Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2077478	04/10/2024
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
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 laboratory's policies and procedures and review of 2021, 2022, and 2023 American Association of Bioanalysts (AAB) and AAB/Medical Laboratory Evaluation (MLE) proficiency testing (PT) records 04/10/24, the laboratory failed to ensure that 3 of 9 attestation statements reviewed were signed by the testing personnel and the laboratory director. Findings: Review of the laboratory's "CMP-001 General Policies and Procedures" revealed "... 3.3 Proficiency Testing ... Proficiency Test samples are to be performed in the same manner patient samples are tested in the laboratory. ... Attestation Sheets must be signed by the performing tech and the Laboratory Director. Review of 2021, 2022, and 2023 AAB and AAB MLE proficiency testing records revealed: 1. Attestation not signed for the 2021 AAB Q3 test event. 2. Attestation not signed for the 2022 AAB Q1 test event. 3. Attestation not signed for the 2023 AAB MLE M1 test event.
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 2021, 2022, and 2023 AAB and MLE PT records and the absence of records 04/10/24, the laboratory failed to maintain a copy of all PT records for a minimum of two years from the date of the PT event for 3 of 9 test events reviewed. Findings: Review of 2021, 2022, and 2023 AAB and AAB/MLE PT records revealed: 1. No attestation statements or report forms available for review for the 2021 AAB Q1 and Q2 test events. 2. No attestation statement or report forms available for review for the 2022 Q2 test event.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2021, 2022, and 2023 AAB) and MLE PT records, and review of "Laboratory Incident Report Form" 04/10/24, the laboratory failed to document evaluation of all ungraded and unacceptable PT results to ensure corrective action was taken and documented as required. Findings: Review of the laboratory's "CMP-001 General Policies and Procedures" revealed "... 3.3 Proficiency Testing ... Once graded PT results are received, review all results to ensure accuracy of testing. Note any incorrect results, or flags, and investigate and comment on errors or flags. ... The Proficiency Testing (PT) Corrective Action Form will be used in response to problems or potential problems related to proficiency testing. ... To ensure accuracy with all proficiency testing, un-graded proficiency testing results will be reviewed and self-graded, to include educational challenges. All failed, self-graded results must be followed up with corrective actions. ..." Review of 2021 and 2022 AAB and 2023 AAB/MLE PT records revealed: 1. 2022 AAB Q1 test event - no corrective action for unacceptable alanine transaminase (ALT) result; no evaluation of ungraded potassium and sodium results. 2. 2022 Q2 Q2 test event - no evaluation of ungraded total protein results. 3. 2022 Q3 test event - no corrective action for unacceptable urine microalbumin /creatinine, buprenorphine, and creatinine results. 4. 2023 M1 - no corrective action for unacceptable albumin, thyroid stimulating hormone (TSH), high density lipoprotein (HDL), direct bilirubin, and low density lipoprotein (LDL) results; no evaluation of ungraded LDL, ALT, aspartate aminotransferase (AST), free triiodothyronine (T3), potassium, and sodium results. Review of "Laboratory Incident Report Form" dated 8/8/23 revealed on page 1 "... PT Records were not uploaded to SharePoint for review and DocuSign. - PT failures went unaddressed or were addressed insufficiently. Investigation is not complete. ... Failure Monitor Logs were not completed for PT. As a result, Gen Supv was unaware of failed analytes and repetition of failures. ..."
