Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0316543	07/17/2024
Name of Provider or Supplier	**Street Address, City, State**	
Family Medicine Group Of Oxford	1397 Belk Blvd, Oxford, MS	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the Vitros 5600 Integrated Chemistry System quality control (QC) records from the date of installation on 9/11/2023 through 7/16/2024, the manufacturer's assay information sheets with acceptable control ranges, and interview with Testing Personnel #1, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to retain the manufacturer's assay information sheets for two of five lots of controls, in use during this time frame, for at least 2 years. Findings include: 1. Review of the Vitros 5600 Integrated Chemistry System QC records from the date of installation on 9/11/2023 through 7/16/2024 revealed three lots of BioRad Liquid Assayed Multiqual controls were used for quality control testing for routine chemistry tests during this time frame. 2. BioRad Liquid Assayed Multiqual control Lot #45810--Level 1 and Level 3--was in use from 9/11 /2023 through 10/31/2023, 7 weeks of the 44 weeks that the Vitros 5600 Integrated chemistry system was in use. The manufacturer's assay information sheet, containing acceptable ranges for routine chemistry tests, for this lot of controls was not available on the day of the survey. 3. Review of the Vitros 5600 Integrated Chemistry System QC records from the date of installation on 9/11/2023 through 7/16/2024 revealed two lots of BioRad Liquichek Immunoassay Plus controls were used for quality control testing for thyroid stimulating hormone (TSH), prostate specific antigen (PSA), testosterone, ferritin, free thyroxine (FT4), free triiodothyronine (FT3), insulin, folate, and vitamin B12 tests during this time frame. 4. BioRad Liquichek Immunoassay Plus control Lot #85320--Levels 1, 2, and 3--was in use from 9/11/2023 through 5/28 /2024, 38 weeks of the 44 weeks that the Vitros 5600 Integrated chemistry system was

	in use. The manufacturer's assay information sheet, containing acceptable ranges for this lot of controls was not available on the day of the survey. 5. In an interview on 7 /17/2024 at 3:30 p.m., Testing Personnel #1 confirmed the manufacturer's assay information sheets, with acceptable control ranges, for BioRad Liquid Assayed Multiqual control Lot #45810 and BioRad Liquichek Immunoassay Plus control Lot #85320 were not retained.
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 Biosite Triage Meter records and interview with Testing Personnel #1 on the CMS 209 personnel form, the laboratory failed to perform calibration verification on the Biosite Triage Meter at least once every 6 months for creatine kinase-MB (CK-MB), troponin, and D-dimer testing for two of three six-month calibration verification procedures due. Findings include: 1. Review of Biosite Triage Meter records since the last survey on 10/11/22 revealed no documentation of calibration verification for CK-MB, troponin, and D-dimer testing since 3/19/23. 2. In an interview on 7/17/24 at 4:15 p.m., Testing Personnel #1 confirmed that calibration verification had not been performed for CK-MB, troponin, and D-dimer testing on the Biosite Triage Meter since 3/19/23. 3. The laboratory failed to perform two of the three, six-month calibration verification procedures due since the last survey-- September 2023 and March 2024. The Biosite Triage Meter was in use for CK-MB, troponin, and D-dimer testing from October 2023 through June 2024, nine months past the calibration verification due date of September 2023. THIS IS A REPEAT DEFICIENCY.
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 the laboratory's Individual Quality Control Plan (IQCP), quality control (QC) records for the Quidel Triage Meter Pro analyzer, and patient test results, the laboratory failed to ensure results of at least two control materials met the manufacturer's criteria for acceptability for 3 of the 4 months reviewed, when 20 patient Troponin I test results were reported. Findings include: 1. The laboratory's IQCP for the Quidel Triage Meter Pro analyzer states that two levels of control will be performed with each new lot of cartridges and at least monthly. 2. Review of QC records for the Quidel Triage Meter Pro analyzer from 12/19/2023 through 5/10/2024 revealed one of two controls was outside the manufacturer's acceptable range for Troponin I with the monthly performance of controls on 1/30/2024, 2/29/2024, and 4/3 /2024. The last acceptable QC results were performed on 12/19/2023, before the Quidel Triage Meter Pro analyzer was taken out of use on 5/10/2024. 3. Review of patient test results revealed Troponin I results were reported on the following 20 patients from 12/20/23 through 5/10/2024: 12/27/2023--Patient #175182 12/28/2023--Patient #175246 01/12/2024--Patient #176010 01/23/2024--Patient #176088 01/25 /2024--Patient #176198 02/07/2024--Patient #176766 02/08/2024--Patient #176851 02 /12/2024--Patient #176967 02/17/2024--Patient #177233 03/08/2024--Patient #178106 03/15/2024--Patient #178384 03/27/2024--Patient #178887 04/01/2024--Patient #179020 04/11/2024--Patient #179464 04/23/2024--Patient #179926 04/30 /2024--Patient #180212 05/02/2024--Patient #180308 05/03/2024--Patient #180404 05 /06/2024--Patient #180423 05/10/2024--Patient #180587
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on review of the verification of performance specifications for the Ortho Clinical Diagnostics Vitros 5600 Integrated Chemistry System, performed at installation in August 2023, and lack of documentation of review of these records, the laboratory director failed to ensure that the verification procedures used were adequate to determine the accuracy, precision, and linearity of the Vitros 5600 Integrated Chemistry System, for ten of ten months in which the analyzer was put in use for patient chemistry and immunoassay testing. Findings include: 1. Review of the verification of performance specifications for the Vitros 5600 Integrated Chemistry System revealed a linearity study, precision, and method comparison with the reference laboratory were performed in August 2023. 2. There was no documentation of review of these records by the laboratory director to ensure the verification procedures were adequate to determine the accuracy, precision, and linearity of the Vitros 5600 Integrated Chemistry System before the system was put in use for patient testing on 9/11/2023.