

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0874933	(X3) Date Survey Completed 01/24/2018
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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
D2010	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)</p> <p>The laboratory must test samples the same number of times that it routinely tests patient samples.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's AAB (American Academy of Bioanalysts) proficiency testing records from 2016 (events 1, 2, and 3) and 2017 (events 1, 2, and 3), and confirmed in interview of facility personnel, the laboratory failed to test proficiency testing samples the same number of times it tests patient samples. The findings were: 1. Review of the laboratory's, "List of Call Values," no laboratory director approval date, revealed the laboratory defined the following alert values: TEST LOW VALUE HIGH VALUE WBC 3.0 k/ul 18. k/ul HGB 10 g/dL 18 g/dL HCT 30% 54% PLT 120 k/uL 1000 k/uL 2. The "List of Call Values," also stated, "Hematology specimen should be run twice for any critical values not on range base of the values mention above." 3. Review of the laboratory's proficiency testing records from AAB 2016 (events 1, 2, and 3) and 2017 (events 1, 2, and 3) revealed the following critical values that were not repeated: 2017 (event 1) ID: Q1 2017 1 WBC = 1.7 HGB = 6.3 HCT = 16.5 PLT = 56 2017 (event 1) ID: Q1 2017 3 WBC = 20 2017 (event 1) ID: Q1 2017 4 WBC = 1.7 HGB = 6.2 HCT = 16.5 PLT = 59 2017 (event 1) ID: Q1 2017 5 WBC = 20.3 2017 (event 2) ID: Q2 2017 2 WBC = 1.8 HGB = 6.2 HCT = 16.5 PLT = 60 2017 (event 2) ID: Q2 2017 4 WBC = 1.8 HGB = 6.2 HCT = 16.6 PLT = 57 2017 (event 2) ID: Q2 2017 5 WBC = 21.7 HGB = 19.8 HCT = 55 2017 (event 3) ID: Q-3 2017 2 WBC = 2.0 HGB = 5.9 HCT = 16.8 PLT = 58 2017 (event 3) ID: Q-3 2017 3 WBC = 20.5 HGB = 19.0 HCT = 54.1 2017 (event 3) ID: Q-3 2017 4 WBC = 2.0 HGB = 5.9 HCT = 16.5 PLT = 54 2017 (event 3) ID: Q-3 2017 5 WBC = 20.5 HGB = 19.1 HCT = 54.0 2016 (event 1) ID: 1 Q1 WBC = 19.7 HGB = 18.1 2016 (event 1) ID: 3 Q1 WBC = 1.9 HGB = 6.2 PLT = 55 2016 (event 1) ID: 4 Q1 WBC = 1.8 HGB = 6.2 PLT = 59 2016 (event 2) ID: 2NDQ 1 WBC = 1.8</p>

HGB = 6.2 HCT = 16.7 PLT = 59 2016 (event 2) ID: Q2-16 3 WBC = 21.5 HGB = 19.5 HCT = 54.7 2016 (event 2) ID: Q1-16 5 WBC = 1.8 HGB = 6.1 PLT = 55 2016 (event 3) ID: Q3 #1 WBC = 1.9 HGB = 6.4 PLT = 57 2016 (event 3) ID: Q3 #3 WBC = 1.8 HGB = 6.5 PLT = 59 2016 (event 3) ID: Q3 #4 WBC = 20.7 HGB = 19.0 HCT = 54.2 2016 (event 3) ID: Q3 #5 WBC = 20.6 HGB = 19.2 HCT = 54.3 4. The laboratory was asked to provide documentation of testing proficiency testing samples the same number of times that it tests patients. No documentation was provided. 5. An interview with the office manager on 01/24/2018 at 1000 hours in the break room confirmed the findings. Key: WBC - white blood cell HGB - hemoglobin HCT - hematocrit PLT - platelet