Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2170137	03/31/2026
Name of Provider or Supplier	**Street Address, City, State**	
Utah Fertility Center - Ogden	1452 E Ridgeline Dr, Ste #201, Ogden, 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
D0000	A validation survey was conducted on 3/31/2026 and standard level deficiencies were cited.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 direct observation, manufacturer's instructions, and interview with testing person-1 (TP-1, as listed in the Form CMS-209), the laboratory failed to monitor and document the storage room temperature where 13 of 13 packages (100 tubes per package) of blood collection tubes were stored. Findings included: 1. During a tour of the storage room on 3/31/2026 at 10:30 am, the following BD Vacutainer blood collection tubes were observed: 100 of Buffered Sodium Citrate (lot #5260120, expiration date 6-30-2026) 100 of SST yellow top (lot #5255593, expiration date 8-31-2026) 600 of K2E (Dipotassium Ethylenediamine-tetraacetic acid) 7.2 mg (lot #5169896, expiration date 10-31-2026) 300 of SST (serum separator tube) tiger top (lot #5105206, expiration date 3-31-2026) Manufacturer's storage requirements stated, "Store tubes at 4-25C (39-77F), unless otherwise noted on the package label." 2. During an interview on 3/31/2026 at 10:30 am, TP-1 confirmed the storage room was not monitored and documented for room temperature.

D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, interview with TP-1, and review of patient results, the laboratory failed to ensure expired Access Sensitive Estradiol Calibrator S0 was not used when diluting 2 of 2 patient samples in 2026. Findings included: 1. During a tour of the storage room on 3/31/2026 at 10:28 am, two boxes of expired Access Sensitive Estradiol Calibrator S0 boxes were observed in the refrigerator (lot #588801, expiration date 11-08-2025). 2. During an interview on 3/31/2026 at 10:28 am, TP-1 confirmed the (expired) Access Sensitive Estradiol Calibrator S0 was in-use to dilute patients when their results exceed a certain concentration (>4,935 pg/mL). 3. Review of electronic patient results included when the expired Access Sensitive Estradiol Calibrator S0 was used to dilute patient Estradiol results: patient #1276 on 1/15/2026 and patient #35839 on 2/13/2026.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on corrective action, laboratory's written policy, quality control records, patient results, and in interview with TP-1, the laboratory failed to ensure their quality assessment was effective for identifying and correcting QC issues for 5 of 5 days reviewed in 2025. Findings included: 1. Review of a document dated 6/10/2025 written by the current technical consultant stated, "After I took this position starting March 17, 2025, I learned that during the time before I started that there were discrepancies in QC that included no documentation of troubleshooting, and/or reporting patient results without appropriately passing quality control. There were no incidents where providers questioned laboratory results and l am confident that with calibrations, range adjustments where appropriate, and better support and training on QC rules, that things could have been properly done. To improve our QC practices company wide, we are in the process of acquiring QC data management software, as well as using frequent and regular reminders of what quality control should look like." 2. Review of the laboratory's "QC Policy, Review and Troubleshooting" (Procedure number: 3.13, effective 1-22-2019) stated, "Results cannot be released on any patient until appropriate QC for that day has been verified as complete and within acceptable range ...Out of control issues should be investigated and documented before testing results are released. a. All values falling outside of 2 SD are to be investigated and determined if the level can be accepted. Additional Westgard rules determining shifts or trends must be considered before accepting the one time, one level out of control value. If no additional issues are noted, results can be released, and the out of control

	can be deemed a random error. b. If 2 levels of control fall outside 2SD on the same day, this indicates a systematic error and should be investigated. c. If 2 consecutive QC values on the same QC level fall outside of 2SD, this indicates a systematic error and should be investigated. d. All values falling outside of 3 SD indicate a systematic error and should be investigated before results are released. e. Other issues such as shifts and wide range variances (two consecutive levels showing a spread of greater than 4 SD) should be investigated as well." (SD=standard deviation) 3. Review of a sample of QC data reports from the Access 2 analyzer and electronic patient results for Prolactin included the following: 1/29/25 - Prolactin level Lot #85362 QC result was 18.40 (>4 SDs), repeated and was 17.90 (>3 SDs), repeated and was 17.42 (>2 SDs) (acceptable range: 14.70 - 17.11 ng/mL) and for level Lot #85363 QC result was 47.52 (>3 SDs), repeated and was 44.96 (>2 SDs) (acceptable range: 36.24 - 44.72 ng /mL). Two of three levels of QC were not acceptable and one patient was reported. 4/3 /25 - Prolactin level Lot #85362 QC result was 17.62 (>2SDs) (acceptable range: 14.70 - 17.11 ng/mL) and for level Lot #85363 QC result was 45.43 (>2SDs) (acceptable range: 36.24 - 44.72 ng/mL). Two of three levels of QC were not acceptable and one patient was reported. 4/14/25 - Prolactin level Lot #85362 QC result was 17.59 (>2SDs) (acceptable range: 14.70 - 17.11 ng/mL) and for level Lot #85363 QC result was 45.74 (>2SDs) (acceptable range: 36.24 - 44.72 ng/mL). Two of three levels of QC were not acceptable and three patients were reported. 4/15/25 - Prolactin level Lot #85362 QC result was 17.22 (>2SDs) (acceptable range: 14.70 - 17.11 ng/mL) and for level Lot #85363 QC result was 46.42 (>2SDs) (acceptable range: 36.24 - 44.72 ng/mL). Two of three levels of QC were not acceptable and two patients were reported. 4/16/25 - Prolactin level Lot #85361 QC result was 8.25 (>2SDs) (acceptable range: 6.67 - 8.13 ng/mL) and for level Lot #85362 QC result was 17.35 (>2SDs) (acceptable range: 14.70 - 17.11 ng/mL). Two of three levels of QC were not acceptable and one patient was reported. There was no documentation of "investigating" when more than one level of QC was out of range (>2 SDs) per the laboratory's policy. The laboratory did not ensure that their quality assessment procedure was effective when these issues were identified. 4. During an interview on 3 /31/2026 at 11:52 am, TP-1 confirmed that all QC must be within 2 SDs before proceeding with patient runs.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance specifications are identified, and that patient test results are reported only when the system is functioning properly; This STANDARD is not met as evidenced by: Based on review of corrective action, interview with the technical consultant, and QC records, the laboratory director failed to ensure remedial actions were taken and documented for patients when QC did not meet acceptability criteria for 5 of 5 days. Findings included: 1. Review of a document dated 6/10/2025 written by the current technical consultant included acknowledging QC issues and a plan moving forward for QC reminders for testing persons. Refer to D5793. 2. During an interview on 3/31 /2026 at 11:44 am, the technical consultant stated they were unaware whether the laboratory director was involved in evaluating patients who may have been affected

	on days when QC was not within range. 3. The laboratory was unable to provide documentation of patients evaluated by the laboratory director when Prolactin QC was not within range. Refer to D5793.