Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 11D0265607	**(X3) Date Survey Completed** 08/07/2018
Name of Provider or Supplier Sgmc Valdosta Medical Clinic	**Street Address, City, State** 3207 Country Club Drive, Valdosta, GA	
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**
D0000	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on August 7, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 review of laboratory records, lack of records to review and staff interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems in the subspecialties of routine chemistry and endocrinology. Refer to: D5413, D5429, D5439, and D5469
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 temperature charts for the freezer used to store calibrators and controls for the Beckman Access 2 endocrinology analyzer, review of temperature requirements posted by the manufacturer on boxes of controls and calibrators used on the analyzer and staff interview, the laboratory failed to store calibrators and controls at the temperature required by the manufacturer. Findings include: 1. Review of temperature storage requirements for the following controls and calibrators used on the Beckman Access 2 endocrinology analyzer revealed Bio-Rad Liquicheck Immunoassay Plus controls must be stored at negative 20 to negative 70 degrees centigrade, 2. Review of temperature charts for the freezer used to store the calibrators and controls revealed the laboratory set the acceptable temperature range at negative 15 to negative 20 degrees. 3. Review of temperature charts for April 2017 through December 2017 revealed the temperature was outside the acceptable range on 190 of 190 days recorded. Review of temperature charts for January through June of 2018 revealed the temperature was outside the acceptable range on 146 of 146 days recorded. 4. Interview with testing personnel #1 (see CMS 209) and the clinical supervisor on August 7, 2018 in the conference room at 1 pm confirmed the acceptable temperature range is set at negative 15 to negative 20 degrees centigrade, the lab was unaware of the storage requirements for the controls and the temperature of the freezer routinely measures outside the acceptable range set by the manufacturer.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interview, the laboratory failed to document weekly maintenance performance on the Beckman Access 2 endocrinology analyzer. Findings include: 1. Review of maintenance requirements for the Beckman Access 2 analyzer revealed a weekly system check is required. 2. Review of maintenance records for the Beckman Access 2 revealed no documentation showing the weekly maintenance was performed in 2017 and 2018.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of pipette calibration records and staff interview, the laboratory failed to perform calibration on the MLA 200 microliter pipette at least every 6 months as required. Findings include: 1. Review of pipette calibration records

	revealed no documentation of calibration between 8/24/16 and 6/26/18 for the the MLA 200 microliter C10252 pipette. 2. Interview with testing personnel # 1 (see CMS 209) and the clinical manager on August 7, 2018 at 2 pm in the conference room confirmed calibration had not been perform on the MLA 200 pipette every 6 months 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 2017 and 2018 laboratory records, lack of records to review and staff interview, the laboratory failed to perform calibration verification at least every 6 months for routine chemistry and endocrinology testing performed on the Beckman Coulter DxC chemistry analyzer and Beckman Coulter Access 2 endocrinology analyzer. Findings include: 1. Review of laboratory records revealed no documentation of 6 month calibration verification for testing performed on the Beckman Coulter DxC chemistry analyzer or the Beckman Coulter Access 2 endocrinology analyzer. 2. Interview with testing personnel # 1 (see CMS 209) and the clinical manager on August 7, 2018 at 3 pm in the conference room confirmed calibration verification has not been performed in 2017 or 2018.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the

	laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2017 and 2018 quality control (QC) records for testing performed on the Beckman Access 2 endocrinology analyzer and the Beckman DxC 600 chemistry analyzer , review of the package inserts for controls used to determine analyzer performance and staff interview, the laboratory failed to establish criteria for acceptability of the controls. Findings include: 1. Review of Levey Jennings charts, BioRad Liquicheck Immunoassay Plus Control assay sheets and results of control values obtained during testing of controls on the Beckman Access 2 endocrinology analyzer revealed the laboratory uses the 3 standard deviation range given by the manufacturer on the assay sheet to determine the acceptable range of control values and has not adjusted their QC ranges to reflect the standard deviation obtained by their laboratory. Review of control values obtained by the laboratory also revealed the standard deviation calculated on testing performed in their laboratory is much lower than the values used to determine acceptability of patient results. 2. Review of Levey Jennings charts, Beckman Coulter UniCel DxC Synchron control assay sheets and results of control values obtained during testing of controls on the Beckman DxC 600 chemistry analyze revealed the laboratory uses an assigned standard deviation and has not adjusted their QC ranges to reflect the standard deviation obtained by their laboratory. Review of control values obtained by the laboratory revealed the standard deviation calculated on testing in their laboratory is much lower than the values used to determine acceptability of patient results. 3. Review of the package insert for the controls revealed each laboratory should establish their own acceptable ranges and use the assayed ranges as a guide. 4. Interview with testing personnel # 1, (see CMS 209) on August 7, 2018 at 3 pm in the conference room confirmed the laboratory uses the standard deviation calculated from the assay sheets supplied by the manufacturer and those ranges are not indicative of ranges obtained by their laboratory.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records and staff interview, the laboratory director failed to provide overall management and direction for the laboratory. Findings include: Refer to D 6020
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of 2017 and 2018 quality control records and staff interview, the laboratory director failed to ensure the quality control program was maintained in the subspecialties of routine chemistry and endocrinology. Findings include: Refer to D 5469
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory documents and staff interview, the technical consultant failed to provide technical and scientific oversight of the laboratory. Findings include: Refer to D 6036, D 6040 and D 6046
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on review of laboratory records and staff interview, the technical consultant failed to ensure the laboratory performed calibration and function checks in 2017 and 2018 on analyzers used to perform testing in the subspecialties of routine chemistry and endocrinology. Findings include: Refer to D 5439
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of laboratory reccords and staff interview, the technical consultant failed to ensure the laboratory performed percision and accurancy testing every 6 months in the subspecialties of endocrinology and routine chemistry in 2017 and 2018. Findings include: Refer to D 5431
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's competency assessment policy, review of competency assessment records and staff interview, the technical consultant failed to evaluate competency on two of three testing personnel (TP) listed on the CMS 209 form. Findings include: 1. Review of the laboratory's personnel competency assessment policy revealed the competency of the primary tech is evaluated by the Laboratory Director, who is also listed as the technical consultant , but the competency of additional testing personnel is evaluated by the primary tech (TP #1, see CMS 209) who does not qualify as a technical consultant. 2. Review of competency assessment records revealed the primary tech, testing personnel #1,(see CMS 209) performed competency assessment for TP # 2 and TP # 3. 3. Interview with TP # 1 (see CMS 209) and the clinical supervisor on August 7, 2018 at 2 pm in the conference room confirmed competency assessment of TP #2 and TP # 3 was performed by TP #1 who does not qualify as a technical consultant.