

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0962396	(X3) Date Survey Completed 11/08/2018
Name of Provider or Supplier Medicine Of Tomorrow Pc	Street Address, City, State 7 West 45th Street, Suite 301, 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 the laboratory's lack of records for waived testing and an interview with the office manager, the laboratory failed to have records available for urinalysis specimens tested on the Clinitek Status using Siemen's Multistix. Findings: The office manager confirmed at approximately 12:00 PM on the date of survey that there were no available procedures, tracking or quality control for the waived urinalysis tests performed in the laboratory. Approximately 500 patient samples were tested during the last year. The missing information includes Analyzer procedure, Multistix package inserts, Multistix lot numbers and quality control records.</p>
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's observation and interviewed staff confirmed that the refrigerator located in the office break room/kitchen is used to store instrument reagents and</p>

patient's specimens. Findings: The testing person verified at 11:30am on the day of survey that the specimen/reagent storage refrigerator was placed in the break room /lunch room the day before survey.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on review of TOSOH AIA-900 Immunoassay Analyzer calibration and calibration verification records, the laboratory failed to perform calibration verification for PSA and Ferritin in August 2018 as required. Findings: 1. It was confirmed at 11:00AM on the date of survey by the laboratory testing person that when the instrument was being reverified, the laboratory failed to perform calibration verification for PSA and Ferritin. 2. Calibration Verification is required because PSA and Ferritin only have two calibrators. 3. Approximately 10 patient specimens were tested during this time period.