

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0394413	<b>(X3) Date Survey Completed</b>  11/30/2021
<b>Name of Provider or Supplier</b>  Oneida Community Health Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5445</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Item 1: Based on surveyor review of the Individualized Quality Control Plan (IQCP), control and patient test records, and interview with a technical consultant, staff A, the laboratory did not meet their stated Quality Control (QC) requirements for testing external controls every thirty days for the Alere Human Immunodeficiency Virus (HIV) Ag/Ab analyte for two of eleven months in 2021. Findings include: 1. Review of the laboratory's IQCP for HIV Ag/Ab testing showed external QC is required every thirty days and with each new lot or shipment of test kits. 2. Review of QC records showed the laboratory performed QC testing on: a. June 3, 2021 and July 28, 2021, with thirty day QC due July 3, 2021. b. September 1, 2021 and October 26, 2021, with thirty day QC due October 1, 2021. 3. Review of patient test records showed the laboratory ran twenty patients between July 3, 2021 and July 27, 2021, with no QC run within thirty days prior to patient testing. Further review of patient test records showed the laboratory ran seventeen patients between October 1, 2021 and October 25, 2021, with no QC run within thirty days prior to patient testing. 4. Interview with staff A on November 30, 2021 at 11:55 AM confirmed the laboratory did not meet their QC requirements for Alere HIV Ag/AB testing for two of eleven months in 2021. Item 2: Based on surveyor review of the Individualized Quality</p>

Control Plan (IQCP), control and patient test records, and interview with a technical consultant, staff A, the laboratory did not meet their stated Quality Control (QC) requirements for testing external controls every thirty days for the Chlamydia /Gonorrhea polymerase chain reaction (PCR) test for two of eleven months in 2021. Findings include: 1. Review of the laboratory's IQCP for Chlamydia/Gonorrhea testing showed external QC is required every thirty days and with each new lot or shipment of test kits. 2. Review of QC records showed the laboratory performed QC testing on: a. March 10, 2021 and April 13, 2021, 2021, with thirty day QC due April 10, 2021. b. September 10, 2021 and October 25, 2021, with thirty day QC due October 10, 2021. 3. Review of patient test records showed the laboratory ran three patients between April 10, 2021 and April 12, 2021, with no QC run within thirty days prior to patient testing. Further review of patient test records showed the laboratory ran twenty-three patients between October 10, 2021 and October 24, 2021, with no QC run within thirty days prior to patient testing. 4. Interview with staff A on November 30, 2021 at 11:55 AM confirmed the laboratory did not meet their QC requirements for Chlamydia/Gonorrhea PCR testing for two of eleven months in 2021.