

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0892142	(X3) Date Survey Completed 06/07/2022
Name of Provider or Supplier Endocrinology & Diabetes Center	Street Address, City, State 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 June 7, 2022 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:
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documentation and an interview, the laboratory failed to retain copies of the attestation statement signed by the laboratory director (LD) and testing personnel (TP) for three (3) of five (5) events reviewed. Findings include: 1. Review of the laboratory's American Proficiency Institute chemistry PT records (2020 Events 2-3, 2021 Events 1-3), a total of 5 events, revealed no signed attestation statements by the LD and TP for: 2020 Event 2, 2020 Event 3, 2021 Event 3. The inspector requested to review the attestation documentation for the 3 events outlined above. No documentation was available for review. 2. An exit interview with the office manager at approximately 4:15 PM on 6/7/22 confirmed the above findings.</p>

D3011

FACILITIES

CFR(s): 493.1101(d)

Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.

This STANDARD is not met as evidenced by:

Based on tour observations, interviews, and a review of procedures, the laboratory failed to follow established safety protocols that prohibited storage of food and beverages in the laboratory on the date of the survey June 7, 2022. Findings include: 1. During a tour of the laboratory on June 7, 2022 at approximately 2:00 PM, the inspector observed food items and a soft drink beverage stored in a table top refrigerator identified as "send out refrigerator". The inspector noted patient blood samples were stored in the refrigerator adjacent to the food storage. The inspector inquired regarding the presence of the food and beverage stored in the laboratory refrigerator. A laboratory staff member (identified as the phlebotomist), responded to the inquiry on 6/7/22 at approximately 2:01 PM: "It is my food. I will get those out of there." The staff member removed the items (fruit and other various lunch food along with a soft drink) and placed them into her personal bag. The office manager, present during the tour, responded at approximately 2:05 PM: "We have protocols that food is not allowed in the laboratory. It is an elementary safety rule and should be followed by everyone working or visiting the laboratory." 2. Review of the laboratory procedure manual revealed a Qualigen Good Laboratory Practice protocol that stated: "Contamination of food and beverages, is a potential route to toxic chemicals or biological agents through ingestion. Laboratory personnel shall not prepare, store, or consume food or beverages in the laboratory." 3. An exit interview with the office manager at approximately 4:15 PM on 6/7/22 confirmed the above findings.

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 review of quality assurance (QA) policy, chemistry analyzer user's guide /procedures, lack of documentation, and an interview, the laboratory failed to retain records of monitoring laboratory room temperature and humidity to ensure proper operating specifications for the Qualigen FastPack System analyzer for four (4) of twelve (12) months reviewed in calendar year 2020. Findings include: 1. Review of the laboratory's Qualigen FastPack QA plan revealed a policy to record the daily laboratory room temperature and humidity. 2. Review of the Qualigen chemistry analyzer 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%".

3. Review of the available temperature/humidity logs for calendar year 2020 revealed no records for the months of September, October, November, and December. The inspector requested to review additional log sheets. The office manager stated on 6/7/22 at approximately 3 PM: "Our lead lab tech left our employment in the timeframe of late October or early November 2020. I will look for the missing logs." 4. An exit interview with the office manager at approximately 4:15 PM on 6/7/22 confirmed the above findings.