

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1034363	(X3) Date Survey Completed 08/16/2018
Name of Provider or Supplier Brian J Williams Dermatology	Street Address, City, State 602 East Fort Union Boulevard 2nd Floor, Midvale, UT	
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 procedure manual review, lack of documentation, and confirmation by staff, the director failed to sign and date the laboratory procedure manual for dermatophyte cultures and potassium hydroxide testing using Chlorizol Black reagent as approved. The laboratory performs approximately 12 to 15 tests per year. Findings include: 1. The laboratory procedure manual failed to include the signature and date the director approved the procedures. 2. In an interview with staff on 08/16/2018 at approximately 12:30 P.M., staff confirmed the procedure manual did not include the director's signature and date of approval.</p>
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:</p>

Based on lack of documentation and interview with staff, the laboratory failed to check 1 of 1 lot number of Chlorizol Black reagent prior to or concurrent with use. The laboratory performed approximately 1 to 2 potassium hydroxide preparations per year using Chlorizol Black reagent. Findings include: 1. The laboratory failed to document they checked Chlorizol Black reagent for lot number 6259 expiring 2018/09/15. 2. In an interview conducted on 08/16/2018 at approximately 12 :00 P.M., staff confirmed they had not recorded they checked each new lot number of reagents in use prior to performing patient tests.