

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0683308	(X3) Date Survey Completed 05/25/2022
Name of Provider or Supplier Internal Medicine Specialists	Street Address, City, State 513 Brookwood Blvd, Suite 50, Birmingham, AL	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Clinitek Advantus records and Operator's Guide, and an interview with Testing Personnel #1, the laboratory failed to perform and document maintenance as defined by the manufacturer. This was noted from the previous survey (02/13/2020) to the current survey (05/25/2022). The findings include: 1. A review of the Clinitek Advantus records revealed no documentation of maintenance. 2. A review of the Clinitek Advantus Operator's Guide revealed on page 37, "...Performing the Daily Cleaning Clean the following parts at least once each day or after running 300 strips, whichever is more frequent...". 3. During an interview on 05/25/2022 at 2:10 PM, Testing Personnel #1 confirmed maintenance for the Clinitek Advantus was not documented. Also, Testing Personnel #1 stated the current maintenance process for the Clinitek Advantus was a weekly cleaning on Fridays, but this process was not documented.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a review of personnel records and an interview with Testing Personnel #1, the Technical Consultant failed to provide documentation of annual competency evaluations for all moderate complexity test systems utilized in the laboratory. This was noted for two out of two testing personnel listed on the CMS - 209 Laboratory Personnel Report. The findings include: 1. A review of personnel records revealed the following: a) Testing Personnel #1's annual competency evaluations were performed on 09/17/2020 and 08/31/2021. However the competencies did not include Microscopic procedures for Urine Sediment, Vaginal Wet Preparation, and Potassium Hydroxide (KOH) Preparation. b) Testing Personnel #2's semi-annual competency evaluation was performed on 07/07/2021, and the annual competency evaluation was performed on 01/31/2022. However the competencies did not include Microscopic procedures for Urine Sediment, Vaginal Wet Preparation, and Potassium Hydroxide (KOH) Preparation. 2. During an interview on 05/25/2022 at 3:45 PM, Testing Personnel #1 confirmed the competency evaluation forms did not include Microscopic procedures.