

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0507358	(X3) Date Survey Completed 01/16/2019
Name of Provider or Supplier Crosbyton Clinic Hospital	Street Address, City, State 710 W Main St, Crosbyton, 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
D2017	<p>REINSTATEMENT OF NONWAIVED LABORATORIES CFR(s): 493.807(a)(b)</p> <p>(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.</p> <p>This CONDITION is not met as evidenced by: Based on a review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with records from American Association of Bioanalysts (AAB), the laboratory did not successfully participate in the specialty of Immunohematology for the analyte Antibody Identification in 3 of 4 events between 2017 and 2018. The findings included: 1. Based on review of the CMS-155 proficiency testing report and AAB records, the laboratory received the following unsatisfactory scores for Antibody Identification: 2017 - Third Event - 0 percent 2018 - Second event - 0 percent 2018 - Third event - 0 percent Score of less than 80 percent are unsatisfactory performance. Unsatisfactory performance on two (2) consecutive events or two out of three (2 out of 3) events is unsuccessful performance. 2. In an interview at 11:28 hours on 01/16/2019 in the laboratory, the Laboratory Manager stated the unsatisfactory scores were received in error. The</p>

Laboratory Manager stated the laboratory did not perform Antibody Identification, only Antibody Screens. The Laboratory Manager stated that in the event a patient specimen had a positive antibody screen, the laboratory would refer the Antibody Identification out to a CLIA certified reference laboratory. The Laboratory Manager stated the unsatisfactory scores were the result of marking "Would Refer" to an Antibody Identification challenge. The Laboratory Manager stated he had contacted AAB and was told by a representative to leave the next challenge blank if the laboratory did not perform the test. The Lab Manager stated the lab received a second 0 percent score for not participating, and that because of the previous submission form error, AAB was expected a response and had graded the laboratory as if they did not participate. Regarding the third event of 2018, the Laboratory Manager stated an AAB representative had instructed the lab to report Antibody Identification in a specific way in order to discontinue the test. Based on review of the AAB score sheet for Antibody Identification for the third event of 2018, the laboratory was sent a score of "DC" for discontinued. The proficiency testing program reported a score to CMS of 0 percent for the third event of 2018.