Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 25D0316543	**(X3) Date Survey Completed** 10/11/2022
Name of Provider or Supplier Family Medicine Group Of Oxford	**Street Address, City, State** 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**
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 the laboratory's Technical Policies and Procedures Manual and personnel records since the last survey on 3/24/21, the laboratory failed to establish written policies and procedures to assess competency of the technical consultant, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, responsible for technical oversight of the laboratory. Findings include: Review of personnel records since the last survey on 3/24/21 revealed no competency assessments performed by the laboratory director of the technical consultant, listed on the CMS 209 personnel form, responsible for technical oversight of the laboratory. Review of the laboratory's Technical Policies and Procedures Manual revealed no written policies and procedures for assessing competency of the technical consultant. THIS IS A REPEAT DEFICIENCY.
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 review of quality control (QC) records for testosterone testing on the Qualigen FastPack IP System from 4/4/22 through 9/30/22, patient test records, and the laboratory's written Individualized Quality Control Plan (IQCP), the laboratory failed to follow its written IQCP for performing external quality control each week of testing for seven weeks during this time frame, when a total of 32 patient testosterone results were reported. Findings include: The laboratory's IQCP states that two levels of external QC are performed each week of testing. Review of QC records for testosterone testing on the Qualigen FastPack IP System and patient test records from 4/4/22 through 9/30/22 revealed two levels of external QC were not performed on the following weeks of patient testing: Week 5/16/22 - 5/20/22--Patient specimens # 153875, #153883, #153880, #153909, #153958 reported. Week 5/23/22 - 5/27/22--Patient specimens #154109, #154131, #154139, #154187 reported. Week 5/31/22 - 6/3 /22--Level 2 control was outside manufacturer's acceptable range--Patient specimens #154246, #154279, #154230, #154396, #154398 reported. Week 6/6/22 - 6/10/22--Patient specimens #154487, #154496, #154492, #154475, #154572, #154588, #154607, #154638, #154642, #154655 reported. Week 8/15/22 - 8/22/22--Patient specimens #157142 and #157311 reported. Week 9/16/22 - 9/22/22--Patient specimen #131306 reported. Week 9/23/22 - 9/30/22--Patient specimens #131723, #131751, #131794, #131801, #131807 reported.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of patient test logs, quality control (QC) records for the Siemens Dimension Xpand chemistry analyzer from 3/1/22 through 8/31/22, manufacturer's package insert for Bio-Rad Liquichek Immunoassay Plus controls, Lot #85231 and Lot #85233, and confirmation by Testing Personnel #1 listed on the CMS 209 personnel form, Bio-Rad Liquichek Immunoassay Plus controls Level 1 (Lot #85231) and Level 2 (Lot #85233) were used for quality control testing for 24 weeks after they had exceeded their expiration date of 2/28/22, with a total of 1,319 thyroid stimulating hormone (TSH) patient results reported, a total of 478 free thyroxine (FT4) patient results reported, and a total of 295 prostate specific antigen (PSA) patient results reported during this time frame. Findings include: Review of the manufacturer's package insert for Bio-Rad Liquichek Immunoassay Plus controls Level 1 (Lot #85231) and Level 3 (Lot #85233) revealed Lot #85231 and Lot #85233 had an expiration date of 2/28/22. Review of QC records for the Siemens Dimension Xpand chemistry analyzer from 3/1/22 through 8/31/22 revealed Lot #85231 and Lot #85233 were used for quality control testing for TSH, FT4, and PSA from 3/1/22 through 8/12 /22. Review of patient test logs from 3/1/22 through 8/12/22 revealed during this time frame, a total of 1,319 TSH patient results, 478 FT4 patient results, and 295 PSA patient results were reported. Testing Personnel #1 confirmed new lots of Bio-Rad Liquichek Immunoassay Plus controls (Lot #85321 and Lot #85323, expiration date 5 /31/24) were put in use on 8/15/22.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the Cell Dyn Emerald hematology analyzer calibration records since the last survey on 3/24/21 and interview with Testing Personnel #1 listed on the CMS 209 personnel form on 10/11/22 at 4:50 p.m., the laboratory failed to perform calibration on complete blood counts (CBC) performed on the Cell Dyn Emerald hematology analyzer every 6 months as required by the manufacturer. Findings include: 1. Review of the Cell Dyn Emerald calibration records since the last survey on 3/24/21 revealed calibration was not performed from 10/2/21 until the Cell Dyn Emerald was taken out of service on 9/28/22. This exceeds the 6 month timeframe required by the manufacturer. 2. Interview with TP #1 on 10/11/22 at 4:50 p.m. confirmed CBC calibrations were not performed every 6 months, as required by the manufacturer. THIS A REPEAT DEFICIENCY.
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 since the last survey on 3/24/21 and interview with Testing Personnel #1 on the CMS 209 personnel form on 10/11/22 at 4:00 p.m., 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. Findings include: 1. Review of Biosite Triage Meter records since the last survey on 3/24/21 revealed no documentation of calibration verification for CK-MB, troponin, and D-dimer testing since the last survey on 3/24/21. 2. In an interview on 10/11/22 at 4:00 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 April 2021, shortly after the last survey on 3/24/21. These calibration verification records (performed in April 2021) were not available for review on the day of the survey, 10/11/22. THIS IS A REPEAT DEFICIENCY.