

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0477910	<b>(X3) Date Survey Completed</b>  08/15/2018
<b>Name of Provider or Supplier</b>  Ridge Road Medical Center,Pa	<b>Street Address, City, State</b>  2306 Ridge Rd Suite 2, Rockwall, TX	
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>D2128</b>	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: . Based on review of API (American Proficiency Institute) proficiency testing (PT) documentation for 2016, 2017 and 2018, confirmed by staff interview, the laboratory failed to take and document remedial action for unsuccessful performance in hematology using the QBC Autoread analyzer. Findings: 1. API PT results for the 2nd event 2017 were reviewed. Scores for Hemoglobin (g/dL) showed the following: Sample Reported Expected Grade QBC-06 10.5 10.6-12.3 Unacceptable QBC-07 10.6 10.4-12.1 Acceptable QBC-08 12.6 9.0-10.5 Unacceptable QBC-09 6.9 6.6-7.7 Acceptable QBC-10 10.5 9.0-10.5 Acceptable Two unacceptable results out of five yielded an overall score of 60%. Documentation did not include remedial action for the unacceptable analyte result. In an interview at the site on 15 August 2018, testing person 1 confirmed that no such action had been taken. .</p>
<b>D5215</b>	<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</p>

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:

. Review of American Proficiency Institute (API) proficiency testing documents for 2016, 2017 and 2018, confirmed by staff interview, revealed the laboratory failed to verify the accuracy of hematology testing performed on the QBC hematology analyzer for which the proficiency testing program either (a) did not obtain sufficient participation (less than 10 submissions) or (b) was unable to reach a consensus using the results received from participating laboratories. Findings: 1. For API hematology testing events 2016 2nd and 3rd events and 2017 1st, 2nd and 3rd event, the samples for White Cell Count ( $\times 10^9/L$ ) were graded as follows: a. Insufficient participation 2016 2nd event: QBC-06 Not Graded QBC-07 Not Graded QBC-08 Not Graded QBC-09 Not Graded QBC-10 Not Graded 2017 2nd event QBC-06 Not Graded QBC-07 Not Graded QBC-08 Not Graded QBC-09 Not Graded QBC-10 Not Graded 2017 3rd event QBC-11 Not Graded QBC-12 Not Graded QBC-13 Not Graded QBC-14 Not Graded QBC-15 Not Graded 2. For the 1st event 2017, the samples for Hemoglobin (g/dL) were graded as follows: 2017 1st event QBC-01 Not Graded QBC-02 Not Graded QBC-03 Not Graded QBC-04 Not Graded QBC-05 Not Graded All "Not Graded" results were marked with the superscript 1, indicating less than 10 participants in the testing group. On the API participant summary sheet, artificial scores of 100% were recorded for all. No documentation of accuracy verification was included in the performance review signed by the laboratory director. In an interview at the site on 15 August 2018, testing person 1 stated that results were self-checked against the comparison group and that no other means of accuracy verification had been used. b. No consensus 1. For API hematology testing in the 3rd event 2016, 1st event 2017 and 1st event 2018, the samples for White Cell Count ( $\times 10^9/L$ ) were graded as follows: 2016 3rd event QBC-11 Not Graded QBC-12 Not Graded QBC-13 Not Graded QBC-14 Not Graded QBC-15 Not Graded 2017 1st event QBC-01 Not Graded QBC-02 Not Graded QBC-03 Not Graded QBC-04 Not Graded QBC-05 Not Graded 2018 1st event QBC-01 Not Graded QBC-02 Not Graded QBC-03 Not Graded QBC-04 Not Graded QBC-05 Not Graded 2. For the 2nd event 2016, 3rd event 2016, 1st event 2017, 2nd event 2017, 3rd event 2017 and 1st event 2018, samples for Platelet Count ( $\times 10^9/L$ ) were graded as follows: 2016 2nd event QBC-06 Acceptable QBC-07 Acceptable QBC-08 Not Graded QBC-09 Acceptable QBC-10 Not Graded 2016 3rd event QBC-11 Not Graded QBC-12 Acceptable QBC-13 Not Graded QBC-14 Acceptable QBC-15 Acceptable 2017 1st event QBC-01 Not Graded QBC-02 Acceptable QBC-03 Not Graded QBC-04 Acceptable QBC-05 Not Graded 2017 2nd event QBC-06 Not Graded QBC-07 Not Graded QBC-08 Not Graded QBC-09 Acceptable QBC-10 Acceptable 2017 3rd event QBC-11 Not Graded QBC-12 Not Graded QBC-13 Acceptable QBC-14 Acceptable QBC-15 Not Graded 2018 1st event QBC-01 Not Graded QBC-02 Acceptable QBC-03 Acceptable QBC-04 Not Graded QBC-05 Not Graded All "Not Graded" results were marked with the superscript 2, indicating no consensus among participants in the testing group. On the API participant summary sheet, artificial scores of 100% were recorded for White Blood Cell Count and Platelet Count. No documentation of accuracy verification was included in the performance review signed by the laboratory director. In an interview at the site on 15 August 2018, testing person 1 confirmed that no other means of accuracy verification had been used.