

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0675182	(X3) Date Survey Completed 09/18/2024
Name of Provider or Supplier Seymour Hospital Laboratory	Street Address, City, State 200 Stadium Drive, Seymour, TX	
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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's verification records for the Siemens' Dimension EXL with LM analyzer, review of patient test records, and staff interview, the laboratory failed to have documentation of verifying 4 of 4 patient normal ranges established for 3 new assays. The findings included: 1. A review of the laboratory's verification records for the Siemens' Dimension EXL with LM analyzer identified 3 new assays were implemented in April 2023. They were: a) C-reactive protein b) Iron c) Total Iron Binding Capacity 2. A review of patient test records determined the following 4 patient normal ranges were in use for the new assays: a) C-reactive protein 0 - 3.0 mg/L b) Iron 65 - 175 ug/dL (Male) 50 - 170 ug/dL (Female) c) Total Iron Binding Capacity 250 - 450 ug/dL 3. The laboratory's verification studies did not have documentation of verifying the identified patient normal ranges. 4. General supervisor number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 09/17/2024 at 1015 hours in the conference room. Key mg/L - milligrams per liter ug/dL - micrograms per deciliter</p>

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 review of the laboratory's calibration verification records for the Siemens' EPOC Blood Analysis System from 2022, 2023 and 2024, and staff interview, the laboratory failed to have documentation of performing calibration verification every six months on 3 of 3 analytes. The findings included: 1. A review of the laboratory's calibration records for the Siemens' EPOC Blood Analysis System from 2022, 2023 and 2024 identified calibration verifications were performed on pH, PO2 and PCO2 on the following days: April 8, 2022 September 6, 2022 (5 months later) January 1, 2023 (4 months later) April 4, 2023 (3 months later) September 9, 2024 (19 months later) 2. Testing personnel number 5 (as listed on Form CMS 209) confirmed the findings in an interview on 09/17/2024 at 1130 hours in her office.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Siemens' Dimension EXL with LM Daily Maintenance logs from June 2024 to August 2024, and staff interview, it was revealed

the laboratory failed to have documentation of performing corrective actions 56 of 56 instances when the daily cuvette temperature was documented outside the manufacturer's required ranges on 56 of 91 test days. The findings include: 1. A review of the laboratory's Dimension Daily Maintenance logs from June 2024 to August 2024 revealed the manufacturer's required operating temperature range for the cuvettes was listed as 36.8 - 37.2 degrees Celsius. 2. Further review of the Daily Maintenance logs from June 2024 to August 2024 identified the following 56 days when the documented cuvette temperature was outside the manufacturer's required range: Date Temperature (degrees C) 6/20 37.3 6/21 37.3 6/22 37.4 6/23 37.3 6/25 37.4 6/26 37.4 6/27 37.4 6/28 37.3 6/29 37.3 6/30 37.3 7/1 37.3 7/3 37.3 7/4 37.3 7/5 37.3 7/6 37.4 7/7 37.3 7/8 37.3 7/9 37.3 7/10 37.3 7/11 37.3 7/12 37.3 7/13 37.3 7/14 37.3 7/25 37.3 7/26 37.3 7/27 37.3 7/30 37.3 7/31 37.3 8/1 37.3 8/2 37.3 8/3 37.3 8/4 37.4 8/5 37.4 8/6 37.3 8/7 37.3 8/8 37.3 8/9 37.3 8/10 37.3 8/11 37.3 8/12 37.4 8/13 37.3 8/14 37.3 8/15 37.3 8/16 37.3 8/17 37.3 8/18 37.3 8/19 37.3 8/20 37.3 8/21 37.3 8/22 37.3 8/24 37.3 8/25 37.4 8/26 37.4 8/27 37.4 8/28 37.4 8/29 37.3 3. General supervisor number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 09/17/2024 at 1330 hours in the conference room.

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 review of the Centers for Medicaid and Medicare services (CMS) 209 form, personnel records and confirmed in interview, the Technical Supervisor failed to provide documentation of initial competency performance for one of four high complexity testing people (TP-4) in 2023. Findings Included: 1. Review of CMS-209 form submitted at time of survey, 09/17/2024, revealed the laboratory employed four high complexity testing persons, performing immunohematology testing. 2. Review of personnel documentation, revealed General Supervisor 1 (GS-1) performed the initial immunohematology competency assessment of TP-4 on 03/20/2023. The surveyor requested documentation of the Technical Supervisor performing the initial competency assessment in 2023 of TP-4 on 09/17/2024 at 10:27 AM, and none was provided. 3. In an interview with GS-1 on 09/17/2024 at 10:28 AM, GS-1 confirmed the Technical Supervisor failed to provide documentation of initial competency performance for one of four high complexity testing people (TP-4) in 2023.

D6151

GENERAL SUPERVISOR RESPONSIBILITIES
 CFR(s): 493.1463(b)(3)(4)

(3) The director or technical supervisor may delegate to the general supervisor the responsibility for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel.

This STANDARD is not met as evidenced by:
 Based on review of the Centers for Medicaid and Medicare services (CMS) 209 form, personnel records and confirmed in interview, the General Supervisor (GS-1) failed to perform an annual competency assessment for one of four high complexity testing

people (TP-2) in 2023. Findings Included: 1. Review of CMS-209 form submitted at time of survey, 09/17/2024, revealed the laboratory employed four high complexity testing persons, performing immunochemistry testing. 2. Review of personnel documentation, revealed no documentation of annual competency performance of TP-2 in 2023. The surveyor requested documentation of the annual competency performance of the above testing person in 2023 on 09/17/2024 at 10:30 AM, and none was provided. 3. In an interview with the General Supervisor (GS-1) on 09/17/2024 at 10:28 AM, after review of documentation, GS-1 confirmed they failed to perform an annual competency assessment on one of four high complexity testing people (TP-2) in 2023.