

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2092961	(X3) Date Survey Completed 10/07/2019
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	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 to be 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 the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D6055	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of patient test records, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant assessing competency of testing personnel before testing patient samples after a new test cartridge was implemented on the Piccolo Xpress chemistry analyzer. Findings include: 1. A review of the laboratory's policy titled 'Annual Policy and Procedures Review' revealed the following: On page 7: 1/15/2019 Updates: "D/C'd CMP Piccolo</p>

Xpress - Replaced with MetLac 12 Piccolo Xpress" 2. A review of patient test records revealed the first chemistry test reported using the MetLac 12 Piccolo Xpress cartridge was on 1/22/19. 3. A review of the laboratory's personnel records revealed the following testing personnel (as indicated on the CMS 209 forms, signed by the laboratory director on 10/6/19) failed to have documentation of competency assessments being performed prior to patient testing: - Testing Person #1 Competency assessed 10/2019 - Testing Person #2 Competency assessed 11/2018 - Testing Person #3 Competency assessed 10/2019 - Testing Person #4 Competency assessed 12/2018 - Testing Person #5 Competency assessed 12/2018 - Testing Person #6 Competency assessed 5/2019 - Testing Person #7 Competency assessed 11/2018 - Testing Person #8 Competency assessed 10/2019 4. The laboratory was asked to provide documentation of the technical consultant performing competency assessments prior to the identified testing personnel performing patient testing. No documentation was provided. 5. An interview with the technical consultant on 10/7/19 at 10:10 a.m. in the office, after review of the records, confirmed the above findings.