

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1034363	(X3) Date Survey Completed 01/08/2021
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: .Based on lack of a competency procedure, lack of competency performance documentation for 1 of 1 year (2019), and interview with staff, the laboratory failed to establish and follow written policies and procedures for assess employee competency for 1 of 1 test person performing dermatophyte test media culture and potassium hydroxide (KOH) testing for the presence or absence of fungi. The laboratory performed approximately 3 Dermatophyte test media cultures and 2 KOH preparations over 2 years (2019 and 2020). Findings include: 1. The laboratory failed to establish a policy that included: direct observation of routine patient test performance, monitoring the recording and reporting of test results; direct observation of performance of instrument maintenance and function checks; assessment of test performance through testing previously analyzed specimens; internal blind testing samples or external proficiency testing samples; and assessment of problem solving skills. 2. In an interview conducted on 01/08/2021 at approximately 1:00 P.M. staff confirmed the laboratory did not have a written policy that describes the procedure for competency evaluation.</p>
D5417	<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</p>

deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on direct observation and confirmation by staff, the laboratory failed to ensure potassium hydroxide reagent was not used past its expiration date. The laboratory performed approximately 2 tests per year. Findings include: 1. The potassium hydroxide reagent with chlorazol black (lot number 8094) available for use on 10/03/2018 expired on 04/04/2020. 2. The laboratory tested patient (date of birth 11/05/1989) on 05/13/2020 using lot number 8094. 3. In an interview conducted on 01/08/2021 at approximately 12:50 P.M., staff confirmed the reagent was expired when used on 05/13/2020 for testing.

D5893

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(b)(c)

(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on patient test records review, quality assessment documentation review and interview with staff, the laboratory quality assessment failed to identify errors between the results recorded in the KOH and Dermatophyte culture log and the test report for 1 of 3 test reports reviewed. The laboratory performed 1 KOH and 1 Dermatophyte culture in 2020. Findings include: 1. Patient test record review for Dermatophyte culture and KOH slide preparation using chlorazol black for patient - date of birth (DOB) 11/05/1989 - collected on 05/02/2020 the test log book reported the dermatophyte culture as positive (reported by the director and the nurse practitioner) and the KOH as positive. The patient chart record included the report that the KOH was positive and the dermatophyte culture was negative. 2. In an interview with staff on 01/08/2020 at approximately 12:55 P.M. staff confirmed the dermatophyte culture report in the chart record did not agree with the result in the log book for dermatophyte culture for patient DOB 11/05/1989 collected on 05/02/2020. The laboratory quality assessment review did not identify the transcription error in reviewing this culture for accuracy in reporting the results.