

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D1019096	(X3) Date Survey Completed 07/19/2022
Name of Provider or Supplier Kansas Spine & Specialty Hospital, Llc	Street Address, City, State 3333 N Webb Road, Wichita, KS	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on an absence of thermometer function check records or certificates of accuracy, protocols for thermometer function checks and interview with the general supervisor (GS), the laboratory failed to define and perform a function check protocol for six of seven thermometers. Findings: 1. No documentation was available for function checks on six of seven thermometers at the time of survey. 2. No documentation was available for the certification of accuracy (NIST traceable) on six of seven thermometers at the time of survey. 3. Protocols for the function checks of thermometers were not made available at the time of survey. 4. Interview with the GS on 7/19/22 at 11:45 a.m. confirmed, the laboratory failed to define and perform a function check protocol for six of seven thermometers.</p>
D6120	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8)</p>

Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on a review of competency assessment records, and interview, the technical supervisor failed to ensure that all six required elements for competency assessment were performed for four of four testing personnel (TP). Findings: 1. Competency assessments in 2021 and to date of survey 2022 for TP #1, 2,3, and 4 did not contain the following required elements: a. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; b. Monitoring the recording and reporting of test results; c. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records; d. Direct observation of performance of instrument maintenance and function checks; e. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and f. Assessment of problem solving skills. 2. All four TP have performed immunohematology testing. TP #4 retired in December 2020. No signature of the technical supervisor of immunohematology was present on the competency documents reviewed at survey. 3. Interview with the GS 7 /19/22 at 8:35 a.m. confirmed, the technical supervisor failed to ensure that all six required elements for competency assessment were performed for four of four testing personnel (TP).