Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0724352	10/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Hale County Hospital	508 Green Street, Greensboro, AL	

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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observations of programmed data in the Sysmex CA-600 Coagulation analyzer, a review of Innovin Protime (PT) reagent "crossover study" records, and interviews with the Laboratory Manager, the surveyor determined the laboratory failed to manually verify the INR (International Normalized Ratio) to ensure all programmed data was entered correctly. This was noted on Innovin reagent in use from 11/9/2017 till the date of the survey on 10/23/2018. The findings include: 1. On 10/23/2018 at 4:05 PM, the surveyor reviewed the programmed data used for the calculation of the INR in the Sysmex CA-600 Coagulation analyzer. The printout listed the normal patient mean as 10.1 seconds, and the ISI (International Sensitivity Index) as 0.98. The Innovin PT reagent lot number (#) was not specified. 2. A review of the "crossover study" records for the Seimens Dade Innovin reagent Lot #539378 (in use since 11/9/2017) revealed the manufacturer's insert specified an ISI of 0.97, and the normal patient mean (for twenty patients) was calculated as 10.7 seconds. 3. During an interview with the Laboratory Manager on 10/23/2018 at 4:20 PM, the above discrepancy was discussed. The Manager explained the Sysmex Technician had assisted her by phone in the entry of the data for the new Innovin lot #539378. The Manager contacted the Sysmex Technician who verified she had assisted in the entry of the data, and theorized the laboratory had failed to save the data as required. A further review of the data in the Sysmex CA-600 revealed the data had actually been saved in the Extended Protime (XPT) channel (used to run abnormally high PT's) only, however it was not entered and saved in the regular PT channel. 4. As the

	interview continued, the surveyor then asked the Laboratory Manager if the laboratory's Innovin "Crossover Study Procedure" included a comparison of the manually calculated INR to the INR calculated by the CA-600 to ensure they are the same. The Manager stated she "had looked at it", however she was unable to provide any documentation of the calculations. Thus the above noted findings were confirmed. .
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 observations, a record review of the 2016-2018 temperature charts, a review of storage requirements for the Biorad QC (Quality Controls) (used for D-Dimer, Chemistry, Endocrinology and Toxicology assays), and an interview with the Laboratory Manager, the surveyor determined the laboratory failed to define appropriate acceptable ranges (as defined by the manufacturer), and ensure QC was stored at temperatures specified by the manufacturer in 2017 and 2018. The findings include: 1. A review of the October 2016 thru October 2018 temperature records for the "Chest Freezer" revealed the laboratory specified an acceptable range of 0 to -25 degrees C (Celsius) on the charts. 2. During an interview on 10/25/2018 at approximately 5:00 PM, the Laboratory Manager stated the Chest Freezer is used to store the Biorad controls. The surveyor and Laboratory Manager then inventoried the contents of the freezer, which included multiple packages (with six bottles each) of Biorad Chemistry/Toxicology QC, Immunoassay QC (for Prostatic Specific Antigen [PSA] and Hormone assays), and Cardiac QC. An icon on each of the Biorad QC packages specified storage requirements of -20 to -70 degrees C. 3. A review of the 2017-2018 temperature charts with the Laboratory Manager revealed the Chest Freezer had consistently maintained temperatures colder than -20 degrees C until March 2017, and thereafter fluctuated. Approximately 50% of the time between March 2017 to October 2018, temperatures were noted to be outside Biorad's required storage temperatures of -20 to -70 degrees C. Testing personnel recorded temperatures in the range of -14 to -19 degrees C 50% of the time with no documentation of corrective action because acceptable range on the chart were 0 to -25 degrees C. 4. As the interview continued at approximately 5:05 PM on 10/25/2018, the Laboratory Manager confirmed the Chest Freezer was not consistently maintaining temperatures in the range required for the long-term storage of the Biorad QC in 2017-2018. The surveyor also discussed the CLIA requirement of following Biorad's QC storage instructions, and the concern of the "acceptable ranges" on the freezer logs not reflecting the manufacturer's storage requirements for the items the freezer contained. [NOTE: This concern was also discussed with the previous Laboratory Manager during the October 2016 Recertification Survey, however no action was taken to ensure correct acceptable ranges (-20 to -70 degrees C) were documented on the temperature chart.] .

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 a review of the calibration and calibration verification records for the Seimens Dimension EXL 120 Chemistry analyzer, and an interview with the Laboratory Manager, the surveyor determined the laboratory failed to perform and document one of two calibration verifications every six months in 2017 as required. The findings include: 1. A review of the tests performed on the Seimens Dimension EXL 120 Chemistry analyzer revealed Sodium (Na), Potassium (K), and Chloride (Cl) were calibrated using two on-board calibrators, and Hemoglobin A1c (HgA1C) was calibrated as needed with a two-calibrator kit. Tests using less than three calibrators require a calibration verification (C/V) every six months. 2. A review of the records for the Seimens Dimension EXL 120 Chemistry analyzer revealed the instrument was installed and validated in August 2016. However there was no documentation of a calibration verification for HgA1C until 7/18/2017, and Na, K, and Cl until 7/14/2017 (an eleven-month gap). 3. During an interview on 10/24/2018 at 1:40 PM, the Laboratory Manager was asked if the laboratory had performed and documented a calibration verification for Na, K, Cl and HgA1C on the Dimension EXL in early 2017. The Laboratory Manager reviewed the records, and stated the calibration verification due in early 2017 "was not done". Thus, the above noted findings were confirmed. .
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 a review of the quality control (QC) records for the DCA Vantage (used for the Urine Microalbumin/ Urine Creatinine ratio testing); a review of patient test results and an interview with the Laboratory Manager, the surveyor determined the laboratory failed to ensure two levels of quality control (QC) were performed as specified in the IQCP (Individualized Quality Control Plan). Two periods in 2016 and 2017 of patient testing were noted when QC had not been performed within the thirty days frequency as required by the IQCP. The findings include: 1. A review of the IQCP for the DCA Vantage revealed two levels of QC should be tested with each new lot number and shipment of reagent cartridges, and every 30 days thereafter whenever there were patients to be tested. The frequency of the QC performance was confusing, so on 10/24/2018 at 3:45 PM the surveyor asked for clarification from the Laboratory Manager who explained QC was not necessarily performed every 30 days. Testing personnel were instructed to review when the last QC was performed when running patient tests; if it was more than 30 days, they should also perform two levels of QC for the Urine Microalbumin/ Urine Creatinine cartridges before running patients. 2. A review of the DCA Vantage QC/patient logs revealed the following: A) QC performed 10/27/16, and then 12/14/16; one patient run between 11/26-12/13/16 (greater than the 30 days since previous QC) B) QC performed 5/15/17, and then 7/10/17; four patients run between 6/14-7/9/17 (greater than the 30 days since previous QC) 3. As the interview continued on 10/24/2018 at approximately 3:55 PM, the Laboratory Manager reviewed the above findings and confirmed testing personnel had failed to follow the IQCP. Five patient Urine Microalbumin/ Urine Creatinine ratios had been performed on the DCA Vantage without the required QC. SURVEYOR:Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor