

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 33D0153364	<b>(X3) Date Survey Completed</b> 04/27/2022
<b>Name of Provider or Supplier</b> O Goussis, Md Pc	<b>Street Address, City, State</b> 2200 Northern Blvd, Suite 209, Greenvale, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2104</b>	<p>ENDOCRINOLOGY CFR(s): 493.843(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of API PT summary reports, the laboratory failed to participate successfully in proficiency testing for the test analytes Estradiol, Parathyroid Hormone, FSH, and BNP. Finding: Following scores were assigned: 2021 first event = 50% 2022 first event = 50%</p>
<b>D5211</b>	<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 review of the American Proficiency Institute (API) Proficiency Testing (PT) summary reports and an interview with the technical consultant, the laboratory failed to review and evaluate the obtained PT results. FINDINGS: 1. 2021 second and third event summary report were not signed by the laboratory director. 2. Confirmed on an interview technical consultant on 4/22/2022 2:00pm</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p>

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on review of the QC and calibration records for the test analytes Testosterone, BNP, Vitamin D and controls for the Allergen testing and interview with the technical consultant, the laboratory performed QC and calibrations using expired materials.

FINDINGS: 1. Testosterone Level Low, Med, High a. Lot#902930489 Exp 12/14 /2020 used on 12/23/2020 and 1/21/2021. b. Lot#902936830 Exp 12/1/21 used on 12/2 /21. c. Lot#902936838 Exp 10/10/21 used on 10/13/21. d. Approximately 20 patients were tested at above dates. 2. Testosterone Calibrator Lot#902931804 Exp 4/30/21 used on 5/19/21 3. BNP Level 1,2,3 Lot# 44K08421 Exp 11/1/2021 used on 11/11 /2021 and 1/19/2022. Approximately 20 patients were tested at above dates. 4. Immuno MCC Level 1,2,3 Lot#32908190 Exp 11/30/202 used on 12/1/21, 12/22/21, 1 /19/22. Approximately 10 patients were tested at above date. Approximately 10 patients were tested at above dates. 5. Vitamin D calibrator Lot#18328U100 Exp 9/20 /21 used on 10/13/2021. 6. Confirmed on an interview with technical consultant on 4 /27/22 about 1:00pm

**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 review of the laboratory's QC policy and QC records for calendar year 2020 through survey date and an interview with the technical consultant, the laboratory failed to establish and follow a QC procedure to include the number, type, frequency controls are performed and the criteria for acceptability. FINDINGS 1. The December 2021 QC records for Vitamin 12 that the testing person accepted 2 out of 3 levels of controls as an acceptable criterion for QC prior to testing patient specimen. 2. The laboratory failed to establish the criteria for QC acceptability. 3. Technical consultant confirmed on an interview on 4/27/2022 about 1:30pm.

**D5783**

**CORRECTIVE ACTIONS**

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must

be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of the Vitamin B12 control records and an interview with the technical consultant, the laboratory failed to perform an evaluation of patient test results to ensure that the results were accurate when the controls were out of range. Finding: Vitamin B12 a. 12/30/21 Level 1 in, level 2&3 out of range, no remedial action b. 12/21/21 Level 1 not performed, level 2 out of range, level 3 in, no remedial action. c. Approximately 20 patient samples were tested and reported for Vitamin B12 on 12/30/21 and 12/31/21 d. Technical consultant confirmed on an interview on 4/27/2022 about 1:00pm.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the Endocrinology QC records, API PT summary reports and Allos Allergen reports and an interview with the technical consultant the laboratory director failed to provide overall management for all phases of laboratory testing. The laboratory director failed to ensure: 1. That the API PT summary reports were reviewed, refer to D6018. 2. That the corrective action was performed for the unsatisfactory PT challenges, Refer to D6019. 3. That the QC program was maintained, refer to D6042. 4. That corrective action was taken and documented, refer to D6044.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on the review of PT summary reports and an interview with the technical supervisor, the laboratory director failed to review the scored proficiency testing reports received from API and Allos reference laboratory to evaluate the laboratory's performance. Refer to D5211, D2104

**D6019**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(4)(iv)

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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on the review of API PT summary reports of Eastern Allergen twice a year verification by the Allos program by Hitachi, the laboratory director failed to perform corrective action for the unacceptable and unsatisfactory scores as follows: The following scores were assigned: Estradiol, Parathyroid Hormone 2021 first event =50% FSH, BNP 2022 first event = 50% Eastern Allergy: Laboratory vs Allos Hitachi Peer Review 2019 second event= 89% 2019 third event= 99%

**D6042**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:

Based on the review of quarterly 2021 Quality Assurance (QA) reports, the technical consultant failed to establish a quality control program and monitor the program to ensure the acceptable levels of analytic performance was maintained throughout the entire testing process. Refer to D5417, D5441 and D5783

**D6044**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(6)

(b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

This STANDARD is not met as evidenced by:

Based on lack of corrective action and an interview with the testing person, the technical consultant failed to ensure that patient test results were not reported when corrective action was not implemented. Refer to D5417, D5441 and D5783