

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2161314	(X3) Date Survey Completed 06/25/2019
Name of Provider or Supplier Adams Endocrinology Associates	Street Address, City, State 20 Expedition Trail, Suite 204, Gettysburg, PA	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review on the laboratory procedure manuals and interview with the laboratory director (LD), the laboratory failed to include the preparation of specimen collection of fine needle aspirate (FNA) samples, step-by-step performance of the FNA adequacy procedure and literature references in the FNA cytology procedure in 2019. Findings Include: 1. On the day of survey, 06/25/2019, review of the laboratory procedure manual revealed the LD did not approve the FNA procedure before patient testing began and the procedure manual did not include the follow: - Requirements for patient preparation; specimen collection, labeling, storage, preservation, processing and specimen acceptability and rejection of FNA samples. - Step-by-step performance of the FNA adequacy procedure. - Pertinent literature references. 2. The LD confirmed the findings above on 06/25/2019 around 9:45 am.</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 of cytology reagents, review of cytology reagent safety data sheets (SDS) and Interview with Laboratory Director (LD), the laboratory failed to follow manufacturer instructions for the storage of 1 of 1 bottle of Statlab Medical Products Hema-Diff #1 Fixative and 1 of 1 bottle of Medite Cancer Diagnostics Sure Thin Preserve Cell Solution. Finding Include: 1. The Statlab Medical Products Hema-Diff #1 Fixative, Section 7: Handling and Storage, Conditions for Safe Storage, Including any Incompatibilities, states " keep in a fire proof place". 2. The Medite Cancer Diagnostics Sure Thin Preserve Cell Solution, Handling and Storage, states "store locked up". 3. On the day of survey, 06/25/2019, review of reagents in the cytology laboratory revealed the following reagents were not being stored in accordance to manufacturers instructions: - 1 of 1 bottle of Statlab Medical Products Hema-Diff #1 Fixative was stored in an wall cabinet. - 1 of 1 bottle of Medite Cancer Diagnostics Sure Thin Preserve Cell Solution was stored out on top of a work bench. 4. The LD confirmed the findings above on 06/25/2019 around 10:30 am.