Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2077478	12/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Waynesboro Family Clinic, Pa	1706 Wayne Memorial Drive, Goldsboro, NC	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of general supervisors (GS) competency records, and interview with GS #3 on 12/5/19, the laboratory failed to assess the competency of GS #3 for 2018 and 2019. Findings: Review of laboratory policies revealed the laboratory had established GS competency assessment policies. Review of personnel competency records revealed the laboratory had assessed the competency of GS #1 and GS #2 in 2018 and 2019. The laboratory failed to assess the competency of GS #3 in 2018 and 2019. Interview with GS #3 at approximately 11:00 a.m. confirmed the laboratory had no documentation of GS #3 competency assessments for 2018 and 2019. He stated he was focused on ensuring the laboratory director had reviewed the competency of GS #1 and GS #2 that he had forgotten to have documentation of his own completed.
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 review of laboratory procedure manual and interview with testing personnel (TP) #1 on 12/05/19, the laboratory procedure manual failed to include complete quality control (QC) procedures for the routine chemistry and endocrinology testing performed on the Synermed IR500 and the TOSOH 900 analyzers. Findings: 1. Review of laboratory procedures for the routine chemistry testing performed on the Synermed IR500 revealed the procedures failed to include the type of QC used for each analyte, the levels of QC used for each analyte, and the frequency of QC. 2. Review of laboratory procedures for the TSH testing performed on the TOSOH 900 analyzer revealed the procedure failed to include the levels of QC used. The "TOSOH TSH" procedure states on page 2 "Material Required: Reagent, Controls, Calibrators ... Biorad Control Set ...". On page 5, it states "... 3. Quality Control Procedure: ... It is recommended that at least two levels of controls, normal and abnormal, be used. Three levels of control may be required. ..." During exit interview at approximately 6: 30 p.m. TP #1 confirmed the laboratory QC procedures were not complete, she stated the QC set up is programmed in the Synermed IR500 and TOSOH 900 analyzers, but there was no written procedure for the type, level and frequency of QC used.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturers' instructions, review of 2018 and 2019 temperature and humidity logs, and interview with GS (general supervisor) #3 on 12/5/19, the laboratory failed to define an acceptable range for humidity that was consistent with manufacturers' instructions. Findings: Review of manufacturers' instructions revealed: a. The Mindray BC-3200 Auto Hematology Analyzer requires that the instrument be operated in an environment with a relative humidity of 30-85%. b. The Tosoh AIA-900 analyzer requires that the instrument be operated in an environment with a relative humidity of 40-80%, non-condensing. Review of the laboratory's 2018 and 2019 temperature and humidity logs revealed the laboratory's acceptable range of 20-70% was not consistent with manufacturers' requirements. During interview at

	approximately 4:05 p.m. GS #3 stated that he thought the manufacturer updated the acceptable humidity range for the Tosoh analyzer, but the update was not available at the time of the survey.
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 2017, 2018, and 2019 hematology records and interview with TP (testing personnel) #1 on 12/5/19, the laboratory failed to verify performance specifications for a loaner hematology instrument used for patient testing. Findings: Review of 2017, 2018, and 2019 Mindray BC-3200 hematology records revealed the analyzer was calibrated 11/20/17, 1/2/18, 7/31/18, 11/9/18, and 8/16/19. There was no documentation available to indicate the instrument was calibrated between 11/9/18 and 8/16/19, a period of approximately 9 months. During interview at approximately 11:40 a.m., TP #1 stated that they had a loaner instrument during that time. She stated the laboratory did not verify the performance of the loaner instrument prior to using it for patient testing. She stated she was told the instrument was calibrated by their management company before it was sent to the laboratory, so additional on-site performance verification was not required.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of manufacturers' instructions, review of 2018 and 2019 temperature and humidity logs, and review of 2018 and 2019 quality assessment records 12/5/19, the laboratory failed to document corrective action for humidity readings outside the acceptable range. Findings: Review of manufacturers' instructions revealed: a. The Mindray BC-3200 Auto Hematology Analyzer requires that the instrument be operated in an environment with a relative humidity of 30-85%. b. The Tosoh AIA-900 analyzer requires that the instrument be operated in an environment with a relative humidity of 40-80%, non-condensing. Review of 2018 and 2019 temperature and humidity logs revealed that the laboratory failed to document corrective action for humidity readings below the laboratory's acceptable range of 20-70%. Examples: a. December 6, 11, 12, 2018; b. January 17, 22, 23, 24, 28, 29, 30, 31, 2019; c. February 11, 14, 19, 20, 26, 28, 2019; d. March 1, 5, 6, 7, 8, 2019. Review of monthly quality assessment checklists revealed no documentation of corrective action for humidity readings below acceptable limits.