

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0142626	(X3) Date Survey Completed 01/02/2018
Name of Provider or Supplier Paul Maller Md	Street Address, City, State 22 South Tyson Ave, Floral Park, 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
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of Quality Control (QC) records and an interview with the laboratory director and the laboratory supervisor/testing person, the laboratory failed to program the manufacturer expected ranges, as defined on the QC assay sheets, into the TOSOH AIA 360 analyzer for Endocrinology testing from 11/1/16 through the survey date. FINDINGS: A) On 1/2/2018 at approximately 11:00 AM, the laboratory director and the laboratory supervisor/testing person confirmed the surveyor's review of QC records finding that the laboratory failed to program the established QC ranges and expected means into the TOSOH AIA 360 analyzer for the Endocrinology tests performed. B) Without the established QC limits, the surveyor could not determine if the quality control results were within the acceptable ranges for the Endocrinology analytes tested on the TOSOH AIA 360 analyzer. C) Approximately 200 patients' specimens were tested and reported for Endocrinology during this time period.</p>

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on a surveyor's review of patients reports and confirmed in an interview with the laboratory director and the laboratory supervisor/testing person at 11:00 AM on 1/2 /18, five of five patient hematology test reports failed to include the name and the address of the laboratory where test was performed.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on a surveyor's review of laboratory's Proficiency Testing (PT) records and interview with the laboratory supervisor/testing person and the laboratory director, the laboratory failed to enroll in Proficiency Testing (PT) for chemistry for the first event in 2017. FINDINGS: The laboratory supervisor/TP and the laboratory director confirmed on 1/2/2018 at approximately 11:00 AM that the laboratory failed to enroll in PT for the specialty of chemistry for the first event in 2017.