Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0724352	11/10/2022
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
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 instructions in the DCA Vantage Analyzer Operator's Guide and an interview with Testing Personnel #2, the laboratory failed to perform calibration verification on the Urine Microalbumin / Urine Creatinine twice a year as required by CLIA regulations. This was noted from the previous survey (9/30 /2021) to the current survey (11/10/2022). The findings include: 1. A review of the calibration instructions in the DCA Vantage Analyzer Operator's Guide revealed

	testing personnel performed a two-point calibration by scanning both sides of a calibration card received with each box of Urine Microalbumin / Urine Creatinine cartridges (a moderate-complexity test). Tests calibrated with less than three calibrators require calibration verification every six months, as per CLIA regulations. 2. During an interview on 11/10/2022 at 11:10 AM, when the surveyor requested the Urine Microalbumin / Urine Creatinine calibration verification records, Testing Personnel #2 stated, "We have never performed a calibration verification on the DCA Vantage Microalbumin / Urine Creatinine". .
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 quality control (QC)/patient test records, a review of IQCP (Individualized Quality Control Plan) documents, and an interview with the General Supervisor, the laboratory failed to ensure two levels of controls were run each day of patient testing or at the interval specified by the laboratory's IQCP for C. diff (Clostridium difficile), Urine Microalbumin /Urine Creatinine ratio, and Serum Ketones. This was noted eleven times from October 2021 - October 2022. The findings include: 1. A review of the quality control/patient test records revealed the following: a) C. diff - one patient test was performed on 10/12/2021 with the last QC run on 10/04/2021. One patient was performed on 01/30/2022 with the last QC run on 01/20/2022. b) Urine Microalbumin /Urine Creatinine ratio- patient tests were performed on 5/18/2022, 5/25/2022, and 5/31/2022 with the last QC run performed on 4/15/2022. c) Serum Ketones - Patient tests were performed on 10/06/2021, 10/08 /2021, 10/10/2021, 1/21/2022, 06/11/2022, and 06/27/2022 with no documentation of quality controls. 2. A review of the IQCP documents revealed the following: a) IQCP for C. diff: a positive and negative control should be performed upon opening the kit and with specimen testing at an interval not less than 7 days or with next procedure if interval is greater than 7 days. b) IQCP for Urine Microalbumin /Urine Creatinine ratio: a positive and negative control should be performed upon opening the kit and with specimen testing at an interval not less than 30 days or with next procedure if interval is greater than 30 days. 3. During an interview on 11/10/2022 at 9:53 AM, the General Supervisor confirmed the above findings. .
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on a review of the test menu and analyzers, and an interview with the General Supervisor (also the Laboratory Manager), the laboratory failed to implement procedures to ensure test results from different analyzers were compared and evaluated twice a year. This affected four analytes from the previous survey (9/30 /2021) to the current survey (11/10/2022). The findings include: 1. A review of the test menu and analyzers revealed four analytes are performed on more than one instrument in the laboratory as follows: A) Troponin-performed on the Seimens Dimension EXL-200 and the Abbott I-Stat B) Hemoglobin A1c-performed on the Seimens Dimension EXL-200 and Seimens DCA Vantage C) Basic Metabolic Profile-performed on the Seimens Dimension EXL-200 and the Abbott I-Stat D) Glucose-performed on the Seimens Dimension EXL-200 and Accuchek Glucometer 2. During an interview on 11/10/2022 at 11:55 AM, the surveyor requested documentation of comparison studies of test results on the two testing platforms. The General Supervisor was not sure the laboratory had performed any comparison studies, and did not provide any documentation of comparison evaluations. .
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on reviews of personnel files, and an interview with the current General Supervisor (also the Laboratory Manager), the Technical Consultant failed to ensure training was performed and documented before testing personnel began patient testing. This affected six of six new testing personnel listed on the Form CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of personnel files revealed no documentation of training for six new testing personnel hired since the date of the previous survey (9/29/2021). Only an initial competency was performed which included a list of instruments and tests with "Yes" under the "Proficiency" column, along with the date, the testing personnel's initials and observer's initials. There were no details on how the testing personnel were trained, or what the training included (such as maintenance, quality control, calibrations, problem resolution, results reporting and other tasks). The surveyor further noted the laboratory did not specify how personnel were trained to collect arterial blood gases. 2. During an interview on 11/9/2022 at 1:05 PM, the current General Supervisor (hired in August 2022) confirmed the above findings, and explained she had continued to use the same system already in use when she "got here" because it "was all that was available". .
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 reviews of personnel records and an interview with the General Supervisor (also, the Laboratory Manager), the Technical Consultant failed to implement a mechanism to assess the six minimal competency assessment criteria required for moderate complexity testing. This was noted from the previous survey (9/30/2021) to the current survey (11/10/2022). The findings include: 1. A review of personnel records revealed competency assessments which included a list of instruments and tests with "Yes" under the "Proficiency" column, along with the date, the testing personnel's initials and the observer's initials. There were no details on how employee competency was assessed, or if the six minimal competency assessment criteria required for moderate complexity testing were considered. 2. The surveyor further noted employee files for Testing Personnel #2, #4 and #5 included a "Performance Assessment" sheet which included five of the six competency assessment criteria, however the "Procedure observed" was not specified. 3. As part of the investigation of a complaint, the surveyor also reviewed files to determine if the staff were assessed on their Arterial Blood Gas (ABG) collection proficiency. A review of the Competency Assessment check off sheet (see #1 above) listed, "ABGs" "Performing Arterial Stick" [and] "Check off on skills sheet" with "Yes" under the "Proficiency" column for the General Supervisor, Testing Personnel #6, and one Phlebotomist. However, the assessment of ABG collection skills were not included on the form entitled, "SKILL /ELEMENT OF KNOWLEDGE", under the section "Specimen Collection and Processing". 4. During an interview with the General Supervisor on 11/9/2022 at 1:05 PM, the surveyor reviewed the six competency assessment criteria required for moderate complexity testing in the CMS booklet, "What Do I Need to Do to Assess Personnel Competency?", listed as follows: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples. f) Assessment of problem solving skills. 5. As the interview continued on 11/9/2022 at 1:35 PM, the surveyor explained the current system failed to specify how the employee competency was assessed, or whether the six required competency assessment criteria for moderate complexity testing were considered for each testing platform. The current General Supervisor (hired in August 2022) confirmed the above findings, and explained the laboratory had continued to use the same system already in use when she "got here" because it "was all that was available". SURVEYOR ID# 32558 and 46292 Licensure and Certification Surveyors