

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0674005	(X3) Date Survey Completed 12/07/2021
Name of Provider or Supplier Salt Lake County Health Department	Street Address, City, State 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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records from American Proficiency Institute (API), laboratory records, and an interview with the laboratory director on 12/07/2021, the laboratory failed to test gram stain proficiency samples in the same manner as patient samples are tested. The laboratory performs approximately 340 gram stains annually. The findings include: 1. A review of PT for gram stain from API Bacteriology 2019 event one, API Bacteriology 2019 event three, and API Bacteriology 2020 event one, the laboratory personnel records identified that five out of five laboratory testing personnel performed PT prior to the due date for the PT event. 2. Laboratory procedure covering proficiency testing states PT samples are to be tested by other staff after the PT results are back. 3. An interview with the laboratory director on 12/07/2021 at approximately 11:00 AM, confirmed that the laboratory tested the sample multiple times before the due date for the PT event.</p>
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</p>

and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on a record review and an interview with the laboratory director, the laboratory failed to have a policy or procedure to assess the competency of testing personnel who performed gram stain tests. The laboratory performed approximately 240 microscopic tests annually. Findings include: 1. A review of the laboratory procedures revealed the laboratory failed to have a procedure or policy to assess the competency for three out of three current testing personnel. 2. An interview on 12/07/2021, at 11:00 AM, with the laboratory director, confirmed the laboratory failed to have a policy or procedure to assess the competency for testing personnel.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on record review, direct observation, and interview with testing personnel, room temperature of the laboratory was not monitored where the Accra Lab gram stains were being performed. The laboratory performs approximately 240 gram stain tests annually. Findings include: 1. Accra Lab gram stain set requires reagents to be stored at 15-30 C. KOH reagent requires to be stored at a 15-35 C. 2. Record review did not include recorded room temperature log. 3. There was no written policy for the monitoring of room temperature. 4. No thermometer was present in the rooms where reagents were stored during observation on 12/07/2021 at approximately 11:00 AM. 5. In an interview on 12/07/2021 at approximately 11:45 PM, testing personnel confirmed room temperature was not monitored in rooms where reagents were stored.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on direct observation and interview with testing personnel, reagents were not properly labeled. The laboratory performs approximately 90 microscopic potassium hydroxide and direct wet mount preparations tests annually. Finding include: 1. Direct laboratory observation 12/07/2021 at approximately 12:30 PM, found that two out of

two bottles of saline were not labeled with their contents, storage requirements, preparation, and expiration dates. 2. In an interview on 12/07/2021 at approximately 12:45 PM, testing personnel confirmed that the bottles of saline were not properly labeled.

D5471

CONTROL PROCEDURES

CFR(s): 493.1256(e)(1)(g)

(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.

This STANDARD is not met as evidenced by:

Based on record review and interview with the laboratory director, the laboratory failed to check quality controls for potassium hydroxide (KOH) for each new lot number and shipment of KOH reagent. The laboratory performs approximately 90 microscopic KOH tests annually. Finding include: 1. The KOH Quality Control procedure states that each new lot of KOH should be tested with a positive and negative control. 2. Record review on 12/07/2021 at approximately 11:19 AM, revealed that positive and negative controls were not tested with each new lot of KOH. 3. In an interview on 12/07/2021 at approximately 11:30 AM, the laboratory director confirmed that quality controls were not evaluated with each new lot of KOH.