Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0316543	03/24/2021
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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of the patient records for the Abbott ID NOW COVID-19 molecular test (including reporting log) and the Healgen COVID-19 IgG/IgM Rapid Test Cassette and an interview with Testing Personnel (TP) #1 at 12:00 pm on 3/24/21, the laboratory failed to report after 9/23/2020 all SARS-CoV-2 results (positive and negatives) to the Secretary of Health and Human Services via the Mississippi State Department of Health (MSDH) Epidemiology program. Findings include: 1. Review of the QC and patient result logs and the positive and negative patient report logs for the Abbott ID NOW COVID-19 test indicated that no SARS-CoV-2 patient results had been reported to MSDH Epidemiology since December 2020. 2. Review of the patient result logs and the positive and negative patient report logs for the Healgen COVID-19 IgG/IgM Rapid Test Cassette indicated that no patient results had been reported to MSDH Epidemiology since December 2020 3. Interview with TP #1 on 3 /24/21 at 12:00 pm confirmed that the laboratory had not reported any COVID-19 test results to MSDH Epidemiology since December 2020.
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 personnel records and interview with the testing personnel (TP) #1 listed on the Centers of Medicare & Medicaid Services (CMS) 209 personnel form at 3:00 pm on 3/24/21, the Laboratory Director failed to follow written policies to assess competency of the TC (technical consultant) at least annually. There was no evaluation for the TC on the day of survey for the years 2019 or 2020. Findings include: 1. Interview with TP#1 at 3:00 pm confirmed there was no competency documented by the laboratory director for the TC since the last survey on 8/7/18. 2. Based on review of the personnel records the day of survey, 3/24/21, the laboratory director failed to follow policies and evaluate the technical consultant at least annually for the years 2019 and 2020. THIS IS A REPEAT DEFICIENCY
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 laboratory proficiency records from 2020 and 2021 and interview with TP #1 at 10:30 am, on the day of survey (3/24/21), the laboratory failed to verify the accuracy of Healgen COVID-19 IgG/IgM Antibody testing at least twice annually since the laboratory began testing with the kit on 8/4/20. Findings include: 1. Review of the proficiency records from 2020 and 2021 revealed the Healgen COVID-19 IgG /IgM Antibody test had not been included. 2. There was no documentation that indicated that the Healgen COVID-19 IgG/IGM antibody test had been verified for accuracy by comparison with another known assay. 3. Interview with TP #1 at 10:30 am on 3/24/21 confirmed that accuracy had not been verified on the Healgen COVID-19 IgG/IgM antibody test kit twice annually.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number of deficiencies cited for analytic systems, the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 to monitor and evaluate the overall quality of the analytic systems and correct identified

	problems as specified in 493.1289 for each specialty and subspecialty of testing performed. Refer to D tag 5421: No performance specifications verified for the Healgen COVID-19 IgG/IgM Rapid Test Cassette kit prior to start of testing. Refer to D tag 5437: Cell Dyn Emerald calibration not performed as required every 6 months. Refer to D tag 5439: Triage Meter SOB panel and Qualigen Fast Past Vitamin D and Testosterone calibration verification not performed as required every 6 months Refer to D tag 5449: Healgen COVID-19 IgG/IgM Rapid Test Cassette tests performed without QC testing. Refer to D tag 5479: Remel RA Rapid test performed with no documentation of QC performed with patients.
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 Healgen COVID-19 IgG/IgM Rapid Test Cassette, lack of documentation of verification of performance specifications, and interview with testing personnel (TP) #1 on 3/24/21 at 10:00 am, the laboratory failed to verify the manufacturer's performance specifications before reporting patient test results. Findings: 1. No documentation of verification of performance specifications for the Healgen COVID-19 IgG/IgM Antibody Rapid Test Cassette was available for review on the day of survey. 2. Interview with TP #1 on 3/24/21 at 10:00 am revealed no verification of performance specifications was completed before testing patients. 3. Seventy-six patients had been tested by the laboratory since 8/4/20.
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 3/4/18 and interview with testing personnel (TP) #1 listed on the CMS (Center for Medicare & Medicaid Services) 209 personnel form at 1:00 pm on the day of survey, the laboratory failed to perform calibration on CBC (complete

