Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0941410	05/17/2018
Name of Provider or Supplier	**Street Address, City, State**	
Children's Clinic Of Harlingen, Pa	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	A recertification survey was performed on May 17, 2018. The laboratory was found to be IN COMPLIANCE with the CLIA regulations and recertification is recommended.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on surveyor observations, review of manufacturer's instructions, review of maintenance records, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to clean the strip holder on the McKesson 120 Urine analzyer. The findings were: 1. Surveyor observation made in the laboratory on 05/17/2018 at 1100 hours revealed the strip reader on the McKesson 120 Urine analyzer was discolored. 2. Review of the manufacturer's instructions for the McKesson 120 Urine analzyer (Number: 1150667601, Effective Date: 2012-02-16) under, "Daily Cleaning" stated, "Clean the Strip Holder." 3. Review of maintenance records from January 2017 to April 2018 revealed no documentation of the facility performing the daily maintenance on the McKesson 120 Urine analyzer 4. Interview with the Operations Manager on 05/17/2018 at 1130 hours in the office confirmed the findings. She revealed she performs the facility's maintenance but has not currently been documenting the maintenance for the urine analyzer.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Sysmex XP300 hematology analyzer, review of the laboratory's maintenance records from January 2017 to April 2018, and staff interview, it was revealed the laboratory failed to have documentation of performing quarterly maintenance as required by the manufacturer. The findings were: 1. A review of the manufacturer's instructions for the Sysmex XP300 hematology analyzer (Revised July 2012) under the section titled "Cleaning and Maintenance" revealed the manufacturer required the following maintenance to be performed every 4500 cycles or every 3 months, whichever occurred first: Clean SRV 2. A review of the laboratory's maintenance records from January 2017 to April 2018 revealed the laboratory failed to have documentation of performing the required quarterly maintenance. Maintenance documentation was as follows: February 2017 December 2017 (10 months later) April 2018 (4 months later) 3. The laboratory was asked to provide documentation of performing the required maintenance. No documentation was provided. 4. An interview with the Operations Manager on 05/17 /2018 at 1030 hours in the office confirmed the findings.