Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0503810	11/11/2020
Name of Provider or Supplier	**Street Address, City, State**	
Mission Pediatric Center	210 South Bryan Road Suite 5a, Mission, 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.
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 manufacturer's instructions for the Coulter Act diff hematology analyzer, review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to have a policy to verify flags on CBC (complete blood count) results. The findings were: 1. A review of the manufacturer's instructions for the Coulter Act diff hematology analyzer (PN 4237416DA) under the section titled "Table 6.4 What Flags Mean" revealed the manufacturer identified the following flags: 1 2 3 4 M The manufacturer then listed the suggestion action to address these flags as "Verify results according to your laboratory's protocol." 2. A review of the laboratory's protocol titled "Policy for Abnormal Differentials" (approved and signed by the laboratory director on 12/24/2013) revealed: "It will be the policy of this laboratory to send out any abnormal differentials to the reference lab, based on the Laboratory Director's discretion. The Laboratory Director will determine if an abnormal differential is required post evaluating CBC results and assessing the patient's clinical findings." The policy did not ensure patient results with flags were verified. 3. An interview with the technical consultant on 11/11/2020 at 1100 hours in the break room revealed this protocol was not what the laboratory was supposed to be doing. She stated results with flags were to be repeated, and, if the flags were not resolved, the results blacked out so the provided could not see them. 4. A review of patient test records from October 12, 2020 to October 31, 2020 identified 31 patients whose results had flags, however, the laboratory did not have documentation of repeating them. This did not follow the protocol the technical consultant said was in place. Note: This is a repeat deficiency from the surveys conducted 01/26/2016 and 12 /07/2017.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Coulter 4C-ES hematology controls, surveyor observation, and staff interviews, it was revealed the laboratory failed have a method to monitor revised expiration dates of controls. The findings were: 1. A review of the manufacturer's instructions for the Coulter 4C-ES hematology control revealed that once opened the control were acceptable for use for 35 days or 20 aspirations, whichever occurred first. 2. Surveyor observation on 11/11 /2020 at 1015 hours of control material currently in use in the laboratory revealed 3 vials of hematology control material with documented opened dates of 10/27/2020. There was no indication of the number of aspirations from each control. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 11/11 /2020 at 11:20 hours in the laboratory revealed that she thought the control were acceptable for use up to 20 or 21 days after opening. She did not know of the limitation of the number of aspirates. 4. An interview with the technical consultant on 11/11/2020 at 1115 hours in the break room revealed that she thought the controls were acceptable for use up to 21 days after opening. This confirmed the findings.

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 records, and staff interview, it was revealed the laboratory failed to have documentation of performing calibrations on the Beckman Coulter AcT diff analyzer every six months. The findings were: 1. A review of the laboratory's calibration records for the Beckman Coulter AcT diff hematology analyzer from 2018, 2019, and 2020 revealed the laboratory performed calibrations on the following times: 06/2018 11/2018 03/2019 05/2019 11/2019 2. Instructions for the Beckman Coulter AcT diff stated calibrations had to be performed following regulations which is at least every six months. 3. The laboratory was asked to provide documentation of performing calibrations in 2020. No documentation was provided. 4. An interview with the technical consultant on 11/11/2020 at 1110 hours in the break room revealed the laboratory may have done a calibration in August or September 2020 but was unable to locate the records. This confirmed the findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's quality control records, and staff interview, it was revealed the laboratory failed to have documentation of verifying new lots of control prior to placing them into service. The findings were: 1. A review of the laboratory's policy titled "Quantitative Control Policy" (approved by the laboratory director on 12/24/2013) revealed: "In an effort to ensure accurate patient results and to comply with CLIA regulations, this lab will

	evaluate all quantitative control to determine if stated control values are within the limits of acceptability for our laboratory. Method: Controls will be run concurrently with patients for at least 5 days. If the mean of all results is within the stated range, then the stated range will be used as the expected range for this lab." 2. A review of the laboratory's quality control records from January 2020 to November 2020 revealed the laboratory place 4 new lots of quality control material into service: Lot: 068600 Lot: 067900 Lot: 089800 Lot: 069800 3. The laboratory was asked to provide documentation of verifying the controls following its policy prior to placing them into service. No documentation was provided. 4. An interview with the technical consultant on 11/11/2020 at 11:26 hours in the break room revealed the laboratory did not verify the controls as required. This confirmed the findings.