

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0724352	(X3) Date Survey Completed 04/30/2025
Name of Provider or Supplier Hale County Hospital	Street Address, City, State 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) reports, and an interview with the Technical Consultant (TC), the laboratory failed to maintain successful PT participation for: 1) D-dimer and INR (International Normalized Ratio) for the following three consecutive events: a) D-dimer; 2022 Events #2 and #3, and 2023 Event #1. b) INR; 2024 Events #1 and #3, and 2025 Event #1. These failures result in a non-initial unsuccessful PT participation. 2) Urine Sediment, Potassium Hydroxide (KOH), and Prothrombin Time for the following two of three testing events: a) A) Urine Sediment; 2022 3rd event 2023 1st event. B) KOH; 2022 3rd event and 2023 2nd event. C) Prothrombin Time; 2024 3rd event and</p>

	<p>2025 1st event. These failures result in a initial unsuccessful PT participation. Refer to D 2130.</p>
D2130	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency test records and an interview with the Technical Consultant (TC), the laboratory failed to achieve satisfactory performance for Urine Sediment, Potassium Hydroxide (KOH), and Prothrombin Time for two of three testing events, and D-dimer and INR (International Normalized Ratio) for three of three testing events. This was noted for proficiency testing records reviewed in 2022 through 2025 for the specialty Hematology. The findings include: 1. A review of the API proficiency test results revealed unsuccessful performance for Urine Sediment, KOH, and Prothrombin Time for two consecutive testing events, as follows: A) Urine Sediment; Hematology 2022 3rd event 50% and 2023 1st event 0%. B) KOH; Hematology 2022 3rd event 50% and 2023 2nd event 50%. C) Prothrombin Time; Hematology 2024 3rd event 0% and 2025 1st event 0%. 2. A review of the API proficiency test results revealed unsuccessful performance for D-dimer and INR for three consecutive testing events, as follows: a) D-dimer; 2022 2nd event 0%, 2022 3rd event 50%, and 2023 1st event 0%. b) INR; 2024 1st event 60%, 2024 3rd event 0%, and 2025 1st event 0%. 2. During an interview on 4-29-2025 at 11:15 AM, the TC confirmed the above findings. .</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on a review of Abbott I-stat quality control (QC) records, Blood Bank QC records, Clostridioides difficile (C.diff) QC records, serum hCG (Human Chorionic Gonadotropin) QC records, and an interview with the Technical Consultant (TC), the laboratory failed to retain documentation of daily QC performed. This was noted for 2023 through 2025. The findings include: 1. A review of the QC records revealed no evidence of the following documentation: a) I-stat Chem 8, CG4, and cTnI QC records for February 2023. b) Blood Bank QC records for February 2023. c) C.diff QC records for January through December 2023 and January through March 2025. d) Serum hCG QC records for January through December 2023, January through December 2024, and January through March 2025. 2. During the exit interview on 4-30-2025 at 3:25 PM, the TC confirmed she could not locate the QC records for the above analyzers.</p>
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p>

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on a review of the API (American Proficiency Institute) proficiency testing (PT) records, corrective action document, and an interview with the Technical Consultant (TC), the laboratory failed to ensure PT results were submitted before the postmark due date. This was noted for three of fourteen events reviewed in 2024. The findings include: 1. A review of the API PT records revealed a score of 0% and "Failure to participate" on 2024 Chemistry Miscellaneous (Chem. Misc.) 1st event, Microbiology 3rd event, and Hematology 3rd event. 2. A further review of the corrective action documents for all 3 events revealed, "Results were not submitted in time by error of the lab manager." 3. During an interview on 4-29-2025 at 11:15 AM, the TC confirmed the above findings.

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 a review of the Chemistry maintenance records, Calibration Verification records, and Quality Control records, the laboratory failed to ensure: A) The Chemistry maintenance was performed and documented per the manufacturer's requirements (refer to D 5429). B) Calibration Verification was performed and documented per CLIA requirements (refer to D 5439). C) Quality Control was performed prior to patient testing (refer to D 5445). .

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

(a)(1) 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 a review of the Chemistry maintenance records and an interview with the Technical Consultant (TC), the Laboratory failed to perform and document weekly and monthly maintenance on the Siemens Dimension EXL 200 LM Chemistry analyzer as per the manufacturer's requirements. Weekly maintenance was noted for five months and monthly maintenance was noted for four months reviewed from 2023 to 2025. The findings include: 1. A review of the Dimension EXL 200 LM Chemistry

analyzer maintenance records revealed no documentation of weekly and monthly maintenance for the following dates: A) Weekly; February and September 2023, January and October 2024, and February 2025. B) Monthly; February and September 2023, January 2024, and February 2025. 2. During an interview on 4-29-2025, at 2:43 PM, the TC confirmed the above findings.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

(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 (C-V) records and an interview with the Technical Consultant (TC), the laboratory failed to ensure C-V was performed and documented on the Seimens Dimension EXL-200 Chemistry / Immunoassay analyzer, the Abbott i-stat back up Chemistry analyzer, and the Siemens DCA Vantage Microalbumin/ Creatinine (MALB/Creat) analyzer. This was noted for 2023 and 2024. The findings include: 1. A review of the C-V records revealed the following: a) Dimension EXL-200 Chemistry / Immunoassay analyzer electrolytes (Sodium, Potassium, and Chloride) were calibrated with two on-board calibrators. A C-V was performed on 6-21-2023 and nine months later on 3-20-2024. No C-V was performed the second half of 2023. b) I-stat analyzer had no C-V documentation for Arterial Blood Gas and Troponin I for 2023 and 2024. c) MALB/Creat analyzer had no C-V documentation for 2023 and 2024. 2. During the exit interview on 4-30-2025 at 3:35 PM, the TC confirmed the above findings.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

(d) 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. (d)(3) At least once each day patient specimens are assayed or examined

perform the following for:

This STANDARD is not met as evidenced by:

Based on a lack of an IQCP (Individualized Quality Control Plan) for serum Human Chorionic Gonadotropin (hCG), serum Ketone quality control records, and an interview with the Technical Consultant (TC), the surveyor determined the laboratory failed to establish an IQCP for serum hCG and follow the IQCP for serum Ketone prior to patient testing. This affected two of four tests, performed by the laboratory. The findings include: 1. Surveyor requested the IQCP and January 2023 through March 2025 quality control records for serum hCG. The TC could not locate the IQCP and quality control documentation. There was 1 patient ran in April 2024. 2. A review of the serum Ketone quality control records revealed patient results for the following dates with no evidence of quality control performed and documented: a) 9/29/2023; 1 patient performed. b) 6/15/2023; 1 patient performed. c) 5/30/2023; 1 patient performed. d) 5/17/2023; 1 patient performed. e) January and February 2025; 4 patients performed. 3. During the exit interview on 4-30-2025 at 3:35 PM, the TC confirmed the above findings.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:

Based on the lack of an IQCP (Individualized Quality Control Plan), and an interview with the Technical Consultant (TC), the surveyor determined the Laboratory Director failed to ensure an acceptable and complete IQCP was established and implemented, which included the three required parts: Risk Assessment (to include five components); Quality Control Plan; and Quality Assessment. This affected two tests, serum Human Chorionic Gonadotropin (hCG), of four tests, performed by the laboratory. The findings include: 1. Refer to D 5445.