

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 22D0949481	<b>(X3) Date Survey Completed</b> 08/22/2018
<b>Name of Provider or Supplier</b> Jose A Monteiro Md, Pc	<b>Street Address, City, State</b> 211 Milliken Blvd, Fall River, MA	
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>D0000</b>	A CLIA recertification survey was conducted for the Jose A Monteiro, MD PC laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
<b>D5421</b>	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer of a new test system before reporting patient test results as evidenced by the following: The laboratory began D-dimer patient testing using the Alere Triage MeterPro analyzer on 1/18/17. Record review revealed that the laboratory did not perform validation studies prior to patient testing. The technical consultant confirmed through interview at 10:30AM that the laboratory did not demonstrate the Alere Triage MeterPro can obtain performance specifications comparable to those established by the manufacturer for D-dimer testing prior to reporting patient test results. The laboratory performs 66 D-dimer tests annually.</p>