

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2003888	(X3) Date Survey Completed 11/30/2022
Name of Provider or Supplier Dermatology Associates & Surgery Center Beckley	Street Address, City, State 94 Brookshire Lane, Beckley, WV	
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
D0000	An announced, on site, routine recertification survey was conducted at Dermatology Associates & Surgery Center Beckley on November 30, 2022, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review , lack of documentation, and interview the laboratory failed to (e)(i) document the verification of new lots of PAS, Colloidal Iron, Iron, Elastic, GMS, and AFB manual staining reagents for positive and negative reactivity before placing into use in 2021 and 2022. Findings: 1. Review of laboratory reagent logs for 2021 and 2022 identified new lots of PAS, Colloidal Iron, Iron, Elastic, GMS, and AFB staining reagents documented with received and dates placed into use. 2. Review of quality control (QC) logs for 2021 and 2022 identified QC documented as being performed on days manual staining procedures were performed. No documentation of evaluation and verification of positive and negative reactivity for new lots of manual staining reagents could be located. 3. An interview with the laboratory manager, 11/30 /22 at approximately 11:30 AM , confirmed the findings.</p>