

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0047301	(X3) Date Survey Completed 09/23/2021
Name of Provider or Supplier Ambermed	Street Address, City, State 826 18th Street, Hoxie, 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 a review of proficiency testing (PT) from the provider American Proficiency Institute (API) performed 5/1/19 to 9/23/21 and interview with General Supervisor #1 (GS#1) revealed that the laboratory director (LD) or designee failed to attest on 6 of 30 events that proficiency testing samples were handled in the same manner as patient samples. Findings: 1. Review of the attestation page for PT from API revealed the LD or designee signature was not present on: a. API 2020 SARS Supplemental 3rd Event b. API 2021 Chemistry Miscellaneous 1st Event c. API 2021 Immunology /Immunohematology 1st Event d. API 2021 Microbiology 2nd Event e. API 2021 Hematology/Coagulation 2nd Event f. API 2021 Chemistry Core 2nd Event 2. Interview with GS #1 on 9/23/21 at 10:30 a.m. confirmed, the LD or designee failed to attest on 6 of 30 events that proficiency testing samples were handled in the same manner as patient samples.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of PT performance evaluation records from API and interview with</p>

technical supervisor #1 (TS#1), the laboratory failed to evaluate its proficiency testing results for 2 events from 4/30/19 to 9/23/21. Findings: 1. 2020 SARS-CoV2 2nd Event. a. All results scored acceptable. b. No evidence of evaluation was available at the time of survey. 2. 2021 Immunology/Immunohematology 1st Event a. All results scored acceptable. b. No evidence of evaluation was available at the time of survey. 3. Interview with TS#1 9/23/21 at 12:15 p.m. confirmed, the laboratory failed to evaluate its proficiency testing results for 2 events from 4/30/19 to 9/23/21.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:
Based on review of the laboratory's 2019, 2020, and 2021 to date of survey API PT documentation and interview with TS#1, the laboratory failed to verify the accuracy of hematology analytes that were assigned a ungraded proficiency testing score for one event from 4/30/19 to 9/23/21. Findings: 1. Review of the laboratory's 2019, 2020, and 2021 to date of survey API PT documentation for hematology analytes found the following ungraded results: 2019 Hematology/Coagulation 1st Event a. Blood Cell Identification samples: DIF-01, ECI-01, 02, 03, 04 and 05 b. Fecal Leukocytes sample FW-01 2. Review of the laboratory's API PT Performance Review and Corrective Action forms failed to find any documentation demonstrating a self-assessment or self-grade of the ungraded samples. 3. Interview with TS#1 on 9/23/21 at 12:15p.m. confirmed, the laboratory failed to verify the accuracy of hematology analytes that were assigned a ungraded proficiency testing score for one event from 4/30/19 to 9/23/21.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:
Based on the review of "Laboratory Quality Assurance Policies and Procedures" and interview with the clinical consultant, the laboratory failed to follow procedure and review Quality Control (QC) monthly by the Lab Director (LD) for three of three months. Findings: 1. Procedure states "The Laboratory Director (Director) reviews all quality control charts and logs on a monthly basis." 2. The QC charts and logs of June 2021, July 2021 and August 2021 were not reviewed by the LD monthly at the time of survey. 3. Interview with the clinical consultant and technical supervisor #2 on September 23, 2021 at 0930 confirmed the laboratory failed to follow procedure, the LD did not review QC and log charts monthly for three of three months..

<p>D5407</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of available documentation and confirmed during interview with the clinical consultant, the laboratory failed to have procedures approved, signed, and dated by the current laboratory director before use. Findings: 1. Upon review of the laboratory procedures, the current laboratory director did not approve, sign, and date the laboratory procedure for: "Authorization For Laboratory Testing Personnel" and "XS-1000i Competency Training New Hire" at time of survey. 2. Interview with the clinical consultant on September 23, 2021 at 9:30 a.m. confirmed, the laboratory failed to have procedures approved, signed, and dated by the current laboratory director before use.</p>
<p>D5553</p>	<p>IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f)</p> <p>(b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient transfusion records and interview with the technical supervisor (TS) #1 and Director of Nursing (DON), reveals that the laboratory and nursing staff failed to perform and document a visual inspection/appearance on 28 of 53 Packed Red Blood Cell (PRBC) units prior to issuance to patients for the last twelve months, September 2, 2020 through September 15, 2021. Findings: 1. Upon review of "Blood Administration Unit Signout Form", the self-check for the Registered Nurse (RN) and laboratory staff failed to document the "Visual appearance acceptable for bacterial contaminate or hemolysis" for 28 of 53 issued PRBC units. 2. The review of the patient transfusion records, the RN and laboratory staff failed to complete and document a visual inspection of PRBC units immediately before distribution for the last twelve months, September 2, 2020 through September 15, 2021, at the time of survey. 3. Interview with the TS#1 and the DON on September 23, 2021 at 12:15 p.m. confirmed, the RN staff and laboratory staff failed to perform visual inspection/appearance immediately prior to issuance on 28 of 53 PRBC units for the last twelve months, September 2, 2020 through September 15, 2021.</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>

This STANDARD is not met as evidenced by:

Based on review of 2019, 2020, and 2021 (to date of survey) PT performance evaluation records and interview with GS#1, the laboratory director failed to ensure all PT reports are reviewed by the appropriate staff to evaluate the laboratory's performance and identify any problems that require corrective action. Findings: 1. Review of 2020 Immunology/Immunohematology 3 rd Event PT Performance Review and Corrective Action form revealed that the laboratory received a "Not Graded" score for the Blood Bank (Antibody Screen/ID sample SER-11. The result is highlighted. 2. No evidence of evaluation or corrective action by the laboratory director or TS for immunohematology was found on the document for this event. 3. Interview with GS#1 on 9/23/21 at 10:30 a.m. confirmed, the laboratory director failed to ensure all PT reports are reviewed by the appropriate staff to evaluate the laboratory's performance and identify any problems that require corrective action.