

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0524018	(X3) Date Survey Completed 08/24/2022
Name of Provider or Supplier Foothill Family Clinic-North	Street Address, City, State 2295 Foothill Drive, 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
D3003	<p>FACILITIES CFR(s): 493.1101(a)(2)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Henry Schein OneStep+ Strep A Dipstick manufacturer's instructions, patient results, observation of the hallways connecting the patient exam rooms, and interview with the technical consultant (TC), the laboratory failed to ensure contamination of patient specimens is minimized. Findings: 1. Review of the Henry Schein OneStep+ Strep A Dipstick manufacturer's instructions stated, "Do not eat, drink, or smoke in the area where the specimens and kits are handled." 2. Interview with the TC confirmed "The MA tape the Strep container with the reagent, test strip and patient specimen to the door of the patient exam room and read the result after the required time." 3. Observation of the hallways connecting the patient exam rooms showed access by patients and staff. Patients including children and staff had access to the taped specimens located on the patient exam room door. Observation of drinks were located in the hallway. 4. The laboratory results approximately 350 rapid Strep A tests. 5. Interview with the TC on August 23, 2022 at 12:00 PM confirmed the laboratory failed to ensure the laboratory area was maintained to minimize contamination of patient specimens.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for</p>

specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on a review of the procedure manual, patient test volumes, and interview with the technical consultant (TC), the laboratory failed to include reference ranges for microscopic urinalysis, relative white blood cell (WBC) counts, and a step-by-step procedure including calculations for using sodium citrate tubes for platelet testing. Findings include: 1. Review of the CBC - Sysmex XN-430/530 procedure on August 24, 2022, at approximately 11:15 AM, showed the laboratory failed to include reference ranges for microscopic urinalysis, relative WBC counts, and a step-by-step procedure including calculations for using sodium citrate tubes for platelet testing. 2. The laboratory reports out approximately 1100 urine microscopic patient results and 10,500 complete blood cell counts annually. 3. Interview on August 24, 2022, at approximately 12:00 PM, the TC confirmed that the laboratory failed to include reference ranges for microscopic urinalysis, relative WBC counts, and a step-by-step procedure including calculations for using sodium citrate tubes for platelet testing.