

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0524261	(X3) Date Survey Completed 01/08/2019
Name of Provider or Supplier E Barry Topham, Md	Street Address, City, State 1775 E 4500 S, Holladay, 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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and confirmation by the director, the laboratory failed to verify dermatophyte culture accuracy at least twice annually for 2 of 2 years of testing reviewed, (2017 and 2018). The laboratory performed approximately 15 cultures per year. Findings include: 1. The laboratory failed to document fungal culture test accuracy at least twice annually in 2017 and 2018. 2. In an interview conducted on 01/08/2019 at approximately 12:45 P.M. the director confirmed the laboratory failed to verify dermatophyte cultures provided accurate results twice a year.</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 deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, patient test records review, and confirmation by the director, the laboratory failed to ensure dermatophyte test media (DTM) was not used</p>

past the manufacturer's expiration date of 2017/09/29 for 2 of 2 cultures reviewed that were inoculated after 2017/09/29 expiration date. The laboratory performed approximately 10 to 15 cultures per year. Findings include: 1. Direct observation of media on 01/08/2019 at approximately 12:45 P.M. DTM media in use (lot number 1627) expired on 2017-09-29. 2. Testing records reviewed for patients # Chan0001 on 06/15/2018 and #And0001 on 11/02/2018 were cultured using the media past the expiration date. The reported results were negative for dermatophytes. 3. In an interview with the director on 01/08/2019 at approximately 12:45 P.M. he stated since the box was open the expiration date was not visible and he failed to notice the media had expired.