Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2034851	06/08/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ayass Laboratory, Llc	8501 Wade Blvd Suite 750, Frisco, TX	

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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and certification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 submitted CMS 209, review of the laboratory's personnel records, review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to have documentation of performing competency assessments on its technical supervisor, technical consultant and general supervisors. The findings include: 1. A review of the laboratory's submitted CMS 209 revealed the laboratory identified the following personnel: 1 technical supervisor 1 technical consultant 3 general supervisors 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of performing competency assessments for the identified personnel. 3. A review of the laboratory's policies

	revealed the laboratory failed to have documentation of a policy defining when and how competency assessments were to be performed on the technical supervisor, technical consultant, and general supervisors. 4. The laboratory was asked to provide documentation of the missing competency assessments. No documentation was provided. 5. An interview with general supervisor number 1 (as listed on Form CMS 209) on June 6, 2022 at 1330 hours in the conference room revealed the facility did not perform competency assessments on the technical supervisor, technical consultant or general supervisors. This confirmed the findings.
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 direct observation, review of manufacturer's instructions, laboratory environmental records (1/2022 - 05/2022) and confirmed in staff interview, the laboratory failed to ensure acceptable temperature ranges were within manufacturer's specifications for the 5 of 5 months in 2022. Findings Included: 1. During a tour of the laboratory, the inspector observed 2 Phadia 250 Immunoassay Analyzers in service (SN: N10350; SN: N10347) in laboratory two. 2. Review of manufacturer's instructions for the Rheumatoid Factor (RF) IgA Reagent, performed on the Phadia Immunoassay Analyzers, revealed the following acceptable room temperature range for proper assay performance: 18-25 C 3. Review of laboratory environmental records revealed the following room temperature range: 18-32 C Further review of environmental records, revealed the following 5 of 5 months in 2022 with the incorrect temperature range: 01/2022; 02/2022; 03/3022; 04/2022; 05/2022 4. During an interview with the laboratory representative on 06/09/2022 at 11:00 a.m. in the conference room, after presentation of findings, the representative confirmed the laboratory failed to ensure acceptable temperature ranges were within manufacturer's specifications for the 5 of 5 months in 2022.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: I. Based on review of Phadia 250 manufacturer's instructions, laboratory maintenance records (07/01/2021-05/31/2022), and confirmed in interview, the laboratory failed to ensure monthly maintenance was performed prior to patient testing for 3 of 16 months reviewed in 2021 and 2022. Findings Included: 1. Review of manufacturer's instructions for the Phadia 250 Immunoassay Analyzer (Version 1.4) revealed the

	following: "Monthly Maintenance Monthly Cleaning Procedure: Using the maintenance solution, perform the automated monthly cleaning procedure. Use Bleach 3-4 times a year. Clean the following with the maintenance solution or bleach monthly: Clean Essential Unit 1: Sample Loading Area Reagent Storage Unit Solid Waste Container Wash, Rinse, Waste Bottles Touch Screen/Reboot Phadia Prime Computer Using hot water, soak transfer and ejection tools Carrier Storage Unit" 2. Review of laboratory maintenance logs for the Phadia 250 revealed the following: "Monthly Maintenance Monthly Cleaning Procedure: Maintenance Solution or Bleach (3-4 times/year) Clean Essential Unit 1: Sample Loading Area Reagent Storage Unit Solid Waste Container Wash, Rinse, Waste Bottles Touch Screen/Reboot Phadia Prime Computer Soak Transfer/Eject Tools (hot water) Clean Carrier Storage Unit" Further review of laboratory maintenance logs for the Phadia 250 revealed the following 3 of 16 months (07/01/2021-05/31/2022) monthly maintenance was not documented: Phadia 250 Serial Number: N10350 a. 07/2021 b. 03/2022 Phadia 250 Serial Number: N10347 c. 05/2022 3. During an interview with Testing Person (TP-4) on 06/07/2022 at 1:00 p.m. in laboratory two, after presentation of findings, TP-4 confirmed the laboratory