Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2262818	(X3) Date Survey Completed 08/21/2025
Name of Provider or Supplier Advanced Genomics	**Street Address, City, State** 275 E Street Rd, Suite A, Feasterville Trevose, PA	

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 lack of documentation and interview with the General Supervisor (GS), the laboratory failed to establish and follow procedures to assess the competency of 1 of 1 GS for their supervisory responsibilities performed from 11/20/2023 to the date of the survey. Findings Include: 1. On the day of survey, 08/21/2025 at 11:45 am, the laboratory failed to provide a procedure for assessing the competency of the laboratory's personnel for their supervisory responsibilities when overseeing virology testing performed from 11/20/2023 to 08/21/2025. 2. The laboratory failed to provide competency assessment records for 1 of 1 GS (CMS 209 personnel #2, dated 08/04 /2025) for their supervisory responsibilities performed from 11/20/2023 to 08/21 /2025. 3. The GS confirmed the findings above on 08/21/2025 at 12:37 pm.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Management Program (QMP), lack of documentation, and interview with the General Supervisor (GS), the Laboratory

	Director (LD) failed to ensure an established Quality Assessment (QA) program was maintained to ensure the quality of services provided by the laboratory for 6 of 6 quarters from 11/20/2023 to the date of survey. Findings include: 1. The laboratory's QMP states, "A mechanism is in place to assess the effectiveness of QMP periodically. This mechanism uses Quality Indicators (QI) developed by the laboratory director and supervisory team of Advanced Genomics." "The QIs are assessed quarterly (as applicable) to assure the highest quality of the laboratory services provided and are updated on a yearly basis." 2. On the date of survey, 08/21 /2025 at 11:45 am, the laboratory failed to provide documentation of the quarterly QI's used to perform periodic QA evaluation to assess the laboratory's pre analytical, analytical, and post-analytical processes for 6 of 6 quarters from 11/20/2023 to 08/21 /2025. 3. The GS confirmed the findings above on 08/21/2025 at 12:37 pm.