Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	33D0153364	08/08/2018

Name of Provider or Supplier	Street Address, City, State
O Goussis, Md Pc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on a surveyor review of proficiency testing (PT) records from the American Proficiency Institute (API) PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the following analyte: Parathyroid Hormone (PTH): 2016 third event = 0% 2017 first event = 0% 2017 second event = 0% Vitamin B12 2017 first event = 67% 2017 second event = 0% 2017 third event = no participation 2018 first event = 100% Vitamin D 2017 first event = 0% 2017 second event = no participation 2018 first event = 0% Refer to : D2107 and D2096

D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) Proficiency Testing (PT) test reports, the laboratory failed to successfully participate in a PT program approved by the Centers for Medicare and Medicaid Services (CMS) for the test the following analytes: The following scores were assigned: Vitamin B12 2017 first event = 67% 2017 second event = 0% 2017 third event = no participation 2018 first event = 100% Vitamin D 2017 first event = 0% 2017 second event = no participation 2018 first event = 0% This is considered repeatedly unsuccessful PT performance.
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) Proficiency Testing (PT) test reports, the laboratory failed to successfully participate in a PT program approved by the Centers for Medicare and Medicaid Services (CMS) for the test the following analytes: The following scores were assigned: Parathyroid Hormone: 2016 third event = 0% 2017 first event = 0% 2017 second event = 0% 2017 third event = No participation 2018 first event = Not graded This is considered repeatedly unsuccessful PT performance.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the surveyor's review of American Proficiency Institute (API) Proficiency Testing (PT) reports and an interview with the technical consultant, the laboratory failed to evaluate, perform and document remedial action for the PT scores of less than 100% for the following analytes: 2017 first event: Estrodial = 67% 2017 second event: Testosterone = 0% Leuteinizing Hormone (LH) = 33% 2017 third event: Cortisol = 20% Total Triiodothyronine (TT3) = 40%
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic

	systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor's review of records and an interview with the technical consultant, the laboratory failed to: 1. Ensure that a comprehensive procedure manual is available for all aspect of the testing process. Refer to D5403; 2. Ensure that the laboratory follows laboratory's temperature policy. Refer to D5413; 3. Ensure that the laboratory discontinued the use of expired QC and calibrator materials. Refer to D5417; 4. Ensure that the Validation study was performed and documented. Refer to D5421; 5. Perform and document calibration for endocrinology and chemistry. Refer to D5437; 6. Perform and document QC for Immunology. Refer to D5449; 7. Perform and document calibration verification for analytes with less than 3 point calibrators. Refer to D5439; 8. Ensure that chemistry and endocrinology QC test results were within acceptable range prior to testing patient specimens. Refer to D5481; 9. Ensure that corrective actions were taken when quality controls were out of range. Refer to D5783
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory's procedure manual and an interview and confirmed with the technical consultant, the laboratory failed to have a procedure manual that is comprehensive. FINDINGS: The procedure manual did not include: 1. Procedure describing the laboratory's turnaround time for endocrinology, immunology and chemistry testing from sample collection to processing and to when final results are entered into the patients' charts; 2. A procedure describing a twice per year verification system for the non-regulated allergy testing. 3. A procedure describing

