

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0525457	(X3) Date Survey Completed 01/11/2018
Name of Provider or Supplier Stone Dermatology	Street Address, City, State 1375 N University Ave, Provo, 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
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 of Potassium Hydroxide (KOH) reagent and confirmation by staff the laboratory failed to ensure KOH reagent was not used past its expiration date for two of eight KOH preparation tests reviewed. Findings include: 1. Potassium hydroxide reagent observed expired 06/2017. 2. Patient testing performed after the KOH reagent expiration date were performed on 09/20/2017 for patient date of birth (DOB) 09/29/1992 and on 12/20/2017 for patient DOB 03/04/1979. 3. Staff confirmed the lab used only one container for KOH testing and it had expired 06 /2017.</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: Based on lack of documentation and interview with staff, the laboratory technical consultant failed to evaluate 1 of 2 testing personnel annually for 2 years of Dermatophyte Test Media culture (DTM). The test person performed from 1 to 5 culture results per year for two years of testing reviewed (2016 and 2017). Findings</p>

include: 1. The laboratory failed to document competency evaluations for DTM tests performed annually in 2016 and 2017. 2. In an interview with staff on 01/11/2018 staff stated the testing person performed fewer than 5 of approximately 50 DTM tests performed per year.