

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2092961	(X3) Date Survey Completed 08/29/2023
Name of Provider or Supplier Complete Care De Zavala	Street Address, City, State 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	A recertification survey was performed on August 29, 2023. The laboratory was found to be IN compliance with the CLIA regulations found at 42 CFR, with standard level deficiencies cited.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on a review of personnel records, American Proficiency Institute (API) records for 2022 and 2023, and confirmed in staff interview, the laboratory failed to have all testing personnel participate in proficiency testing for 10 of 15 testing events. Findings included: 1. A review of the submitted Centers for Medicare and Medicaid Services (CMS) form 209 revealed 9 designated testing personnel (TP#1 - TP#9). 2. A review of API proficiency testing records for 2022 and 2023 revealed the following: a) 2023 Hematology/Coagulation 2nd event TP#5 (as listed on the CMS form 209): Samples tested HSY06 - HSY10 b) 2023 Hematology/Coagulation 1st event TP#5: Samples tested HSY01 - HSY05 c) 2023 Microbiology 2nd event TP#8: Samples tested RSP06 - RSP09 TP#5: Samples tested RSP10 d) 2023 Microbiology 1st event TP#1: Samples tested RSP01 TP#8: Samples tested RSP02 - RSP05 e) 2022 Hematology 3rd event TP#7: Samples tested HSY11 TP#5: Samples tested HSY12 - HSY 15 f) 2022 Hematology 2nd event TP#5: Samples tested HSY06 - HSY10 g) 2022 Hematology 1st event TP#1: Samples tested HSY01 TP#5: Samples tested HSY 02 - HSY05 h) 2022 Microbiology 3rd event TP#4: Samples tested RSP11 - RSP15 i) 2022 Microbiology 2nd event TP#8: Samples tested RSP06 - RSP10 j) 2022 Microbiology 1st event TP#8: Samples tested RSP01 - RSP05 Proficiency testing was not performed by TP#2, TP#3, TP#6, TP#7, nor TP#9. 3. During an interview on 08</p>

	<p>/29/2023 at 0930 hours in the conference room, after review of the following records, Technical Consultant #1 (as listed on the CMS form 209) confirmed the findings.</p>
<p>D5209</p>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the submitted CMS form 209, laboratory policy, and confirmed in staff interview, the laboratory failed to establish and follow a policy for assessing the competency for 1 of 1 Technical Consultants. Findings included: 1. A review of the submitted CMS form 209 listed 1 Technical Consultant. 2. A request was made for a policy for assessing the competency of Technical Consultants. No policy was provided. 3. During an interview on 08/29/2023 at 1030 hours in the conference room, after review of the above records, Technical Consultant #1 confirmed the findings.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, a review of laboratory policy, patient records, and confirmed in staff interview, the laboratory failed to follow laboratory policy for resolving and reporting platelet flags for 3 of 4 CBC Sysmex results (July 2023 through August 2023). Findings included: 1. During a tour of the laboratory on 08/29/2023 at 0915 hours, one Sysmex XP-300 (Serial number C0564) was observed in use. 2. The laboratory policy titled "Laboratory Procedure CBC Sysmex XP-300" (signed by the Laboratory Director on 09/02/2021) stated "Platelet Flags: Any platelet count >50 with AG flags will be repeated on the original, properly and well mixed sample ... If the AG flag remains, sample will be sent to reference laboratory for confirmatory analysis. The original platelet result should be masked before providing the physician with the CBC results." 3. A review of Sysmex 300-XP patient records tested by the laboratory from July 2023 through August 2023 revealed the following: a) Patient ID 082101 Test date and time: 08/21/2023 at 0243 hours Reported platelet result: "AG* 237" b) Patient ID 073006 Test date and time: 07/30/2023 at 2136 hours Reported platelet result: "AG* 311" c) Patient ID 072805 Test date and time: 07/28/2023 at 1928 hours Reported platelet result: "AG* 115" The laboratory failed to mask the flagged platelet results prior to reporting to the physician and failed to send samples to the reference laboratory for confirmation. 4. During an interview on 08/29/2023 at 1315 hours in the conference room, after review of the above records, Technical Consultant #1 confirmed the findings. Word key: CBC = Complete blood count AG = agglutination</p>
<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT</p>

