

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0941410	(X3) Date Survey Completed 04/07/2022
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 surveyed on April 7, 2022 and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended.
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of the laboratory's American Academy of Family Physicians (AAFP) proficiency testing records and confirmed in interview of facility personnel, the laboratory failed to ensure proficiency testing samples were handled the same as patient samples for 2 of 4 testing events reviewed.. The findings included: 1. Review of the laboratory's policy titled "Procedure for Proficiency Testing" approved by the laboratory director on October 9, 2014 stated, "...Survey material will be handled the same way any routine specimen would be." 2. Review of proficiency testing records from 2021 (events 1, 2, and 3) and 2022 (event 1) found the following testing events were tested on more than one day prior to result submission: Hematology (event 2) Specimen #6 Tested on 06-15-2021 @ 15:30 Tested on 06-15-2021 @ 15:32 (did not meet any laboratory criteria for repeat analysis) Hematology (event 3) Specimen #12 Tested on 10-08-2021 @ 12:51 Tested on 10-13-2021 @ 16:40 Specimen #14 Tested on 10-08-2021 @ 12:43 Tested on 10-</p>

13-2021 @ 16:41 3. The laboratory was asked to provide documentation of handling proficiency testing samples the same as patient samples. No documentation was provided. 4. An interview with the primary testing person on April 7, 2022 at 10:15 hours confirmed the findings. She stated that she had repeated them because she was unsure about the flags.