

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2161314	(X3) Date Survey Completed 07/05/2023
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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Procedure manual, and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy of the Fine Needle Aspirate examination in Exfoliative Cytology from 2021 to 07/05/2023 as required. Findings Include: 1) On the day of the survey 07/05/2023 at 11:30 AM, the laboratory could not provide a procedure manual for verification of the accuracy of the Fine Needle Aspirate examination performed in the laboratory. 2. At the time of the survey, the laboratory could not provide documentation of verification activities performed. 3. Laboratory performed 150 Fine Needle Aspirate testing (CMS 116 Annual Volume). 4. LD confirmed the findings above on 07/05/2023 around 12:30 PM.</p>
D5441	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:

Based on a lack of laboratory's quality control (QC) records, a review of the procedure manual, and an interview with the Laboratory Director (LD), the laboratory failed to perform and document QC for Fine Needle Aspirate slide staining performed in Exfoliative Cytology from 04/13/2021 to the date of the survey. Findings include: 1. On the day of the survey, 07/05/2023 at 12:00, the laboratory failed to provide QC documentation for the Fine Needle Aspirate testing performed in Exfoliate cytology from 2021 to 2023. 2. The laboratory could not provide a QC procedure for the Fine Needle Aspirate test. 3. The laboratory performed 150 Cytology tests in 2022 (CMS 116 annual volume). 4. LD confirmed the finding above on 07/05/2023 around 01:00 PM.