Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0022561	10/02/2019
Name of Provider or Supplier	**Street Address, City, State**	
Reception And Medical Center Clinical Laboratory	7765 S County Road 231, Lake Butler, FL	

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 unannounced recertification survey was conducted on 10/2/19 at Reception and Medical Center, a clinical laboratory in Lake Butler, Florida. Reception and Medial Center is in not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on a review of the Individualized Quality Control Plan (IQCP) records and interview with laboratory staff, the facility failed to document how it will monitor the pre-analytic testing process for the blood gas analyzer (Abbott i-Stat). Findings include: A review of the IQCP documentation for the blood gas analyzer showed that there was no assessment of the pre-analytic testing process and how problems will be corrected. The interview with the laboratory manager on 10/2/2019 at 11:00am confirmed the IQCP was incomplete. .
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on review of the laboratory procedure manual, IQCP, quality control records, and staff interviews, the laboratory failed to have a procedure manual and IQCP signed by the laboratory director (refer to D5407); failed to document a complete IQCP for the blood gas analyzer (refer to D5441 & D5445); failed to run quality control testing per procedure (refer to D5481); and failed to have a quality assessment procedure in place for analytic systems (refer to D5791). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. .
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 a review of the Individualized Quality Control Plan (IQCP), procedure manual, and interview with laboratory staff, the laboratory failed to have the IQCP and laboratory procedure manual signed and dated by the laboratory director. Findings include: 1. The IQCP documentation provided at the time of survey did not have a date or signature showing approval by the laboratory director. 2. The record review of the procedure manual showed the laboratory director had not signed the procedure manual since 2014. Interview with the laboratory manager on 10/2/19 at 11:15 AM confirmed that the laboratory director had not signed the laboratory procedure manual or the IQCP.
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 a review of the Individualized Quality Control Plan (IQCP) records and interview with laboratory manager, the laboratory failed to document a complete IQCP for the blood gas analyzer (Abbott i-Stat). Findings include: A review of the IQCP Quality Control Plan (QCP) documentation for the blood gas analyzer showed that there was no documentation of the number, type, frequency of testing, and criteria for acceptable quality control (QC) results. The interview with the laboratory manager on 10/2/19 at 11:00am confirmed the IQCP was incomplete.

D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Individualized Quality Control Plan (IQCP) records and interview with laboratory manager, the laboratory failed to document a complete IQCP for the blood gas analyzer (Abbott i-Stat). Findings include: A review of the IQCP Risk Assessment (RA) documentation for the blood gas analyzer showed that there was no assessment for the entire testing process of the required elements: specimen, test system, reagent, environment, and testing personnel. The interview with the laboratory manager on 10/2/19 at 11:00am confirmed the IQCP was incomplete.
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 record review and interview with laboratory staff, the laboratory failed to perform blood gas quality controls (QC) that were not expired, failed to run the required internal control required by the manufacturer, and failed to run three levels of QC prior to reporting patient results. Findings Include: 1. Record review of the laboratory's Blood gas QC records for May 2019 showed on 5/9/19, 5/17/19, and 5/29 /19 the QC Level 3 used had lot number 321100 and expired on 4/30/2019. At the time of survey, the number of patients tested was unable to be determined. 2. Review of the i-Stat system manual indicated users need to "verify the performance of each analyzer on site using the Electronic Simulator once a day on the days the analyzers are in use". At the time of survey, the laboratory was unable to provide documentation to show the Electronic Simulator was ran on each day of patient testing. 3. Review of the laboratory's QC procedure indicated "weekly Trilevel 1,2 & 3 will be performed". The QC documentation on 2/27/19 showed Level 3 was not performed. The interview with the laboratory manager on 10/2/19 at 11:55am confirmed the laboratory had performed QC using expired controls, the laboratory failed to run the Electronic Simulator daily, and failed to document three levels of QC.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the Individualized Quality Control Plan (IQCP) records and interview with laboratory manager, the laboratory failed to document how it will monitor the analytic testing process for the blood gas analyzer (Abbott i-Stat). Findings include: A review of the IQCP documentation for the blood gas analyzer showed that there was no assessment of the analytic testing process and how problems will be corrected. The interview with the laboratory director on 10/2/19 at 11:00am confirmed the IQCP was incomplete. .
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on a review of the Individualized Quality Control Plan (IQCP) records and interview with laboratory manager, the laboratory failed to document how it will monitor the post analytic testing process for the blood gas analyzer (Abbott i-Stat). Findings include: A review of the IQCP documentation for the blood gas analyzer showed that there was no assessment of the post analytic testing process and how problems will be corrected. The interview with the laboratory manager on 10/2/19 at 11:00am confirmed the IQCP was incomplete.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of the Individualized Quality Control Plan (IQCP) records, QC documentation, and interview with laboratory manager, the laboratory director failed to ensure complete documentation of an IQCP for the blood gas analyzer (Abbott i-Stat), failed to ensure the performance of blood gas quality controls (QC) that were not expired, failed ensure the internal control required by the manufacturer was performed daily, and failed ensure three levels of QC were performed prior to reporting patient results. Findings include: 1. A review of the IQCP Quality Control Plan (QCP) documentation for the blood gas analyzer showed that there was no documentation of the number, type, frequency of testing, and criteria for acceptable quality control (QC) results. laboratory 2. A review of the IQCP Risk Assessment

	(RA) documentation for the blood gas analyzer showed that there was no assessment for the entire testing process of the required elements: specimen, test system, reagent, environment, and testing personnel. 3. A record review of the laboratory's Blood gas QC records for May 2019 showed on 5/9/19, 5/17/19, and 5/29/19 the QC Level 3 used had lot number 321100 and expired on 4/30/2019. At the time of survey, the number of patients tested was unable to be determined. 4. The review of the i-Stat system manual indicated users need to "verify the performance of each analyzer on site using the Electronic Simulator once a day on the days the analyzers are in use". At the time of survey, the laboratory was unable to provide documentation to show the Electronic Simulator was ran on each day of patient testing. 5. The review of the laboratory's QC procedure indicated "weekly Trilevel 1,2 & 3 will be performed". The QC documentation on 2/27/19 showed Level 3 was not performed. The interview with the laboratory manager on 10/2/19 at 11:55am confirmed the laboratory had performed QC using expired controls, the laboratory failed to run the Electronic Simulator daily, failed to have a completed IQCP, and failed to document three levels of QC.
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 a review of the Individualized Quality Control Plan (IQCP), procedure manual, and interview with laboratory staff, the laboratory director failed to sign and date the procedure manual and IQCP. Findings include: 1. The IQCP documentation provided at the time of survey did not have a date or signature showing approval by the laboratory director. 2. The record review of the procedure manual showed the laboratory director had not signed the procedure manual since 2014. Interview with the laboratory manager on 10/2/19 at 11:15 AM confirmed that the laboratory director had not signed the laboratory procedure manual or the IQCP.