

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D2094447	(X3) Date Survey Completed 09/13/2019
Name of Provider or Supplier Overland Park Regional Med Center Er Of Olathe	Street Address, City, State 13505 South Alden, Olathe, 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 the laboratory's College of American Pathologists' (CAP) proficiency testing (PT) documentation and interviews with technical Consultant (TC) #1 and #2 the laboratory failed to review and evaluate the results obtained on proficiency testing performed for analyte assigned a proficiency testing score that did 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). Findings Include: 1. Review of the laboratory's 2019 CAP PT documentation found CAP scored the following samples as "Educational challenge": a.FH9-B Auto Differentials, FH9 2019 Blood Cell ID (Educational) BCP-16-20 b. CGL-A and CGL-B 2019 activated APTT,Qual CG L01-05 and CGL-06-1 **. The samples were not graded and no self-assessment or self-evaluation was present** 2. TC #1 and #2 stated the laboratory did not have documentation of a self-assessment or self-evaluation for the CAP "Educational Challenges" samples listed above available for review. The interview occurred 09/13/2019 at 10:49 AM.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and</p>

identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of patient test reports and interview with the laboratory technical consultant (TC) #1 and #2, the laboratory failed to include the name and address of the laboratory performing the test. Findings: 1. Review of the selected patient test report for I-Stat analytes showed a lack of the name and address of the laboratory where the test was performed. 2. Interview with TC #1 and #2 on September 13, 2019 at 11:00 AM confirmed the laboratory failed to include name and address on the patient report.