	blood count) 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 from 3/4/18 through 3/24/21 revealed calibration had not been performed since 3/11/20. This exceeds the 6 month timeframe required by the manufacturer. 2. Interview with TP #1 at 1:00 pm on 3/24/21 confirmed CBC calibrations were not performed every 6 months as required by the manufacturer.
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: A. Based on review of Biosite Triage Meter records from 3/2/19 through 3/24/21 and confirmation with testing personnel (TP) #1, the laboratory failed to perform calibration verification on the Biosite Triage Meter chemistry analyzer every 6 months for the Shortness of Breath (SOB) cardiac panel (CK, troponin, BNP, D-dimer). Findings include: 1. Review of the laboratory Biosite Triage Meter SOB panel (CK, Troponin, BNP and D-dimer) from 3/2/19 through 3/23/21 revealed calibration verification had not been performed on the SOB panel. 2. Interview with TP #1 at 2: 00 pm confirmed that calibration verification had not been performed on the SOB cardiac panel every 6 months as required by the manufacturer. B. Based on review of the Qualigen Fast Pack System records from 3/2/19 through 3/23/21, and confirmation with TP #1, the laboratory failed to perform calibration verification on the Qualigen Fast Pack system every 6 months for Vitamin D and testosterone. 1. Review of the manufacturer's requirements for the Qualigen Fast Pack Testosterone and Vitamin D assays indicate that calibration verification is required every 6 months for both assays. 2. Review of the Qualigen Fast Pack testosterone records from 4/3/19 through 3/24/21 revealed no calibration verification had been performed. 2. Review of the Qualigen Fast Pack Vitamin D records from 3/4/19 through 3/9/21 revealed calibration verification had been performed on 1/29/20, 2/12/20 and 3/9/21. The time periods from 3/4/19 to 1/29/20 and 2/12/20 to 3/9/21 exceed the manufacturer's calibration

	verification requirement. 3. Interview with TP #1 at 2:00 pm confirmed that calibration verifications had not been performed on the Vitamin D or testosterone in the time frame required by the manufacturer.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation of quality control records for the Healgen COVID-19 IgG/IgM Rapid Test Cassette and interview with testing personnel (TP) #1 at 10:30 am on 3/24/21, the laboratory failed to include a positive and negative control on each day of patient testing for the Healgen COVID-19 IgG/IgM Rapid Test Cassette performed from 8/4/20 through 3/24/21 for antibodies to SARS-CoV-2. Findings Include: 1. Review of the annual laboratory test count revealed 76 patients had been tested with the Healgen COVID-19 IgG/IgM Rapid Test since the lab started using this test kit on 8/4/20. 2. Review of the Healgen COVID-19 IgG/IgM Rapid Test Cassette kit revealed there was no quality control (QC) material (positive or negative) available. 3. Interview with TP #1 indicated that the manufacturer had not provided QC material in the kit and none had been obtained by the laboratory. 4. Interview with the TP #1 at 10:30 am on 3/24/21 confirmed that TP were not performing two levels of QC each day of patient testing with the Healgen COVID-19 IgG/IgM Rapid Test Cassette.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation of quality control records for the BioKit rheumajet RF (rheumatoid factor) from 1/31/19 through 3/24/21 and interview with staff at 2:00 pm, the laboratory failed to document as performed the quality control (QC) results for the rheumajet RF test kit each day of testing patients. Findings include: 1. There was no documentation to indicate that QC was performed each day of patient testing as required. 2. Interview with TP #1 confirmed that QC material, both positive and negative, was being tested along with patient samples each day of testing. QC results were not documented in any way. Patient results were entered directly into the LIS, so no log was kept on which QC results might be noted. 3. The laboratory performed approximately 304 RF patient testing between 1/31/19/ and 3/24/21. THIS IS A REPEAT DEFICIENCY
D6019	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records from 2018, 2019, 2020 and 2021 and lack of documentation of corrective action available, the laboratory director failed to ensure an approved corrective action plan was followed when the laboratory scored below 80% (unacceptable or unsatisfactory) on an analyte. Findings Include: 1. Review of the Casper Proficiency report and the laboratory proficiency result records for 2018, 2019, 2020 and 2021 confirmed the following proficiency results had scores less than 80%. a. Cholesterol -1st event 2019 - 60% b. Cholesterol - 3rd event 2020- 60% c. Vitamin D- 3rd event 2020- 50% d. Vitamin D - 1st event 2021 -50% e. Testosterone - 3rd event 2020 - 50% f. Testosterone - 1st event 2021 - 50% 2. There was no corrective action documented and reviewed by the laboratory director for any of the above unacceptable results.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) records on 3/24/21, review of the Centers of Medicare and Medicaid Services (CMS) 209 personnel form and interview with TP #1 (as listed on the CMS 209 form), the technical consultant failed to evaluate and document the performance of laboratory TP #1, #2, #3, responsible for moderate complexity testing, at least annually since 8/4/18. Findings include: 1. Based on lack of evaluation/competency assessments available for review, annual evaluations /competencies for TP #1, TP #2, and TP #3 had not been performed since the last survey on 8/4/18. 2. Interview with TP #1 confirmed the annual evaluation /competencies for TP #1, TP #2, and TP #3 had not been documented as performed by the technical consultant.