Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0715039	11/07/2018
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
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 observation, review of laboratory procedure manuals and interview with Testing Personnel (TP) #1, the laboratory failed to have all procedure manuals in use, signed by the current director. Findings include: 1. On the day of survey, 11/07/2018, review of laboratory procedures manuals revealed, the current laboratory director did not have documentation of acceptance of Ortho Vitros 350 and Beckman Coulter Access 2 operations manuals as the chemistry analyzers policy and procedure manuals. 2. TP#1 confirmed the findings above on 11/07/2018 around 11:30 am.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of serum hCG quality control (QC) records and interview with the Testing Person (TP) #1, the laboratory failed to include two control materials of different concentrations for the Consult Diagnostic serum hCG combo kit, at least once each day of patient testing in 2017. Findings include: 1. On the day of survey, 11

	/07/2018, review of Consult Diagnostic serum hCG combo kit QC records, revealed that QC was performed on a weekly bases and not once each day of patient testing in 2017. 2. In 2017, 1 Serum HCG was performed. 3. TP#1 confirmed the finding above on 11/07/2018 around 12:15 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 Ortho Clinical Diagnostics Vitros 350 Quality Control documents and interview with Testing Personnel (TP) #1, the Laboratory failed to document all corrective actions taken when quality control for the Ortho Clinical Diagnostics Vitros 350 performs outside of established operating parameters or performance specifications in 2018. Findings include: 1. On the day of survey, 11/07/2018, the laboratory failed to document corrective action for quality control on 11/01/2018 that were outside of limits. 2. A code of F2 was present on quality control documents, per Ortho Clinical Diagnostics Vitros 350 operations manual, the corrective action for F2 is to "review, edit and repeat test". The laboratory could not provide documentation of correction action performed. 3. TP #1 confirmed the findings above on 11/07/2018 around 11:45 am.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the review of American Association of Bioanalysts (AAB) 2017 and 2018 proficiency testing (PT) records and interview with Testing Personnel (TP) #1, the laboratory director failed to identify problems that required a corrective action for Chemistry PT results in 2017 and 2018. Findings Include: 1. On the day of survey, 11/07/2018, review of AAB PT records revealed, no correction action was documented for: - AAB 2017 Chemistry, Event #1, 80% NA (sodium). - AAB 2017 Chemistry,

	Event #2, 80% ALT (Alanine transaminase). 2. The laboratory director acknowledged the scores of 80% with their signature, but no assessment was made. 3. TP #1 confirmed the findings above at 11/07/2018 around 10:00 am.