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2021, 2022, and 2023 SLP Urine LCMS Confirmation PT records and SLP Urine Drug Screening PT records 04/10/24, the laboratory failed to ensure the accuracy of testing, not included in routine PT, were verified at least twice a year when alternate PT results were found unacceptable. Findings: Review of the laboratory's "CMP-001 General Policies and Procedures" revealed "... 3.3 Proficiency Testing ... When testing is performed on analytes that are not regulated, an alternate proficiency must be performed twice a year to validate the accuracy of the testing procedure. ... To ensure accuracy with all proficiency testing, un-graded proficiency testing results will be reviewed and self-graded, to include educational challenges. All failed, self-graded results must be followed up with corrective actions. ..." 1. Review of 2021, 2022, and 2023 SLP Urine LCMS Confirmation PT records revealed: a. 2022 SLP UR-B event - no corrective action documented for unacceptable results for zopiclone, methadone, norhydrocodone, phencyclidine (PCP), ecstasy (MDMA), fentanyl, JWH-073 4-butanoic acid, and norfluoxetine. b. 2023 SLP UR-A event - no graded results available for review. c. 2023 SLP UR-B event - no corrective action documented for unacceptable results for morphine and aOH-alprazolam. 2. Review of 2021, 2022, and 2023 SLP Urine Drug Screening PT records revealed: a. 2021 SLP Urine Drug Screening Proficiency Testing 2nd Q event - no corrective action for alcohol (ETOH) when 2 of 2 results were unacceptable. b. 2022 SLP Urine Drug Screening Proficiency Testing 1st Q event - no corrective action for ETOH when 2 of 2 results were unacceptable. c. 2023 SLP Urine Drug Screening Proficiency Testing 3rd Q event - no corrective action for alcohol ETOH when 2 of 2 results were unacceptable.
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 manufacturer's instructions, review of 2021, 2022, 2023, and 2024 temperature and humidity logs, and interview with the general supervisor (GS) 04/10 /24, the laboratory failed to define an acceptable freezer temperature range that was consistent with manufacturer's instructions for storage of the MAS ChemTRAK H Unassayed control material and the BIO-RAD Liquichek Immunoassay Plus Control Levels 1, 2, and 3. Findings: Review of manufacturer's product insert for the MAS ChemTRAK H Unassayed control material revealed "...Storage and Stability ... This product is stable until the expiration date on the box when stored at -25 to -15 degrees C (Celsius). For optimum performance, DO NOT store in a self-defrosting freezer and maintain at -25 to -15 degrees C until thawing for use. ..." Review of manufacturer's

	product insert for the BIO-RAD Liquichek Immunoassay Plus Control Levels 1, 2, and 3 revealed " ... STORAGE AND STABILITY This product will be stable until the expiration date when stored unopened at -20 to -70 degrees C. ..." Review of the laboratory's temperature and humidity logs revealed the freezer temperature range was listed as less than or equal to -20 degrees C. During interview at approximately 4:00 p. m., the GS confirmed that the acceptable range on the log was too broad for storage of the MAS ChemTRAK H Unassayed control material and the BIO-RAD Liquichek Immunoassay Plus Control Levels 1, 2, and 3.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of 2020, 2021, 2022, 2023 and 2024 Liquid Chromatography-Mass Spectrometry (LCMS) "performance verification" logs, "Preparations Log/pH calibrations" logs, and "76 Analyte Calibration Exclusion" logs" and interview with compliance specialist (CS) 04/10/24, the laboratory failed to document all required maintenance for the performance of toxicology testing on the LCMS analyzer. Findings: Review of laboratory policy, CMP-001, "General Policies and Procedures"revealed "Maintenance...Maintenance is documented on the appropriate instrument form in addition to any necessary corrective action.". 1. Review of 2020, 2021, 2022, 2023 and 2024 LCMS "performance verification" logs, "TOX-LCMS-102", revealed no documentation for the following months: a. 2020 - June - 1 of 12 months reviewed. b. 2022 - June, July, August, September, October, November, and December - 7 of 12 months reviewed. c. 2023 - January, February, March, and April - 4 of 12 months reviewed. 2. Review of 2020, 2021, 2022, 2023 and 2024 LCMS "Preparations Log/pH calibrations" logs, "TOX-LCMS-103", revealed no documentation for the following months: a. 2020 - June - 1 of 12 months reviewed. b. 2022 - June, July August, September, October, November, and December - 7 of 12 months reviewed. c. 2023 - January, February, March, and April - 4 of 12 months reviewed. 3. Review of 2020, 2021, 2022, 2023 and 2024 LCMS "76 Analyte Calibration Exclusion" logs, "TOX-LCMS-119", revealed no documentation for the following months: a. 2022 - June, July, August, September, October, November, and December - 7 of 12 months reviewed. b. 2023 - January, February, March, and April - 4 of 12 months reviewed. Interview with CS at approximately 12:00 p.m. confirmed the maintenance of the LCMS was not documented as required.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)

