Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2034851	07/25/2024
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	The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493. 1421 Condition: Laboratories Performing Moderate Complexity Testing; Testing Personnel 493. 1487 Condition: Laboratories Performing High Complexity Testing; Testing Personnel 493. 1441 Condition: Laboratories Performing High Complexity Testing; Laboratory Director
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the laboratory's test menu, the laboratory's records, and staff interview, the laboratory failed to have documentation of verifying the accuracy of one of twenty-eight antibodies tested on the Thermo Fisher Phadia 250 analyzer at least twice annually in 2023. Findings include: 1. A review of the laboratory's test menu revealed the following non-regulated analyte RNP-70 antibody was tested by the laboratory using the Thermo Fisher Phadia 250 analyzer in 2023. 2. A review of the laboratory's records from 2023 revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for the RNP-70 antibody. 3. In an interview on 7/25/24 at 10:50 a.m. in the conference room, after review of the records, the general supervisor confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to have documentation of one of one policy that includes the acceptability criteria for the seven standards included in the 46 plex panel for cytokine testing on the Luminex Flex Map 3D System. Findings include: 1. A review of the laboratory's policies revealed the laboratory failed to have documentation of a policy that includes the acceptability criteria for the seven standards included in the 46 plex panel for cytokine testing on the Luminex Flex Map 3D System. 2. A review of the laboratory's records revealed the laboratory ran 7 standards for each 46 plex panel and the percent recovery was calculated. 3. In an interview on 7/23/24 at 11:00 a.m. in the conference room, after review of the records, the general supervisor confirmed the policy needed to be updated to include standards with a percent recovery of greater than 80% is considered acceptable.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the Sysmex XN-Series XN-L Verification Manual, the laboratory's verification studies for the Sysmex XN-550 hematology analyzer, the XN-550 General Information manual, the laboratory's policies, and staff interview, the laboratory failed to have documentation of performing one of one stability study on patient specimens for complete blood count testing on the Sysmex XN-550 analyzer. Findings included: 1. A review of the Sysmex XN-Series XN-L Verification Manual (Document Number: 1251-LSS, Rev. 2, Dec 2016) revealed the following: "Method Verification Protocols The CAS is to verify that the analyzer meets manufacturer's

	performance claims by performing the following studies: -Reportable Range -Carryover It is the customer's responsibility to perform additional studies, following the requirements of their accrediting agency. The following protocols are provided: -Correlation Studies -Sensitivity Study -Reference Range Verification -Stability Study -Mixing Study Typically, integration studies are performed on new analyzers to verify and document satisfactory analyzer performance according to the manufacturer's specifications. It is up to the laboratory to perform more extensive studies if they deem it necessary to satisfy regulatory requirements over and above what is contained in these protocols." 2. A review of the XN-550 General Information manual (AP966434, October 2014) defined whole blood stability for refrigerated temperature (2-8C) specimens as 48 hours. 3. A review of the laboratory's policy tiled 'Whole Blood on the Sysmex XN-L 550' revealed the following: "Specimens kept at refrigeration 2-8C are acceptable for analysis for up to 72 hours from collection." 4. A review of the laboratory's verification records revealed the laboratory performed studies in September 2017 for the Sysmex XN-550 hematology analyzer (serial number: 12850). 5. Further review of the laboratory's verification records revealed the laboratory failed to have documentation of performing a stability study that extended the stability of patient's whole blood specimens run on the Sysmex XN-550 hematology analyzer to 72 hours. 6. In an interview on 7/25/24 at 1:30 p.m. in the conference room, after review of the records, the general supervisor confirmed the above findings. Key: C = degrees Celsius
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based upon review of manufacturer instructions, calibration records and interview of facility personnel the laboratory failed to calibrate five of five Chemistry analytes at least once every six months when using the Vitros 350 Chemistry analyzer. The findings included: 1. Review of the Vitros Instructions For Use found under the heading "When to Calibrate: When the slide lot number changes When Critical system parts are replaced When government regulations require. For Example, in the USA, CLIA regulations require calibration or calibration verification at least once every 6 months." 2. Review of the calibration records for the following analytes found the laboratory failed to calibrate at least once every six months: Calcium - Last calibration performed 06/21/2023. The laboratory tested 589 patient specimens between December 20, 2023 and July 25, 2024 without calibration after 13 months and five days. Magnesium - Last calibration performed July 14, 2023. The laboratory tested 518 patient specimens between January 13, 2024 and July 25, 2024 without calibration after 6 months and 11 days. Phosphorous - Last calibration performed October 4, 2023. 214 patient specimens tested between April 3, 2024 and July 25,

	2024 without calibration after three months and 21 days. Lipase - Last calibration performed November 8, 2023. The laboratory tested two patient specimens between May 7, 2024 and July 25, 2024 without calibration after two months and 18 days. Lactate Dehydrogenase (LDH) - Last calibration performed December 2, 2023. The laboratory tested 79 patient specimens between July 1, 2024 and July 25, 2024 without calibration after 24 days. 3. During interview of the general supervisor conducted July 25, 2024 at 3:50 PM, he confirmed the laboratory failed to calibrate the Chemistry analytes at least once every six months.