failed to document monthly maintenance for 3 of 16 months (07/01/2021-05/31/2022) in 2021 and 2022. II. Based on review of Phadia 250 manufacturer's instructions, laboratory maintenance records (02/01/2022-05/31/2022), and confirmed in interview, the laboratory failed to ensure weekly maintenance was performed prior to patient testing for 1 of 14 weeks reviewed in 2022. Findings Included: 1. Review of manufacturer's instructions for the Phadia 250 Immunoassay Analyzer (Version 1.4) revealed the following: "Weekly Maintenance- Weekly Rinse Procedure Perform the following weekly- Clean Essential Units 1: Sample Loading Area Reagent Storage Unit Solid Waste Container Wash and rinse waste bottles. ** Be sure to clean and rinse bottles thoroughly. Touch Screen Reboot Analyzer" 2. Review of laboratory maintenance logs for the Phadia 250 revealed the following: "Weekly Maintenance- Weekly Rinse Procedure Perform the following weekly- Clean Essential Units 1: Sample Loading Area Reagent Storage Unit Solid Waste Container Wash and rinse waste bottles. ** Be sure to clean and rinse bottles thoroughly. Touch Screen Soak Transfer/Eject Tools (hot water) Reboot CPU" Further review of laboratory maintenance logs for the Phadia 250 revealed the following 1 of 14 weeks (02/01/2022-05/31/2022), weekly maintenance was not documented: Phadia 250 Serial Number: N10350 Week 4: 02/2022 3. During an interview with Testing Person (TP-4) on 06/07/2022 at 1:00 p.m. in laboratory two, after presentation of findings, TP-4 confirmed the laboratory failed to document weekly maintenance 1 of 14 weeks in 2022 (02/01/2022-05/31/2022).
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's chemistry quality control records from 2021, and staff interview, it was revealed the laboratory failed to have documention of monitoring quality control values over time to detect shifts and trends. The findings include: 1. A review of the laboratory's chemistry quality control records from 2021 revealed the following controls were tested: Vitros Performance Verifier 1 Lot: W8380 expiration: 2022-11-23 Vitros Performance Verifier 2 Lot: V8380 expiration: 2022-6030 2. Further review of the laboratory's chemistry control records from 2021 revealed the laboratory did not have documentation monitoring the quality control values over time. 3. The laboratory was asked to provide the missing documentation. No documentation was provided. 4. An interview with the technical supervisor on 06 /08/2022 at 1045 hours by phone revealed the laboratory did not monitor quality control values over time. This confirmed the findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the Babies Finder 1.5 Sars-CoV-2 RT PCR methodology, review of the laboratory's procedures, review of the laboratory's quality control records from April 25, 2022 to June 6, 2022, review of patient test records from May 1, 2022 to June 6, 2022, and staff interview, it was revealed the laboratory failed to have documentation of testing quality control material each day of patient testing. The findings include: 1. The laboratory performed testing utilizing the Babies Finder 1.5 Sars-CoV-2 RT PCR methodology. This methodology is not FDA approved and has not had an EUA (emergency use authorization) granted by the FDA. Therefore, it is considered a laboratory developed test and quality control testing must be performed each day of patient testing. 2. A review of the laboratory's procedure titled "SOP for Performing RT-PCR Assay for FINDER SARS-CoV-2 Test on the FINDER 1.5 Instrument" (approved 2/6/2022) under the section titled "Quality Control" revealed: "The performance of the FINDER 1.5 system can be verified by analyzing external quality control specimens. It is recommended that positive and negative quality control specimens should be tested when: - A new lot of FINDER SARS-CoV-2 Test kits is received - Qualifying performance of a new operator - Otherwise required by federal, state, or local regulations, accrediting groups, or the site's Quality Control (QC) procedures." 3. A review of the laboratory's quality control records for the Babies Finder 1.5 from April 25, 2022 to June 6, 2022 revealed quality control testing was performed with each new kit or each new operator. Quality control was tested on the following days: April 25, 2022 May 6, 2022 May 21, 2022 June 3, 2022 4. A review of patient test records from May 1, 2022 to June 6, 2022 identified the following patients whose samples were tested on days without documentation of quality control testing being performed: a) May 2, 2022 Accession: 2205020056 b) May 4, 2022 Accession: 2205040034 Accession: 2205040035 c) May 9, 2022 Accession: 2205090001 Accession: 2205099044 Accession: 2205099107 d) May 12, 2022 Accession: 2205120022 e) May 13, 2022 Accession: 2205130080 Accession: 2205130084 f) May 16, 2022 Accession: 2205160112 Accession: 2205160113

