

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0312039	(X3) Date Survey Completed 02/15/2023
Name of Provider or Supplier Scott County Community Hospital, Inc	Street Address, City, State 18797 Alberta St, Oneida, TN	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on request of the Laboratory's Calibration records for the Hematology analyzer, review of the Laboratory's calibration procedure and upon interview with the Laboratory Manager, determined the laboratory failed to follow the laboratory's policy to ensure that calibration was performed at six month intervals for 2021 and 2022. The findings include: 1. A request of Calibration records for the hematology analyzer (Advia 2120) revealed one calibration performed on 10.3.2022. No other calibration documented for 2021 and 2022, thus not being performed at 6 months intervals. 2. Laboratory's Hematology analyzer, Advia 2120 Calibration procedure states, "Technologist/technicians will follow the procedures below in accordance with regulatory requirements. Calibrate on an as needed basis and in each of the following cases: o at installation o when there is a significant shift in control values after replacing a critical hydraulic or optical component o when installing reagents with a different lot number o any time commercial control products and/or moving averages are out of range and you have verified that the out-of-control condition is not instrument related o every 6 months 3. An interview with the Laboratory Manager at approximately 2:00 p.m. on February 15, 2023 confirmed the laboratory failed to follow the laboratory's policy to ensure that calibration was performed at six month intervals for 2021 and 2022.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p>

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:

Citation #1 1. Based on observation of the laboratory thermometers, review of the laboratory's Thermometer Calibrations policy and upon interview with the Laboratory Manager, it was determined the laboratory failed to ensure accuracy of thermometers from January 26, 2023 through February 15, 2023. The findings include: 1. Observation at approximately 9:15 a.m. on February 15, 2023, of laboratory thermometers, revealed expired accuracy verification for the following 5 thermometers: a. Refrigerator #1 (VSR37644702), freezer thermometer (210062574)-expiration date of 1/26/23 b. Refrigerator #4 (115430201140416), freezer thermometer (210062582) -expiration date of 1/26/23 c. Refrigerator #4 (115430201140416), refrigerator thermometer (210062510)-expiration date of 1/26/23 d. Refrigerator #5 (2539639013), freezer thermometer (210062590) -expiration date of 1/26/23 e. Refrigerator #5 (2539639013), refrigerator thermometer (210062572) -expiration date of 1/26/23 2. Review of the laboratory's Thermometer Calibrations policy states, "Thermometers will be replaced upon expiration. If not replaced, then they will be calibrated annually or if there is any reason to suspect changed or damage." 3. An interview at approximately 2:00 p.m. on February 15, 2023 with the Laboratory Manager confirmed that thermometer accuracy verifications for 5 thermometers had not been performed from January 26, 2023 through February 15, 2023. Citation #2 2. Based on observation of the laboratory's hallway storage room, request of the laboratory's environmental logs, review of manufacturer's storage requirements listed on the Siemens Advia 2120i reagent bottles, and interview with the laboratory manager, determined the laboratory failed to document environmental conditions and ensure proper storage of Siemens Advia 2120i reagents for February 15, 2022 through February 15, 2023. The findings include: 1. Observation of the laboratory's hallway storage room revealed Siemens Advia 2120i Perox 1,2, & 3 reagents on shelves and no device for temperature monitoring. 2. Request for laboratory's hallway storage room environmental logs revealed none were present. 3. Review of the manufacturer's storage requirements listed on the Siemens Advia 2120i reagent bottles states, "store at 15-30 degrees Celsius." 4. An interview at approximately 2:00 p.m. on February 15, 2023 with the Laboratory Manager confirmed that the laboratory failed to ensure proper storage of Siemens Advia 2120i reagents for February 15, 2022 through February 15, 2023.

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 review of the laboratory's Individualized Quality Control Plan (IQCP) for iSTAT CG4+ systems in the Respiratory Therapy department, lack of external monthly quality control (QC) documentation and interview via email with the Respiratory Therapy Laboratory Manager, determined the laboratory failed to follow their IQCP for performing monthly external QC for the iSTAT CG4+ for July 10, 2022 to August 13, 2022 for 26 patients tested. The findings include: 1. Review of IQCP for iSTAT CG4+ systems in the Respiratory Therapy department states, "External quality control=Assay normal and abnormal quality control every 30 days, upon opening a new lot #, and new shipment." 2. Lack of external monthly QC documentation for the iSTAT CG4+ systems in the Respiratory Therapy department from July 10, 2022 to August 13, 2022 for 26 patients tested. 3. Interview via email on February 16, 2023 with the Respiratory Therapy Laboratory Manager confirmed the laboratory failed to follow their IQCP for performing monthly external QC for the iSTAT CG4+ for July 10, 2022 to August 13, 2022 for 26 patients tested.

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 observation of the Laboratory's two Triage Meters in use for performing Brain Natriuretic Peptide (BNPs), lack of documentation of twice a year comparison evaluation for 2022 and upon interview with the Laboratory Manager, it was determined the laboratory failed to perform and document twice a year evaluation between the two Triage Meters for performance of BNPs in 2022. The findings include: 1. Observation of the Laboratory's Alere Triage Meter (S#00079631) and Biosite Triage Meter (S#00055727) in use for performing Brain Natriuretic Peptide (BNPs) in the laboratory for patient testing. 2. Lack of documentation for twice a year comparison evaluations between the two instruments for 2022. 3. An interview at approximately 2:00 p.m. February 15, 2023 with the Laboratory Manager confirmed the laboratory failed to perform and document twice a year evaluation between the two Triage Meters for performance of BNPs in 2022.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for 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; (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 Testing Personnel (TP) listed on the Center for Medicare and Medicaid (CMS) Form 209, competency documentation and interview with the Laboratory Manager, determined the Supervisor failed to document training and competencies for 2022. The findings include: 1. One of six Testing Personnel (TP#3) listed on the CMS Form 209, lacked annual competency documentation for 2022. 2. Two of six Testing Personnel (TP#1 & TP#4) listed on the CMS Form 209, hired 6.27.2022 (TP#1) and hired 11.15.2022 (TP#4), lacked training and competency documentation upon hire. 3. An interview at approximately 2:00 p.m. on February 15, 2023 with the Laboratory Manager confirmed that 1 of 6 TP lacked annual competency documentation for 2022, 2 of 6 TP lacked training and competency upon hire dates of 6.27.2022 and 11.15.2022.