Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2197387	05/27/2025
Name of Provider or Supplier	**Street Address, City, State**	
Breakthrough Genomics	25 Mauchly, #313, Irvine, CA	

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 review of personnel competency assessment records, review of seven (7) randomly selected patient test results and interview with the Laboratory Director (LD), the laboratory failed to assess employee competency. The findings included: 1. It was the practice of the laboratory to perform high complexity Molecular Diagnostic, testing. The Clinical Laboratory Scientist (CLS) were responsible for testing. The last competency assessment for the CLS was on 03/09/2022. 2. The LD affirmed on May 27, 2025, at approximately 12:00 pm, that the CLS did not have competency assessments for 3 of 3 years. 3. The laboratory's testing declaration form, signed by the laboratory director on May 5, 2025, stated that the laboratory performed approximately 887 tests annually.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) records and interview with the Laboratory Director (LD), the laboratory failed to verify the accuracy for SARS-CoV-2, RSV and influenza A/B test results at least twice annually for three of three years.

	The findings included: 1. The laboratory performed molecular testing of SARS-CoV-2, RSV and influenza A/B, which are not listed in the subpart I of the 42 CFR part 493. For the test procedure not listed in subpart I the laboratory must verify the accuracy of the test procedure twice annually. 2. On 05/27/2025 at approximately 12: 00 PM, the LD confirmed that the laboratory did not verify the accuracy of the molecular testing twice annually in 2023, 2024 and 2025. 3. The laboratory's testing declaration form, signed by the laboratory director on May 5, 2025, stated that the laboratory performed approximately 887 tests annually. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor review of preventive maintenance (PM) records, and interview with the Laboratory Director (LD), the laboratory failed to perform the annual preventive maintenance for two Quant Studio 5 Real-Time PCR (qPCR) analyzers in 2024 and 2025. The findings included: 1. It was the practice of the laboratory to use Quant Studio 5 Real-Time PCR (qPCR) analyzer for detection of SARS-CoV-2, RSV and influenza A/B. The laboratory had two Quant Studio 5 Real-Time PCR (qPCR) analyzers. The Quant Studio 5 Real-Time PCR (qPCR) requires performance of annul PM. 2. The laboratory PM records for the (qPCR) analyzer showed the laboratory did not perform PM for two of two analyzers after July 2023. The LD affirmed on May 27, 2025, at approximately 12:30 pm, that the laboratory did not perform the required PM for both analyzers in 2024 and 2025. 3. The laboratory's testing declaration form, signed by the laboratory director on May 5, 2025, stated that the laboratory performed approximately 887 tests annually.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(g) (d)(3)(v) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control (QC) records, review of seven (7) randomly selected patient test results and interview with the laboratory director on 05/27/2025, the laboratory failed to review the results of quality control materials from 08/08/2023 to 09/07/2024. The findings included: 1. The laboratory's QC testing records showed that the laboratory performed QC on Quant Studio 5 Real-Time PCR (qPCR) analyzers after each run. The laboratory stopped reviewing the QC results after 08/07/2023. Without reviewing the quality control material on the day of patient testing the instrument's proper performance cannot be assessed. Therefore, the

	accuracy of the patients' test results rendered by the laboratory cannot be assured and might have harmed patients. 2. On May 27, 2025, at approximately 12:30 PM, the laboratory director affirmed that the laboratory did not review the quality control material on the day of patient testing from 08/08/2023 to 09/07/2024. 3. The laboratory's testing declaration form, signed by the laboratory director on May 5, 2025, stated that the laboratory performed approximately 887 tests annually.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on interview with Laboratory Director (LD), review of seven (7) randomly selected patient test results, review of the records for proficiency testing, personnel competency assessment and preventive maintenance, on May 27, 2025, the laboratory Director failed to provide overall management and direction in accordance with 493. 1445 of this subpart. The findings included: 1.The LD failed to ensure that prior to testing patients' specimens, personnel have demonstrated that they can perform all testing operations reliably to provide and report accurate results; D5209 2. The Laboratory director failed to ensure that the accuracy of the molecular diagnostic tests was verified at least twice annually. See D5217 3. The LD failed to ensure the laboratory performed the annual preventive maintenance for (qPCR) analyzers. See D5429 4. The LD failed to ensure that the quality control was maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See 5455