Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0892142	03/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Endocrinology & Diabetes Center	3205 Churchland Boulevard, Chesapeake, VA	

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
D0000	An announced CLIA recertification survey was conducted at Endocrinology and Diabetes Center on March 1, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
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 laboratory tour, review of the laboratory's quality assurance (QA) policy, Qualigen FastPack chemistry analyzer user's guide and procedures, and an interview, the laboratory failed to monitor and record laboratory room temperature and humidity to ensure proper operating specifications for three (3) of three (3) Qualigen FastPack System analyzers from March 2016 to the date of the survey on 3/1/18. Findings include: 1. During a tour at approximately 1:00 PM on 3/1/18, the inspector was unable to locate the devices utilized for monitoring the laboratory room temperature and humidity. The inspector asked to view the thermometer and humidity meters. The primary testing personnel stated: "I do not have a thermometer or humidity meter in the lab. I have to go out to the front lobby and I record the thermostat reading from the front office onto my temperature log sheets. I go to the utility room in the rear of the building to read the humidity meter located in that room." 2. Review of the laboratory's Qualigen QA plan revealed a policy to record the daily laboratory room

	temperature and humidity. 3. Review of the Qualigen User's Guide and procedure manual revealed instructions to ensure instrument storage and operating specifications: "The instrument's operating temperature should be maintained at 15-32 C and humidity range should be monitored to verify 10-80%". 4. In an interview with the office manager at approximately 2 PM on 3/1/18, it was confirmed that the laboratory failed to record and monitor the laboratory room temperature and humidity ensuring proper operating specifications for three (3) of three (3) Qualigen FastPack System analyzers for twenty-four (24) of twenty-four (24) months reviewed.
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 a tour, review of the Qualigen FastPack manufacturer's user guide, the laboratory's equipment maintenance records, patient test log, and an interview, the laboratory failed to follow their calibration maintenance protocols for two (2) of two (2) positive displacement sample pipettes while reporting five thousand six hundred seventeen (5,617) patient test results during the fourteen (14) months reviewed. Findings include: 1. During a laboratory tour on 3/1/18 at approximately 1:00 PM, the inspector noted two (2) Gilson Guest 100 microliter (ul) pipettes in use for patient sample preparation in testing Thyroid Stimulating Hormone (TSH), Thyroxine (FT4), and Vitamin D on the Qualigen FastPack analyzer. The pipette serial numbers (SN) are listed below: Pipette 1 -SN JD 05888, Pipette 2 -SN JD 05887. 2. Review of the Qualigen manufacturer's user guide revealed a policy "Annual Recalibration of the Positive Displacement Sample Pipette" which outlined instructions for pipette calibrations. The policy stated: "Proper performance of pipette is critical to obtain accurate results. The pipette included with the FastPack System is a costly piece of equipment that requires periodic recalibration which must be done by a factory certified dealer". 3. Review of the laboratory's 2016 and 2017 equipment maintenance records revealed: Pipette 1 -SN JD 05888- calibration performed on 1/25/16, calibration expiration date 1/25/17 Pipette 2 -SN JD 05887- calibration performed on 1 /25/16, calibration expiration date 1/25/17 The inspector requested to review the annual pipette calibration documentation for calendar years 2017 and 2018. No documentation was available for review. 4. Review of the laboratory's 2017 Qualigen patient test log revealed the following number of patient tests were reported while utilizing the pipettes listed above: TSH: two thousand five hundred three (2,150); FT4: two thousand one hundred seventy-five (2,175); Vit D: nine hundred thirty-nine (939); a total of five thousand two hundred sixty-four (5,264) patient test results were reported during the lapse in pipette calibration protocols. 5. In an interview with the office manager on 3/1/18, at approximately 2:00 PM, it was confirmed that the laboratory failed to follow the annual calibration maintenance protocols for two (2) of two (2) sample pipettes utilized for Qualigen FastPack TSH, FT4, and Vitamin D patient testing during the fourteen (14) months reviewed as outline above.

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 a review of the laboratory's 2016 and 2017 proficiency testing (PT) results and an interview, the laboratory director failed to document review of the laboratory's performance in seven (7) of eight (8) endocrinology chemistry PT events reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) chemistry PT records revealed no documentation of review of results by the lab director for the following seven (7) events: 2016 Event 1 Chemistry, 2016 Event 3 Chemistry, 2017 Event 1 Core Chemistry, 2017 Event 1 Miscellaneous Chemistry, 2017 Event 2 Core Chemistry, 2017 Event 2 Miscellaneous Chemistry, 2017 Event 3 Core Chemistry. 2. In an interview with the office manager on 3/1/18, it was confirmed that the lab director failed to document review and evaluation of the laboratory's chemistry PT performance on the seven (7) events listed above in calendar years 2016 and 2017.