

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0449989	<b>(X3) Date Survey Completed</b>  04/27/2022
<b>Name of Provider or Supplier</b>  Sabetha Community Hospital	<b>Street Address, City, State</b>  603 South 14th Street, Sabetha, KS	
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>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) from the provider American Proficiency Institute (API) performed in 2021 and interview with Technical Consultant #1 (TC#1) revealed that the Laboratory Director (LD) or approved designee failed to attest on two events that proficiency testing samples were handled in the same manner as patient samples at time of survey. Findings: 1. Review of the attestation pages for PT from API revealed no signature of the LD or approved designee was present on API 2021 events: a. Immunology/Immunoematology 1st Event, the designee signature on attestation was not qualified per CFR 493.1449(q)(2)(i) b. Immunology /Immunoematology 3rd Event 2. Interview with the TC#1 on 4/27/2022 at 11:40 a. m. confirmed, the LD or approved designee failed to attest on two events that proficiency testing samples were handled in the same manner as patient samples at time of survey.</p>
<b>D6117</b>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4)</p> <p>The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.</p>

This STANDARD is not met as evidenced by:

Based on the review of immunohematology records from 1/3/22 to date of survey for the thermographic temperature chart recordings for blood unit storage and interview with Technical Consultant #1 (TC#1), the technical supervisor (TS) for immunohematology failed to evaluate the QC program, ensure analytical performance, and ensure storage of blood units were maintained at acceptable levels. Findings: 1. No documentation of review by the TS of immunohematology for QC and thermographic temperature chart recordings for blood unit storage, and emergency release requests were available for 1/3/22 to date of survey. 2. Review of the thermographic chart recordings was not performed by a TS qualified by CFR 493.1449(q)(2)(i). 3. Interview with TC#1 on 4/27/22 at 14:45 a.m. confirmed, the TS for immunohematology failed to evaluate the QC program, ensure analytical performance, and ensure storage of blood units were maintained at acceptable levels.