Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2040798	(X3) Date Survey Completed 02/20/2019
Name of Provider or Supplier Reproductive Care Center Layton	**Street Address, City, State** 1725 E 1450 S Suite 300, Clearfield, 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
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 procedure manual review, lack of documentation, and interview with staff, the laboratory failed to perform a negative and positive control each day of testing for semen fructose for 2 years of testing reviewed from 02/2017-02/2019. Findings include: 1. The procedure manual included a method for a fructose test, as part of their semen analysis test, performed when samples did not contain sperm cells. 2. The laboratory lacked documentation of quality control sample testing for the fructose test. 3. The technical supervisor stated during interview on 02/20/2019 at approximately 12: 00 p.m., they tested a normal semen sample if a sample tested negative for fructose to check their reagent, but they did not run a negative and positive control each day of testing.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, and interview with staff, the laboratory failed to document stain quality each day of testing for the LeucoScreen stain used in semen analysis testing for 2 of 2 years of testing reviewed from 02/2017-02/2019. Findings include: 1. The procedure manual contained a procedure for performing a LeucoScreen stain used for the determination of peroxide-positive white blood cells (WBCS) in semen for samples that contained a large number of round cells. 2. The laboratory lacked documentation they evaluated the LeucoScreen stain for intended reactivity each day of use. 3. In an interview with staff on 02/20/2019 at approximately 12:00 pm, the technical supervisor stated they did not document the quality of the LeucocScreen screen and did not have a method to determine if the stain worked if they did not see WBCS in the sample.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on patient test report review and interview with staff, the test report failed to include the location where sperm morphology testing was performed for 4 of 5 semen analysis test reports reviewed. Finding include: 1. Semen analysis test reports for patient 53873 tested on 12/01/2017, patient 54631 tested on 03/15/2018, patient 56145 tested on 07/17/2018, and patient 33489 tested on 10/30/2018, failed to include the location where the sperm morphology portion of the semen analysis was performed. 2. In interview with staff on 02/20/2019 at approximately 2:00 p.m., the technical supervisor stated the sperm morphology portion of semen analysis for their Layton laboratory is routinely performed by him at their Sandy location. Staff stated the testing location listed on the test report is determined by the location where the testing was ordered and does not always reflect the location where testing is actually performed.