

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0875486	(X3) Date Survey Completed 11/17/2021
Name of Provider or Supplier Barry M Schwartz Md Pc	Street Address, City, State 23 East 79th 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the manufacturer's packet inserts for the Siemens Multistix and interview with the laboratory director/testing person, the laboratory failed to follow the manufacturer's requirements for performing external positive and negative controls with each new vial opened for the Siemens urine Multistix 10SG FINDINGS: 1. The laboratory director confirmed on Nov. 17, 2021, at approximately 11:00 AM, that the surveyors findings that the laboratory failed to follow the manufactures Quality Control (QC) requirements for external controls. 2. The packet insert for the Siemens Multistix requires that external controls be performed with each new Vial of Multistix opened. a. QC was not performed on 2 vials of reagent strips, lot #103603, expiration date 9/30/22 3. The laboratory did not perform QC from January 1, 2021 through survey date. 4. Approximately 250 patient's specimens were tested and reported for urinalysis during the above time frame.</p>
D5637	<p>CYTOLOGY CFR(s): 493.1274(d)(1)(ii)</p> <p>(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor's review of the laboratory's cytology procedure manual, daily cytology workload list and an interview with the laboratory director/pathologist, the laboratory director acting as the technical supervisor failed to follow established workload limit assessment procedures. Refer to D5645 FINDINGS: The pathologists confirmed on November 17, 2021 at 10 AM, the surveyor's findings that the workload list for calendar years 2019, 2020 and 2021 through survey date the laboratory pathologist, acting as the technical supervisor, failed to perform and document the six-month reassessment for the workload list for above calendar years.

D5645

CYTOLOGY
CFR(s): 493.1274(d)(3)

(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory.

This STANDARD is not met as evidenced by:
Based on surveyor's review of the Cytology procedure manual and current workload records and an interview the pathologist/laboratory director, the pathologist failed to follow the established workload procedure. FINDINGS: 1. The pathologist/laboratory director confirmed on November 17, 2021 at approximately 10:00 AM, the surveyor's findings that the pathologist, the primary reader, failed to follow the established workload procedure for the calendar years 2019, 2020 and 2021 through survey date a. Surveyor reviewed the form titled, "Daily Cytology Workload" for the calendar years 2019, 2020 and 2021 through survey date and found that the pathologist name, and the location of the laboratory were not incorporated in the form. 2. Surveyor could not determine if the Daily Cytology Workload forms for the above calendar years were for this location.