

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0681749	<b>(X3) Date Survey Completed</b>  12/12/2018
<b>Name of Provider or Supplier</b>  Kansas Pathology Services, Llc	<b>Street Address, City, State</b>  1212 E 27th Street Unit B, Hays, KS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: A review of American Proficiency Institute (API) proficiency, Quality Control, Quality Assessment, and Interview with staff revealed the laboratory failed to verify the accuracy for the analyte Prostatic Specific Antigen (PSA) for the 2nd event of 2017 and 1st event 2018 . Finding were as follows: 1. Based upon a review of AP I 2nd event 2017 received a grade of 67% on PSA 1 st event 2018 received a grade of 67%. The laboratory failed to produce corrective action. This was confirmed in interview w ith Testing Personnel #1 :from CMS form 209 on 12/12/2018 at 10:00 hrs</p>
<b>D5783</b>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(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.</p> <p>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</p>

Finding were as follows 1. Interview with Testing Person #1 on 12/12/2018 at 10:40 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 Control (BioRad Multiquel 1,2,3) and Interview with staff revealed the laboratory failed to have a plan that covered all aspects of the laboratory in September 2018 Finding were as follows: a. Shifts and Trends for Chemistry analytes of BUN and Creatinine failed to be addressed. BUN and Creatinine were equal to or outside of 2 standard deviations for month of September of 2018 . b .The above was confirmed by the Testing Person #1 on 12/12/2018 at 1100am