Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0266067	08/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
Southwest Georgia Regional Medical Ctr	361 Randolph Street, Cuthbert, 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,29 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:
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 the review of the Platelet Transfusion procedure, the Blood Bank Worksheet (BBW) and staff interview the laboratory failed to follow the patient retype if a type has not been ordered in the last 70 hours. Findings: 1. Review of the Platelet Transfusion procedure states that when an order is placed for a platelet transfusion if a blood type has been collected in the last 70 hours the new order will be added to the previous order and notification sent to the laboratory. Review of the BBW the laboratory exceeded the 70 hour limit 3 times in May 2017, and one time in June 2017. 2. Interview with staff #1(CMS form 209), on August 29, 2018, at approximately 6:25 pm in the hospital conference room confirmed the aforementioned.
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 the Blood Bank(BB) Refrigerator temperature monitoring graphs, and staff interview the laboratory failed to change the monitoring graph wheel every week (7 days). Findings: 1. Review of the BB refrigerator temperature monitoring graphs, the laboratory failed to change the graph wheel every week 37 weeks out of 52 weeks in 2017, and 15 weeks out of 34 weeks in 2018. 2. Interview with staff #1 (CMS for 209) on August 29, 2018, at approximately 6:23 pm in the hospital conference room confirmed the aforementioned.
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 document review and staff interview, the lab failed to perform maintenance per the manufacturer's manual and the lab's procedure manual (SOP). Findings include: 1. Review of the TOSOH AIA 900 maintenance procedures and log sheets revealed the lab did not perform or record the substrate background counts each day of use. The background counts were not logged: 4 of 31 days in January 2018, 3 of 31 days in March 2018, 1 of 30 days in April 2018, 2 of 31 days in May, and 1of 30 days in June 2018. 2. Review of the TOSOH AIA 900 maintenance procedures and log sheets revealed the lab did not perform or record maintenance: 1 of 31 days in March 2018, and 1 of 30 days in June 2018. 3. Interview with the general supervisor (CMS 209 form) on 8/29/18 in the hospital conference room at approximately 6:00 PM, confirmed the aforementioned. 4. Review of the Beckman/Coulter Iris iChem Velocity urinalysis Maintenance procedure, the laboratory was not changing the dessicant every 5 days and/or with addition of urine chemistry strips. Documented dates of addition of the dessicant exceeded the 5 day limit, 3 times in April 2018, one time in May 2018, one time in June 2018, 2 times in July of 2018. 5. Interview with staff #1 (CMS 209 form) on August 29, 2018 at approximately 6:10 pm, in the hospital conference room confirmed the aforementioned (#4).
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 calibration documents and staff interview, the laboratory failed to calibrate the DXC AU700 chemistry analyzer per manufacturer's instructions. Findings include: 1. Review of DXC AU700 calibration documents/ log sheets revealed the lab did not perform or document creatinine calibration every 24 hours. The calibration was not documented 2 of 30 days in June 2018; or 5 of 31 days in July 2018. 2. Interview with the lab general supervisor (CMS 209 form) on 8/29/18 in the hospital conference room at approximately 6:00 PM, confirmed the creatinine calibrations were not documented.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Quality Control(QC) documents for the Wet Prep procedure and staff interview, the laboratory failed to document Quality Control as required. Findings: 1. Review of the QC documents showed that the laboratory was not documenting the QC for the Wet Prep procedure. Use of posted photomicrographs for comparison and documentation of review was not being performed. 2. Interview with staff #1 (CMS form 209) on August 29, 2018 at approximately 6:20 pm in the hospital conference room, confirmed that the lab was not documenting comparison and review of posted photomicrographs for the Wet Prep procedure. Based on review of the Blood Bank (BB) Quality Control (QC) documents, the Blood Bank Worksheet (BBW), and staff interview, the laboratory failed to perform and or document completely the QC results for the BB reagents. Findings: 1. Review of the BBW and the BBQC log, the laboratory failed to document QC for the following days BB testing was performed: May 5, 2017 May 10, 2017 May 24, 2017 December 19, 2017 January 8, 2018 June 6, 2018 June 11, 2018 June 18, 2018 June 27, 2018 July 10, 2018 2. Interview with staff #1(CMS form 209) on August 29, 2018 at approximately 6:10 pm in the hospital conference room, confirmed on the above dates QC was not performed.
D5539	ROUTINE CHEMISTRY CFR(s): 493.1267(c)(d) For blood gas analyses, the laboratory must perform the following: (c) Test one sample of control material each time specimens are tested unless automated instrumentation internally verifies calibration at least every 30 minutes. (d) Document

	all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the iSTAT Arterial Blood Gas (ABG) procedure, and staff interview the laboratory failed to perform Quality Control (QC) as required. Findings: 1. Review of the iSTAT ABG procedure, the laboratory was performing the external Electronic Simulator every 8 hours of patient testing. External liquid controls were to be run with each new lot number, each shipment, and at least monthly. The laboratory was only performing equivalent quality testing and had not established an Individual Quality Control Plan(IQCP) for ABG. 2. Interview with staff #1 (CMS form 209), on August 29, 2018, at approximately 6:15 pm, in the hospital conference room, confirmed that the laboratory had not established an IQCP for ABG.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) logs and staff interview, the testing personnel (TP) failed to follow QC procedures to document all QC activities. Findings include: 1. Review of urinalysis QC logs revealed the TP failed to perform or document urine microscopic QC: 4 of 31 days in March 2018 and 1 of 31 days in May 2018. 2. Interview with the lab general supervisor (CMS 209 form) on 8/29/18 at 4 PM in the hospital conference room confirmed the urine microscopic QC was documented for the aforementioned dates.