Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0189070	10/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bucktail Medical Center	1001 Pine Street, South Renovo, 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) 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 American Association of Bioanalysts (AAB) and Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records and interview with the Technical Supervisor (TS)#2, the Laboratory Director (LD) failed to sign the AAB and WSLH PT attestation statement documents for 2019, 2020, and 2021. Findings include: 1. On the day of survey, 10/13/2021, review of AAB and WSLH PT records revealed, that 9 of 9 immunohematology attestation statements were not signed by the LD for 2019, 2020, and 2021. 2. The laboraotry could not provide attestation statement for WSLH Chemistry event 2 in 2020. 3. The TS#2 confirmed the findings above on 10/13/2021 at 11:25 a.m.
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: A. Based on review of the laboratory's Employee Competency procedure and interview with Testing Personnel (TP) #2, the laboratory failed to have a complete policy to assess the competency of 1 of 2 Technical Supervisor (TS) and 1 of 1

	General Supervisor (GS) for their supervisory roles from 10/13/2019 to the date of survey. Findings include: 1. On the day of survey, 10/13/2021, the TP#2 could not provide a competency assessment policy to assess the competency of the following personnel from 10/13/2019 to the date of survey: - 1 of 2 TS (on CMS 209, listed as personnel #2). - 1 of 1 GS (on CMS 209, listed as personnel #2). 2. The TP#2 confirmed the finding above on 10/13/2021 around 10:15 a.m. B. Based on lack of annual competency records, review of the laboratory's Employee Competency procedure,and interview with Testing Personnel (TP) #2, the laboratory failed to follow their procedure for competency assessment for all TP who performed patient testing in Hematology, Chemistry, Microbiology, and Blood Bank for 2019 and 2020 Findings include: 1. The laboratory procedure manual titled "Employee Competency Assessment" states: - "Competency of testing personnel at the Bucktail Medical center laboratory is assessed on a yearly basis". - "The laboratory competency Form will be used for each technologist working at Bucktail Medical Center clinical laboratory and staff trained to performed testing in the Emergency Department". 2. On the day of survey 10/13/2021, TP#2 could not provided the following competency assessment for the testing personnel: - 2019 : 1 of 2 TP (CMS 209 personnel #3) responsible for testing in hematology, chemistry, microbiology and blood bank. 8 of 8 TP (CMS 209 personnel #4, 5, 6, 7, 8, 9, 10, and 11) responsible for testing at the emergency department (EPOC, Istat, and Sysmex POCH 100I). - 2020: 1 of 2 TP (CMS 209 Personnel #3) missing competency assessment documentation for hematology, Istat, and Sysmex POCH 100I. 8 of 8 TP (CMS 209 personnel #4, 5, 6, 7, 8, 9, 10, and 11) responsible for testing at the emergency department (EPOC, Istat, and Sysmex POCH 100I). 3. The TP#2 confirmed the findings above on 10/13/2021 at 10:15 a.m.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) documents and interview with the testing personnel (TP)#2, the laboratory failed to establish a quality assurance policy from 10 /13/2019 to the date of survey. Findings Include: 1. On the day of survey, 10/13/2021, the laboratory could not provide a policy for monitoring its pre-analytical, analytical, and post analytic programs form 10/13/2019 to the date of survey. 2. The TP#2 confirmed the finding above on 10/13/2021 around 11:55 a.m.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6)

	The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the review of the Epoc Blood Gas System procedure and interview with the technical supervisor (TS), the laboratory failed to include the laboratory's system for reporting patient results in the Epoc Blood Gas System procedure. Findings Include: 1. On the date of survey, 10/13/2021, review of the Epoc Blood Gas System procedure revealed, the Epoc Blood Gas System procedure did not include the laboratory's system for reporting patient results. 2. The TS confirmed the finding above on 10/13/2021 around 1:30 pm.
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 observation of the laboratory and interview with the technical Supervisor (TS) #2, the laboratory failed to perform maintenance on 1 of 1 Excursion Trac Thermometer and 1 of 1 Taylor Thermometer from 10/13/2019 to the day of survey. Findings include: 1. On the day of survey, 10/13/2021, observation of the laboratory revealed, 1 of 1 Excursion Trac Thermometer (S/N: 180049523) was due for maintenance on 1/19/2020 and 1 of 1 Taylor Thermometer (S/N: 5935) in the ER was not calibrated. 2. The laboratory could not provide a thermometer maintenance procedure policy. 3. The TS confirmed the findings about on 10/13/2021 around 2:30 pm.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (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) #2, the laboratory failed to include two control materials of different concentrations for blood gases tests performed on 1 of 1 Epoc Blood Gas System at

	least once each day for patient testing from 2020 to the date of survey. Findings include: 1. On the day of survey, 10/13/2021, review of QC records revealed, the laboratory did not perform two levels of control materials of different concentrations at least once a day for 1 of 1 Epoc Blood Gas System from 01/01/2020 to 10/13/2021. 2. In 2020 - 72 blood gas tests were performed. 3. In 2021 - 280 blood gas tests were performed. 4. TS#2 confirmed the finding above on 10/13/2021 around 1:00 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 review of chemistry calibration records, interview with the Technical Supervisor (TS), the laboratory failed to have a system in place, that twice a year evaluates and defines the relationship between the Beckman Coulter AU480 and the Epoc Blood Analysis System from 10/13/2019 to the day of survey. Findings Include: 1. On the days of survey, 10/13/2021, the laboratory was unable to provide relationship studies performed at least twice a year on the Beckman Coulter AU480 and the Epoc Blood Analysis System from 10/13/2019 to 10/13/2021. 2. The laboratory could not provide a procedure for evaluating the relationship between two instruments that perform the same tests. 3. In 2020 - 72 blood gas tests were performed. 4. In 2021 - 280 blood gas tests were performed. 5. The TS confirmed thin findings above on 10/13/2022 around 1:15 pm.
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 review of the American Association of Bioanalysts (AAB) and Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records and interview with the Technical Supervisor(TS)#2) , the laboratory failed to identify problems that required a corrective action for AAB and WSLH PT results for Chemistry and Hematology in 2019, 2020, and 2021. Findings Include: 1. On the day of survey, 10/13 /2021, review of AAB and WSLH proficiency Testing records revealed the following events were not assessed by the laboratory: - AAB 2019 Chemistry Event 3: 50% PSA . - WSLH 2020 Hematology Event 3: 80% manual differential. - WSLH 2021 Urinalysis Event 1: 50% Urine Cast. 2. The TS#2 acknowledged the scores with their signature, but no assessment was made. 3. The TS#2 confirmed the findings above on 10/13/2021 at 09:40 a.m.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d)

	(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the technical supervisor (TS), the laboratory failed to have the required records accessible during the course of the laboratory survey performed on 10/13/2021. Findings Include: 1. On the day of survey, 10/13/2021, the laboratory could not provide the following records upon request: - Epoc Blood Gas System Calibration records. - Epoc Blood Gas System calibration verification records. - ER mini refrigerator temperature records from October 2019 to May 2020. 2. The TS confirmed the findings above on 10/13/2021 around 2:00 pm.