

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0047301	(X3) Date Survey Completed 04/05/2018
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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>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).</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and confirmed by laboratory testing personnel #1 (refer to the Laboratory Personnel Report) at 9:00 am on 4/5/2018, the laboratory failed to perform a self-evaluation of ungraded PT scores for three out of six PT testing events in 2016-2017 (2016 events 1 and 3 and 2017 event 1). The findings include: 1. For 2016 testing event 1, the laboratory received ungraded PT test scores for the following: *Hematology / Coagulation Survey - APTT, specimen COA-04 and COA-05 2. For 2016 testing event 3, the laboratory received ungraded PT test scores for the following: *Hematology / Coagulation Survey - APTT, specimen COA-15 *Chemistry Group 2 - Free Thyroxine, specimen CH-13 *Chemistry Group 2 - Thyroid Stimulating Hormone, specimen CH-13 3. For 2017 testing event 1, the laboratory received ungraded PT test scores for the following: *Chemistry Core - Triglycerides, specimen CH-01 *Chemistry Core - Free Thyroxine, specimen CH-01</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p>

This STANDARD is not met as evidenced by:
Based on review of American Proficiency Institute (API) proficiency testing (PT) records and confirmed by laboratory testing personnel #1 (refer to the Laboratory Personnel Report) at approximately 10:00 am on 4/5/2018, the laboratory failed to ensure that evaluation of an unacceptable proficiency testing event was documented. The Findings include: 1. API 2016 Chemistry Group 2, 3rd Event - Gentamicin specimen CH-13 reported 0.5 acceptable range 0.7 - 1.3. No corrective action documentation was provided.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
Based on review of the operator's manuals, temperature and humidity logs, and confirmed by testing personnel #1 (refer to the Laboratory Personnel Report) at 11:00 on 4/5/2018, the laboratory failed to meet the manufacturer's humidity requirements for the Sysmex XS-1000i hematology analyzer and the Sysmex CA-600 coagulation analyzer for 135 out of 151 days from 11/1/2017 to 3/31/2018. The findings include: 1. Review of the Sysmex XS-1000i hematology manufacturer's operators guide defined the relative humidity requirement to be within the range of 30% - 85%. 2. Review of the Sysmex CA-600 coagulation manufacturer's operators guide defined the relative humidity requirement to be within the range of 30% - 85%. 3. Review of the temperature and humidity logs from 11/1/2017 to 3/31/2018 revealed 135 out of 151 days had humidity readings below the required 30%.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
A review of the Quality Control (QC) procedure and interview with staff revealed the laboratory failed to produce a policy concerning a failed QC concerning patient results Finding were as follows a. Interview with General Supervisor from the CMS 209 04 /05//2018 at 10:30 hrs. confirmed the laboratory failed to have the policy, (All patients test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected).

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

A review of Quality Assessment and Interview with staff revealed the laboratory failed to have a plan that covered all aspects of the laboratory. Finding were as follows: 1. Based upon the Quality Assessment Action plan the laboratory failed to establish a action plan for any QC failure. Therefore, the accuracy or reliability of the QC plan cannot be verified. This was confirmed in interview with General Supervisor on 04/05/2018 at 11;30 hrs.