

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0023780	<b>(X3) Date Survey Completed</b>  11/28/2018
<b>Name of Provider or Supplier</b>  Melbourne Medical Laboratory	<b>Street Address, City, State</b>  95 Bulldog Blvd Ste 103, Melbourne, FL	
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>D2123</b>	<p>HEMATOLOGY CFR(s): 493.851(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to participate in proficiency testing (PT) that resulted in a score of zero (0)% or the Hematology /Coagulation testing third event in 2017. Findings: Review of the American Proficiency Institute (API) records for 2018 Hematology/Coagulation 3rd Event showed the laboratory received a score of 0% for all analytes to be tested. Notes on the API "Performance Summary" sheet stated "Failure to Participate". During an interview on 11/26/18 at 3:25 PM, Testing Personnel A acknowledged that he failed to get the test results submitted on time.</p>
<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>

This STANDARD is not met as evidenced by:  
 Based on record review and interview, the laboratory failed to verify the accuracy at least twice annually of parathyroid, opiates, total iron-binding capacity (TIBC), low-density lipoprotein cholesterol (LDL), direct bilirubin and urine sediment in 2017, and phosphate in 2018 Findings: The laboratory is enrolled in proficiency testing (PT) with American Proficiency Institute (API). API provides PT samples for analytes in Chemistry - Miscellaneous two times a year, and for analytes in Chemistry - Core and Hematolog/Coagulation three times a year. Review of the laboratory's API PT records showed that the laboratory failed to verify the accuracy by obtain two successful scores of at least 80% or above annually for the following results. 2017 Chemistry - Miscellaneous 1st Event - Parathyroid 67% 2nd Event - Parathyroid 67% 2017 Chemistry - Miscellaneous 1st Event - Opiates 100% 2nd Event - Opiates 67% 2017 Chemistry - Core 1st Event - TIBC 100% 2nd Event - TIBC 0% 3rd Event - TIBC 0% 2017 Chemistry - Core 1st Event - LDL Cholesterol 20% 2nd Event - LDL Cholesterol 100% 3rd Event - LDL Cholesterol 0% 2017 Chemistry - Core 1st Event - Bilirubin, Direct 100% 2nd Event - Bilirubin, Direct 40% 3rd Event - Bilirubin, Direct 0% 2017 Hematology / Coagulation 1st Event - Urine Sediment 100% 2nd Event - Urine Sediment 50% 3rd Event - Urine Sediment 0% 2018 Chemistry - Core 1st Event - Phosphate 40% 2nd Event - Phosphate 20% During an interview on 11/27/18 at 3:20 PM, Testing Personnel A acknowledged that they had some unsuccessful PT results.

**D5439**

**CALIBRATION AND CALIBRATION VERIFICATION**  
 CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:  
 Based on record review and interview, the laboratory failed to perform and document calibration on the Horiba Medical ABX Pentra XL800 hematology analyzer at least twice a year in 2017. Findings: Review of calibration records on the ABX Pentra XL800 showed that calibration was performed only once in 2017 on 4/25/17. During an interview on 11/28/18 at 11 AM, Testing Personnel A acknowledged that the calibration was performed only once in 2017.