

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0139025	(X3) Date Survey Completed 03/01/2018
Name of Provider or Supplier Ruth K Treiber Md	Street Address, City, State 175 Purchase St, Rye, 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
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 a lack of records and an interview with the Moh's processor, the laboratory obtained and began testing on the new Avantik cryostat instrument in November 2017 and failed to validate the instrument prior to patient testing.</p>
D6094	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, surveyor's observation, and an interview and confirmed by the Moh's processor on March 1, 2018 at approximately 1:15 PM, the laboratory director failed to ensure that the QA program for histology pathology testing was maintained to ensure quality laboratory services. Refer to: D5421</p>