Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2235336	07/28/2022
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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Through a review of documentation for the four proficiency testing events completed by the laboratory in 2022, lack of documentation, and interviews with staff, it was determined the laboratory testing personnel and director failed to sign the attestation statements for four of four proficiency testing events completed by the laboratory. Survey findings include: A) A review of the proficiency test documentation for 2022 revealed the laboratory performed proficiency testing CAP-COV-A-2022, CAP-BOR-A-2022, CAP-IDBN-A-2022 and API Microbiology 2022 2nd event and the attestations for all events were not signed by the testing personnel or the laboratory director or designee. B) Laboratory employee, identified as #1 on the CMS 209 form, confirmed, in an interview at 10:20 on 7/28/22, that the forms lacked the required signatures.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

	This STANDARD is not met as evidenced by: Through review of laboratory policy and procedure and interview it was determined that the laboratory failed to follow policy pertaining to shipping conditions. Findings follow: A) Review of the laboratory policy and procedure and package insert for TaqPath RT-PCR Covid-19, FluA, FluB Kit revealed that COVID specimens are to be shipped on ice or specimens would be rejected. B) In an interview on 7/28/22 at 10:26 AM , the laboratory staff member, identified as number 1 on a separate employee list, confirmed that the specimens identified above were accepted for testing despite being shipped in storage conditions that failed to meet laboratory policy. Specimens were transported in FedEx non insulated large clinical packages for overnight shipping. C) In an email on 7/28/22 at 2:46 PM , the laboratory staff member, identified as number 1 on the CMS 209 form, confirmed that the specimens identified above were accepted for testing despite being shipped in storage conditions that failed to meet laboratory policy.
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: Through observation, review of temperature records, lack of documentation and interview it was determined that the laboratory failed to monitor the temperature of one of three rooms in which supplies with storage temperature requirements were stored on each day of operation. Findings follow: A) During a tour of the laboratory on 7/27/22 at 11:30 AM three rooms containing items with a temperature storage requirement , the two main laboratory rooms and a separate storage area separated from the main laboratory by a closable door, were observed. B) During a review of the laboratory's temperature records it was noted that temperature records for only the main laboratory rooms were presented. C) During a tour of the laboratory on 7/27/22 at 11:30 am, 10 boxes of Thermo-Fisher deep well 96 plates lot # 000313265 expiration date 2023-07-25 and a storage temperature requirement of 15 degrees C. to 30 degrees C. were observed in the separate storage room. D) Upon request, the laboratory could not present the temperature records for the storage room in which the supplies identified above were stored,. E) In an interview on 7/28/22 at 10:20 am. the laboratory staff member, identified as number one on the CMS 209 form, stated that the daily temperature of the storage room in which the supplies, identified above, were stored had not been monitored and recorded..
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Through a review of personnel files for fifteen of the fifteen testing personnel listed on the CMS-209 form, lack of documentation as well as interviews with staff, it was determined the laboratory director failed to specify, in writing, the procedures each testing person can perform and whether supervision is required for 15 of the 15 testing personnel. Survey findings follow: A) Review of the personnel files for fifteen testing personnel, listed as #4 through #8 and # 11 though #20 on the CMS 209 form, revealed that no written authorization identifying which tests the individual was authorized to perform with or without supervision was present. B) Upon request, the laboratory was unable to produce written authorization from the laboratory director identifying which tests the personnel identified above were authorized to perform. C) In an interview on 7/27/22 at 3:30 pm the laboratory staff member, identified as number one on the CMS 209 form, confirmed that the laboratory director had not provided written authorization to test for the personnel identified above.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Through a review of the form CMS-209, a review of educational credentials for employees #13, #16, #18, #19, (as listed on the form CMS-209), and interviews with laboratory staff, it was determined four of fifteen testing personnel failed to meet the qualifications for high complexity testing personnel as evidenced by: D6171 - testing personnel failed to meet the educational qualifications for high complexity testing personnel
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or

medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Through a review of the form CMS-209, a review of credentials for employees #13, #16, #18, #19 (as listed on the form CMS-209), lack of documentation and interviews with laboratory staff, it was determined four of fifteen testing personnel failed to meet the educational qualifications for high complexity testing personnel. Survey findings include: A) During a review of the form CMS-209 it was revealed that the laboratory had fifteen individuals listed as testing personnel (listed as #4 through #8, and #11 through #20). B) Review of the educational credential for testing personnel # 13, as listed on the CMS 209 form, revealed a diploma from the Republic of Phillipines Nueva Elija University of Science and Technology. C) Upon request, the laboratory could not provide a certificate of educational equivalency for the foreign graduate identified above. D) Review of the educational credential for testing personnel # 16, as listed on the CMS 209 form, revealed the employee had no educational credentials

	provided other than a certificate in Histotechnology. E) Review of the educational credential for testing personnel # 18, as listed on the CMS 209 form, revealed the employee had an "unoffical transcript" listing nine semester hours in "clinical laboratory" from Remington University and four semester hours in Biology from the University of Arkansas at Little Rock. F) Review of the educational credential for testing personnel # 19, as listed on the CMS 209 form, revealed a diploma from Tallina Tervishoa Korgkool with an educational equivalency provided by Educational Credential Evaluators of a high school diploma. G) In an interview on 7/27/22 at 3:30 pm, the laboratory staff member, identified as number one of the CMS 209 form, confirmed that the testing personnel identified above lacked the qualifications for high complexity testing and performed such testing at the laboratory.