Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 53D1020856	**(X3) Date Survey Completed** 09/08/2020
Name of Provider or Supplier Crossroads Healthcare Clinic	**Street Address, City, State** 100 Central Ave, Ste 173, Cheyenne, WY	
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**
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to enroll in an approved proficiency testing program for the complete blood count (CBC) testing performed on the PocH-100i instrument. The laboratory performed 3 CBC tests since receiving the instrument in June of 2020. Findings include: 1. The laboratory lacked documentation of enrollment in an approved proficiency testing program for CBC testing on the PocH 100i instrument. 2. In an interview conducted on 09/08/2020 at approximately 1:30 P.M., staff confirmed they had not enrolled in an approved proficiency testing program for CBC testing.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and

	rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, and interview with staff, the laboratory failed to establish a written policy for specimen collection, and labeling for compete blood counts tests. The laboratory performed 3 patient complete blood count (CBC) tests since June of 2020 when the instrument was installed. Findings include: 1. Procedure manual review failed to include the instructions for patient specimen collection that included the method the laboratory used to identify the patient, patient preparation and specimen collection instructions. 2. The laboratory used the PocH 100i operator's manual as their procedure manual. The PocH 100i operator's manual failed to include instructions for how the laboratory was to label patient specimens to ensure positive identification. 3. In an interview conducted on 09 /08/2020 at approximately 1:45 P.M., staff confirmed they had not added laboratory specific information to the manufacturer's operator's manual for how the laboratory collected patient CBC specimens from clinic patients.
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 procedure manual review, lack of documentation, and interview with staff, the laboratory procedure manual failed to include: step by step instructions for reporting results that are flagged by the blood cell counter; the laboratory's established reportable range for Complete Blood Cell tests (white blood cells [WBC], red blood cells [RBC], hemoglobin, hematocrit, mean cell volume [MCV], platelets, and white blood cell differential); control [QC] procedures including corrective actions to take when control or calibration results failed to meet the laboratory's criteria for acceptability; imminently life-threatening test results, the laboratory's system for entering results in the patient record; and the description of the course of action to take if the CBC test system becomes inoperable. Findings include: 1. Procedure manual review included the PocH 100i operator's manual as the laboratory procedure manual. The operator's manual did not include procedures unique to the laboratory for

	what to do when the instrument flags test results either for being out of the normal range or of questionable reliability; reportable ranges for WBC, RBC, Hemoglobin, Hematocrit, MCV, Platelets and WBC differential; the number and frequency QC materials to perform each day of testing; what to do and how to record actions taken when QC or calibration is out of range, how to report and how to document critical values are reported according to the established policy; how to enter CBC results into the patient's record; and what steps staff is to take when the system becomes inoperable. 2. In an interview conducted on 09/08/2020 at approximately 3:45 P.M., staff stated their procedure did not include the required elements for a CBC procedure manual.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, and interview with staff, the laboratory director failed to sign and date as approved the PocH 100i operator's manual as approved. Findings include: 1. Procedure manual review failed to include the date the director approved the procedure. 2. In an interview with staff on 09/08 /2020 at approximately 1:45 P.M., staff confirmed the laboratory had not signed and dated the procedure manual as approved.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on PocH 100i cell counter instrument verification documentation review, lack of documentation, and interview with staff, the laboratory failed to verify accuracy, precision, and reportable range for complete blood count tests and failed to establish a normal range for patient test results. The laboratory tested 3 patients since June 2020 when the instrument was installed. Findings include: 1. Verification documentation review of manufacturer'sinstallation checks failed to verify the manufacturer's stated precision specifications using two levels of materials near the manufacturer's stated precision specification claims; failed to include reportable range verification at the upper and lower ranges of the manufacturer's stated reportable range (or verify the reportable range for use in the laboratory that is less than the manufacturer's stated claims using materials of known concentrations); and failed to verify the manufacturer's specification for accuracy in terms of statistical summarization of how near the value the laboratory assayed to that of a material of known concentration. 2. In an interview conducted on 09/08/2020 at approximately 3:15 P.M., staff confirmed