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 upon review of the laboratory quality control policy, manufacturers instructions for use, quality control records and interview of facility personnel, the laboratory failed to follow their own written procedure for establishing statistical parameters for four of four Chemistry analytes tested on the Beckman Coulter DXI600. The findings included: 1. Review of the laboratory quality control policy for the DXI 600 found on page 9: " Means are established with every new lot of controls by running 10 - 20 data points. Means + SDs are used. The SD could be calculated or a historic SD. Alternatively, when 10 - 20 data points cannot be established, the package insert mean and historical SD might be used." 2. Review of the BIO-RAD controls instructions for use found under the heading ASSIGNMENT OF VALUES: " The mean and corresponding + 3 SD ranges in the Assignment of values Delta Charts (Available separately) were derived from replicate analyses and are specific to this lot of product." 3. Review of the Assignment of Values provided for the following analytes found the defined means and + 3SD ranges: Liquichek Immunoassay Plus Control lot 85360 Expiration 2025-05-31 Insulin - Level 1 Mean = 15.9 uIU/mL with a 3 SD range of 13.3 - 18.6 Level 3 Mean = 158 uIU/mL with a 3 SD range of 129 - 187 PSA - Level 1 Mean = 0.262 ng/mL with a 3SD range of 0.192 - 0.332 Level 3 Mean = 25.2 ng/mL with a 3SD range of 20.5 - 29.8 TSH - Level 1 Mean = 0.751 uIU/ mL with a 3SD range of 0.649 - 0.852 Level 3 Mean = 32.4 uIU/ mL with a 3 SD range of 26.7 - 38.1 Liquichek Cardiac Markers Plus Control Lot 67700 Expiration 2025-2-28 Troponin - Level 1 mean = 0.438 ng/mL with a 3SD range of 0.241 - 0.635 Level 3 Mean = 6.05 ng/mL with a 3 SD range of 3.092 to 9.019 4. Review of the quality control records found the laboratory defined the means and 2SD limits as: Liquichek Immunoassay Plus Control lot 85360 Expiration 2025-05-31 Insulin - Level 1 Mean = 18.1040 uIU/mL with a 2 SD range of 15.454 - 20.754 Level 3 Mean = 158 uIU/mL with a 2 SD range of 139.61 - 197.61 PSA - Level 1 Mean = 0.342 ng/mL with a 2 SD range of 0.272 - 0.412 Level 3 Mean = 25.2 ng/mL with a 2 SD range of 20.5 - 29.8 TSH - Level 1 Mean = 0.751 uIU/ mL with a 2 SD range of 0.649 - 0.852 Level 3

	Mean = 32.4 uIU/ mL with a 2 SD range of 26.7 - 38.1 Liquichek Cardiac Markers Plus Control Lot 67700 Expiration 2025-2-28 Troponin - Level 1 mean = 0.139 ng /mL with a 2 SD range of 0.0736 - 0.2044 Level 3 Mean = 6.055 ng/mL with a 2 SD range of 3.091 to 9.019 5. During interview of the General Supervisor conducted July 24, 2024 at 2:12 PM he confirmed that he did not always establish the means using 10 - 20 data points or using historical performance to establish acceptable ranges.
