Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2092961	11/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Complete Care De Zavala	4999 De Zavala Road, San Antonio, 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 representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification 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 Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 random review of the laboratory's patient Complete Blood Count (CBC) test reports from January of 2021, review of the Quality Assurance (QA) reports for 2021 and staff interview it was determined the laboratory's QA failed to detect and correct problems in sample collection versus sample receipt time documentation. Findings included: 1. Review of a sampling of patient reports from January of 2021 revealed the following patients' samples had the collection time documented as being after the documented time of sample receipt in the laboratory: Patient: NAIMA000 Sample: 010113 Collected: 01/01/2021 at 09:24 PM Received: 01/01/2021 at 09:19 PM Sample documented as received in the laboratory before it was collected. Patient:

	EL0FA000 Sample:010507 Collected: 01/05/2021 at 07:15 PM Received: 01/05/2021 at 07:10 PM Sample documented as received in the laboratory before it was collected. Patient: DUFCH000 Sample: 010508 Collected: 01/05/2021 at 09:53 PM Received: 01 /05/2021 at 09:45 PM Sample documented as received in the laboratory before it was collected. Patient: CASSE000 Sample: 010808 Collected: 01/08/2021 at 05:09 PM Received: 01/08/2021 at 05:00 PM Sample documented as received in the laboratory before it was collected. Patient: BARBR001 Sample: 011207 Collected: 01/12/2021 at 09:24 PM Received: 01/12/2021 at 09:19 PM Sample documented as received in the laboratory before it was collected. 2. Review of the laboratory's QA reports for 2021 revealed no record of detection of the issue with collection versus receipt time discrepancy. 3. In an interview on 11/09/2021 at 1245 hours in the office the Technical Consultant stated that the error should have been detected and corrected as part of QA. This confirmed the 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 review of the laboratory's Sysmex XP-300 hematology analyzer's Instructions for Use, review of a sampling of patient test records and staff interview it was determined the laboratory failed to establish/follow protocols for addressing flagged results. Findings included: 1. Review of the Sysmex XP-300 hematology analyzer's Instructions for Use revealed: Page 8-4: "Sign: Explanation: [+] Result exceeds the upper patient limit. [-] Result exceeds the lower patient limit. [*] Result is unreliable." And Page 8-5: "Flag: (10) [DW] Explanation: Distribution width can not be calculated." "Flag:(14) [AG] Explanation: The particle count equal to or less than WBC-LD has exceeded the range." 2. Comparison of a sampling of patient instrument results to results filed in patients records for 11/04/2021 and 11/05/2021 revealed the following results containing flags were reported to provider: Patient: ALSBA001 Sample ID 110402, tested 11/04/2021 at 15:29 Instrument printout results: MCV result contained [+] PLT result contained [AG][*] RDW-SD result contained [+] RDW-CV result contained [+] Final report filed in patients chart showed the same flags with the results as the original instrument printout. Patient: PETIS001 Sample ID 110503, tested 11/05/2021 at 16:10 Instrument printout results: HGB result

