Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 46D0935188	**(X3) Date Survey Completed** 08/23/2022
Name of Provider or Supplier Foothill Family Clinic - South	**Street Address, City, State** 6360 S 3000 E Ste 100, 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 review of proficiency testing for 2020, 2021, and to date August 23, 2022, patient test volumes, and interview with the technical consultant (TC), the laboratory failed to verify the accuracy of the nonregulated analyte, manual Semen analysis (presence or absence only). Findings: 1. Review of 2020, 2021, and to date August 23, 2022 proficiency testing, showed no enrollment for the nonregulated analyte, manual Semen analysis (presence or absence only). 2. No documentation was available for review to verify the accuracy of the nonregulated analyte of manual Semen analysis (presence or absence only). 3. The laboratory reports out approximately 20 manual Semen analysis (presence or absence only) annually. 4. Interview with the TC on August 23, 2022, at 12:30 PM confirmed that the laboratory failed to verify the accuracy of the nonregulated analyte of manual Semen analysis (presence or absence only).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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 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 an 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. A review of the CBC - Sysmex XN-430/530 procedure on August 23, 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 3900 urine microscopic patient results and 10,500 complete blood cell counts annually. 3. Interview on August 23, 2022, at approximately 11:25 AM, 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.