Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2259195	12/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Adma Biocenters Georgia, Inc	2718 W Thomas St, Hammond, LA	

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	An Initial survey was performed on December 28, 2022 at ADMA BioCenters Georgia, INC, CLIA ID # 19D2259195. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 policies and interview with personnel , the laboratory failed to establish complete written competency assessment policies that included blind sample testing. Findings: 1. Review of the laboratory's "Digital Refractometer Evaluation Performance Observation Checklist" policy revealed the laboratory did not include the following one (1) of six (6) procedures as a minimal requirement: a) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. In interview on December 28, 2022 at 12:12 pm, the Regional Quality Assurance Manager confirmed the laboratory did not include the identified monitor as part of their competency assessment policy for testing personnel.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or

	examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish complete performance specification verification policies. Findings: 1. Review of the laboratory's "Digital Refractometer Qualification Procedure" revealed the laboratory did not include detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run, as well as, operator variance), reportable and reference range studies, and actions to take when data from the studies fail to meet acceptability criteria. 2. In interview on December 28, 2022 at 12:58 pm, the Center Quality Manager confirmed the laboratory's policy did not include the identified information.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to have policies related to complaints and record retention approved and signed by the Laboratory Director. Findings: 1. Review of the laboratory's policies revealed the following policies did not include the Laboratory Director's approval/signature: Complaints Record retention 2. In interview on December 28, 2022 at 3:18 pm the Center Quality Manager confirmed the Laboratory Director did not approve/sign the identified policies.
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 observation by surveyors, review of the laboratory's policies, performance specification studies, test menu, and interview with personnel revealed the laboratory failed to have complete precision studies for seven (7) refractometers utilized for total protein testing. Findings: 1. Observation by surveyors during the laboratory tour on December 28, 2022 at 10:32 am revealed the laboratory utilizes Reichart Refractometers for total protein testing. 2. Review of the laboratory's "Digital Refractometer Qualification Procedure" policy revealed the laboratory did not include detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run, as well as, operator variance), reportable and reference range studies, and actions to take when data from the studies fail to meet acceptability criteria. 3.

	Review of the laboratory's performance specification records revealed the laboratory did not include the following: (Instruments: D304001, D304002, D304003, D304004, D304005, D304005, D304006, and D304007) a) Participation by the laboratory's testing personnel (Not applicable to Instrument D304007) b) Summary of how studies were conducted c) Precision studies that included day to day studies (Not applicable to Instrument D304007) d) Reportable range e) Reference range 4. In interview on December 28, 2022 at 12:58 pm the Center Quality Manager stated the new center development team performed the validation (performance specification) studies for the refractometers, not laboratory personnel. 5. In interview on December 28, 2022 at 1:17 pm, the Regional Operations Manager confirmed the laboratory did not include the the identified items in their performance specification studies. 6. Review of the laboratory's test menu revealed the laboratory performs 10,000 total protein tests annually.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure performance specification studies were complete. Refer to D5421.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) 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 on review of policies, personnel records, and interview with personnel, the Laboratory Director failed to ensure one (1) of seven (7) Testing Personnel reviewed had documentation of training for Total Protein testing. Findings: 1. In interview on December 28, 2022 at 11:01 am, the Regional Quality Assurance Manager stated the Laboratory Director performed Total Protein testing on donors in July 2022 until qualified staff were hired. 2. Review of the "Digital Refractometer Evaluation Performance Observation Checklist" revealed "The CLIA Director is required to evaluate employees performing moderate complexity testing initially, semi-annually,

	and annually after that. Employees performs the following critical steps with 100% accuracy before performing tasks independently." 3. Review of personnel records for the Laboratory Director revealed there was not documentation of training for Total Protein testing. 4. In further interview on December 28, 2022 at 12:51 pm, the Regional Quality Assurance Manager confirmed the laboratory did not have documentation of training for Total Protein testing for the Laboratory Director.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure complete policies and procedures for assessing personnel competency were established. Refer to D5209.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish complete performance specification verification policies. Refer to D5401. 2. The laboratory failed to have policies related to complaints and record retention approved and signed by the Laboratory Director. Refer to D5407.
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 policies, personnel records, and interview with personnel, the Laboratory Director failed to provide written job responsibilities for laboratory personnel. Findings: 1. Review of the laboratory's policies and personnel records revealed the laboratory did not include written job responsibilities for the duties of Clinical Consultant and Technical Consultant. 2. In interview on December 28, 2022 at 3:58 pm, the Center Quality Manager confirmed the laboratory did not include written job responsibilities for the identified personnel roles.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of policies, personnel records, laboratory's CMS 209 form, and interview with personnel, the Technical Consultant failed to ensure review of the assessments of test performance through previously analyzed, internal blind samples, or external proficiency testing samples for five (5) testing personnel in 2022. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed the Laboratory Director serves as the Technical Consultant. 2. Review of the laboratory's "Proficiency Testing Procedure" under "Staff Competency Assessments" revealed the following: "Provide the proficiency test samples and a copy of the Results Reporting Form to each staff member trained in Donor Screening and instruct them to test the samples according to Steps 4.1 through 4.6 of this procedure. A preceptor/designee will grade the internal staff assessment using the acceptable ranges included on the score sheet provided by AAB." 3. Review of "Staff Competency Assessments" records for Testing Personnel 1 through Testing Personnel 5 revealed American Association Bioanalysts (AAB) proficiency samples 11 through 15 were testing by each testing personnel in November 2022. 4. Further review of the "Staff Competency Assessments" records for Testing Personnel 1 through Testing Personnel 5 revealed the Technical Consultant did not review/assess their results. 5. In interview on December 28, 2022 at 12:12 pm, the Regional Quality Assurance Manager confirmed the Technical Consultant did not assess the results for proficiency samples tested for competency.