Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2235336	05/29/2024
Name of Provider or Supplier	**Street Address, City, State**	
Infinite Genomics Llc	4850 Northshore Lane, North Little Rock, AR	

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: Review of the CMS 209 form, lack of documentation and interviews with laboratory staff, determined the laboratory failed to assess employee competency as directed in personnel requirements. Survey findings follow: A) Review of the CMS 209 form submitted by the laboratory revealed that the laboratory staff member (#2 on the CMS 209 form) was listed as the technical supervisor, laboratory staff member (#6 on the CMS 209 form) was listed as general supervisor. B) Review of personnel records for laboratory staff member (# 2 on the CMS 209 form) revealed that no competency evaluation for the position of technical supervisor was present for calendar year 2022 or 2023, review of personnel records for laboratory staff member (# 6 on the CMS 209 form) revealed that no competency evaluation for the position of general supervisor was present for calendar year 2022 or 2023. C) Upon request, the laboratory was unable to provide documentation of competency determinations for calendar year 2022 and 2023 for the positions of technical supervisor or general supervisor for the personnel identified above. D) In an interview at 1:00 p.m. on May 29, 2024 the health system staff member (# 2 on the Entrance/Exit Conference Attendance Record) confirmed that competency determinations have not been performed on the personnel designated as technical supervisor and general supervisor.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Review of the laboratory's policy and procedure manual, lack of documentation, and interviews, determined the laboratory failed to follow written Quality Assessment (QA) policies and procedures to monitor, assess and correct problems identified in the laboratory. Findings Follow: A) The laboratory policy and procedure manual states under the policy "Quality Assessment Plan" that "all QA activities will be documented on Quality Assessment Review Form" and "completed forms, supporting documentation, and notations related to QA activities must be submitted by the last day of the scheduled month and retained for at least two years". B) Upon request, the laboratory was unable to provide "Quality Assessment Review" forms for 2022 and 2023 C) In an interview on 01:32 p.m.on 5/29/24, laboratory staff member (#2 as identified on form CMS 209) when asked if the laboratory had the quality assessment calendar and quality assessment review forms for 2022 and 2023, replied "no".
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (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 review of policy and procedure manuals, temperature logs, and interview with staff, the laboratory failed to follow instructions for operational environment policies for temperature requirements. Findings follow: A) Review of the following procedures: "Respiratory Pathogen Panel (RPP), Wound Plus, Womens Health Plus, Urinary Tract Infection (UTI), Nail Panel, and Sexually Transmitted Infection (STI)" revealed reagents listed in all the procedures have temperature requirements such as: Binding Solution (15C to 25C), Wash solution (15C to 30C), Elution solution (15C to 30C), Nucleic Acid Beads (15C to 30C), and Proteinase K solution (15C to 30C). B) Review of the electronic Temperature/Humidity log for Laboratory Transfer, Extraction and PCR rooms April 16, 2024, revealed no temperatures were recorded. May 29, 2024, revealed no temperatures were recorded. C) During an interview on 5 /29/2024 at 15:42 p.m. the Laboratory Directory listed on the CMS-209 form, confirmed the temperature are not being recorded.
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: Through observation and interview with laboratory staff it was determined that the laboratory had supplies available for use after their expiration date. Findings follow: A) During a tour of the laboratory on 5/29/24 at 3:28 p.m. one (of one) package of Beckton Dickson (BD) Vacutainer Urine C+S tube (Ref: 364951, Lot: 2069973, expiration date 09/30/2023) was observed in the laboratory, available for use beyond their expiraton date. B) During a tour of the laboratory on 5/29/24 at 3:28 p.m. one (of one) package of BD Vacutainer UA Preservative (Ref: 364957, Lot: 2011946, expiration date 07/2023) was observed in the laboratory, available for use beyond their expiraton date. C) During a tour of the laboratory on 5/29/24 at 3:23 p.m. one (of one) package of Applied Biosystems (ABI) 384-Well Spectral Calibration Plate with TAMRA Dye (Ref: 4432296, Lot: 2305260, expiration date 05/05/2024) was observed in the laboratory, available for use beyond their expiraton date D) During a tour of the laboratory on 5/29/24 at 3:37 p.m. one (of one) package of ABI QuantStudio 12K Flex Openarray Accessories Kit Starter (Ref: 4469586, Lot: 2208388, expiration date 09/15/2023) was observed in the laboratory, available for use beyond their expiraton date E) During a tour of the laboratory on 5/29/24 at 3:23 p. m. one (of one) package of ABI 384-Well Spectral Calibration Plate with NED Dye (Ref: 4432302, Lot: 2305305, expiration date 05/10/2024) was observed in the laboratory, available for use beyond their expiraton date F) During a tour of the laboratory on 5/29/24 at 3:23 p.m. one (of one) package of ABI TaqMan RNase P Fast 384-Well Instrument Verification Plate (Ref: 4455280, Lot: 2305948, expiration date 02/22/2024) was observed in the laboratory, available for use beyond their expiraton date G) In an interview on 05/29/2024 at 3:38 p.m. general supervisor #1, as listed on the CMS-209 form, confirmed that the items, identified above, had exceeded their expiration date and were available for use.
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: Through a review of Laboratory test reports and interview with staff it was determined the laboratory test reports failed to include the Specimen Type. Survey findings include: A. A review of laboratory test reports (three of seven) revealed the laboratory results reports reviewed failed to include the specimen type on the final report. Lab Accession number: 16209, 16148, and 16216. B. In an interview at 14:42 on 5/29/2024 the laboratory director (as listed on the form CMS-209) confirmed the laboratory test report did not include specimen type on the final report.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: . Review of personnel files for four testing personnel listed on the form CMS-209, lack of documentation, and interviews with laboratory staff, determined the laboratory director failed to authorize two of four testing personnel to perform testing without direct supervision. Survey findings include: A) During a review of personnel files for four testing personnel listed on form CMS-209 (Personnel #'s 3,4,5,6) the surveyor determined employee numbers 4 and 5 (as listed on the form CMS-209) failed to have written authorization, from the laboratory director, to perform high complexity testing without direct supervision. B) In an interview, at 01:00 p.m.. on 5/29/24, laboratory employee #2 (as listed on the form CMS-209) confirmed the lack of written authorizations to test for employee #'s 4 and 5 (on form CMS 209).