Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D2049037	(X3) Date Survey Completed 05/01/2023
Name of Provider or Supplier Planned Parenthood Assn Of Utah-Metro Clinc	**Street Address, City, State** 160 S 1000 E Suite 120, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on record review of personnel competency records and interview with testing personnel (TP), the laboratory failed to ensure competency assessment was performed for one of one Technical Consultants (TC) based on the specific position responsibilities listed in Subpart M. Findings include: 1. Review of personnel competency records revealed the laboratory lacked documented competency assessment for one of one TC since the last survey on 01/12/2021. 2. Interview conducted on 05/01/2023, at approximately 10:50 AM, with TP #4 confirmed the laboratory did not have a competency assessment for one of one TC.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review laboratory record review, and interview with testing personnel (TP), the laboratory failed to follow the procedure for reviewing Individualized Quality Control Plan (IQCP). Findings include: 1. Review of the IQCP for Doctor's Kit DLS

	RhD 25 test revealed that the IQCP should be "reviewed on a regular basis". 2. A review of laboratory records revealed the laboratory failed to review the IQCP since the last survey was conducted on 01/12/2021. 3. An interview on 05/01/2023, at 12:05 PM, with TP #4 confirmed the laboratory failed to review the IQCP on a regular basis.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 and interview with Testing Personnel (TP), the laboratory failed to ensure that Human Whole Blood K2EDTA RH controls were not used past the expiration date. The laboratory performs 168 Rhesus (Rh) factor tests annually. Findings include: 1. Direct observation of laboratory refrigerator revealed Human Whole Blood K2EDTA RH controls lot numbers HMN1079001 and HMN1079000 with an expiration date of 03/21/2023 and control lot numbers HMN1090963 and HMN1090964 with an expiration date of 04/21/2023. 2. In an interview conducted on 05/01/2023, at approximately 12:25 PM, the TP #4 confirmed the controls were expired.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on record review and interview with testing personnel (TP), the laboratory did not establish calibration verification procedures and logs for the calibration for laboratory thermometers. The laboratory performs 168 Rhesus (Rh) factor tests annually. Findings include: 1. Record review of the laboratory procedures revealed the laboratory failed to establish calibration, calibration verification procedures and documentation logs for the calibration of laboratory thermometers. 2. Record review of thermometer S/N 122480457 package insert revealed that the calibration for the thermometer was due on 08/24/2014 3. In an interview on 05/01/2023 at approximately 12:45 PM, the TP #4 confirmed the laboratory failed to establish procedures for calibration verification procedures and documentation logs for the calibration for laboratory thermometers.