Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D2178580	10/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Allergenis Clinical Laboratory	C/O Lankenau Institute For Medical Research, Wynnewood, 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 review of the laboratory's competency assessment procedure and interview with the general supervisor (GS), the laboratory failed to follow their established procedure to assess the competency of 1 of 1 technical supervisor (TS) and 1 of 1 GS for their supervisory responsibilities performed from 12/22/2021 to the date of the survey. Findings include: 1. The laboratory's General Competency Assessment procedure states, " A competency assessment is required for any duties that the laboratory director has delegated to the supervisor as well as requirements that are specified in the CLIA regulations for this position. The laboratory director can perform and sign off on the competency for the Clinical Laboratory Supervisor." 2. On the day of survey, 10/30/2023 at 10:03 am, the laboratory failed to provide competency assessment records for 1 of 1 TS (CMS 209 personnel # 5) and 1 of 1 GS (CMS 209 personnel # 2) for their supervisory responsibilities performed from 12/22 /2021 to 10/30/2023. 3. The GS confirmed the finding above on 10/30/23 around 01: 30 pm.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test

	results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, instrument to instrument comparison records, and interview with the technical supervisor (TS), the laboratory failed to have a system that twice a year evaluates the relationship between 2 of 2 Luminex 200 analyzers used for immunology testing from 12/22/2021 to the date of the survey. Findings include: 1. The laboratory's Comparability of Instrument procedure states, " AllerGenesis utilizes two Luminex 200 instruments to perform specimen analysis. This procedure describes instrument to instrument comparison which is documented at least twice a year. At least twice per year the quality control data are specifically evaluated for instrument-to-instrument comparison." 2. On the date of the survey, 10 /30/23 at 11:14 , the laboratory failed to provide documentation of the biannual comparisons of test results performed for 2 of 2 Luminex 200 analyzers used for immunology testing from 12/22/2021 to 10/30/23. 3. The laboratory performed 162 immunology examinations in 2022 (CMS 116 annual volume). 4. The TS confirmed the findings above on 10/30/2023 at 01:30 pm.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the 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 quality assurance (QA) documentation and interview with the quality consultant, the laboratory director (LD) failed to ensure a QA program was maintained to ensure the quality of services provided by the laboratory for 4 of 10 months in 2023. Findings include: 1. On the day of survey 10/30/2023 at 11:44 am., the laboratory could not provide documentation for the periodic QA evaluation performed to assess the laboratory's pre-analytical, analytical, and post-analytical processes for the following 4 of 10 months in 2023: - July 2023 - August 2023 - September 2023 - October 2023 2. The quality consultant confirmed the findings above on 10/30/23 at 01:30 pm.
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limted to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) competency assessment records and interview with the general supervisor (GS), the laboratory failed to include the assessment of problem solving skills in the competency evaluaitons assessed for 1 of 3 TP that performed immunology testing in 2023. Findings: 1. On the date of they survey, 10/30/23 at 11:07 am, review of TP competency assessments revealed the laboratory failed to include the assessment of problem solving skills in the

	competency evaluations assessed for 1 of 3 TP (CMS 209 TP #3) that performed immunology testing in 2023. 2. The GS confirmed the finding above on 10/30/23 at 01:30 pm.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the general supervisor (GS), the laboratory failed to have the required records accessible during the course of the laboratory survey performed on 10/30/2023. Findings Include: 1. On the day of the survey, 10/30/2023 at 12:20 pm, the laboratory could not provide the following records upon request: -Quality control (QC) records for 2 of 2 Luminex 200 analyzers from 12/22/2021 to 10/30/2023. -QC corrective action documentation for 2 of 2 Luminex analyzers from 12/22/2021 to 10/30/2023. -Electronic patient test requisitions from 12/22/2021 to 10/30/2023. 2. The GS stated during an interview, 10 /30/2023 at 01:30 pm, that the laboratory has not had network access since May 2023, and could not retrieve any documents stored on the laboratory's information system (LIMS Apollo).