

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0154059	(X3) Date Survey Completed 01/07/2020
Name of Provider or Supplier Shapiro, Goldman & Tawil Md Pc	Street Address, City, State 130 Brighton Beach Avenue, 3rd Floor, Brooklyn, 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 quality control (QC) records, manufacturer's packet inserts for Alere Triage Metro-pro analyzer, Henry Schein True Metrix Pro Glucometer, urine Quantimetrix Dropper controls and an interview with the testing person, the laboratory failed to follow the manufacturer's requirements for external controls from 1/01/2018 through survey date. FINDINGS: 1. The testing person confirmed on January 7, 2020 at approximately 2:00 PM that the laboratory failed to follow the manufacturer's packet insert for the B-type Natriuretic Peptide (BNP) test cassettes performed on the Alere Triage Metro-pro analyzer. This instrument requires external controls be performed with each new lot and/or shipment and/or every 30 days. a. the laboratory failed to perform the required external control from 01/01/2018 through survey date. b. approximately 427 patient samples were tested and reported during this time period. 2. The packet insert for the Henry Schein True Metrix Pro Glucometer requires that external controls be performed with each new lot and/or vial of glucose test strips. a. the laboratory failed to perform the required external control from 01/01/2018 through survey date. b. approximately 6 patient samples were tested and reported during this time period. 3. The laboratory did not retain the QC records for the Quantimetrix urine external controls from 01/01/2018 through 12/23/2019. Approximately 2,154 patient samples were tested and reported during this time period.</p>
D5441	CONTROL PROCEDURES

CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a surveyor's review of Hemochron Jr. Signature manufacturer's control requirements, QC records and an interview with the testing person, the laboratory failed to follow the laboratory's established QC procedure and manufacturer's requirements for the Hemochron Jr. Signature device from 1/01/2018 through survey date. FINDINGS: 1. The testing person confirmed on January 7, 2020 at approximately 2:30 PM, that the laboratory failed to perform Liquid Quality Control (LQC) as required by the manufacturer of the Hemochron Jr. Signature device from 1/1/2018 through survey date. 2. The laboratory performs Prothrombin time (PT), International Normalised Ratio (INR) and Partial Thrombin Time (APPT) on the Hemochron Jr. Signature device. 3. Approximately 412 patients were tested and reported for PT/INR and 153 patients were tested and reported for APPT during the time period.