	-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of 2022, 2023 and 2024 hematology calibration records and interview with compliance specialist 04/10/24, the laboratory failed to perform calibration of the MindRay hematology analyzer since August of 2023, a period of approximately 8 months. Findings: Review of laboratory policy, CMP-001, "General Policies and Procedures" revealed "CALIBRATION...Automated cell counters will be calibrated at least every six months.". Review of 2022, 2023 and 2024 hematology calibration records for the MindRay analyzer revealed the laboratory failed to perform calibration since August of 2023, a period of approximately 8 months. Interview with CS at approximately 2:20 p.m. confirmed the laboratory had not performed calibration of the MindRay analyzer since August of 2023.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of 2020, 2021, 2022, 2023 and 2024 Liquid Chromatography-Mass Spectrometry (LCMS) toxicology quality control (QC) records and interview with compliance specialist 04/10/24, the laboratory failed to document and/or perform QC of the LCMS toxicology analyzer for a period of 6 months, September 2022 thru March 2023. Approximately 58, 072 toxicology tests were performed. Findings: The laboratory maintains monthly Levey-Jennings (LJ') graphs to document daily QC results for the toxicology testing performed on the LCMS analyzer. Review of 2020, 2021, 2022, 2023 and 2024 LCMS QC records revealed no documentation of monthly LJ graphs from September 2022 thru March 2023, a period of 6 months. Interview with CS at approximately 12:00 p.m. confirmed the LJ graphs documenting QC from September 2022 thru March 2023 were not available. She also confirmed 58, 072 toxicology tests were performed from September 2022 thru March 2023.
D6076	LABORATORY DIRECTOR

	CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on 2020, 2021, 2022, 2023 and 2024 laboratory record review and interviews with CS and GS 04/10/24, the laboratory director (LD) failed to provide oversight of the laboratory services to ensure accurate and reliable test results. Findings: 1. The LD failed to ensure PT attestation statements were signed by the TP and LD. The LD also failed to ensure all PT records were retained by the laboratory for at least 2 years. See D6089. 2. The LD failed to ensure a corrective action plan was followed when PT results were found unacceptable. See D6092. 3. The LD failed to ensure the maintenance of established laboratory quality assessment (QA) programs. See D6094. 4. The LD failed to ensure acceptable levels of performance for the toxicology and hematology testing performed. See D6095. 5. The LD failed to ensure all corrective actions were completed for deviations found by the CS during an audit on 08/08/23, approximately 8 months prior to survey. See D6096.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2021, 2022, and 2023 AAB and MLE PT records and the absence of records 04/10/24, the LD failed to ensure PT attestation statements were signed by the TP and LD. The LD also failed to ensure all PT records were retained by the laboratory for at least 2 years. Findings: 1. The LD failed to ensure PT attestation statements were signed by the TP and LD. See D2009. 2. The LD failed to ensure all PT records were retained by the laboratory for at least 2 years. See D2015.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of 2021, 2022, and 2023 AAB and MLE PT records, review of 2021, 2022, and 2023 SLP Urine LCMS Confirmation PT records and SLP Urine Drug Screening PT records and review of "Laboratory Incident Report Form" 04/10/24, the LD failed to ensure a corrective action plan was followed when PT results were found unacceptable. Findings: See D5211 and D5217.