

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0988305	(X3) Date Survey Completed 03/28/2019
Name of Provider or Supplier Marina Diagnostic Lab Llp	Street Address, City, State 1616 Voorhies Avenue, Suite A, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of TOSOH AIA-900 instrument tapes and an interview with the testing person the laboratory had no compilation of quality control (qc) records enabling the surveyor to review qc records for more than a single day. Findings: It was confirmed by the testing person at 11:30 AM on 3/28/19 that the only way to review qc for all chemistry and endocrinology and immunology tests run on the TOSOH -900 analyzer was by going through the rolled printouts on the TOSOH analyzer. 1. The laboratory had no system to track and record qc results over time to look for shifts and trends and to ensure results were within acceptable ranges. 2. Lot numbers for QC material were also unable to be matched with the package insert acceptable values.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of American Proficiency Institute (API), College of American Pathologists (CAP) and Center for Medicaid and Medicare Services (CMS) Proficiency Testing (PT) reports, and an interview with the testing person at 3:30PM</p>

on 3/28/19, the laboratory failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the following analytes: 2017 second event Total Calcium = 80% Free T4 = 80% WBC Differential + 93% 2017 third event: TSH = 80% WBC Differential + 93% 2018 first event: Total Calcium = 80% Total Iron = 80% 2018 third event: WBC Differential = 87%

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on surveyor review of the laboratory's procedure manual and the maintenance records for the laboratory's instruments and interview with the testing person, the laboratory failed to establish a procedure that allows for a reduction of certain maintenance requirements for their analyzers based on their limited use. Findings: 1. During the review of maintenance sheets on the Pentra 400 Chemistry analyzer and the TOSOH Immunoassay analyzer and confirmed in an interview with the testing person at approximately 3:00 PM on March 28, 2019, the laboratory had spread out the weekly and monthly requirements based on the limited use of the analyzers which was limited to once or twice a week. 2. The laboratory had no procedure allowing for a reduction of the maintenance schedule.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

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.

This STANDARD is not met as evidenced by:

Based on surveyor's review of the laboratory's Quality Control (QC) records for hematology, chemistry, endocrinology and general immunology and confirmed in an interview with the supervisor/testing person, the laboratory failed to perform a lot to lot comparison of assayed QC materials. Findings: 1. The supervisor/testing person confirmed at 3:30 PM on 3/28/18 that the laboratory does not test new lots of control

against the current lot before using the new lot as primary QC. 2. This was noted for the Horiba controls used for general immunology, chemistry, endocrinology and hematology.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on surveyor's review of the laboratory records and an interview with the laboratory testing person, the laboratory director failed to ensure that the QC program for endocrinology testing was maintained to assure quality of laboratory services.

Refer to: D3031, D5433 and D5469.