Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0503928	01/26/2022
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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2021, review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to have documentation of testing proficiency samples the same number of times as patient samples. The findings include: 1. A review of the laboratory's policy titled "Policy for repeating CBC's and Communicating Critical Values" (signed by the laboratory director on 12/30/2020) revealed: "In an effort to ensure accuracy in patient CBC testing, it is the policy of this laboratory to repeat tests when these are critical" WBC less than 2 or greater than 20 HGB less than 7.5 or greater than 18 HCT less than 25 or greater than 55 PLT less than 50 or greater than 800 2. A review of the laboratory's American Proficiency

	Institute's proficiency testing records from 2021 identified the following proficiency testing samples who results met the laboratory's criteria for repeating, however the facility failed to have documentation of doing so: a) 2021 event 1 sample 2 HGB: 5.6 sample 4 HGB: 6.0 b) 2021 event 2 sample 8 HGB: 6.0 sample: 9 HGB: 5.6 c) 2021 event 3 sample 11 HGB: 5.3 sample 15 HGB: 6.2 HGB: 18.1 3. The laboratory was asked to provide documentation of repeating the proficiency samples as they would patient samples. No documentation was provided. 4. An interview with the technical consultant on 01/26/2022 at 1010 hours in the break room - after her review of the records- confirmed the findings. KEY CBC's - complete blood counts WBC- white blood cells HCT - hematocrit HGB- hemoglobin PLT - platelet
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's policies, review of patient test records from October 2021 to January 2022 and staff interview, it was revealed the laboratory failed to have documentation of reporting 539 COVID 19 test results as required by 400.200 performed over 55 days. Findings include: 1. Review of the laboratory's test menu revealed the facility started testing for COVID antigen utilizing the Quidel Sofia SARS antigen test in August 2020. 2. Review of the laboratory policy (signed 10/12/2021) revealed: "It is the policy of this Clinic to report all Positive and Negative COVID 19 Antigen testing results to the State Department of Health. All positive results will be faxed the same day or next day and negative results will be faxed throughout the month. Several Fax numbers will be available. Please keep confirmations of all faxed documents." 3. Review of the laboratory's COVID 19 Rapid Antigen patient test records from 10/12/2021 to 12/31/2021 revealed the laboratory failed to have documentation of reporting 539 COVID 19 results over 55 test days. (Refer to COVID 19 Rapid Antigen Test Log.) a) October 2021 84 negative results not reported 2 positive results not reported 12 test days b) November 2021 188 negative results not reported 7 positive results not reported 22 test days c) December 2021 227 negative results not reported 31 positive results not reported 21 test days 3. The laboratory was asked to provide documentation of the fax confirmations or of the fax machine log to verify that results had been reported as required. No documentation was provided. 4. An interview with the technical consultant on 01/26/2022 at 1130 hours in the break room revealed the laboratory did not have documentation to verify results had been reported. This confirmed the findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from 2021, and staff interview, it was revealed the laboratory failed to retain package inserts for 6 of 6 lots used in 2021. The findings include: 1. A review of the laboratory's quality control records from 2021 revealed the laboratory utilized the following 6 lots of quality control material in 2021: 135214 126814 118414 110014 101614 029814 2. The laboratory was asked to provide the package inserts for each of the identified 6 lots used. No documentation was provided. 3. An interview with the technical consultant on 01/26/2022 at 0930 hours in the break room revealed the laboratory did not retain the package inserts. This confirmed the findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was determined the laboratory failed to meet the requirements for analytic systems. The findings include: 1. The laboratory failed to follow its policy for flagged CBC results (refer to D5403). This is a repeat deficiency from the survey conducted 11/06/2019 2. The laboratory failed to have documentation of performing required maintenance (refer to D5429). 3. The laboratory failed to have documentation of performing corrective actions (refer to D5785).
