Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	33D0858246	08/28/2018
Name of Provider or Supplier	**Street Address, City, State**	
Andres Urena Md	104 19 Lefferts Blvd, South Richmond Hill, 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	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on the lack of internal quality control (QC) records for the Abaxis Piccolo chemistry analyzer and an interview with the testing person, the laboratory failed to retain the internal QC records for the chemistry analyzer from January 1, 2018 through survey date. FINDINGS: The testing person confirmed on August 28, 2018 at approximately 11:00 AM, the laboratory failed to retain the daily internal IQCP electronic QC printouts for the Abaxis Piccolo chemistry analyzer from January 1, 2018 through survey date. Approximately 50 patient samples were tested and reported during this time-period. a. the laboratory is using serum samples, therefore this test method is moderate complexity for the Abaxis Piccolo chemistry analyzer.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's Quality Assessment (QA) policy /procedure and an interview, with the testing person, at the time of the onsite survey,

	the laboratory failed to follow their established written QA policy and have a mechanism to monitor, assess and when indicated correct problems identified in the general laboratory system for chemistry testing.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on the lack of Abaxis Piccolo manufacturer's test system instructions, operators manual and an interview with testing person, the laboratory failed to retain a copy of the Abaxis Piccolo operators manual.
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 Qualigen Fast Pack analyzer temperature requirements, lack of temperature records and interview with the testing person, the laboratory failed to follow the manufacturer's temperature requirement and record the refrigerator and room temperatures and the laboratory humidity. FINDINGS: 1. The testing person confirmed on August 28, 2018 at approximately 11:30 AM , the laboratory failed to monitor and document the refrigerator temperatures, room temperatures and humidity as required by the manufacturer's criteria for the storage of the reagents and quality controls and for proper storage of the patients' specimens from January 1, 2018 through survey date. 2. The Qualigen manufacturer temperature requirements are for room 15-32 C or 59-90 F; refrigerator 2-8C or 36-46F and humidity 10-80%. 3. Approximately 200 patient samples were tested and reported during this time-period.
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 endocrinology calibration records for the Qualigen analyzer and an interview with the testing person, the laboratory failed to perform the six-month calibration verification for the endocrinology analyzer as required by the manufacturer for the analyzer. FINDINGS: The testing person confirmed on August 28, 2018 at approximately 11:30 AM, that the laboratory failed to perform the six-month calibration verification due on 06/12/2018. Approximately 20 patient specimens were tested and reported from 06/12/2018 through survey date.
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 the lack of QC records for the Abaxis Piccolo chemistry analyzer and an interview with the testing person, the laboratory failed to perform the required controls for the Abaxis Piccolo analyzer from 01/12/2018 through survey date. FINDINGS: The testing person confirmed on August 28, 2018 at approximately 11:00 AM, the laboratory failed to perform the Abaxis manufacturer's required QC every 30 days and/or each new lot of test cassette from 01/12/2018 through survey date. a. the laboratory is using serum samples, therefore this test method is moderate complexity for the Abaxis Piccolo chemistry analyzer.
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 testing person, the laboratory director failed to provide overall management of the laboratory. The laboratory

	director failed to ensure that the laboratory: 1. maintained the laboratory's QC program for chemistry and endocrinology, refer to D6020. 2. follow the QA policy when quality control and calibration issues were identified, refer to D6021.
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 an interview with the testing person, the laboratory director failed to ensure that the QC program for endocrinology and chemistry testing was maintained to assure quality of laboratory services. Refer to: D5437 and D5441.
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 the surveyor's review of the endocrinology calibration records, QC records and an interview with the testing person, the laboratory director failed to ensure that QA policy was followed when problems were identified. Refer to D3031, D5291, D5405 and D5413.