	Accession: 2205160124 g) May 17, 2022 Accession: 2205170045 h) May 24, 2022 Accession: 2205240032 i) May 25, 2022 Accession: 2205250075 Accession: 2205250213 Accession: 2205250234 j) May 26, 2022 Accession: 2205260014 Accession: 2205260015 Accession: 2205260084 k) May 28, 2022 Accession: 2205280006 Accession: 2205280057 l) May 30, 2022 Accession: 2205300047 Accession: 2205300048 m) May 31, 2022 Accession: 2205310001 n) June 2, 2022 Accession: 2206020043 Accession: 2206020066 o) June 4, 2022 Accession: 2206040124 p) June 6, 2022 Accession: 2206060032 Accession: 2206060033 5. The laboratory was asked to provide documentation of performing quality control testing each day of patient testing. No documentation was provided. 6. An interview with general supervisor number 1 (as listed on Form CMS 209) on 06/07/2022 at 1445 hours in the conference room - after her review of the records- confirmed the findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for the Immunocap Specific IgE controls, quality control reports (10/01/2021-05/31/2022), review of patient test records, and staff interview, it was revealed the laboratory failed to ensure all quality control values were acceptable prior to reporting patient results for 1 of 5 reports reviewed in 2021 and 2022. Findings Included: 1. Review of manufacturer's instructions for the Immunocap Specific IgE controls revealed the following: "Immunocap Specific IgE: Directions for Use Control's Available: ImmunoCAP Specific IgE L (Low) ImmunoCAP Specific IgE M (Mid) ImmunoCAP Specific IgE H (High) Control specimen: Good laboratory practice requires quality control specimens should be included in every run. Performing laboratory should adhere to local policies and procedures and all applicable federal, state and local regulations." 2. Review of laboratory quality control reports for the Immunocap Specific IgE controls revealed the following: Laboratory Report 10/26/2021 Quality Controls Lot: CYYB1 a. ImmunoCAP Specific IgE H Measured at 12:47:04 PM Result: Low b. ImmunoCAP Specific IgE H Measured at 03:44:20 PM Result: Low c. ImmunoCAP Specific IgE H Measured at 04:22:05 PM Result: Low d. ImmunoCAP Specific IgE H Measured at 06:36:05 PM Result: Low e. ImmunoCAP Specific IgE H Measured at 06:36:35 PM Result: Low f. ImmunoCAP Specific IgE H Measured at 07:10:20 PM Result: Low The laboratory failed to document an acceptable value for the ImmunoCAP Specific IgE H quality control. 3. Review of final patient reports revealed one patient sample tested and reported on days of failed quality control: Date PErformed: 10/26/2021 Specimen Number: 2110270156 Measured at 03:48:50 PM 4. During an interview with Testing Person (TP-4) on 06/07/2022 at 1:00 p.m. in laboratory two, after presentation of findings, TP-4 confirmed the laboratory failed to ensure all quality control values were acceptable prior to reporting patient results for 1 of 5 reports reviewed in 2021 and 2022.
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: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's records and staff interview, it was revealed the laboratory director failed to have documentation of a job description for the technical consultant. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 1 technical consultant. 2. A review of the laboratory's personnel records revealed the laboratory director failed have documentation of a job description for the technical consultant. 3. An interview with general supervisor number 1 (as listed on Form CMS 209) on 06/07/2022 at 1300 hours in the conference room confirmed the findings.
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: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's records and staff interview, it was revealed the laboratory director failed to have documentation of job descriptions for the technical supervisor and 2 of 3 general supervisors. The findings include: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 2 technical supervisor and 3 general supervisors. 2. A review of the laboratory's personnel records revealed the laboratory director failed have documentation of a job description for the technical supervisor and 2 of 3 general supervisors. They were (as listed on Form CMS 209): general supervisor 2 general supervisor 3 3. An interview with general supervisor number 1 (as listed on Form CMS 209) on 06/07/2022 at 1300 hours in the conference room confirmed the findings.