Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1021534	(X3) Date Survey Completed 07/18/2023
Name of Provider or Supplier Reddy Childrens Clinic Pa	**Street Address, City, State** 4501 Hale Dr, Suite 2, 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	Based on an announced validation inspection, the laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview, the laboratory failed to ensure testing personnel signed the attestation statement attesting that PT samples were tested in the same manner as patient specimens for Complete Blood Count (CBC) for one of four events reviewed. Findings follow. A. Review of the American Association of Bioanalysts (AAB) 1st, 2nd, and 3rd events of 2022 and the 1st event of 2023, showed in the 1st event of 2023 there was no signed attestation statement. B. Interview with the Technical Consultant on July 18, 2023 at 1330 hours acknowledged the laboratory was unaware they had to print the [attestation statement] form from their website when AAB and MLE merged in 2023 and AAB stopped providing one in the survey packet. KEY: MLE = Medical Laboratory Evaluation
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory policy and procedure, test reports, and interview, the laboratory failed to follow manufacturer's instructions and its own policy for sending out specimens with Histogram flags performed on the Sysmex XP-300 for Complete Blood Counts (CBCs) for eight of eight test reports with flags reviewed. Findings follow. A. Review of the Sysmex XP-300 Instructions for Use, revised March 2017, on chapter 8.3 Histogram Flags stated, "Various information can be obtained from the histograms. The XP-300 extracts the characteristics of the histogram and displays them as histogram flags... When the histogram flags are displayed, perform analysis again. If afterwards the flags are still displayed, the sample is considered to correspond to one of the following." 1. For the flag WL under "Probable Sample Cause" stated "Incomplete lysing of red blood cells, presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc." And under Correction stated, "1) Centrifuge sample and replace the plasma with equal volume of saline of Cellpack and repeat analysis. 2) check smear, etc." 2. For the flag RL under "Probable Sample Cause" stated, "Presence of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, etc." And under Correction stated, "1) Manual red blood cell count of sample. 2) check smear, etc." 3. For the flag AG under "Probable Sample Cause," stated "Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc." and under Correction stated to "1). Check smear, etc." B. Review of the laboratory's policy and procedure titled Policy for Abnormal Differentials, approved 12/05/2019, stated "It will be the policy of this laboratory to send out all abnormal differentials. This laboratory will perform only normal differentials. A normal differential will be described as having only normal cells: Lymphocytes, Monocytes, Basophils, Eosinophils, Neutrophils, and normal size and shape RBC and Platelets. If your CBC instrumentation is showing alarms (R1, R2, M3, etc) in the differential section of the report, it will be considered an abnormal differential and should be send out." C. Review of 8 of 8 patient test reports with flags showed results were reported for indices with Histogram Flags as found below with the date of testing, patient date of birth, and the indices with the Histogram flagged on the instrument printouts: Test Date patient's DOB Flags 1. 04/27/2023 05/26/2018 WBC WL*, PLT AG*, LYM% WL*, MXD% WL*, NEUT% WL* 2. 04/27/2023 01 /23/2018 PLT AG* 3. 03/29/2023 12/01/2021 PLT AG* 4. 01/27/2023 09/08/2011 PLT AG* 5. 12/27/2022 11/30/2013 PLT AG* 6. 11/26/2021 10/01/2008 PLT AG* 7. 11/30/2021 02/12/2021 WBC WL*, PLT AG*, LYM% WL*, MXD% WL*, NEUT% WL*, LYM# WL*, MXD# WL*, NEUT# WL* 8. 11/21/2021 03/19/2020 WBC WL*, RBC RL, HCT RL, MCV RL, MCH RL, PLT RL, LYM% WL*, MXD% WL*, NEUT% WL*, LYM# WL*, MXD# WL*, NEUT# WL* D. Interview with the Technical Consultant on July 18, 2023 at 1525 hours confirmed they should be sending out the flagged specimens, but may modify the procedure to redact the flagged results. KEY: WBC = White Blood Cells RBC = Red Blood Cells HCT = Hematocrit MCV = Mean Corpuscular Volume MCH = Mean Corpuscular Hemoglobin PLT = Platelets LYM% = % Lymphocytes MXD% = % Mixed /Monocytes NEUT% = % Neutrophils MXD# = absolute Mixed/Monocytes NEUT# = absolute Neutrophils
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedures, calibration records, and interview, the laboratory failed to perform calibrations at least every 6 months on the Sysmex XP-300 Hematology analyzer for two out of four events reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Calibration Validation, approved 12/05/2019, stated, "It is policy of this lab to validate calibrations: Every 6 month Following a complete reagent change Following major preventive maintenance Following replacement of a critical part or when Shifts or Trends in QC are seen". B. Review of calibrations records showed calibrations were performed on: 1. 04/21/2021, 2. 02/25/2022, (elapsed time 10 months 4 days) 3. 09/15/2022, 4. 04/21/2023 (elapsed time 7 months 6 days). C. Interview with the Technical Consultant on July 18, 2023 at 1450 hours acknowledged they went a little long on calibrations because the service contract ran out and too much time had gone by, so the technical consultant showed them how to do calibrations and the lab is doing them now.