

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0957688	(X3) Date Survey Completed 07/28/2021
Name of Provider or Supplier Kansas Heart Hospital	Street Address, City, State 3601 N Webb Rd, 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
D2009	<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 the review of proficiency testing (PT) records and interview, the laboratory failed to attest that proficiency testing samples were handled in the same manner as patient samples. Findings: 1. Review of PT records performed from 3/14/19 to date of survey from the provider American Proficiency Institute (API) revealed that 7 of 12 event attestation statements did not contain the signatures of the testing personnel for: a. 2019 Chem-Core 2nd Event, samples 1B06 - 1B10 b. 2019 Hemo/Coag 3rd Event, samples MED11 - MED15 c. 2020 Hemo/Coag 1st Event, samples MED01 - MED05 d. 2020 Chem-Core, 2nd Event, samples 1B06 - 1B10 e. 2020 Chem-Core, 3rd Event, samples 1B11 - 1B15 f. 2020 Hemo-Coag, 3rd Event, samples MED11-MED15 g. 2021 Hemo-Coag 1st Event, samples MED01-MED05 2. Interview with the General Supervisor #1 (GS#1) on 7/28/21 at 11:15 a.m. confirmed, the laboratory failed to attest that proficiency testing samples were handled in the same manner as patient samples.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p>

This STANDARD is not met as evidenced by:
 Based on the lack of procedures for review and interview revealed that the laboratory failed to have written, approved procedures for emergency release of blood products, preparation of fresh frozen plasma for transfusion, and preparation of cryoprecipitate for transfusion. Findings: 1. This facility was performing blood and blood product transfusions at the time of survey, and has contracted immunohematology testing with the American Red Cross (ARC). 2. Request to review procedures related to the transfusion of blood and blood products revealed a lack of procedures available for the following: a. Emergency Release of Blood/Blood Products b. Preparation of Fresh Frozen Plasma for Transfusion c. Preparation of Cryoprecipitate for Transfusion 3. The procedures for these processes provided at survey were documents for ARC personnel and did not contain directions for the site receiving the blood products. The documents were not identified as procedures for Kansas Heart Hospital and did not have the signature of the laboratory director. 4. Interview with GS#1 7/28/21 at 12:20 p.m confirmed, the laboratory failed to have written, approved procedures for emergency release of blood products, preparation of fresh frozen plasma for transfusion, and preparation of cryoprecipitate for transfusion.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
 CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
 Based on review of the laboratory's method verification documentation, non-waived test list, and interview, the laboratory failed to verify that the reference intervals (normal values) were appropriate for the laboratory's patient population prior to reporting patient test results. Findings: 1. Review of the method verification of the Ortho Vitros 7600, Serial # 7600416 revealed the laboratory performed an instrument verification in February 2020. The laboratory started reporting patient test results on 3 /10/2020. 2. The KS-CLIA-PS01, non-waived test list provided at the time of survey, listed 36 analytes as performed on the Ortho Vitros 7600. 3. No documentation for verification of the manufacturer's normal values were available for 36 of 36 analytes at the time of survey. 4. Interview with GS#1 on 7/28/21 2:10 p.m. confirmed, the laboratory failed to verify that the reference intervals (normal values) were appropriate for the laboratory's patient population prior to reporting patient test results.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) 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 upon a review of the laboratory's personnel competency assessment records and staff interview, the laboratory's technical consultant (TC) failed to perform the competency assessment of 26 of 64 moderate complexity testing personnel and failed to include all 6 required elements in 12 of 12 moderate complexity testing personnel.

Findings: 1. Review of competency assessment of 26 of 64 moderate complexity testing personnel revealed the assessment was performed by testing personnel who did not qualify as a technical consultant. 2. Review of the iSTAT competency revealed the competency failed to include assessment of test performance through previously analyzed, internal blind or external proficiency samples for 12 of 12 moderate complexity testing personnel. Only 1 of 12 competencies was signed by a technical consultant. 3. Interview with GS#1 7/28/21 at 10:15 a.m. confirmed, the laboratory's technical consultant (TC) failed to perform the competency assessment of 26 of 64 moderate complexity testing personnel and failed to include all 6 required elements in 12 of 12 moderate complexity testing personnel.