

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0452541	(X3) Date Survey Completed 07/31/2018
Name of Provider or Supplier Osborne County Memorial Hospital	Street Address, City, State 237 West Harrison Street, Osborne, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Review of the Sysmex Ca600 Normal Patient Mean records for 2017 and 2018 and interview with General Supervisor #1 (laboratory personnel report CMS-209), the laboratory failed to retain the documentation of the normal patient mean assay sheets for the required two year period. Findings were: a.. At the time of the survey July 31, 2018 the laboratory failed to produce the documentation of the Normal Patient Mean studies for 2017 for the CA600 Coagulation analyzer , this was confirmed in interview with General Supervisor #1 July 31, 2016 at 10:00 hrs</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: A review of Coagulation Quality Control and reagents log .revealed the laboratory</p>

failed to log the the lot numbers of the current lot of reagent and Quality Control in use Findings were: a. The above findings were confirmed by interview with the general supervisor on 7/31/2018 at 13:50 hours in the laboratory.

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 07 /31//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).