Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D2108787	10/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Manchin Clinic Of Bridgeport	409 West Main Street, Bridgeport, WV	

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
D0000	An announced, on site, recertification survey was conducted at Manchin Clinic Bridgeport on October 14, 2020, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on a review of the laboratory proficiency testing (PT) records from the American Proficiency Institute (API) and an interview with the technical consultant (TC), the laboratory failed to attain a score of at least 80 percent for each analyte in the API 2019 Hematology/Coagulation 1st testing event. Findings: 1. Review of API records identified unsatisfactory performance scores for leukocyte count, platelet count, and white blood cell differential for the 1st testing event of 2019. a. 60% for leukocyte count b. 60% for platelet count c. 73% for white blood cell differential 2. Review of 2019 1st testing event Hematology/Coagulation identified an investigation for the unsatisfactory performance scores. 3. During an interview with the TC, on 10 /14/2020 at approximately 8:50 AM, the TC stated the unsatisfactory scores of the 2019 1st testing event were due to testing personnel error.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the

	manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a review of written laboratory policies and procedures (P&P), calibration records, quality control records, and an interview with the technical consultant (TC), the laboratory failed to document and perform calibration of the ACT2 Diff analyzer at the frequency specified by the manufacturer. Findings: 1. A review of written laboratory P&P identified the frequency of calibration for the ACT2 Diff as every 6 months, as a step in the process of resolving QC issues, and after major maintenance. 2. A review of 2019 ACT2 Diff calibration records identified a documented calibration performed on 8/29/2019. No calibration records of the ACT2 Diff could be located for 2020. The last documented calibration of the ACT2 Diff was 8/29/2019, surpassing the time frame of the manufacturer requirement for calibration every 6 months. 3. Review of quality control records identified no systemic issues with the 3 levels of QC ran each day of patient testing. 4. During an interview with the TC, on 10/14/2020 at approximately 10:00 AM, the TC stated that no calibration documentation after the 8/29/2019 calibration could be located. The TC stated that calibrators will be ordered and the calibration will be performed on the ACT2 Diff before the laboratory returns to patient testing. Due to the loss of testing personnel the laboratory has not been performing patient testing.
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 a review of laboratory calibration records, quality control records, and an interview with the technical consultant (TC), the laboratory failed to meet the calibration verification requirements (b)(1) and (b)(3) for the ACT2 Diff analyzer. Findings: 1. Review of 2019 and 2020 calibration records identified a failure to follow manufacturer instructions for the calibration of the ACT2 Diff analyzer. Refer to D5437. 2. The lack of calibration every 6 months on the ACT2 Diff analyzer in 2020 is a failure to meet the calibration verification requirement for automated cell counters. 3. Review of quality control records identified no systemic issues with the 3 levels of QC ran each day of patient testing. 4. During an interview with the TC, on 10 /14/2020 at approximately 10:00 AM, the TC stated that no calibration documentation after the 8/29/2019 calibration could be located. The TC stated that calibrators will be ordered and the calibration will be performed on the ACT2 Diff before the laboratory returns to patient testing. Due to the loss of testing personnel the laboratory has not been performing patient testing.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of laboratory quality control records and an interview with the technical consultant (TC), the laboratory failed to (e) document all control procedures performed. Findings: 1. Review of the QC log for point of care testing identified no documentation of QC performed on the current lots in use for the Consult McKesson FLU A/B and Strep A test kits. Manufacturer instructions require external QC be performed once per kit. a. The last FLU A/B QC documented was lot 449A21A on 4 /02/2019. The lot 440A11, expiration 1/31/2022, of FLU A/B test kits were located in the laboratory. b. No documentation of QC for Strep A could be located. The lot STA9092021, expiration 9/30/2021, of Strep A test kits were located in the laboratory. 2. During an interview with the TC, on 10/14/2020 at approximately 10:15 AM, the TC stated that no documentation of calibrations performed after September 2019 could be located. The TC also stated that the documentation of the QC for FLU A/B and Strep A would have been documented in the log book the surveyor reviewed.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of laboratory quality control records and calibration records, the laboratory director failed to ensure that the quality control program of the laboratory was maintained. Findings: 1. A review of quality control records identified a lack of documentation of quality control for the McKesson FLU A/B and Strep A test kits. Refer to D5441. 2. A review of calibration records identified no documentation of calibration for the ACT2 Diff since September 2019. Refer to D5437 and D5439.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory calibration records for the ACT2 Diff hematology analyzer, quality control (QC) records for point of care testing, and an interview with the technical consultant (TC), testing personnel failed to document all quality control activities and instrument calibrations performed. Findings: 1. Review of the ACT2 Diff calibration records identified the last documented calibration as 8/29/2019. Adhering to the manufacturer instructions for calibration frequency, a calibration was due February 2020 and August 2020. No records of calibrations performed after September 2019 could be located. 2. Review of the QC log for point of care testing identified no documentation of QC performed on the current lots in use for the Consult McKesson FLU A/B and Strep A test kits. a. The last FLU A/B QC documented was lot 449A21A on 4/02/2019. The lot 440A11, expiration 1/31/2022, of FLU A/B test kits were located in the laboratory. b. No documentation of QC for Strep A could be located. The lot STA9092021, expiration 9/30/2021, of Strep A test kits were located in the laboratory. 3. During an interview with the TC, on 10/14/2020 at approximately 10:15 AM, the TC stated that no documentation of calibrations performed after September 2019 could be located. The TC also stated that the documentation of the QC for FLU A/B and Strep A would have been documented in the log book the surveyor reviewed.