

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2182922	(X3) Date Survey Completed 09/22/2021
Name of Provider or Supplier Saint Louis County Public Health - North Central	Street Address, City, State 4000 Jennings Station Road Room, Saint Louis, MO	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) and interview with the general supervisor (GS) #1, the laboratory failed to maintain a copy of all PT records for 2020 and 2021. Findings: 1. Review of 2020 and 2021 PT testing showed no instrument print outs or manual documentation of PT results. 2. Interview with the GS #1 on September 22, 2021 at 10:30 AM confirmed the laboratory failed to maintain a copy of all records pertaining to PT.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p>

	<p>This STANDARD is not met as evidenced by: Based on review of procedures and interview with general supervisor (GS) #1, the laboratory failed to establish a written procedure to assess competency. 1. Review of procedures showed no procedure to assess competency. 2. Interview with GS #1 on September 22, 2021 at 10:30 AM confirmed the laboratory failed to establish a written procedure to assess competency.</p>
<p>D6086</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on review of Hologic Panther Fusion verification procedures and interview with the general supervisor (GS) #1, the laboratory director failed to ensure verification procedures used were adequate to determine the accuracy, precision, and other pertinent performance characteristics. Findings: 1. Review of Hologic Panther Fusion verification procedures showed no accuracy, precision, analytical sensitivity, analytical specificity to include interfering substances, reportable range and reference intervals (normal values) for SARS COVID 19. 2. Interview with GS #1 on September 22, 2021 at 10:30 AM confirmed the laboratory director failed to ensure verification procedures for the Hologic Panther Fusion was adequate for SARS COVID 19.</p>
<p>D6091</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2020 and 2021 proficiency testing (PT) and interview with the general supervisor (GSA) #1, the laboratory director failed to ensure all PT reports were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: 1. Review of 2020 PT showed PT event 3 gram stain reaction: 80 percent with no corrective action. 2. Review of 2021 PT showed PT event 1 gram stain reaction: 80 percent with no corrective action. 3. Review of 2021 PT showed PT event 2 gram stain reaction: 80 percent with no corrective action. 4. Interview with GS #1 on September 22, 2021 at 10:30 AM confirmed the laboratory director failed to ensure all PT reports were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p>