

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0976698	(X3) Date Survey Completed 03/20/2018
Name of Provider or Supplier David S Becker Md, Pc	Street Address, City, State 205 East 69th Street, New York, NY	
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
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of humidity records and an interview with the office manager, the laboratory failed to follow the manufacturer's instructions for the Avantik cryostat to monitor and document the room humidity where testing is performed. Findings Include: It was confirmed by the office manager on March 20, 2018, approximately 12:00 PM that the Moh's technologist failed to follow the manufacturer's, written criteria to monitor and document the humidity of the room where Moh's testing is performed from July 2017 through the date of this survey.</p>
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>

This STANDARD is not met as evidenced by:
Based on a lack of records and an interview with the office manager, the laboratory obtained and began testing on the new Avantik cryostat instrument in July 2017 and failed to validate the instrument prior to patient testing.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's records and an interview with the office manager, the laboratory director failed to ensure that the laboratory follow the manufacturer's instruction to monitor and document the humidity of the room where Moh's testing is performed and the laboratory perform validation for the new cryostat instrument prior to patient testing. Refer to D5413 and D5421