Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0715039	07/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cherry Tree Medical Assoc Inc	25 Highland Park Dr, Suite 103, Uniontown, 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 AAB-Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interview with testing personnel #2 (TP), the laboratory director/designee (LD) and TP failed to sign 9 of 11 AAB-MLE PT attestation statement documents for chemistry, and hematology testing performed in 2021 and 2022. Findings Include: 1. On the day of the survey, 07/19/2023 at 08:33 am, the following 9 of 11 AAB-MLE PT attestation statements reviewed were not signed by the LD/designee and TP in 2021 and 2022: - 2021 Event Q2: Chemistry and Non-chemistry - 2021 Event Q3: Non-chemistry - 2022 Event Q1: Chemistry and Non-chemistry - 2022 Event Q2: Chemistry and Non-chemistry - 2022 Event Q3: Chemistry and Non-chemistry 2. TP #2 confirmed the findings above on 07/19/2023 around 12:30 pm.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's procedures, operator manuals, and interview with testing personnel #2 (TP), the laboratory failed to have a complete written procedure manual for hematology and chemistry testing performed that met the requirements of 493.1251 from 08/03/2021 to the date of the survey. Findings include: 1. On the day of the survey, 7/19/2023 at 09:26 am, review of the procedure manuals for hematology and chemistry testing revealed the operators manual were used to perform testing on the following from 01/01/2021 to 07/18/2023: - Ortho Clinical Diagnostics Vitro 350 (chemistry) - Ortho Clinical Diagnostics Vitro ECI (chemistry) - Beckman Coulter Act Diff 2 (hematology) 2. Review of the operators manual revealed that the test system instructions used failed to include the following requirements of 493.1251: - Step by step performance of the procedure including test calculations and interpretation of results - Preparation of slides, solution, calibrators, controls, reagents, stains, and other material used in testing. - Control procedures - Corrective action to take when calibrations or control results fail to meet the laboratory criteria for acceptability - Limitations in the test methodology, including interfering substances. - 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. - Description of the course of action to take if a test system becomes inoperable. 3. TP #2 confirmed the findings on 7/19 /2023 at 12:30 pm.
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 review of the laboratory's Ortho Clinical DiagnosticsVitros ECI verification of performance specifications records and interview with testing personnel #2 (TP), the laboratory failed to provide complete validation records for the required performance specifications for 1 of 1 analytes tested on the Ortho Clinical Diagnostics Vitros ECI chemistry analyzer before reporting patient results from 07/10/2023 to the date of the survey. Findings Include: 1. On the day of survey, 07/19/2023 at 09:28 am, the laboratory could not provide documentation of a reference range/normal value study appropriate for the laboratory's patient population for the following 1 of 1 chemistry analytes performed on the Ortho Clinical Diagnostics Vitros ECI from 07/10 /2023 to 07/19/2023: - B-type natriuretic peptide (NBNP2) 2. The laboratory could not provide a procedure for new method/test validation. 3. TP # 2 confirmed the findings above on 07/19/2023 around 12:30 pm.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b),

	which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's general temperature and cleaning checklist logs, and interview with testing personnel #2 (TP), the laboratory failed to document the corrective actions taken when the acceptable room temperature range was exceeded for 2 of 2 months reviewed from 08/03/2021 to the date of the survey. Findings include: 1. On the day of survey, 07/19/2023 at 9:47 AM, review of the laboratory's general temperature and cleaning checklist logs revealed the acceptable room temperature range (22 to 25 degrees Celsius), was exceeded for the following days: a. 24 of 25 days of patient testing in August 2022. b. 22 of 22 days of patient testing in September 2022. 2. The laboratory could not provide documentation for the corrective actions taken when the acceptable room temperature range was exceeded in August and September 2022. 3. TP #2 confirmed these findings on 07/19/2023 around 12:30 PM.