Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D1010280	(X3) Date Survey Completed 06/23/2022
Name of Provider or Supplier University Of Utah Genome Depot	**Street Address, City, State** 15 N 2030 E, 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 and interview with the technical consultant (TC), the laboratory failed to have a written procedure to assess the competency for one of one technical consultant. The laboratory performs approximately 450 PCR tests to identify genetic mutations annually.Findings include: 1. A review of the laboratory procedures on 06/23/2022 revealed the laboratory failed to have a policy or procedure to assess the competency of the position of technical consultant. 2. A review of the laboratory procedures on 06/23/2022 revealed the laboratory failed to have a policy or procedure to assess the competency of testing personnel. 3. An interview on 06/23/2022, at 15: 10, the technical consultant confirmed the laboratory failed to have a policy or procedure to assess the competency for the position of technical consultant.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on record review and interview with the technical consultant, the laboratory failed to ensure the twice-yearly evaluation on two of two Applied Biosystems 2720 Verti thermocyclers that compares the relationship between instruments. The laboratory performs approximately 450 PCR tests to identify genetic mutations annually. 1. During record review on 06/23/2022, no comparison study was available that evaluated or defined the relationship between different instruments running the same test on two of two Applied Biosystems 2720 Verti thermocyclers. 2. The laboratory failed to include an instrument-to-instrument comparison procedure in the laboratory's quality assessment procedure. 3. In an interview on 06/23/2022 at 15:10, the technical consultant confirmed that they have not performed an instrument-to-instrument comparison study on two of two Applied Biosystems 2720 Verti thermocyclers.