Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0189070	06/11/2019
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
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 Laboratory procedure manuals and interview with the labortaory manager (LM), the laboratory failed to establish a complete competency assessment procedure to assess the competency of testing personnel (TP) who performed chemistry, hematology, immunohematology, and urinalysis tests and technical consultants in 2018. Findings Include: 1. On the day of survey, 06/11/2019, review of personnel records revealed, the laboratory failed to provide a complete written policy on how to assess the competency of testing personnel (TP) who performed chemistry, hematology, immunohematology, and urinalysis tests and clinical consultant competency in 2018. 2. The laboratory could not provide competency assessment records from in 2018 for: - 1 of 2 TP who performed chemistry, hematology, immunohematology, and urinalysis tests. - 9 to 8 TP who performed chemistry tests (Troponin, Lactic acid and Blood Gases). - 1 of 1 technical consultant. 3. In 2018 (01 /01/2018 to 12/31/2019), 41,388 patient tests were analyzed. 4. The LM confirmed the findings above on 06/11/2019 around 09:30 am.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on review of procedure manuals and interview with the laboratory Manager (LM), the labortaory failed to have a written procedure manual (1 of 1) available to testing personnel (TP) for the coagulation tests performed on the Sysmex CA 660. Findings Include: 1. On the day of survey, 06/11/2019, the laboratory could not provide 1 of 1 procedure manual for coagulation tests performed on the Sysmex CA 660. 2. The LM confirmed the findings above on 06/11/2019 around 12:15 am.
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 interview with the laboratory Manager (LM) and a review of calibration verification (Cal Ver.) records at the time of inspection, the laboratory failed to perform calibration verification on the Chemistry AU480 analyzer and TOSOH AIA 360 once every 6 months for 7 of 7 analytes Cal. Ver. record's reviewed from 9/21/17 through the date of survey 6/11/2019. Findings include: 1. From 2017 to the date of survey, the following Chemistry tests were performed on the AU480 analyzer - Creatine, ALP (Alkaline Phosphatase), HDL (high-density lipoprotein) CO2 (Carbondioxide), Fe (Iron), ETOH (Ethyl alcohol). While the PSA (Prostate-specific antigen) test was performed on the TOSOH AIA 360. 2. Records reviewed at the time of inspection revealed the following Calibration Verification dates: Routine Chemistry Creatinine - 1/29/18, 5/10/19 (once a year) ALP - 1/29/18 (once a year) HDL - 9/21/17, 5/10/19 (No Cal Ver. performed in 2018) CO2, Fe, ETOH - 1/24/18, 1 /21/19 (once a year) Endocrinology PSA - 11/28/18 (once a year) 3. Patient testing performed from 2017 to 6/14/2019: YEAR 2017 2018 2019 Creatinine 2208 2195 1006 ALP 1697 1657 827 HDL 1187 1217 597 YEAR 2017 2018 2019 CO2 2136 2121 983 Fe 105 105 41 ETOH 33 13 8 4. The LM interviewed on 6/13/19 around 09: 40 am during the inspection confirmed the above findings.

D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Abbott i - stat quality control (QC) logs and interview with laboratory manager (LM), the laboratory failed to perform control procedures as required for the Troponin, Lactic acid, and Blood gases tests performed on the Abbott i- stat analyzer at least once each day of testing from 7/7/2017 through the date of survey. About 2 of 2 years records reviewed Findings include: 1. The following tests were performed on the I- Stat analyzer with the catridges listed: Troponin - cTnl Lactic acid - CG4+ Blood Gases - CG4+ 2. Records reviewed at the time of survey revealed, the laboratory performed external QC monthly for the Troponin, and Lactic acid tests from 7/7/17 through the date of survey. The laboratory did not have an Individualized Quality Control Plan (IQCP). 3. Blood gas analysis was performed on 1of 1 patient specimen on May 1, 2019 with no external QC. Troponin tests (476 patients) and Lactic acid tests (202 patients) performed in 2018 and 2019 with external QC performed monthly. 4. The LM confirmed the findings above at 9:35 am on 6/11/19.
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 review of urine sediment microscopic examination records, and interview with the laboratory manager (LM), the laboratory failed to document QC procedures performed for 1044 of 1044 patient specimens examined for urine sediment microscopic procedure from 2017 to the date of survey. Findings Include: 1. On the day of survey, 06/11/2019, review of urine sediment microscopic examination records revealed the laboratory did not document QC procedures performed each day of patient testing from 08/02/2017 to 06/11/2019. 2. In 2017 (08/02/2017 to 12/31/2017), 255 Urine Sediment Microscopic Examination were analyzed. 3. In 2018 (01/01/2018 to 12/31/2018), 558 Urine Sediment Microscopic Examination were analyzed. 4. In 2019 (01/01/2019 to 06/11/2019), 231 Urine Sediment Microscopic Examination were analyzed. 5. The LM confirmed on 06/11/2019 around 10:45 am.