	contained [-] HCT result contained [-] MCV result contained [-] MCH result contained [-] MCHC result contained [-] PLT result contained [*] RDW-CV result contained [+] MPV result contained [DW] Final report filed in patients chart showed the same flags with the results as the original instrument printout. 3. In an interview on 11/09/2021 at 1310 hours in the office the Technical Consultant stated that the flagged results should not have been reported to provider. This confirmed the findings. Legend: HGB = hemoglobin HCT = hematocrit MCV = mean corpuscular volume MCH = mean corpuscular hemoglobin MCHC = mean corpuscular hemoglobin concentration PLT = platelet RDW-SD = red cell distribution width - standard deviation RDW-CV = red cell distribution width - coefficient of variation MPV = mean platelet volume
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 review of the laboratory's Sysmex XP-300 hematology analyzer's performance verification studies, review of the Sysmex hematology analyzer's Instructions for Use and staff interview it was determined the laboratory failed to verify patient normal ranges by including 9 patient samples with abnormal results out of 14 samples used in the verification process. Findings included: 1. Review of the laboratory's Sysmex XP-300 hematology analyzer's patient's normal range verification studies signed by the Laboratory Director on 07/15/2021 revealed 9 of 14 patients had the following results: Sample: 070905 NEUT# result contained [+] Sample: 071010 LYM# result contained [+] Sample: 071003 RDW-SD result contained [-] Sample: 071102 NEUT# result contained [+] Sample: 071204 RDW-SD result contained [-] Sample: 071310 NEUT# result contained [+] Sample: 070304 RDW-SD result contained [-] Sample: 071103 NEUT# result contained [+] Sample: 070501 NEUT# result contained [+] 2. Review of the Sysmex hematology analyzer's Instructions for Use revealed: Page 8-4: "Sign: Explanation: [+] Result exceeds the upper patient limit. [-] Result exceeds the lower patient limit. 3. In an interview on 11/09/2021 at 0930 hours in the office the Technical Consultant, after review of the data, confirmed the findings. Legend: NEUT = neutrophils LYM = lymphocytes RDW-SD = red cell distribution width - standard deviation
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 Sysmex hematology analyzer's quality control (QC) records from July 15th to October 15th of 2021, and staff interview it was determined the laboratory failed to document over time evaluation of QC data to look for shifts and trends for 2 of the 3 months reviewed. Findings included: 1. Review of the Sysmex hematology analyzer's quality control (QC) records from July 15th to October 15th, 2021 revealed no documentation of over time evaluation of QC data to look for trends and shifts until October 10th of 2021. Note: The instrument was placed in use on July 15th, 2021. 2. The laboratory was asked to provide documentation of overtime evaluation of QC for the time interval prior to October 10th, 2021 and no such documentation was provided. 3. In an interview on 11/09/2021 at 0945 hours in the office the Technical Consultant stated that there should have been an over time evaluation of QC data performed. This confirmed the findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records for the Sysmex XP-300 hematology analyzer form July to October of 2021, review of the Sysmex controls' new lot verification records and staff interview it was determined the laboratory failed to document verification of new control lots with concurrent testing for 1 of 1 lot changes reviewed. Findings included: 1. Review of the laboratory's quality control (QC) records for the Sysmex XP-300 hematology analyzer form July to October of 2021 revealed the laboratory implemented new hematology controls lot # 12230 (expiration: 2021/11/17) on 08/26/2021. There was no documentation of concurrent quality control testing with the previous controls' lot # 11390 (expiration: 2021/08/25). 2. Review of the Sysmex controls' new lot verification records revealed no documentation of new controls' verification studies for controls' lot # 12230 (expiration: 2021/11/17). 3. The laboratory was asked to provide documentation of new controls' lot verification for lot # 12230 and no such documentation was provided. 3. In an interview on 11/09/2021 at 1000 hours in the office the Technical Consultant confirmed the findings.

D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the laboratory's Sysmex XP-300 hematology analyzer's quality control (QC) records, review of the Sysmex controls' new lot verification studies, review of overtime evaluation of QC and staff interview it was determined the laboratory's Technical Consultant failed to ensure the QC program is maintained through out the testing process. Refer to D5421, D5441 and D5469.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the laboratory's competency assessments, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing the annual competencies to include observation of testing and maintenance. The findings include: 1. A review of testing personnel competency assessments from 2020 and 2021 revealed annual competencies were documented as being performed on specific days and the technical consultant signed the assessments at a later date. Examples are: a) Testing personnel #1 Assessment performed: 11/06 /2020 Signed by Technical consultant: 11/08/2021 b) Testing personnel #2 Assessment performed: 02/2021 Signed by Technical consultant: 04/08/2021 Assessment performed: 08/2021 Signed by Technical consultant: 11/08/2021 c) Testing personnel #3 Assessment performed: 12/2020 Signed by Technical consultant: 11/2021 d) Testing personnel #4 Assessment performed: 12/2020 Signed by Technical consultant: 11/2021 e) Testing personnel #5 Assessment performed: 05 /2021 Signed by Technical consultant: 11/2021 2. The laboratory was asked to provide documentation of the technical consultant performing the competency assessments on the day indicated - including the necessary observations. No documentation was provided. 3. An interview with the technical consultant on 11/09 /2021 at 0930 hours in the break room revealed the competency assessment were performed by other laboratory personnel and then signed off by the technical consultant on a later date. This confirmed the findings.