

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0941410	(X3) Date Survey Completed 10/08/2020
Name of Provider or Supplier Children's Clinic Of Harlingen, Pa	Street Address, City, State 608 N Ed Carey Drive, Harlingen, 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	The laboratory was found to be in compliance with the CLIA regulations at 42 CFR. Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of the laboratory's environmental records, and confirmed in interview of facility personnel, the laboratory failed to establish an acceptable room temperature range according to the manufacturer's specifications. The findings were: 1. Review of the manufacturer's instructions for the Sysmex hematology analyzer (Code No. AU553517, May 2014) stated the operating temperature of the analyzer is, "15-30 degrees Celsius" or 59.0-</p>

86.0 degrees Fahrenheit. 2. Review of the laboratory's environmental records from April, May, June 2020 found the laboratory had established its room temperature as 48-86 degrees Fahrenheit. 3. The laboratory failed to establish an acceptable room temperature range according to the manufacturer's instrumentation specifications. 4. An interview with testing personnel #1 (as listed on Form CMS 209) on October 8, 2020 at 11:00 hours in office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, review of the laboratory's quality control records, patient records, and confirmed in interview of facility personnel, the laboratory failed to ensure at least two levels of quality control were acceptable prior to testing patients for 2 of 70 random patient testing days from October 2018 to October 2020. The findings were: 1. Review of the laboratory's policy titled, "Quality Policies" review date October 1, 2014, it stated, "The laboratory supervisor/testing personnel reviews all the quality control records daily. If any controls are out of range, he/she takes immediate action. He/she is also responsible for performing analyses (standards, controls, patient samples) and fills out daily quality control records. Responsible for detected Q.C. problems as they occur and taking immediate action or consulting with the Medical Director as needed." 2. Review of quality control records from October 2018 to October 2020 found the following two patient testing days when only one level of quality control was acceptable: Date: 08-04-2020 Lot #: not legible Only 1 level of acceptable quality control documented Date: 08-18-2020 Lot #: not legible Only 1 level of acceptable quality control documented 3. Review of patient records found the following patient samples were performed when only one level of quality control was documented: 08-04-2020 Sample 1: Patient initials AL Time: 10:43 a.m. Result finalized in patient chart 08-04-2020 Sample 2: Patient initials AB Time: 10:29 a.m. Result finalized in patient chart 08-18-2020 Sample 1: Patient initials SO Time: 11:09 a.m. Result finalized in patient chart 08-18-2020 Sample 2: Patient initials JS Time: 18:12 p.m. Result finalized in patient chart 4. The laboratory failed to ensure at least two levels of quality control were acceptable prior to testing patients. 5. Interview with testing personnel #1 (as listed on Form CMS-209) on October 8, 2020 at 11:10 hours in the office confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services