

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0220587	(X3) Date Survey Completed 02/28/2025
Name of Provider or Supplier Frederick Internal Med & Endocrine Svc, Pa	Street Address, City, State 65c Thomas Johnson Drive, Frederick, MD	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the testing person (TP), the laboratory's practice didn't match the procedure for labeling cytology slides. Findings: 1. The "Thyroid Fine Needle Aspiration Adequacy Assessment" procedure stated to "Obtain two clean glass slides and label the frosted end of the slide with patient name, date, and medical record number with a pencil." 2. During the survey on 02/28/2025 at 10:30 AM, the TP confirmed that they label the slide with the patient's name, date of birth, and the letter A or B if multiple nodules were assessed.</p>
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 of the procedure manual and interview with the practice administrator (PA), not all procedures were approved, signed, and dated by the laboratory director. Findings: 1. The procedure manual included procedures that were not approved, signed and dated by the laboratory director including the "Thyroid Fine Needle Aspiration Adequacy Assessment" testing procedure and the procedures for</p>

	<p>Document Control System, Laboratory Equipment, Personnel Training, Competency Assessment, and Review of Quality Control Compliance. 2. During the exit interview on 02/28/2025 at 12:00 PM, the PA confirmed that not all procedures were approved, signed, and dated by the laboratory director.</p>
<p>D5415</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation and interview with the testing person (TP), the laboratory failed to label the Coplin staining jars with the identity and expiration dates of the staining reagents located within. Findings: 1. The laboratory performed a Hema-Diff stain on fine needle aspiration biopsy slides that utilized four Coplin staining jars containing three stains and deionized water. 2. The Coplin jars were not labeled with the identity and expiration dates of the contents contained within. 3. During the survey on 02/28/2025 at 10:30 AM, the TP confirmed that the Coplin staining jars were not labeled to indicate the contents' identity and expiration date.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the testing person (TP), the laboratory did not document the lot numbers and expiration dates for staining reagents. Findings: 1. The laboratory performed a Hema-Diff stain on fine needle aspiration biopsy slides that included three stains and deionized water. 2. The procedure manual included a "Laboratory Reagent and Supply Log" to document each reagent lot number, expiration date, received date, and date put into use. 3. During the survey on 02/28/2025 at 10:30 PM, the TP confirmed that the "Laboratory Reagent and Supply Log" was not used to document staining reagent lot number details and that the information was not documented anywhere else.</p>
<p>D5473</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:
Based on review of the procedure and interview with the practice administrator (PA), the laboratory failed to document whether staining materials demonstrated intended reactivity each day of use. Findings: 1. The laboratory performed a Hema-Diff stain on fine needle aspiration biopsy slides. 2. The "Thyroid Fine Needle Aspiration Adequacy Assessment" procedure stated "A quality control [QC] slide must be evaluated each day a slide is prepared. The control slide may be a patient slide. The slide should be evaluated to ensure proper staining technique. Mark on the Stain QC chart whether staining is acceptable or unacceptable." 3. The procedure included a template "Hema-Diff Quality Control" log (QC log). 4. During the survey on 02/28/2025 at 11:45 AM, the PA confirmed that stain acceptability was not documented on the QC log or anywhere else.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of the procedure manual and interview with the practice administrator (PA), there was no documentation that testing person #2 was trained on performing the staining procedures. Findings: 1. The laboratory performed a Hema-Diff stain on fine needle aspiration (FNA) biopsy slides. 2. The Laboratory Personnel Report (form CMS-209) listed two testing personnel. Testing person #2 performed the staining procedure. 3. During the survey on 02/28/2025 at 10:50 AM, the PA confirmed that there was no documentation showing that testing person #2 was trained on how to perform the staining procedure for the FNA biopsy slides.