Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0724352	09/30/2021
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
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) Proficiency Testing records and an interview with General Supervisor #2, the Laboratory failed to review and evaluate all results less than 100%. This was noted on 4 out of 38 Testing Events from 2019 - 2021. The findings include: 1. A review of Proficiency Testing records revealed the following: a) 2019 Hematology/Coagulation 3rd Event - 80% Blood Cell Identification and 80% Monocytes with no corrective action documented for unacceptable results. b) 2020 Hematology/Coagulation 2nd Event - 80% Monocytes with no corrective action documented for unacceptable result. c) 2020 Hematology /Coagulation 3rd Event - 60% Monocytes with corrective action documented as memo sent out to technicians about proper mixing of samples and 0% Nasal Smear with no corrective action documented for unacceptable result. d) 2021 Hematology /Coagulation 1st Event - 80% Blood Cell Identification, 80% MCHC, and 0% Vaginal Wet Preparation with no corrective action documented for unacceptable results. 2. During an interview on 09/29/2021 at 4:00 PM, General Supervisor #2 confirmed the above events did not have proper corrective action documented for results with a score less than 100%.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

	This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) Proficiency Testing records and an interview with General Supervisor #2, the Laboratory failed to verify the accuracy of API results that were not evaluated. This was noted on 7 out of 38 Testing Events from 2019 - 2021. The findings include: 1. A review of Proficiency Testing records revealed the following: a) 2019 Hematology/Coagulation 2nd Event - Blood Cell ID was not graded due to being educational samples. No documentation of self-evaluation. b) 2020 Chemistry - Core 2nd Event - Lactate (i-STAT) was not graded due to no appropriate peer group. No documentation of self-evaluation. c) 2020 Hematology/Coagulation 1st Event - Blood Cell ID was not graded due to being educational samples and Fecal Leukocytes (Microscopy) not graded see data summary. No documentation of self-evaluation. d) 2020 Hematology/Coagulation 2nd Event - Blood Cell ID was not graded due to being educational samples. No documentation of self-evaluation. e) 2020 Hematology/Coagulation 3rd Event - Blood Cell ID was not graded due to being educational samples and Urine Sediment #6 was not graded due to no consensus. No documentation of self-evaluation. f) 2020 Immunology/Immunohematology 3rd Event - Antibody Screen #11 was not graded due to no consensus. No documentation of self-evaluation. g) 2021 Hematology /Coagulation 1st Event - Blood Cell ID was not graded due to being educational samples. No documentation of self-evaluation. 2. During an interview on 09/29/2021 at 4:00 PM, General Supervisor #2 confirmed the above events were not graded by API and a self evaluation of the results were not performed.
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 a review of American Proficiency Institute (API) Proficiency Testing records and an interview with General Supervisor #2, the Laboratory failed to achieve satisfactory performance for Lactate (i-STAT) and for Monocytes (Sysmex XS-1000i) resulting in failure to verify accuracy at least twice annually for these analytes. This was noted from 2020 Chemistry - Core 3rd Event to 2021 Chemistry - Core 2nd Event (Lactate) and from 2020 Hematology 3rd Event to 2021 Hematology 1st Event (Monocytes) . The findings include: 1. A review of Proficiency Testing records revealed the following: a) 2020 Chemistry - Core 3rd Event - Lactate (i-STAT) scored 0%. b) 2021 Chemistry - Core 1st Event - Lactate (i-STAT) scored 0%. c) 2021 Chemistry - Core 2nd Event - Lactate (i-STAT) scored 0%. d) 2020 Hematology 3rd Event - Monocytes scored 60%. e) 2021 Hematology 1st Event - Monocytes scored 60%. 2. During an interview on 09/29/2021 at 4:00 PM, General Supervisor #2 confirmed the laboratory has failed the last three events for Lactate (i-STAT) due to not converting the units and has failed two out of three events for Monocytes.
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 calibration verification records for the i-STAT (blood gases, Chemistry 8+, and Troponin I), Procedure Manual for the i-STAT system, and an interview with General Supervisor #2, the laboratory failed to follow the manufacturer's requirements for calibration verification. This was noted on one out of five calibration verifications reviewed from 2019 - 2021. The findings include: 1. A review of calibration verification records for the i-STAT revealed the last calibration verification was performed 11-19-2020 for blood gases, Chemistry 8+ and Troponin I cartridges. The next calibration verification was due in May 2021. 2. A review of the Procedure Manual for the i-STAT system revealed on page 15 "...Calibration For blood gas and chemistry cartridges, a one-point calibration is automatically performed as part of the test cycle each time a cartridge is tested. A multi-point calibration curve, defined by coefficients in the CLEW software, are stable over many lots and are adjusted as needed with the CLEW updates scheduled two times a year..." 3. During an interview on 09/29/2021 at 4:40 PM, General Supervisor #2 confirmed the calibration verification had not been performed since 11/19/2020 and should be performed every 6 months.
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, IQCP (Individualized Quality Control Plan), and an interview with General Supervisor #2, the laboratory

	failed to ensure two levels of controls were run for C. diff (Clostridioides difficile) Quik Chek Complete at an interval not less than 7 days per the laboratory's IQCP. This was noted five times from January 2019 - September 2021. The findings include: 1. A review of the quality control/patient test records revealed the following: a) one patient was performed on 08/07/2019 and the last QC run was 07/15/2019 b) one patient was performed on 01/04/2020 and the last QC run was 12/03/2019 c) two patients were performed on 03/24/2021 and the last QC run was 02/19/2021 d) one patient was performed on 03/27/2021 and the last QC run was 02/19/2021 e) one patient was performed on 05/23/2021 and the last QC run was 05/03/2021. 2. A review of the IQCP revealed a positive and negative control should be performed upon opening kit and with specimen testing at an interval not less than 7 days or with next procedure if interval is greater than 7 days. 3. During an interview on 09/30/2021 at 2:45 PM, General Supervisor #2 confirmed the above findings.
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 a review of serum hCG (human chorionic gonadotropin) quality control (QC), Rapid Response hCG Pregnancy (Urine/Serum) Procedure, and an interview with General Supervisor #2, the laboratory failed to run QC at least once a day when testing patients. This was noted three times from January 2019 - July 2021. The findings include: 1. A review of serum hCG QC revealed the following: a) 11/11/2019 one patient was performed and no QC documented for this day. b) 05/06/2021 one patient was performed and no QC documented for this day. c) 07/05/2021 one patient was performed and no QC documented for this day. 2. A review of the Rapid Response hCG Pregnancy (Urine/Serum) Procedure revealed under External Quality Control "...Controls are to be run every 7 days or before the next patient..." No Individualized Quality Control Plan was available for serum hCG. 3. During an interview on 09/30/2021 at 2:45 PM, General Supervisor #2 confirmed QC is required to be done daily with patients but the procedure was not edited when this change took place.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of the personnel records and an interview with the General Supervisor #2, the Technical Supervisor failed to evaluate and document the performance of an individual at least semiannually during the first year of patient testing. This was noted on one of three new personnel records reviewed by the

	surveyor. The finding include: 1. A review of the personnel records revealed Testing personnel #6 semiannual evaluation was not performed. Testing Personnel #6 initial training was documented 10/19/2020 and no other competency assessments. 2. During an interview conducted on 09/29/2021 at 12:06 PM, the General Supervisor #2 confirmed that semiannual evaluation was not performed for Testing personnel #6.