	calibration verification for analytes with less than 3 point calibrators. PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEYS CONDUCTED ON APRIL 1, 2015 AND OCTOBER 21, 2016.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a surveyor's review of laboratory's temperature records and interview with the technical consultant, the laboratory failed to follow the manufacturer's temperature requirement and failed to follow the laboratory's temperature policy for the laboratory testing. FINDINGS: 1. On August 8, 2018 at approximately 1:30 PM the technical consultant confirmed surveyor's findings that the laboratory failed to monitor and document the refrigerator, room, humidity and freezer temperatures as required by the manufacturer's criteria and required by the laboratory's temperature policy, for the storage of the reagents and quality controls and for proper storage of the patients' specimens in September 2017 and April 2018. 2. The laboratory failed to monitor and document room temperature and humidity, as required by the laboratory's temperature policy, in October and November 2017. 3. Approximately 400 patient samples were tested and reported during the above time frames.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) 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 a surveyor's review of the calibration records and an interview with the technical consultant, the laboratory failed to discontinue the use of the expired calibration materials. FINDINGS: 1. On August 8, 2018 at approximately 1:30 PM the technical consultant confirmed surveyor's findings that the laboratory used expired calibration materials for the following chemistry and endocrinology analytes: A. From July 27, 2017 through June 28, 2018 Anti Immunoglobulin was calibrated using calibrator lot # 744139 expired 6/30/17 B. From July 29, 2018 through the survey date Vitamin D was calibrated using the calibrator lot # 76193U100 expired 7/28/18 C. From October 26, 2017 through November 3, 2017 TT3 was calibrated using the calibrator Lot # 65121U100 expired 10/25/17 D. From June 25, 2018 through the survey date Testosterone was calibrated using the calibrator lot # 90291381 expired 6 /24/18 2. On August 8, 2018 at approximately 1:30 PM the technical consultant confirmed surveyor's findings that the laboratory used expired Quality Control (QC) materials for the following endocrinology and chemistry analytes: A. Folate was

	tested on 7/18/18 using the QC materials (Bio Rad Levels 1, 2, 3) lot #95400 expied 5 /31/15 B. Folate was tested on 5/4/17 using level 1, 2, 3 Bio Rad controls lot # 51350U100 expired 2/20/16 C. PTH was tested on 6/7/18 using level 1, 2, 3 Bio Rad Controls lot # 01612B000 expired 1/20/13 D. Prolactin was tested on 1/12/18 using expired level 1 control . 3. Approximately 200 patients were tested for the above analytes using the expired calibration materials during the above time frame and Approximately 200 patients were tested for the above analytes using the expired QC materials during the above time frame.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on lack of validation records and an interview with the technical consultant, the laboratory failed to perform and document a complete method validation for the Abbott Architect and the Hitachi CLA -1 analyzers when the laboratory moved to a new location on April 28, 2017 prior to patient testing. Findings: 1. On July 8, 2018 at approximately 1:30 PM the technical consultant confirmed that validation study was not performed for the Abbott Arichitect and the Hitachi CLA -1 analyzers prior to patient testing after the analyzers were transported to the new laboratory location on April 28, 2017. 2. Approximately 500 patient specimens were tested and reported for hematology during above time frame.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a surveyor's review of chemistry and endocrinology calibration records and interview with the technical consultant, calibration of the chemistry and endocrinology analyzer was not performed at the frequencies required by the laboratory's calibration protocol and by the manufacturer of the analyzer. FINDINGS: 1. On August 8, 2018 at approximately 1:30 PM the technical consultant confirmed

