Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0993634	03/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Frix-Jennings Clinic Pc	1314 Hwy 45 Bypass Suite D, Henderson, TN	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory's records for validation of the Beckman Coulter (BC) AcT Diff 2 complete blood count (CBC) instrument, the laboratory's policy regarding new method implementation and interview with the technical consultant, the laboratory failed to follow policy for new method implementation for the Beckman Coulter AcT Diff 2 CBC instrument in 2017. The findings include: 1. Observation of the laboratory on March 15, 2018 at 8: 45 am revealed the BC AcT Diff 2 CBC instrument (serial #AS45585) in use for patient testing. 2. Review of the laboratory's records for validation of the BC AcT Diff 2 instrument revealed the following: first date of patient testing 3-21-2017; no approval of the studies by the laboratory director; reportable range study performed on 6-21-2017 after patient testing had begun. 3. Review of the laboratory's policy for new method implementation revealed the following statement: "When a new instrument is received, the tech consultant should be notified immediately before the instrument is introduced into the laboratory. NO PATIENTS MAY BE RUN ON THE NEW INSTRUMENT UNTIL THE VALIDATION PROCESS HAS BEEN COMPLETED AND THE LAB DIRECTOR HAS SIGNED THE DOCUMENT TO INDICATE HIS APPROVAL." 4. Interview with the technical consultant on March 15, 2018 at 3:15 pm confirmed that the laboratory began patient testing on the BC AcT Diff 2 on 3-21-2017 without laboratory director approval, the technical consultant was not notified of

	the new instrument in the laboratory, the validation process was not completed prior to patient testing and the laboratory failed to follow policy for new method implementation in 2017.
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 observation of the laboratory, review of the laboratory's studies for verification of manufacturer's reportable range, the Ortho document with manufacturer's stated dynamic ranges, the laboratory's chart for reportable range and interview with the technical consultant, the laboratory failed to verify the manufacturer's reportable range for the amylase analyte in 2016. The findings include: 1. Observation of the laboratory on March 15, 2018 at 8:45 am revealed the Ortho Vitros 350 (instrument identification number J21649) in use for patient testing. 2. Review of the laboratory's studies performed on November 9, 2016 for verification of manufacturer's reportable range revealed the amylase analyte was tested from 30 U/L to 644 U/L. 3. Review of the Ortho document titled "Vitros Analyte Summary Chart" revealed a 'dynamic' range of 30 to 1200 U/L. 4. Review of the laboratory's chart in use for reportable ranges revealed a reportable range of 30-1200 U/L for the amylase analyte. 5. Interview with the technical consultant on March 15, 2018 at 4:00 pm confirmed that the laboratory uses the Ortho Vitros 350 instrument for patient testing beginning November 14, 2016, uses the manufacturer's stated reportable ranges, and failed to verify the manufacturer's reportable range for the amylase analyte prior to patient testing in 2016.