Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0657610	09/19/2018
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
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 of review of laboratory's Quality Assurance manual and interview with the laboratory Manager (LM), the laboratory failed to establish and follow written procedures including CLIA requirements to assess all personnel competency assessments from 2017 to the date of survey (04/20/2017 to 09/18/2018). Findings include: 1. On the day of survey, 09/18/2018, The laboratory failed to provide a written competency assessment policy that assess CLIA's 6 points of competency for laboratory personnel (11 of 11) and a policy to assess supervisory personnel (2 of 2). 2. In 2017: 241, 259 patient tests were performed in the laboratory. 3. In 2018 (01/01 /2018 to 09/18/2018) : 85,044 patient tests were performed in the laboratory 4. The LM confirmed the findings on 09/18/2018 around 9:00 am.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

	This STANDARD is not met as evidenced by: Based on observation of the Blood Gases laboratory, review of Blood Gases laboratory temperature records and interview with the Testing personnel (TP) #10, the laboratory failed to monitor and document the condition of storage for 12 of 12 boxes of OPTI Check Multi Analyte Control and OPTI CCA Cassettes from 2017 to the date of survey. Findings include: 1. OPTI Check Multi Analyte Control package insert under Storage and and Handling states, "Store unopened ampoules at room temperature 15-30 degrees Celsius (59-86 degrees Fahrenheit)". On the box of the OPTI CCA Casettes states,"store at 4-30 degrees Celsius. 2. A the day of survey, 09/18 /2018, the laboratory could not provide room temperature records where 4 of 4 boxes of OPTI Check Multi Analyte Control (Lot #7111) and 8 of 8 boxes of OPTI CCA Cassettes (Lot#815100) are stored. 3. From 04/20/2017 to 12/31/2017, 135 blood gases tests were performed. 4. From 01/01/2018 to 09/18/2018, 105 blood gases tests were performed. 5. The LM confirmed the findings above on 11:00 am.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on laboratory tour, observation of Omega microscopes and interview with Laboratory Manager (LM), the laboratory failed to document maintenance for 1 of 1 Omega microscopes used for urine microscopic analysis from 2017 to the time of survey. Findings include: 1. On the day of survey, 09/18/2018, the laboratory failed to calibrate 1 of 1 Omega microscopes (Model #0897845) used urine microscopic analysis. Sticker on the microscope stated, "Serviced on: 8/26/2016 and Due: 08 /2017". 2. From 04/20/2017 to 12/31/2017, 950 Urine Microscopic analysis tests were performed. 3. From 01/01/2018 to 09/18/2018, 888 Urine Microscopic analysis tests were performed. 4. The LM confirmed the findings above on 09/18/2018 around 12: 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 the review of Urine Microscopic Analysis procedure, Bleeding Time test procedure and interview with the Laboratory Manager, the laboratory failed to document quality control (QC) for Urine Microscopic Analysis and Bleeding time test each day of patient testing in 2017 to the date of survey. (04/20/2017 to 09/18/2018). Findings Include: 1. On the day of survey 09/18/2018, the surveyor asked the Laboratory manager if the laboratory documents Urine Microscopic Analysis and

	Bleeding time test quality control, the laboratory manager stated "the laboratory does have urine microscopic books but daily QC is not document and quality control is no performed for the Bleeding time test". 2. From 04/20/2017 to 12/31/2017, 950 Urine Microscopic analysis tests were performed. 3. From 01/01/2018 to 09/18/2018, 888 Urine Microscopic analysis tests were performed. 4. From 01/01/2018 to 09/18/2018, 1 Bleeding Time test was performed. 5. The Laboratory Manager confirmed the findings above around 01:00 pm.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of the CMS Laboratory Personnel Form (CMS Form - 209), review of laboratories personnel credentials, and interview of the Laboratory Manager, the laboratory failed to ensure that 1 of 2 Technical consultant meets the qualification requirements under 42 C.F.R. 493.1411 for blood gas testing on the OPTI CCA-TS2 Blood Gas from 2017 (04/20/2017) to the date of survey. Refer to D6035 .
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in

	biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of the CMS Laboratory Personnel Form (CMS Form - 209), review of laboratories personnel credentials, and interview of the Laboratory Manager (LM), the laboratory failed to ensure that 1 of 2 Technical Consultants (TC) meets the qualification requirements under 42 C.F.R. 493.1411 for blood gas testing on the OPTI CCA-TS2 Blood Gas from 2017 (04/20/2017) to the date of survey. Findings Include: 1. CMS Form - 209, signed by the Laboratory Director on 08/30/2018, lists laboratory personnel #10 as a TC. 2. On the day of survey, 09/18/2018, review of blood gas records revealed that Testing Personnel (TP) #10 signs of on personnel competencies and reports. Further review of TP #10's education credentials revealed, the personnel holds an associates degree in respiratory therapy, which does not meet the minimal educational qualifications under C.F.R. 493.1411 to perform technical consultant responsibilities. 4. From 04/20/2017 to 12/31/2017, 135 blood gases tests were performed. 5. From 01/01/2018 to 09/18/2018, 105 blood gases tests were performed. 6. The LM confirmed the findings above on 09/18/2018 around 09:30 am.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure 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 the review of American Proficiency Institute (API) 2017 proficiency testing (PT) scores and interview with laboratory manager (LM), the laboratory failed to identify problems that required a corrective action for API PT results for Thyroid Stimulating Hormone (TSH) and Uric Acid Testing in 2017. Findings Include: 1. On the day of survey, 09/18/2018, review of API 2017 proficiency Testing revealed: TSH - Event # 2 - score of 80%. Uric Acid - Event # 2 - score of 80%. 2. The laboratory director acknowledged the score of 80% with their signature, but no assessment was made. 3. The LM confirmed the findings above on 10:15 am.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 the laboratory's quality assurance procedure and interview with the laboratory manager (LM) the laboratory failed to ensure that quality assessment programs are maintained and documented to assure the quality of laboratory from 2017 (04/20/2017) to the date of survey. Findings include: 1. On the day of survey, 09

	/18/2018, A review of the laboratory's manuals revealed that the laboratory failed to establish a complete written policy for how to assess the quality of its laboratory systems and how often quality systems will be reviewed. 2. The LM confirmed the findings above on 09/18/2018 around 10:30 am.