Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0674005	01/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Salt Lake County Health Department	610 S 200 E #2154, Salt Lake City, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on quality assessment documentation review, lack of documentation, and interview with staff, the laboratory failed to verify potassium hydroxide (KOH) and saline wet preparations (wet prep) test accuracy at least twice annually for 1 of 2 years reviewed (2018). The laboratory performed approximately 500 tests per year. Findings include: 1. Quality assessment records failed to include KOH and wet prep accuracy verification in 2018. 2. In an interview on 01/07/2019 at approximately 5:10 P.M., the laboratory director stated the laboratory did not verify KOH and Wet Prep testing in 2018.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on reagent records review, lack of documentation, quality assessment plan review, and interview with staff, the laboratory failed to follow policy to review reagent records that document the dates reagents were no longer in use to ensure patient testing was performed with reagents that were not expired. The laboratory

	performed approximately 1000 Gram's Stains, potassium hydroxide, and saline wet preparations per year using 5 staining reagents for Gram's stains and 2 reagents for KOH and Wet prep tests. Findings include. 1. Reagent records review included logs for testing personnel to record the date the reagents were received, lot numbers, expiration dates, dates in use and the date the reagent was taken out of use or finished. 2. The laboratory failed to record the dates reagents were taken out of use or the dates replacement reagents were put into use to document that expired reagent were not used beyond their expiration dates for KOH lot numbers 6240 expiration date of 08/20 /2018, saline lot number 16182 expiration date 06/20/2017. 3. The laboratory quality assessment procedure review included a plan for the laboratory director to review reagent records every two weeks to ensure documentation was maintained. The laboratory reagent logs failed to include documentation the reagent records were reviewed every 2 weeks. 4. In an interview with the laboratory director on 01/07 /2019, the director confirmed the laboratory had not maintained reagent record documentation.