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 a review of the laboratory's policies, a random review of the laboratory's Human XL Cytokine Fixed Panel [46 plex] run sheets from October 2023 to June 2024, and staff interview, the laboratory failed to ensure the high and low limits of detection were acceptable prior to reporting patient test results for four of four days reviewed for cytokine testing on the Luminex Flex Map 3D system. Findings include: 1. A review of the laboratory's policy titled 'SOP for Performing Single plex and Multiplexed Sandwich ELISA for the Detection and Quantification of Cytokines in Serum Samples on FLEXMAP3D System' revealed the following: "Control Results and Interpretation HOD and LOD controls will be accepted if they are within 15.5% CV of their expected values." 2. A random review of the laboratory's Human XL Cytokine Fixed Panel [46 plex] run sheets from October 2023 to June 2024 revealed the laboratory calculated the % difference for the high limit of detection (HOD) and low limit of detection (LOD) and not the %CV. 3. In an interview on 7/23/24 at 10:30 a.m. in the conference room, the general supervisor said that the policy was incorrect, the laboratory used the % difference to determine control acceptability, not the % CV. 4. Further review of the Human XL Cytokine Fixed Panel [46 plex] run sheets revealed the following 4 days when the % difference for the HOD and LOD were above 15.5% for several cytokines and patient results were reported: Date: 10/1/23 Alpha2-Macroglobulin % difference 17.39% for HOD * 44 patient tests reported Date: 4/24/24 Eotaxin % difference 27.41% for HOD IL-9 % difference 17.71% for LOD PDGF-AA % difference 19.30% for LOD and 16.60% for HOD * 50 patient tests reported Date: 6/3/24 Eotaxin % difference 27.13% for HOD PDGF-AA % difference 18.19% for LOD and 18.49% for HOD TNFa % difference 20.89% for LOD * 45 patient tests reported Date: 6/16/24 Eotaxin % difference 24.68% for LOD and 28.94% for HOD MIP-1b % difference 16.65% for LOD CD40L % difference 17.54% for LOD and 17.13% for HOD IP-10 % difference 17.44% for LOD GROb % difference 16.18% for LOD Fit-3L % difference 18.24% for LOD Granzyme-B % difference 15.79% for LOD IL-12p70 % difference 16.63% for LOD IL-17E % difference 15.64% for LOD PDGF-AA % difference 27.05% for LOD and 20.10% for HOD TGFa % difference 19.04% for LOD TNFa % difference 28.25% for LOD TRAIL % difference 15.79% for LOD * 38 patient tests reported 5. In an interview on 7/23/24 at 10:30 a.m. in the conference room, after review of the records, the general supervisor confirmed the above findings.
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 a review of the laboratory's records and staff interview, the laboratory failed to have documentation of performing two of two analyzer comparison studies in 2023 on the four Thermo Fisher Phadia 250 analyzers. Findings include: 1. A review of the laboratory's records revealed the laboratory used the following 4 Thermo Fisher Phadia 250 analyzers for testing in 2023: - Thermo Fisher Phadia 250 serial number: 10270 - Thermo Fisher Phadia 250 serial number: 10276 - Thermo Fisher Phadia 250 serial number: 10347 - Thermo Fisher Phadia 250 serial number: 10350 2. Further review of the laboratory's records revealed the laboratory failed to have documentation of performing 2 analyzer comparison studies in 2023 on the four Phadia analyzers. 3. In an interview on 7/25/24 at 1:30 p.m. in the conference room, after review of the records, the general supervisor confirmed the above findings.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's XN-Check quality control (QC) records from November 2023 to May 2024, the laboratory's records, and staff interview, the laboratory failed to have documentation of corrective action six of six times when the daily QC run on the Sysmex XN-550 hematology analyzer failed to meet the laboratory's acceptability criteria. Findings include: 1. A review of the laboratory's policy titled 'Quality Controls Policy' revealed the following: "Daily QC review should be done by the technologist operating the instrument. It should include: a) Documentation of any out of control QC, repeats and actions. b) Documentation of new lot numbers, calibration problems. c) Documentation of Maintenance." 2. A review of the laboratory's XN-Check Quality Control records from November 2023 to May 2024 revealed the following 6 days when QC was run on the Sysmex XN-550 hematology analyzer (serial number: 12850) and there was no documentation of corrective action for QC failures: Date: 11/3/23 XN Control Level 3 was run at 18:14 and failed for MONO# and MONO% Date: 11/4/23 XN Control Level 3 was run at 20: 14 and failed for LYMP# Date: 2/2/24 XN Control Level 3 was run at 16:46 and failed for MCV Date: 2/10/24 XN Control Level 3 was run at 19:47 and failed for HCT, MCV, and MCHC Date: 5/23/24 XN Control Level 1 was run at 17:13 and failed for RBC and MCH Date: 5/24/24 XN Control Level 1 was run at 18:15 and failed for RDW-CV 3. A review of the laboratory's records revealed the laboratory estimated performing an average of 41,921 hematology tests annually. 4. In an interview on 7/25/24 at 1:30 p.m. in the conference room, after review of the records, the general supervisor confirmed the above findings. Key: MONO# = absolute value of monocytes MONO% = percent monocytes LYMP# = absolute value of lymphocytes MCV = mean corpuscular volume HCT = hematocrit MCHC = mean

