Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0941410	03/06/2024
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
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Sysmex EIGHTCHECK 3WP X-TRA hematology controls, observations, review of policies and procedures and interview of facility personnel,the laboratory failed to document revised expiration dates for one of one opened lot of control materials. The findings included: 1. Review of the manufacturer's instructions for the Sysmex EIGHTCHECK 3WP X-TRA hematology controls (Revision 03/2023) under the section titled Storage and shelf life after first opening: "Opened vials and vials which have been sampled by cap piercing will retain stability for 14 days if stored at 2 - 8C after being recapped." 2. Observations made in the laboratory found one vial each of the low, normal and high controls in the refrigerator with no documentation of the new expiration date after opening. The controls had "hashmarks" to document the number of times used. 3. Review of the Lab Procedure found on page 14 under the heading Reagents: All reagents must be properly labeled with the date of receipt, date placed in service, and expiration date. " 4. During interview of testing person one conducted March 6, 2024 at 10:28 AM, she confirmed that the laboratory did not change the expiration date on the control once it was opened. She went on to say that the hashmarks were made on the controls for each use, and they used the controls 14 times before changing the vials.
D5781	CORRECTIVE ACTIONS

	CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory policy, quality control records, review of CBC Logs and interview of facility personnel,the laboratory failed to document corrective actions 13 of 29 occasions when Hematology quality control failures occurred between July 2022 and October 2023. The findings included: 1. Review of the laboratory policy found on page 10 under the heading CHARTS\RECORDS: "Every quality control decision must be recorded with the date and the signature of the person making the decision. The record should include clearly marked control limits and a place in which out of tolerance limits are noted. These notes must include date, response taken to correct any problems, and the initials of the analyst." 2. Review of quality control records found 13 occurrences when quality control failures were identified without documentation of corrective actions by laboratory staff as follows: July 2022 - Quality control failures for platelets occurred on 3 of 3 dates using lot 21100710 (low control). July 1, 2022 - tested once July 5, 2022 - tested four times July 6, 2022 - tested once September, 2023 - Quality control failures for platelets occurred on 1 of 12 dates using lot 31650710 (low control). September 13, 2023 - tested five times. October 2023 - Quality control failures for platelets occurred on 2 of 11 days. October 12, 2023 - tested once October 13, 2023 - tested once. 3. Review of the CBC logs for July 2022, September 2023 and October 2023 found no documentation of corrective actions taken when quality control results failed to meet the laboratory specifications for acceptability. 4. During interview of testing person one conducted March 6, 2024 at 10:28 AM, she confirmed that the laboratory did not document corrective actions when quality control failures occurred as per their own written policy.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Review quality control records, patient test records and interview of facility personnel found that the laboratory director failed to ensure that the Hematology quality control program had been established and maintained. (See D5415 and D5781)