	CBC controls were the only assayed material they have available. They confirmed the manufacturer's installation documentation failed to include the assay value for the approximately 6 CBC runs documented to determine if the instrument accurately or precisely reported the test results.
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 lack of documentation and interview with staff, the laboratory failed to document the performance and evaluation of instrument start up background counts and perform an instrument shutdown each day of testing for 3 of 3 test days reviewed. Findings include: 1. The laboratory failed to document they followed the PocH 100i manufacturer's instructions to perform instrument start up each day of testing to ensure the instrument background checks were equal to or less than the specified limits for White Blood Cells, Red Blood Cells, Hemoglobin, and Platelets each day of testing on test dates: 08/25/2020, 08/26/2020, and 09/08/2020. 2. The laboratory failed to follow the manufacturer's instructions to perform a shutdown each day of testing. 3. In an interview conducted on 09/08/2020 at approximately 2:15 P.M., staff stated they did not document instrument start up was acceptable or that shutdown was performed each day of testing for 3 of 3 test days reviewed.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on patient test records review, lack of documentation, and interview with staff, the laboratory failed to maintain an information or record system to record the dates of all specimens tested including the identity of the personnel who performed the complete blood count (CBC) tests. The laboratory performed 3 CBC tests from August 25, 2020 through September 8, 2020. Findings include: 1. Patient test records review failed to include a system to record all of the CBC specimens and the dates the laboratory performed tests. 2. In an interview conducted on 09/08/2020 at approximately 3:15 P.M., staff confirmed they did not establish a system to record the specimens and dates CBC tests were performed. The staff stated on two of the three CBC instrument printouts performed they used the patients chart number, and on one CBC printout they used the date of birth to identify the patient. Staff stated they did not have a written instruction for what to do with the instrument printouts used to

	hand enter CBC results into the electronic medical record. Staff confirmed they did not have a system in place to maintain the identity of the specimens tested once the instrument memory is full then begins to dump data.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on patient test reports review, and interview with staff, the laboratory the normal values in the electronic medical record (EMR)were not the same as the normal values on the instrument printout. The laboratory performed 3 complete blood counts since the instrument was installed in June of 2020. Findings include: 1. Patient test reports review for patient 41090 that was tested for a CBC on 09/08/2020 was entered into the electronic medical records during the survey. The normal range values in the EMR were not the same as those on the instrument printout. The units of measure for white blood cells on the print out were the printed value times 1000 (10 to the power of 3) per millimeter cubed. The units of measure in the EMR were the printed value times 100,000 (10 to the power of 5 per L.) 2. Patient test report template review in the EMR listed the white blood cell differential as including Granulocytes (AKA Neutrophils), Lypmphocytes, Monocytes, Eosinophils, and Basophils. The laboratory instrument reported Granulocytes (or Neutrophils), Lymphocytes and Mixed (a combination of Monocytes, Eosinophils, and Basophils). 3. In an interview conducted on 09/08/2020 at approximately 3:45 P.M., staff confirmed the laboratory test report failed to include the laboratory's established reference intervals as printed on the instrument printout.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, and interview with staff, the laboratory director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided for Complete Blood Cell Count tests for general laboratory, pre-analytic, analytic, and post-analytic portions of testing. Findings include: 1. Procedure manual review lacked qualify assessment plans for general laboratory operations (Example: proficiency testing, confidentiality, and personnel competency procedures); pre-analytic testing (Example: test requisition, specimen collection, and labeling...); analytic (Example: quality control review including Levy/Jennings chart review for shifts and trends, reagent expiration review, instrument preventive maintenance...); and post analytic

	portion of testing (Example: test reports, corrected reports, reporting delays....). 2. In an interview conducted on 09/08/2020 at approximately 3:55 P.M., staff confirmed the laboratory had not developed quality assurance plan that reviewed general laboratory, pre-analytic, analytic, and post analytic portions of CBC testing.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory director failed to ensure that prior to testing 3 of 3 patient's specimens, personnel have the appropriate education and experience, receive the appropriate training, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results for complete blood cell (CBC) testing. Findings include: 1. The laboratory director failed to ensure two of two laboratory testing personnel documented appropriate training for CBC testing on the PocH 100i cell counter and one of 2 testing personnel had the appropriate education. 2. In an interview conducted on 09/08/2020 at approximately 2:30 P.M., staff confirmed the laboratory lacked documentation of PocH 100i training for CBC testing and one test person lacked education documentation.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on lack of documentation and interview with staff, one of two laboratory testing personnel failed to provide documentation to qualify as a moderate complexity testing. (See D6065)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an

	accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on personnel records review, lack of documentation, and interview with staff, one of two testing personnel lacked documentation to qualify as a moderate complexity test person for complete blood cell count tests. The laboratory performed 3 patient tests since instrument installation in June of 2020. Findings include; 1. Personnel records review lacked documentation 1 of 2 tasting personnel (person A) lacked documentation to quality as a moderate complexity test person. 2. In an interview conducted on 09/08/2020 at approximately 1:45 P.M., staff (test person A) confirmed they did not have documentation available to verify moderate complexity qualifications.