

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0312039	(X3) Date Survey Completed 07/25/2024
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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the manufacturer control package insert, and interview with the laboratory supervisor, the laboratory failed to label three of three control vials used for performing quality control on the Complete Blood Count (CBC) hematology analyzer with an open date and a revised expiration date on the date of the survey (07.22.2024). The findings include: 1. Observation of the laboratory on 07.22.2024, at 9:00 a.m., revealed the Sysmex XN-550 (serial number 27402) used for patient testing. Also observed were three levels of Sysmex XN-L check controls (L1: lot 41801401, L2: lot 41801402, and L3: lot 41801403) not labeled with an open date and revised expiration date. 2. A review of the manufacturer's control package insert revealed that the controls remained stable for 15 days after opening. 3. An interview with the laboratory supervisor on 07.22.2024 at 9:00 a.m. confirmed the above survey findings.</p>
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on a review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report (CLIA) (FORM CMS-209), testing personnel (TP) records, laboratory policy review, and staff interview, the technical supervisor failed to evaluate the semiannual competency for two of two (TP5 and TP6) new testing personnel who began patient testing in 2023. The findings include: 1. A review of the FORM CMS-209 revealed seven personnel (TP1 through TP7) who performed high-complexity patient testing. TP5 and TP6 were new testing personnel listed since the last laboratory survey. 2. A review of the laboratory's testing personnel records revealed no documentation of semiannual competency for TP5 and TP6 during the first year of testing in 2023. 3. A review of the section titled "Procedure" in the laboratory's New Laboratory Employee Orientation policy revealed the following statement: "Competency assessment will be completed at 6 months and 1 year of employees hire date." 4. An interview with the laboratory supervisor on 07.22.2024 at 11:20 a.m. confirmed the above survey findings.