Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0214558	(X3) Date Survey Completed 02/27/2025
Name of Provider or Supplier Crossroads Medical Laboratory Llc	**Street Address, City, State** 4801 Dorsey Hall Drive Suite 200, Ellicott City, MD	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the technical consultant (TC), the laboratory failed to ensure that the attestation worksheets were signed and retained according to the PT provider instructions for all disciplines performed in the laboratory. Findings: 1. The microbiology, chemistry, and hematology PT records from the third event in 2023 through the third event in 2024 were reviewed. 2. The PT attestation worksheets showed that the name of the "analyzer"/testing person (TP) had not been entered into the PT database. The printed forms did not list the "analyzer" along with the signature of the TP and the date each test was performed. The name of the laboratory director (LD) was typed onto the form, but the signature of the LD and the date was not present showing that the forms had been reviewed prior to submission. 3. During the survey on 02/24/2024 at 2:50 PM, the TC confirmed that the PT attestation worksheets failed to have the signature and date of each TP and the LD attesting that the samples were tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on procedure manual, laboratory reagent package insert, and patient log record review and interview with the technical consultant (TC), the laboratory failed to follow the manufacturer's instructions for performing bacteriology testing. Findings: 1. The laboratory performs presumptive identification of group A streptococcus on throat cultures, using Taxo A discs which are impregnated with low levels of Bacitracin. 2. The procedure, "Throat Culture (Strep Select Plate Method)," under "Plate Reading and Interpretation" states to "Read plates after 24 hours to 48. Plates may be incubated up to 72 hours"; however 3. Review of the package insert for the "BD BBL Taxo A Discs for Differentiation of Group A Streptococci" showed that culture plates must be incubated "at 35 to 37C for 18 to 24 hours" before being read or interpreted. 4. Review of "Patient Logs" labeled "Source: Throat" from September through December 2024 showed that for 15 of 17 patients, the laboratory evaluated the culture plates at 24 and 48 hours after inoculation and did not follow the manufacturer's instructions for performing throat cultures using the Taxo A disc. 5. During an interview on 02/24/2025 at 2:50 PM the TC confirmed that the laboratory did not follow the manufacturer's instructions for performing throat cultures.
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 procedure manual, laboratory reagent package insert, and patient log record review and interview with the technical consultant (TC), the laboratory failed to perform two levels of quality control (QC) each day of testing as required in paragraph (d)(3) of this section for the qualitative detection of infectious mononucleosis heterophile antibodies (mono) in serum. Findings: 1. The laboratory performs mono testing using the "Henry Schein One Step+ Ultra Mono Test Kit." The test can be performed using serum or whole blood samples. 2. During an interview on 02/24/2025 at 11:20 AM, the TC stated that the laboratory performs mono testing on serum samples, not whole blood. 3. Review of the "Ultra Mono Test Kit" package insert showed that the "CLIA Complexity" of the test is "Moderate for Serum and Plasma." 4. A review of "mono" patient logs showed that QC was performed on 12/19/2023 (kit lot # 06231257, expiration date: 07/31/2024), and on 09/13/2024 (kit lot #

	06241092, expiration date: 02/28/2025). The laboratory records did not include documentation of two levels of QC each day of testing for mono. 5. The laboratory tested 16 patients between 12/19/2023 and 07/26/2024 on kit lot # 06231257, and tested 15 patients between 09/13/2024 and 02/06/2025 on kit lot # 06241092. 6. The laboratory is required to test two levels of QC materials each day of testing unless they have a written Individualized Quality Control Plan (IQCP). An IQCP plan requires the laboratory to perform a Risk Assessment that includes an evaluation of the specimen used; environment for testing; integrity of the reagent; components of the test system; and competency of the testing personnel; a Quality Control Plan listing the number, type, frequency of testing, & criteria for acceptable results of the QC; and a Quality Assessment plan to monitor the effectiveness of the laboratory's IQCP. 7. During an interview on 02/24/2025 at 2:50 PM, the TC confirmed that the laboratory failed to perform two levels of QC each day of mono testing, and failed to have an established IQCP for performing mono testing on serum in order to reduce the frequency with which QC was required.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of the manufacturer's validation protocol and the validation summaries, and interview with the technical consultant (TC), the laboratory failed to define the limits of acceptability for each analyte validated on the new analyzer. Findings: 1. The "Assay Performance Verification Interpretive Guide" provided by the manufacturer of the ADVIA Centaur XPT (chemistry analyzer) provides the user with an assessment tool for the analytes tested. 2. The first page of the validation study for the new chemistry analyzer states "VALIDATION AND EVALUATION HAS BEEN EVALUATED AND ACCEPTED BY:." This is followed by the signature and date of the director, lab manager, and the technician from the manufacturer of the analyzer. 3. The validation summaries showed the data for repeatability, linearity, analytical range verification, regression analysis, and comparisons. The documentation failed to include the limits of acceptability for the percent coefficient of variation (%CV) for reproducibility, limits of acceptability for the observed mean vs. the expected mean for the analytical range; and limits of acceptability for the comparison of patient results from one analyzer to another. 4. During the survey on 02/24/2024 at 2:50 PM, the TC confirmed that the validation summaries failed to include specific limits of acceptability for the %CV, the observed vs. expected mean and the comparison of patient results showing that the values obtained met a predefined criterion of acceptability.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 "Quality Assurance Program" and an interview with the technical consultant (TC), the laboratory director (LD) failed to review all proficiency testing (PT) results. Findings: 1. The PT section of the "Quality Assurance Program" states "All proficiency testing results are reviewed by the lab director." 2. The PT records from the third event in 2023 through the third event in 2024 were reviewed for a total of four events. The routine PT summaries had not been reviewed, only the investigations of PT failures. 3. During the survey on 02/24/2024 at 2:50 PM, the TC confirmed that the routine PT summaries for all events had not been documented as having been reviewed by the LD per the "Quality Assurance Program."