the relationship between automated white blood cell (WBC) count differentials performed on 1 of 1 Beckman Coulter DxH600 hematology analyzers and manual microscopic WBC differentials performed from 04/20/2021 to the day of the survey. Findings include: 1. On the day of the survey, 05/17/2023 at 12:00 pm, the laboratory could not provide documentation of the biannual comparison of test results for WBC differentials performed on the Beckman Coulter DxH600 (automated) and microscopic WBC differentials (manual) from 04/20/2021 to 05/17/2023. 3. The laboratory performed 84,344 hematology tests in 2022 (CMS-116 annual volume). 4. TS #1 confirmed the findings above on 05/17/2023 around 03:00 pm.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's daily temperature log records and interview with technical supervisor #1 (TS), the laboratory failed to document all corrective actions taken when room temperatures exceeded acceptable ranges for 27 of 61 days from 09 /01/2022 to 10/31/2022. Findings include: 1. The laboratory daily temperature log states, optimal laboratory room temperatures (20- 25 degrees Celsius). 2. On the day of the survey, 05/17/2023 at 10:32 am, review of the laboratory's daily temperature log records revealed the room temperature for the following 27 of 61 days exceeded acceptable ranges (20-25 degrees Celsius) from 09/01/2022 to 10/31/2022: - Room Temperature Supply: 3 of 30 days in September 2022 were below the acceptable range. - Room Temperature Blood Bank: 12 of 30 days in September 2022 were below the acceptable range. - Room Temperature Supply: 5 of 31 days in October 2022 were below the acceptable range. - Room Temperature Blood Bank: 14 of 31 days in October 2022 were below the acceptable range. 3. TS #1 could not provide documentation of the corrective actions taken for out-of-range temperatures from 09 /01/2022 to 10/31/2022. 4. TS #1 confirmed the finding above on 05/17/2023 around 03:00 pm.