	corpuscular hemoglobin concentration RBC = red blood cell MCH = mean corpuscular hemoglobin RDW-CV = red cell distribution width calculation
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a random review of patient test reports, and staff interview, the laboratory failed to ensure the reference intervals for Hemoglobin A1c (HbA1c) were correct on five of five random patient test reports reviewed from February to June 2024. Findings include: 1. A review of the laboratory's policy titled 'Hemoglobin A1c, Bio-Rad D-10' revealed the following: "Reference Intervals The non-diabetic reference range for D10 Hemoglobin A1c is 4.3 to 5.6%." 2. A random review of patient test reports from February to June 2024 revealed the reference intervals for Hemoglobin A1c on the following 5 patient reports did not match the intervals defined in the laboratory's policy: Patient ID: 2402070005 Date tested: 2/7/24 HbA1c range: 0.0 - 5.6% Patient ID: 2403290010 Date tested: 3/29/24 HbA1c range: 0.0 - 5.6% Patient ID: 2405040009 Date tested: 5/4 /24 HbA1c range: 0.0 - 5.6% Patient ID: 240530001 Date tested: 5/30/24 HbA1c range: 0.0 - 5.6% Patient ID: 2406120005 Date tested: 6/12/24 HbA1c range: 0.0 - 5.6% 3. In an interview on 7/24/24 at 10:30 a.m. in the conference room, after review of the records, the general supervisor confirmed the above findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found one of three testing personnel failed to have documentation available to ensure they met minimum education requirements for performing moderate complexity testing in Chemistry, Immunology and Hematology. (See D 6065)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy 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; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have

	successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel found that one of three testing personnel failed to have documentation of education for performing moderate complexity testing in Hematology, Immunology and Chemistry. The findings included: 1. Review of the CMS report 209 Laboratory Personnel Report identified three testing personnel performing moderately complex testing. 2. Review of personnel records found no foreign credential evaluation for education received outside the United States for testing person three (hire date 10/21/2017). 3. During interview of the manager conducted July 24, 2024 at 2:12 PM, she confirmed that a course by course evaluation of education was not available for review.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, the laboratory director failed to to provide overall management and direction. (See D6079)
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 upon review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel, the Laboratory director failed to ensure two of eleven testing personnel met the minimum education requirements for performing moderate and high complexity procedures in Immunology, Chemistry and Hematology. (See D 6063 and D 6102)

D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based upon review of the CMS Report 209 Laboratory Personnel Report, personnel records and interview of facility personnel, the Laboratory director failed to ensure one of eight testing personnel met the minimum education requirements for performing high complexity testing procedures in Immunology. (See D 6170)
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: Based on a review of the CMS-209 Laboratory Personnel Report, laboratory personnel records and interview of facility personnel, the laboratory failed to ensure one of three testing personnel met the minimum education qualifications for the high complexity tests performed in Immunology. (see D6170)
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based upon review of the CMS Report 209 Laboratory Personnel Report, laboratory personnel records and interview of facility personnel, the laboratory failed to ensure one of eight testing personnel met the minimum education requirements for high complexity testing in Immunology. The findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory designated eight testing personnel performing high complexity testing. 2. Review of laboratory personnel records for Testing Person nine (hire date 09/21/2021) found no evaluation of credentials for degrees awarded outside the United States. The laboratory manager offered a transcript from Calicut University with no course by course evaluation. 3. During interview of the laboratory manager conducted July 23, 202411:13 AM, she confirmed she did not have an evaluation of foreign credentials for testing person nine.