

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1048996	(X3) Date Survey Completed 04/23/2018
Name of Provider or Supplier Your Doc's In	Street Address, City, State 8163 Ocean Gateway, Easton, MD	
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
D6049	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.</p> <p>This STANDARD is not met as evidenced by:</p> <p>I. Based on review of the temperature records and interview with the technical consultant, the technical consultant did not ensure that the testing personnel were documenting the correct temperature on the PM (evening) worksheets. Findings: 1. The PM temperature worksheets for 2017 and 2018 were reviewed. 2. The second column on the worksheet requires the testing person to document the "Lab Refrig PM (34-36F)." The temperatures documented for 2017 through March 2018 were documented as a single digit, e.g., 3, 4, 5 or 6 and were not within the defined reference range of 34-36. 3. The third column on the worksheet requires the testing person to document the "Lab Freezer PM (0 to -4F)." The temperatures documented for 2017 through March 2018 were documented as double digits, e.g., 17, 18, 19, 20, 21, 22 or 23 and were not within the defined reference range of 0 to 4. 4. During the survey on 04/23/17 at 11:30 AM the technical consultant confirmed that the testing personnel on the evening (PM) shift were not documenting the refrigerator and freezer temperatures using the required temperature reference ranges. II. Based on review of the temperature records and interview with the technical consultant, the technical consultant did not ensure that the testing personnel were documenting corrective actions when the temperature was not within the acceptable reference range on the PM (evening) temperature worksheets. Findings: 1. The PM temperature worksheet for December 2017 was reviewed. 2. The column labeled "Lab Freezer PM (0 to -4F)" showed that on 12/04/17 the temperature was documented as "-21(adjusted)." The temperature was not within the defined range of acceptability and the records did not identify if the -21 was the adjusted result or the result prior to the adjustment. 2. The</p>

column labeled "Lab Freezer PM (0 to -4F)" showed that on 12/04/17 the temperature was documented as "-24(adj)." The temperature was not within the defined range of acceptability and the records did not identify if the -24 was the adjusted result or the result prior to the adjustment. 3. During the survey on 04/23/17 at 11:30 AM the technical consultant confirmed that the testing personnel on the evening (PM) shift were not documenting corrective actions taken when adjusting the temperature of the laboratory freezer. III. Based on review of the temperature records and interview with the technical consultant, the technical consultant did not ensure that the testing personnel were documenting the temperature each day of testing on the PM (evening) temperature worksheets. Findings: 1. The PM temperature worksheet for December through August 2017 was reviewed. The laboratory is open 7 days a week. 2. The PM worksheet was missing recorded refrigerator and freezer temperatures 2 of 30 days for December 2017; 4 of 30 days for November; 4 of 31 days for October 2017; 4 of 30 days for September 2017; and 3 of 31 days for August 2017. 3. During the survey on 04/23/17 at 11:30 AM the technical consultant confirmed that the testing personnel on the evening (PM) shift were not documenting refrigerator and freezer temperatures each day of testing.

D6072

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:
Based on review of the calibration records and interview with the technical consultant, the testing personnel did not follow the laboratory's procedures when documenting calibration activities. Findings: 1. According to the procedure manual the testing personnel are required to initial laboratory work performed. 2. The calibration records for the hematology analyzer were reviewed for 2016 and 2017. The calibration worksheets did not include the identity of the person who performed the calibration. 3. During the survey on 04/23/18 at 11:30 AM the technical consultant confirmed that the testing person was not initialing the calibration records.