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 the laboratory's policies, review of patient test records, and staff interview, it was revealed the laboratory failed to follow its own policy for addressing flags on complete blood count (CBC) results. The findings include: 1. A review of the laboratory's policy titled "Policy for Handling Abnormal CBC's and their Flags (signed by the laboratory director on 12/30/2020) revealed: "If you CBC instrument is showing alarms or flags, it will be considered abnormal. The lab will send out the specimen for a peripheral smear or manual diff if quantity is sufficient to the Reference Lab. All abnormal flagged results will be crossed out." 2. A sampling of patient test results from December 2021 to January 2022 identified the following patient results with flags for which the laboratory did not have documentation of sending out to the reference lab and/or did not cross out the flagged results prior to reporting the provider: a) test date: 12/27/2021 test time: 07:5510 Patient 1 Patient initials: AZ Flagged results: Neutrophils * Lymphocytes * Monocytes * IG * b) test date: 12/27/2021 test time: 08:36:36 Patient 2 Patient initials: CV Flagged results: Neutrophils * Lymphocytes * Monocytes * IG * c) test date: 12/28/2021 test time: 10: 49:57 Patient 3 Patient initials: CB Flagged results: Platelet * MPV * d) test date: 12 /28/2021 test time: 10:48:20 Patient 4 Patient initials: AB Flagged results: Platelet * MPV * e) test date: 12/28/2021 test time: 13:40:08 Patient 4 Patient initials: AM Flagged results: Neutrophils * Lymphocytes * Monocytes * IG * f) test date: 12/28 /2021 test time: 13:41:15 Patient 5 Patient initials: JM Flagged results: Neutrophils * Lymphocytes * Monocytes * IG * g) test date: 01/11/2022 test time: 13:04:20 Patient 6 Patient initials: CS Flagged results: RBC * HCT * MCV * MCH * MCHC * h) test date: 01/17/2022 test time: 16:04:47 Patient 7 Patient initials: CR Flagged results: Platelet * MPV * i) test date: 01/17/2022 test time: 16:10:28 Patient 8 Patient initials: SC Flagged results: Platelet * MPV * j) test date: 01/17/2022 test time: 16:24:50 Patient 9 Patient initials: JR Flagged results: Platelet * MPV * k) test date: 01/18/2022 test time: 10:57:40 Patient 10 Patient initials: SF Flagged results: Platelet * MPV * l) test date: 01/20/2022 test time: 7:41:17 Patient 11 Patient initials: CM Flagged results Platelet * MPV * Neutrophils * Lymphocytes * Monocytes * IG * 3. An interview with the technical consultant on 01/26/2022 at 1115 hours in the break room - after her review of the records- confirmed the findings. Key MPV - mean platelet volume RBC - red blood cell HCT - hematocrit MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin MCHC- mean corpuscular hemoglobin concentration NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 11/06/2019
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 XN-330 hematology analyzer, review of the laboratory's maintenance records from 2021, and

	staff interview, it was revealed the laboratory failed to have documentation of performing required daily maintenance for 303 of 309 work days. The findings include: 1. A review of the manufacturer's instructions for the Sysmex XN-330 hematology analyzer under the section titled "Sample Explorer & Maintenance" revealed the manufacturer required a shutdown to be performed daily on the analyzer. 2. A review of the laboratory's Sysmex XN-330 maintenance records from January 2021 to December 2021 revealed the laboratory failed to have documentation of performing the required daily maintenance for 303 of 309 days. a) January 2021 24 of 26 days without documentation b) February 2021 24 of 24 days without documentation c) March 2021 27 of 27 days without documentation d) April 2021 26 of 26 days without documentation e) May 2021 25 of 25 days without documentation f) June 2021 26 of 26 days without documentation g) July 2021 27 of 27 days without documentation h) August 2021 26 of 26 days without documentation i) September 2021 26 of 26 days without documentation j) October 2021 26 of 26 days without documentation k) November 2021 25 of 25 days without documentation l) December 2021 21 of 25 days without documentation. 3. The laboratory was asked to provide documentation of performing the required shutdown each day of use. No documentation was provided. 4. An interview with the technical consultant on 01/26 /2022 at 1230 hours - after her review of the records- confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the laboratory's environmental monitoring records and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the room humidity or refrigerator temperature were documented outside the laboratory's acceptable ranges. The findings include: 1. A review of the laboratory's environmental monitoring records from March 2021 and May 2021 revealed the laboratory had the following defined acceptable ranges: Room temperature: 68 - 77 F Room humidity: 30 - 80% Refrigerator temperature: 35 - 46 F 2. Further review of the records identified the following days where the laboratory documented values outside its acceptable ranges, but failed to have documentation of performing corrective actions: a) March 2021 Humidity 3/3 29% 3/5 25% 3/8 22% 3 /9 25% 3/13 29% 3/16 25% 3/17 25% 3/18 25% 3/19 26% 3/20 25% 3/23 28% 3/24 25% 3/25 25% 3/26 25% 3/27 25% 3/29 29% 3/31 20% b) May 2021 Refrigerator Temperature 5/1 34F 5/5 32F 5/6 30F 5/8 30F 5/10 30F 5/11 30F 5/12 32F 5/15 34F 5 /17 33F 5/18 34F 5/19 31F 5/20 30F 5/21 33F 5/22 32F 5/24 30F 5/25 34F 5/27 33F 5 /28 32F 5/29 34F 5/31 34F 3. The laboratory was asked to provide documentation of performing corrective actions on the identified days. No documentation was provided. 4. An interview with the technical consultant on 01/26/2022 at 1130 hours in the break room - after her review of the records - confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's monthly quality assurance reports from 2021, review of the laboratory's records, and staff interview, it was revealed the laboratory's monthly review failed to identify problems in analytic systems. The findings include: 1. A review of the laboratory's monthly quality assurance reports from 2021 revealed for 12 of 12 months the report stated that: "All required maintenance was performed and documented as required by the manufacturer." and, "All temperature records were found to be within the specified ranges." 2. A review of the laboratory's records revealed that there was missing documentation of maintenance (refer to D5429) and missing documentation of corrective actions for environmental records out of the laboratory's acceptable ranges (refer to D5785).
D6021	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 quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's monthly quality assurance reports from 2021, review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality assurance plan could identify problems in analytic systems (refer to D5791).
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of laboratory records, manufacturer's instructions, patient reports, and confirmed in interview, the technical consultant failed to identify training needs of testing personnel. The findings include: Testing personnel were not: 1. Following the laboratory's policies (refer to D5403). 2. Performing maintenance as required (refer to D5429). 3. Peforming correction actions as required (refer to D5785).