Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D0694939	10/28/2020
Name of Provider or Supplier	**Street Address, City, State**	
Central Georgia Infectious Diseases, Llc	458 Hemlock Street, Suite 200, Macon, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) survey was completed on October 28, 2020. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following Condition and Standard deficiencies were cited:
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) provider documents, test list, and staff interview, the laboratory did not order the correct Chemistry PT, for the year 2020, to cover all analytes that are tested and reported out at the facililty. Findings: 1. Review of the test list for chemistry, the facility performs the following test: ALT/SGPT Creatinine AST/SGOT Glucose Total Bilirubin Potassium Blood Unea Nitrogen Sodium Calcium Triglycerides Chloride Uric Acid Cholesterol Alkaline Phosphatase Cholesterol/HDL Albumin CO2 Total Protein 2. Review of the API documents the selected Basic Chemistry Program does not include testing for Alkaline Phosphatase, Albumin, and Total Protein. 3. Interview with staff #2 (CMS form 209), on October 29, 2020 at approximately 5:30 pm, in the conference room confirmed the aforemention information.

D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents the laboratory failed to participate successfully (100%) in PT for 2020 first event and third event for the analyte Chloride. Reference D2087
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT), the laboratory failed to attain a score of at least 80% for the first event and third event for 2020, analyte Chloride. Findings: 1. Review of the API, PT evaluation reports for 2020, the first and third events, showed that the laboratory scored a 40% on Chloride for the first event and 60% on the third event. 2. Interview with staff #2 (CMS-209) on October 28, 2020, at approximately 6pm in the conference room, confirmed that the scores for the analyte Chloride for 2020 PT for the first event was 40%, and the third event was 60%.
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 Employee Competency documents, and staff interview the

	laboratory failed to provide training and competency documents, for both of the testing personal(TP).. Findings: 1. Based on review of the Employee Competency documents, for the two TP, one had no training documents or competency documents, and one had an Initial training and competency documents but did not have a 6 month competency. 2. Interview with staff #2(CMS 209 form) on October 28, 2020, at approximately 5pm in the conference room confirmed that one TP did not have any training or competency records, and one TP did not have a 6 month competency.
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 Quality Control (QC) documents for the Pentra Micro 60 (Pentra 60) Hematology analyzer, the laboratory failed to monitor the accuracy and precision of the complete analytic process. Findings: 1. Based on review of the QC documents for the Pentra 60, the laboratory failed to routinely print the Levy Jennings (LJ) charts for each Lot of QC material. From November 2019, to September 2020, the laboratory only printed LJ charts for January and February 2020, for hematology QC.. 2. Interview with staff #2 (CMS-209 form) on October 28, 2020 at approximately 4:30 pm in the conference room, confirmed that the laboratory had not printed LJ charts from November 2019 to September 2020, except for January and February 2020 for hematology QC.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute(API) Proficiency Testing(PT) documents for 2020, and staff interview, the Laboratory Director (LD) failed to ensure that all necessary remedial actions was taken and documented. Findings: 1. Based on the API documents for 2020, for Chemistry event one, the laboratory scored a 40% on Chloride, and a 60% on Glucose, and the third event scored a 60 % on Chloride.

	There was no corrective action for the unsatisfactory results. 2. Interview with staff #2 (CMS 209 form) on October 28, 2020 at approximately 5:45, in the conference room, confirmed that there was no corrective action for the unsatisfactory scores.
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 review of the Employee Competency documents, and staff interview the Laboratory Director(LD) failed to provide training and competency documents, for both of the testing personal(TP). Findings: 1. Based on review of the Employee Competency documents, for the two TP, one had no training documents or competency documents, and one had an Initial training and competency documents but did not have a 6 month competency. 2. Interview with staff #2(CMS 209 form) on October 28, 2020, at approximately 5pm in the conference room confirmed that one TP did not have any training or competency records, and one TP did not have a 6 month competency.