

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2095215	(X3) Date Survey Completed 06/16/2022
Name of Provider or Supplier Foothill Family Clinic Draper	Street Address, City, State 13953 S Bangerter Parkway, Draper, 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 record review and interview with the technical consultant (TC), the laboratory failed to have a procedure to assess the competency for one of one technical consultant. Findings Include: 1. A review of the laboratory procedures revealed the laboratory failed to have a policy or procedure to assess the competency of the position of technical consultant for 1 of 1 technical consultant. 2. An interview on 06/16/2022, at 14:30, the Technical Consultant (TC), confirmed the laboratory failed to have a policy or procedure to assess the competency for the position of technical consultant.</p>
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review, direct observation, and interview with Testing Personnel #3 (TP3) and Technical Consultant (TC), expiration dates were not written on open vials</p>

of hematology controls (Coulter 4C-ES Cell Control) and Potassium Hydroxide (KOH) reagent. The laboratory runs approximately 3,000 hematology tests per year. Findings include: 1. During observation of laboratory on 06/16/2022 at 14:40, laboratory failed to document expiration dates on 3 of 3 open tubes of Coulter 4C-ES Cell Control. 2. Record review of the package insert for Coulter 4C-ES Cell Control showed an open vial expiration of 35 days from the date of open. 3. An interview on 06/16/2022 at 15:25 with TC confirmed that they do not write expiration date upon opening Coulter 4C-ES Cell Control.

D5435

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
Based on record review, direct observation, and interview with the technical consultant, 3 of 3 thermometers used to monitor room temperature, freezer temperature, and refrigerator temperature had expired calibrations and were not calibrated per manufacturer's instructions. Findings include: 1. Record review failed to include documentation of calibrating thermometers. 2. The laboratory failed to have a written policy for the calibration of thermometers for room temperature, freezer, or refrigerator. 3. In an interview on 06/16/2022 at 15:25, the Technical Consultant (TC) confirmed that thermometers are not calibrated and that there is no policy to calibrate thermometers.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review, interview with Technical Consultant (TC), and direct observation of testing area, controls are not being performed each day of patient testing for Potassium Hydroxide (KOH) prep slides. The laboratory performs approximately 13 KOH tests per year. 1. Record review did not include records of quality control (QC) being performed prior to patient testing. 2. In an interview on 06/16/2022 at 15:25, the TC confirmed that KOH controls are not run with each day of patient testing. 3. During observation of laboratory on 06/16/2022 at 14:40 no controls for KOH testing were found in the laboratory.