

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0384022	(X3) Date Survey Completed 02/27/2019
Name of Provider or Supplier Iowa Specialty Hospital Belmond	Street Address, City, State 403 First Street Southeast, Belmond, 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 Architect c4000 and Abbott Architect i1000SR performance specification records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 1:30 pm on 02/27/2019, the laboratory failed to perform the performance specification of reportable range for three out of three new analytes (lactic acid, procalcitonin, and total testosterone) added from 2017-2018. The findings include: 1. The laboratory began performing patient testing on the Abbott Architect c4000 test system for the analyte, lactic acid, in November 2017. 2. The laboratory began performing patient testing on the Abbott Architect i1000sr test system for the analyte, procalcitonin, in November 2017. 3. The laboratory began performing patient testing on the Abbott Architect i1000sr test system for the analyte, total testosterone, in May 2018. 4. For the analytes, lactic acid, procalcitonin and total testosterone, the laboratory performed and documented the performance specifications of accuracy, precision and verification of the reference intervals. 5. At the time of the survey, personnel identifier #2 confirmed that the laboratory did not perform and document the performance specification of reportable range for the analytes, lactic acid, procalcitonin and total testosterone.</p>