

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2116797	(X3) Date Survey Completed 02/23/2018
Name of Provider or Supplier Erica Smithberger Md PI DBA	Street Address, City, State 2010 Thonotosassa Rd, Plant City, FL	
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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager, the laboratory failed to follow their procedures for chemical waste disposal for an undetermined amount of time. Findings Included: During an interview on 02/23/18 at 10:20 a.m., the Laboratory Manager revealed that all chemical waste was disposed of by being poured down the sink drain. Review of policies and procedures (last reviewed by Laboratory Director on 08/23/17) revealed that "Hazardous liquid waste will be placed in the 2.5 gallon hazardous waste container stored next to the cryostat machine." The 2.5 gallon hazardous waste container was observed beside the cryostat machine empty on 02/23/18 at 11:00 a.m. Observation of the Safe Clear, Hemotoxylin, Eosin, 95% Reagent Alcohol, and 100% Reagent Alcohol bottles all state "Dispose of contents/container to an approved waste disposal plant."</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

Based on observation, record review and interview with the Laboratory Manager, the laboratory failed to store chemicals per manufacturers instructions since 12/26/17.

Findings Included: Tour of the laboratory on 02/23/18 at 9:15 a.m., revealed that the temperature in the laboratory was warm. Review of the thermometer revealed that the temperature in the room was 86 degrees Fahrenheit. During an interview on 02/23/18 at 9:15 a.m., the Laboratory Manager revealed that the laboratory moved to that location on 12/26/17 and that the laboratory had a stand alone air conditioning unit that was only ran when testing occurred. She also confirmed that the chemicals were stored in the laboratory even when testing was not being performed and the air conditioning unit was turned off. Review of the Scott's tap waster substitute (Lot #1714522 exp 05/31/18) states that it needs to be stored at a maximum temperature of 86 degrees Fahrenheit. The emergency eyewash stated that it needs to be stored at a maximum temperature of 77 degrees Fahrenheit.