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 laboratory policy, review of 2020, 2021, 2022, 2023 and 2024 LCMS "Daily Quality Assurance" logs, monthly quality assurance monitors, LCMS toxicology and TOSOH chemistry analyzer LJ graphs, and interview with CS 04/10 /24, the LD failed to ensure the maintenance of established laboratory QA programs. Findings: 1. The LD failed to ensure LCMS "Daily Quality Assurance" logs were retained and signed off. Findings: Review of laboratory policy, CMP-001, "General Policies and Procedures" revealed "3.2.5 Quality Assessment Review...All quality assessment activities are documented and reviewed per specifications on monthly basis. Reviews should be retained electronically or placed in appropriate binders and signed off by the Laboratory Director/Designee and the Compliance Team. All completed forms, supporting documentation, and notations related to QA activities must be retained...". Review of 2020, 2021, 2022, 2023 and 2024 LCMS "Daily Quality Assurance" logs, revealed no documentation for the following months: a. 2020 - March, April, May and June - 4 of 12 months reviewed. b. 2022 - June, July August, September, October, November, and December - 7 of 12 months reviewed. c. 2023 - January, February, March, and April - 4 of 12 months reviewed. Interview with CS at approximately 12:00 p.m. confirmed the LCMS daily QA was not maintained and documented as required. 2. The LD failed to ensure LCMS and TOSOH LJ graphs were retained and/or reviewed monthly by the general supervisor (GS) and quarterly by the LD. Findings: Review of laboratory policy, CMP-001, "General Policies and Procedures" revealed "3.2.3 Analytical Systems...Quality Controls... Levey Jennings graphs are reviewed and signed monthly by the General Supervisor and quarterly by the Laboratory Director/Designee." Review of monthly "Quality Assurance Monitors", "CMP-131", revealed under section "Quality Control...Levy Jennings charts were stored for any necessary corrective action.". Review of 2022 and 2023 monthly "Quality Assurance Monitors", "CMP-131", that were retained by the laboratory, revealed the LD signed their review of the following monthly monitors on May 2, 2023. The LCMS LJ graphs were not retained during the time period in which the LD signed their review. (see D5481) a. September 2022. b. November 2022. c. February of 2023. Review of 2020 and 2021 LCMS and TOSOH LJ graphs revealed the following LJ graphs had no documentation of GS or LD review. a. April 2020 - LCMS b. August 2020 - TOSOH c. November 2020 - LCMS d. January 2021 - LCMS e. March 2021 - LCMS f. July 2021 - TOSOH g. August 2021 - LCMS
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of 2020, 2021, 2022, 2023 and 2024 LCMS "performance verification" logs, "Preparations Log/pH calibrations" logs, and "76 Analyte Calibration Exclusion" logs", review of 2020, 2021, 2022, 2023 and 2024

	LCMS toxicology QC records and interview with CS 04/10/24, the LD failed to ensure acceptable levels of performance for the toxicology and hematology testing performed. Findings: 1. The laboratory failed to document all required maintenance for the performance of toxicology testing on the LCMS analyzer. See D5433. 2. The laboratory failed to perform calibration of the MindRay hematology since August of 2023. See D5439. 3. The laboratory failed to document and/or perform QC for the LCMS testing for a period of 6 months, September 2022 thru March 2023. See D5481.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of "Laboratory Incident Report Form", and review of 2020, 2021, 2022, 2023 and 2024 laboratory records 04/10/24, the LD failed to ensure completion of all corrective actions for deviations found by the CS during an audit on 08/08/23, approximately 8 months prior to survey. Findings: Review of "Laboratory Incident Report Form", signed by LD 09/14/23, revealed the following: "Corrective Actions taken: 'CS' is sending available documentation to DocuSign for review. In addition, 'Compliance Specialist' has organized SharePoint and is attempting to locate missing documents. Patient lookback will be performed by SLP staff following completion of the audit. Please refer to audit report at end of this Report Form. 'Former GS' will receive additional training by 'Staff'. 'Former compliance specialist' resigned on 8/3 /23;...". Review of 2020, 2021, 2022, 2023 and 2024 laboratory records revealed the following corrective actions had not been completed by time of survey: a. LCMS maintenance logs, LCMS and TOSOH LJ graphs were not located and/or reviewed. See D5433 and D6094. b. No documentation of patient look backs.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of personnel records 04/10/24, the technical supervisor failed to ensure that a semiannual competency evaluation was conducted and documented for 1 of 4 testing personnel (TP #1) for testing performed on the Synermed IR-500 analyzer. Findings: Review of the laboratory's "CMP-001 General Policies and Procedures" revealed "... 1.2 Competency Assessment ... The Technical Supervisor/Laboratory Director is responsible for performing and documenting competency assessments. ... Upon completion of initial competency, employees will be re-evaluated at 6 months and 12 months, and then annually thereafter. ..." Review of personnel records revealed TP #1

	had an initial competency for the Synermed IR-500 documented on 05/20/22. There was no documentation of a semiannual competency for the Synermed IR-500 for TP #1.