Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0503928	11/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Rainbow Pediatric Clinic	902 S Airport Drive Ste 1, Weslaco, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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.
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 the laboratory's American Proficiency Institute's (API) proficiency testing records from 2018 and 2019, and staff interview, it was revealed the laboratory failed to have documentation of testing personnel signing 2 of 12 attestation statements. The findings were: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2018 & 2019 (Hematology & Microbiology events 1, 2, and 3) revealed the laboratory failed to have documentation of testing personnel signing the attestation statements for 2 of 12 testing events: 2019

	(Hematology) Event 1 2019 (Microbiology) Event 3 2. An interview with the technical consultant on November 6, 2019 at 10:00 hours in the break room confirmed the findings.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records and confirmed in interview of facility personnel, the laboratory failed to achieve at least an 80% for the regulated analyte WBC Differential. The findings were: 1. Review of the laboratory's API proficiency testing records for Hematology 2018 and 2019 (events 1, 2, and 3) revealed the following: Hematology 2019 (event 1) WBC Differential = 52% 2. Interview with Testing Personnel #1 (as listed on Form CMS-209) on November 6, 2019 at 09:45 hours in the break room confirmed the findings. He revealed that the failure was due to not following API's instructions. He went on to say it was the first API event they participated in since they implemented a new analyzer. Key: CMS - Centers for Medicare and Medicaid Services
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification records for the Sysmex XN-330 hematology analyzer and confirmed in interview of facility personnel, the laboratory failed to retain system performance records. The findings were: 1. Review of the laboratory's verification records for the Sysmex XN-330 hematology analyzer revealed the instrument was put into use on February 14, 2019. 2. Review of the verification records revealed the laboratory failed to retain verification data. Missing records were: a. Raw data used to perform the accuracy assessment b. Raw data used to perform the precision study 3. Interview with Testing Personnel #1 (as listed on Form CMS-209) on November 6, 2019 confirmed the findings. He revealed that he has contacted the person who installed the instrument on several occasions, but he has not heard back from them. Key: CMS - Centers for Medicare and Medicaid Services
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.

	(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions, review of patient test results, and confirmed in interview of facility personnel, the laboratory's policy for abnormal flags failed to ensure results were accurate prior to their release to the healthcare provider. The findings were: 1. Review of the laboratory's policy titled, "Policy for Abnormal Differentials" approved by the laboratory director on March 28, 2013 stated, "It will be the policy of this laboratory to send out abnormal differentials to the reference lab based on the Laboratory Director's discretion ..." 2. Review of the manufacturer's instructions for the Sysmex XN-330 hematology analyzer (Code No. AK803790) under, "Display of analysis result data" it stated: Display * Meaning Low reliability Description Indicates that the reliability of the data is low 3. Random review of patient test records from October and November 2019 found the following patient results with abnormal flags that had not been verified prior to their release to the healthcare provider: See Patient Alias List 4. Interview with the technical consultant on November 6, 2019 at 11:10 hours in the break room confirmed the findings.
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 manufacturer's instructions, review of the laboratory's new lot verification records, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to run controls in parallel for at least 10 times over 5 days. The findings were: 1. Review of the manufacturer's instructions "Product Notification" (Document No. 62-1399, 07/2017) under, "Action" it stated, "9. When changing control lots, it is recommended to run current and new controls in parallel at least 10 times over 5 days." 2. Review of the laboratory's lot number verification records revealed that the laboratory has had one lot number change since the new instrument was introduced in February 2019. Previous Lot: 915814 Expiration Date: 09-17-2019 3. Further review of the lot verification records revealed the laboratory ran controls in parallel for 3 days for one time per day: Previous Lot: 915814 Date & Time Run: 09-13-2019 @ 08:21 09-14-2019 @ 08:11 09-17-2019 @ 08:21 New Lot: 924214 Date & Time Run: 09-13-2019 @ 17:14 09-14-2019 @ 08:43

	09-17-2019 @ 08:07 4. Interview with Testing Personnel #1 (as listed on Form CMS-209) on November 6, 2019 at 11:15 hours in the break room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of instrument verification records for the Sysmex XN-330 hematology analyzer, manufacturer's instructions, and confirmed in interview of facility personnel revealed the laboratory failed to have documentation of performing complete system verification studies (patient normal ranges) prior to patient testing. The findings were: 1. Review of the laboratory's policy titled, "Pre-Use Test System Validation of Performance" approved by the laboratory director on March 2, 2000 stated, "This laboratory will perform pre-use test system validation and will document the comparison of patient test results with an alternate method or comparison of split samples with an established method. Comparison will be made to determine: accuracy, precision, reportable range." The laboratory's policy failed to include verification of patient normal range. 2. Review of the laboratory's system verification records for the Sysmex XN-330 revealed the laboratory implemented the new analyzer in February 14, 2019 (over 8 months ago). The following patient normal reference ranges were available in the analyzer available for patient use: a. Females (ages 2-12 years) b. Males (ages 2-12 years) c. Females (ages >12-21 years) d. Males (ages >12-21 years) 3. Review of the manufacturer's instructions for the Sysmex XN-330 hematology analyzer under, "Instrument Specifications" revealed the following reference ranges: a. Females (ages 2-12 years) b. Males (ages 2-12 years) c. Females (ages >12-21 years) d. Males (ages >12-21 years) The laboratory is currently using the manufacturer's patient normal ranges, but did not perform a verification. 4. An interview with the technical consult on November 6, 2019 at 11:00 hours in the break room confirmed the findings.
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: Based on review of laboratory policy, review of the laboratory's American Proficiency

	Institute (API) proficiency testing records, and confirmed in interview of facility personnel, the laboratory director failed to ensure the approved corrective action plan was followed when the laboratory had a PT failure. The findings were: 1. Review of the laboratory's policy titled, "Proficiency Testing" approved by the laboratory director on March 2, 2000, it stated, "Use the "Proficiency Testing Remedial Action Log Sheet" to help resolve and document failed proficiency testing." 2. Review of the laboratory's API proficiency testing records for Hematology 2018 & 2019 (events 1, 2, and 3) revealed the following for 2019 (event 1): Analyte Score IG absolute 0% IG percent 0% WBC Differential 52% Basophils 0% Eosinophils 0% Monocytes 0% 3. Review of the records for the proficiency testing event revealed that the laboratory had not performed any corrective action, nor did they use the "Proficiency Testing Remedial Action Log Sheet." 4. Interview with Testing Personnel #1 (as listed on Form CMS-209) on November 6, 2019 at 09:45 hours in the break room confirmed the findings. He revealed that the failure was due to not following API's instructions. He went on to say it was the first API event they participated in since they implemented a new analyzer. Key: CMS - Centers for Medicare and Medicaid Services