Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0657610	04/10/2025
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation and interview with General Supervisor (GS) #1, the laboratory director (LD)/designee failed to attest to the routine integration of samples into the patient workload for 16 of 24 PT events performed for Immunology, Immunohematology, Chemistry, Microbiology and Hematology in 2023, 2024 and 2025. Findings include: 1. On the days of survey 04/09/2025 and 04 /10/2025, review of the laboratory's API PT records revealed, the laboratory director (LD)/designee failed to document the attestation of the routine integration of samples into the patient workload for the following 16 of 24 API PT events: - API 2023 Immunology/Immunohematology 3rd Event - API 2023 Chemistry Miscellaneous 2nd Event - API 2024 Chemistry Core 1st and 3rd Events - API 2024 Chemistry Miscellaneous 1st and 2nd Events - API 2024 Immunology/Immunohematology 1st, 2nd and 3rd Events - API 2024 Microbiology 1st, 2nd and 3rd Events - API 2024 Hematology/Coagulation 1st, 2nd and 3rd Events - API 2025 Microbiology 1st Event 2. GS #1 confirmed the findings above on 04/10/2025 at 10:57 am.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel competency assessment policy, lack of documentation and interview with General Supervisor (GS) #1, the laboratory failed to follow an established competency assessment policy to assess the competency of 1 of 1 Technical Supervisor (TS) and 2 of 2 General Supervisors (GS) for their supervisory responsibilities performed in 2023 and 2024. Findings Include: 1. The laboratory's Clinical Staff Competency Assessment policy states, "Competency assessment is required for all supervisors for those duties in which they are delegated to perform. Competency is performed annually." 2. On the days of survey, 04/09/2025 and 04/10/2025, the laboratory failed to provide documentation of the annual competency assessment for the following personnel for their supervisory responsibilities performed in 2023 and 2024: - 1 of 1 TS (CMS 209 personnel #2). - 2 of 2 GS (CMS 209 personnel #2, #3). 3. GS #1 confirmed the findings above on 04/10 /2025 at 10:57 am
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 review of the laboratory's proficiency testing policy, lack of documentation and interview with General Supervisor (GS) #1, the laboratory failed to verify twice annually the accuracy of Direct Antiglobulin Test (DAT) (unregulated) examinations performed for 23 of 23 months from 05/17/2023 through the days of survey. Findings include: 1. The laboratory's proficiency testing policy states, "Alternative assessment procedures may be used for unregulated analytes or to investigate a failure or ongoing problem: 1. Other PT programs offered by manufacturers 2. Split samples with another laboratory (not currently PT testing) 3. Direct Observation 4. Peer consensus 5. Controls or calibrators (must be a different lot number that those used for current calibration and/or QC)." 2. On the days of survey, 04/09/2025 and 04/10/2025, the laboratory failed to provide documentation of the twice annual verification of accuracy for DAT examinations performed from 05/17/2023 to 04/10/2025. 3. The laboratory performed 1 DAT from 05/17/2023 to 04/10/2025. 4. GS #1 confirmed the findings above on 04/10/2025 at 10:57 am
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on lack of documentation and interview with General Supervisor (GS) #1, the laboratory failed to document a positive and negative control each day of patient testing for Trichomonas (wet mount) and Potassium Hydroxide (KOH) microscopic examinations performed for 23 of 23 months from 05/17/2023 to the days of survey. Findings include: 1. The laboratory's Wet Prep and KOH Testing procedure states "QC: technologist will sign off on log sheet after reviewing posted photographic QC."

	2. On the days of survey 04/09/2025 and 04/10/2025, the laboratory failed to provide documentation of the positive and negative control performed every day of patient testing for wet mount and KOH microscopic examinations performed from 05/17 /2023 to 04/10/2025. 3. The laboratory performed 22 wet prep procedures from 05/17 /2023 to 04/10/2025. 4. GS #1 confirmed the above findings on 04/10/2025 at 10:57 am.
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. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with General Supervisor (GS) #1, the laboratory failed to evaluate twice a year the relationship between automated white blood cell (WBC) count differentials performed on 1of 1 Beckman Coulter DxH 600 hematology analyzer and manual microscopic WBC differentials performed from 05 /17/2023 to 04/10/2025. Findings include: 1. On the days of survey, 04/09/2025 and 04 /10/2025, the laboratory failed to provide documentation of the biannual comparison of test results between the automated WBC differentials performed on 1 of 1 Beckman Coulter DxH 600 hematology analyzer and manual microscopic WBC differentials performed from 05/17/2023 to 04/10/2025. 2. The laboratory performed 2492 manual microscopic WBC differentials from 05/17/2023 to 04/10/2025. 3. GS #1 confirmed the findings above on 04/10/2025 at 10:57 am. *REPEAT DEFICIENCY
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on review of the laboratory's Pennsylvania Department of Health (PA DOH) and American Proficiency Institute (API) proficiency testing (PT) records, lack of documentation and interview with General Supervisor (GS) #1, the Laboratory Director (LD) failed to ensure the review of results obtained to evaluate laboratory performance for 3 of 4 PA DOH Toxicology PT events performed in 2023 and 5 of 24 API PT testing events performed for Hematology, Immunology, Immunohematology, Chemistry and Microbiology in 2023, 2024 and 2025. Findings Include: 1. On the days of survey 04/09/2025 and 04/10/2025, review of the laboratory's PA DOH PT result records revealed no review was documented for evaluation of the satisfactory results obtained for the following 3 of 4 PA DOH Toxicology PT events performed in 2023: - Blood/Serum Alcohol test event 2023-2. - Urine Drugs of Abuse test event 2023-II and 2023-III. 2. Review of the laboratory's API PT records on 04/09/2025 and 04/10/2025 revealed no review was documented for the evaluation of unacceptable and not graded results for the following analytes in 5 of 24 API PT testing events

	performed for Hematology, Immunology, Immunohematology, Chemistry and Microbiology in 2023, 2024 and 2025: - Eosinophil % - COU-15 (unacceptable), Glucose (WB) - GLU-06 (unacceptable): API 2023 Hematology/Coagulation 3rd Event - Blood Bank (Compatibility) SER-12 (not graded): API 2023 Immunology /Immunohematology 3rd Event - Total Bilirubin CH-02, 03 and 05 (not graded), Acetaminophen CH-05 (unacceptable): API 2024 Chemistry - Core 1st Event - Vaginal Wet Preparation VA-02 (not graded): API 2024 Hematology/Coagulation 2nd Event - Parainfluenza 2 RSP-04 (unacceptable), Parainfluenza 3 RSP-04 (unacceptable): API 2025 Microbiology 1st Event 3. GS #1 confirmed the findings above on 04/10/2025 at 10:57 am.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of quality assurance (QA) records, lack of documentation and interview with General Supervisor (GS) #1, the Laboratory Director (LD) failed to ensure a QA program was maintained and documented to ensure the quality of services provided by the laboratory for 12 of 12 months from June 2023 to June 2024. Findings include: 1. The laboratory's Quality Assurance policy states, "Identified quality issues are addressed in laboratory meetings to ensure corrective action and monitoring. Laboratory meetings will be held at least quarterly (four times per year). Laboratory meeting minutes are posted. All quality assurance records and PI projects are kept on file for a period of two years." 2. On the days of survey, 04/09/2025 and 04 /10/2025, the laboratory failed to provide documentation for the periodic QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes for 12 of 12 months from June 2023 to June 2024. 3. GS #1 confirmed the findings above on 04/10/2025 at 10:57 am.