Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0394413	11/19/2025
Name of Provider or Supplier	**Street Address, City, State**	
Oneida Community Health Center	525 Airport Dr, Oneida, WI	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory personnel records and policies, and interview with the Laboratory Director, the laboratory did not establish a policy for evaluating the competency of seven of seven personnel performing delegated responsibilities in the Clinical Laboratory Improvement Amendment (CLIA) named positions, clinical consultant (CC) and technical consultant (TC). Findings include: 1a. Review of the laboratory's personnel records revealed the Laboratory Director delegated responsibilities to six individuals in the TC position using the form, "2025 Assignment of Designee/Technical Consultant". The form did not include an assessment of competency for the six individuals. 1b. Review of the laboratory's personnel records revealed no evidence the Laboratory Director delegated responsibilities and evaluated competency of the individual in the CC position. 2. Review of the laboratory's policies revealed the laboratory had a policy for competency evaluation, "Laboratory Staffing and Competency", but there was no evidence the policy defined a process for competency evaluation of individuals in the CC and TC positions, including when competency is assessed after personnel are delegated to the CC and TC positions, and the frequency at which competency is assessed thereafter. 3. Interview with the Laboratory Director on November 19, 2025, at 9:40 AM confirmed the laboratory did not establish written policies that defined a process, including time and frequency, for evaluating the competency of personnel performing delegated responsibilities in the TC and CC positions.
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 surveyor review of calibration verification records and interview with the Laboratory Director, the laboratory did not perform calibration verification at least once every six months for one of three tests that require calibration verification since the laboratory transitioned all chemistry testing to the QuidelOrtho Vitros 5600 on September 20, 2023. Findings include: 1. Review of calibration verification records showed no evidence the laboratory performed calibration verification at least once every six months for the B12 test on the QuidelOrtho Vitros 5600 analyzer since the laboratory started using the analyzer to perform chemistry testing on September 20, 2023. 2. Interview with the Laboratory Director on November 19, 2025, at 1:15 PM confirmed the laboratory did not perform calibration verification for the B12 test at least once every six months since the laboratory started using the QuidelOrtho Vitros 5600 analyzer to perform chemistry testing on September 20, 2023.