

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0666786	(X3) Date Survey Completed 03/12/2019
Name of Provider or Supplier Regional Medical Center	Street Address, City, State 709 West Main Street, Manchester, IA	
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
D5421	<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 review of Abbott ci4100 chemistry analyzer performance specification records and confirmed by laboratory personnel identifier #10 (refer to Laboratory Personnel Report) at approximately 1:40 pm on 03/12/2019, the laboratory failed to perform and verify the performance specification of reportable range for the analyte, procalcitonin. The findings include: 1. The laboratory started performing patient testing for the analyte, procalcitonin, in September of 2017. 2. At the time of the survey, the laboratory did not have documentation verifying the reportable range for this analyte.</p>
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p>

This STANDARD is not met as evidenced by:

Based on observations made during the survey and interview with laboratory personnel identifier #10 (refer to Laboratory Personnel Report) at approximately 10:00 am on 03/12/2019, the laboratory failed to perform comparisons between the Bactec FX40 and Bactec 9050 blood culture analyzers twice annually for four out of four semiannual time periods (March 2017 - March 2019). The findings include: 1. A tour of the laboratory indicated that the laboratory performed blood cultures using both the Bactec FX40 and the Bactec 9050 analyzers. 2. Laboratory personnel identifier #10 confirmed that the laboratory performed the majority of blood cultures on the Bactec FX40, but used the Bactec 9050 as a backup analyzer. 2. At the time of the survey, the laboratory did not have documentation of comparisons performed between the Bactec FX40 and Bactec 9050 analyzers.