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 direct observation, review of Sysmex Insight reports, and confirmed in staff interview, the laboratory failed to investigate abnormal results as required by the manufacturer for 3 of 18 months (January 2022 through July 2023). Findings included: 1. During a tour of the laboratory on 08/29/2023 at 0915 hours, 1 Sysmex XP-300 (Serial number C0564) was observed. 2. A review of the Sysmex Insight reports, under the section titled "QC Data Parameter SDI Ranges" revealed: "If your CV is 1.5 times greater than the Group CV, your result is presented in bold type and an investigation is warranted." 3. A review of Sysmex Insight peer Group Comparison reports from January 2022 through July 2023 revealed the following bolded CV results: a) Lot 2278, Cumulative Report 10/5/2022 - 01/11/2023, review date of 02/09/2023 White Blood Cell count (WBC) Level 1 CV 5.9 White Blood Cell count (WBC) Level 3 CV 8.1 Red Blood Cell count (RBC) Level 3 CV 5.8 Hemoglobin (HGB) Level 3 CV 8.2 Hematocrit (HCT) Level 3 CV 5.7 Mean Corpuscular Hemoglobin (MCH) Level 3 CV 7.4 Mean Corpuscular Hemoglobin Concentration (MCHC) Level 3 CV 7.4 Platelet (PLT) Level 3 CV 6.5 Mixed Blood Cell Count percent (MXD%) Level 1 CV 23.3 Mixed Blood Cell Count percent (MXD%) Level 3 CV 11.5 Neutrophil percent (NEUT%) Level 1 CV 3.9 Neutrophil percent (NEUT%) Level 3 CV 4.6 Lymphocyte count (LYM#) Level 3 CV 8.2 Mixed Blood Cell Count (MXD#) Level 1 CV 33.3 Mixed Blood Cell Count (MXD#) Level 3 CV 10.5 Neutrophil count (NEUT#) Level 1 CV 8.7 Neutrophil count (NEUT#) Level 3 CV 8.3 b) Lot 2278, Period 2, 11/07/2022 - 12/09/2022, review date of 03/30/2023 WBC Level 3 CV 6.4 RBC Level 3 CV 4.5 HGB Level 3 CV 6.3 HCT Level 3 CV 4.4 MCH Level 3 CV 5.7 MCHC Level 3 CV 5.7 PLT Level 3 CV 5.3 MXD% Level 3 CV 10.0 NEUT% Level 3 CV 3.9 LYM# Level 3 CV 6.5 NEUT# Level 3 CV 7.0 c) Lot 2278, Lot-to-date, 10/05/2022 - 12/14/2022, review date of 03/30/2023 WBC Level 1 CV 5.9 WBC Level 3 CV 6.4 RBC Level 3 CV 4.5 HGB Level 3 CV 6.3 HCT Level 3 CV 4.4 MCH Level 3 CV 5.7 MCHC Level 3 CV 5.7 PLT Level 3 CV 5.3 MXD% Level 1 CV 21.2 MXD% Level 3 CV 10.0 NEUT% Level 3 CV 3.9 LYM# Level 3 CV 6.5 MXD# Level 1 CV 33.3 NEUT# Level 1 CV 8.7 NEUT# Level 3 CV 7.0 4. During an interview on 08/29/2023 at 1115 hours in the conference room, Technical Consultant #1 was asked to provide documentation of investigations for the above flagged CV results. None were provided. This confirmed the findings. Word Key: QC = Quality Control SDI = Standard Deviation Index CV = Coefficient of Variation