	that the documentation of the Abbott Architect Plus analyzer calibration records were not available for the following analytes: A. No records of calibration for PTH and Vit B12, from January to July 2017 and from May 4, 2018 through the survey date B. No records of calibration for prolactin from April through May 2018, from February through May 2017, from July through August 2017. C. No records of calibration for Vit B12 from January through April 2018 and from April through October 2017 D. No calibration records for Vit D from June 2018 through the survey date E. Calibration for PTH failed on 10/12/17. No records of acceptable calibration for PTH on 10/12/17 F. Calibration for Brain Natriuretic Peptide (BNP) failed on 3/29/18. No records of acceptable calibration for BNP on 3/29/18 G. Calibration for Tyroid-Stimulating Hormone (TSH) failed on 6/23/17. No records of calibration for TSH on 6 /23/18. 2. Approximately 400 patient specimens were tested and reported for the above analytes during the above time period when analyzer was out of calibration.
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 the surveyor's review of the laboratory's calibration verification records and an interview with the laboratory technical consultant, the laboratory failed to perform calibration verification at least once every six months for endocrinology and chemistry testing on the Abbott Architect analyzer in calendar year 2017 and up to survey date. FINDINGS: At approximately 1:00 PM on August 8, 2018, the technical consultant confirmed the laboratory had not performed calibration verification on the Abbott Architect for analytes, Follicle Stimulating Hormone (FSH), TT3, TSH, Prolactin, Progesterone, and Ferritine, with less than three point calibrators. Approximately 400 patients were tested during this time period. PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEY CONDUCTED ON OCTOBER 21, 2016.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and interview with the technical consultant, the laboratory failed to perform and document the positive and negative controls with each patient test run for the Allergy testing from November 2016 through the survey date. FINDINGS: 1. The technical consultant confirmed on August 8, 2018 at 1:30 PM that the quality control records for the Allergy testing were not available for review at survey for 36 allergens tested on the Hitachi CLA-1 analyzer from November 2016 through survey date. 2. No records of Luminometer testing available from November 2016 through the survey date. 3. Approximately 550 patient samples were tested & reported for Allergy during the above time frame.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a surveyor's review of chemistry and endocrinology quality control (QC) records and an interview with the technical consultant, the laboratory failed to ensure that chemistry and endocrinology QC test results were within acceptable range prior to testing patient specimens. Findings Include: Review of QC records found and it was confirmed with the technical consultant on July 8, 2018 at approximately 1:30 PM during review of QC data that the following levels of control material were out of acceptable range and remediation was not performed: 1. On 6/7/18 two out of three controls were out of acceptable range for vitamin B12. 2. On 10/2/17, 11/17/17, and 3 /9/18 two out of three controls were out of range for TT3 3. On 1/19/18 two out of three controls were out of range for cortisol, FSH, progesterone, prolactin, and folate 4. On 3/9/18, 4/20/18, 4/26/18 two out of three controls were out of range for LH2 5. On 3/23/18 two of three controls were out of range for progesterone 6. On 1/12/18 two out of three controls were out of range for prolactin 7. On 12/1/16 three out of three controls were out of range for estrodial, TT3, cortisol, FT4, progesterone, prolactin 8. On 12/2/16 and 12/9/16 three out of three controls were out of range for B12 9. On 4/27/17, 5/4/17, 11/9/17, 11/30/17 three out of three controls were out of range for cortisol 10. On 5/4/17 three out of three controls were out of range for folate PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEY CONDUCTED ON OCTOBER 21, 2016.
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 a surveyor's review of the chemistry and endocrinology QC and calibration records and an interview with the technical consultant, the laboratory failed to perform and document corrective action when QC and calibration results were out of acceptable range and failed to evaluate all patient test results obtained for each unacceptable test run through the last acceptable test run to determine if patient test results were adversely affected. Refer to: D5481 PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEY CONDUCTED ON JANUARY 21, 2016.
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 surveyor findings and interview with the laboratory technical consultant, the laboratory director failed to provide overall management of the laboratory. The laboratory director failed to ensure that the laboratory: 1. Maintained the plan of correction from the surveys conducted on 4/1/15 and 10/21/16; 2. successfully participate in PT. Refer to D6016 3. maintained the laboratory's QC program for chemistry, immunology and endocrinology, refer to D6020. 4. maintained the laboratory's established QA program for all phases of laboratory testing, refer to D6021. PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEY CONDUCTED ON OCTOBER 21, 2016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on the surveyor's review of the API PT program records and confirmed with the technical consultant, the laboratory director failed to ensure that the laboratory successfully participated in a PT program for Chemistry and Endocrinology. Refer to: D2096, D2107, D5211 PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEY CONDUCTED ON OCTOBER 21, 2016.

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 the surveyor's review of the laboratory's quality control (QC) records and confirmed in an interview at the time of this survey with the technical consultant, the laboratory director failed to ensure that the QC program for endocrinology, chemistry and immunology testing was maintained to assure quality of laboratory services. Refer to: D5437, D5439, D5449, D5481, D5783 PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEY CONDUCTED ON OCTOBER 21, 2016.
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the laboratory quality assessment records (QA), and interview with the technical consultant, the laboratory director failed to follow the laboratory's QA procedures. Findings Include: At approximately 1:00 PM on August 8, 2018, the technical consultant confirmed that although the QA reviews were performed by the laboratory's technical consultant, the laboratory failed to ensure that actions taken to prevent recurrence of the original problem. Refer to D5403, D5413, D5417, D5421 PLEASE NOTE: THIS IS A REPEATED CITATION FROM THE SURVEYS CONDUCTED ON APRIL 1, 2015 AND OCTOBER 21, 2016.