Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0933268	10/08/2020
Name of Provider or Supplier	**Street Address, City, State**	
Pediatrics Of Greater Houston	7900 Fannin, Suite 3300, Houston, 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.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, laboratory's College of American Pathologists (CAP) proficiency testing records from 2019 and 2020, and staff interview, it was revealed the laboratory failed to treat proficiency testing samples the same as patient samples for 9 of 25 samples in 5 events. The findings were: 1. A

	review of the Laboratory procedure titled "Laboratory Operating Procedures" signed (02/02/2015 by the laboratory director) under "Proficiency Testing" states "Proficiency testing samples must be handled and tested according to manufacturer instructions. Regarding criteria for testing decisions and result interpretation, proficiency testing samples are to be handled in the same manner as patient specimens." 2. A review of the laboratory's policy titled "Medonic M Series CBC Analyzer" under "Handling of Abnormal and Flagged Results (sic)"states " For WBC /WBC Diff flags, repeat the testing after doing the following: Make sure the EDTA sample has been allowed to sit for 15 20 minutes before it is analyzed. This will allow for the anticoagulant and the blood to equilibrate. Always mix the sample well before analyzing. If WBC/WBC Diff flags are not resolved. DO NOT REPORT PATIENT RESULTS. Refer sample to the send out lab for testing when requested by physician." 3. Review of CAP Proficiency testing records from 2019 (Hematology events 1, 2, and 3) and 2020 (Hematology events 1 and 2) found no documentation of the repeat analysis for the flags per the lab policy for 9 of 25 PT specimens. Sample Test Date Time Flags 2019 Event 1 FH-02 02/04/2019 18M54M14 Too many WBC populations; slide review advised 2019 Event 2 FH2-07 05/16/2019 11M12M39 Measurement statistics warning; reanalyze FH2-09 05/16/2019 11M05M09 Measurement statistics warning; reanalyze Too many WBC populations; slide review advised FH-10 05/16/2019 10M59M26 Too many WBC populations; slide review advised 2019 Event 3 FH2-11 11/08/2019 17M43M13 Measurement statistics warning; reanalyze FH2-12 11/08/2019 17M45M07 Measurement statistics warning; reanalyze FH2-13 11/08/2019 17M47M04 Measurement statistics warning; reanalyze Too many WBC populations; slide review advised 2020 Event 1 FH2-03 02/04/2020 15M53M32 Too many WBC populations; slide review advised 2020 Event 2 FH2-08 05/14/2020 14M52M51 Too many WBC populations; slide review advised 4. An interview with the technical consultant on 10/08/2020 at 1045 hours in conference room confirmed the findings proficiency testing were not being repeated according to their lab policy.
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 College of American Pathologists (CAP) proficiency test (PT) records from 2020 and confirmed by interview, the laboratory failed to obtain at least 80% for hematology analyte hematocrit for 1 of 3 testing events in 2020. (CAP second event) The findings were: 1. Review of CAP PT records for 2020 for hematocrit revealed the laboratory received the following score: 2020 2nd event - 60% 2. In an interview with the techincial consultant on 10/08/2020 at 1145 hours the office, after review of the records, confirmed the findings.
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 manufacturers instruction, surveyor observation, and confirmed in interview of facility personnel, the laboratory failed to document quality control with the revised open expiration dates. The findings were: 1. Review of the Boule Con Diff Tri Level instructions under "Storage and Stability" states "Open vial stability 14 days after opening when returned to the refrigerator after each use." 2. Surveyor observation made on October 08, 2020 at 1112 hours found one Boule control (Lot # 220600 exp 10/22/20) with no documentation of the open expiration date. 3. An interview with the technical consultant on 10/8/20 at 1115 hours in the office revealed that the "7-14" was not the revised expiration date nor was it the opened date. 4. The findings were confirmed in interview with testing person #1 (as listed on Form CMS 209) on October 08, 2020 at 1112 hours in the laboratory. She stated that it must be a mistake "They would never have a control in the refrigerator with an expiration date from July".
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 laboratory policy, the manufacturer's instructions for the Medonic M-series hematology analyzer, review of the laboratory's maintenance records from 2018 to 2020, and staff interview, it was revealed the laboratory failed to have documentation of performing all required maintenance required prior to patient testing. The findings were: 1. A review of the manufacturer's instructions for the Medonic M-series hematology analyzer (SN 27451) under the section titled "Maintenance" revealed the following maintenance was required by the manufacturer: a. Daily -Clean the aspiration and pre-dilute probes using an alcohol wipe. - Remove possible traces of salt crystals or blood at the top of the aspiration and pre-dilute probes, probe rinse cup, and around top of sampling device probe inlet (if applicable) using a paper tissue with a disinfecting solution. b. Monthly -. Clean the aspiration probes using an alcohol wipe. - Fill a cup with 10 ml 2% hypochlorite (Bottle # 2 from Boule Cleaning Kit) and one cup with 18 ml diluent. -. Aspirate the hypochlorite as a pre-dilute sample. - Run 2 blank samples by aspirating diluent as a pre-diluted sample. - Perform a background check, in pre-dilute mode, to verify all values are within range. - Clot Prevention This process will decrease the risk of debris material building up in the instrument system. This should be performed at least once a month or every 1000 samples. c. Six Month -To increase the life of internal tubing in the instrument, the following cleaning is strongly recommended. - Follow instruction for the Boule Cleaning kit to clean the instrument. - The six-month cleaning procedure takes approximately on hour and 15 minutes to complete. 2. A review of laboratory policy titled "Laboratory Operating Procedures" under "Instrument Maintenance" states " Routine and non-routine instrument maintenance will be performed according to manufacturer's recommendations. Maintenance will be documented on the daily maintenance log sheet." 3. Review of the laboratory's maintenance records from October 2018 to January 2020 revealed the laboratory failed to have documentation of

	performing the following maintenance: a. Daily October 2018 (2 of 22 days missing) October 1, 2018 October 2, 2018 July 2019 (1 of 25 days missing) July 9, 2019 January 2020 (8 of 22 days missing) January 6, 2020 January 10, 2020 January 15, 2020 January 16, 2020 January 17, 2020 January 20, 2020 January 27, 2020 January 30, 2020 b. Monthly (1 of 10 missing) October 2018 c. Six Month (3 of 4 missing) March 2019 September 2019 January 2020 3. The laboratory was asked to provide documentation of the missing maintenance being performed. No documentation was provided. 4. An interview with the technical consultant 10/08/2020 at 1125 hours in the office confirmed they were missing the daily, monthly and six-month maintenance documentation.
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 manufacturer's Medonic Hematology analyzer instruction, calibration records, and confirmed in interview of facility personnel, the laboratory failed to document the calibrations on the Medonic Hematology analyzer every six months per manufacturer's instructions. The findings were: 1. A review of the manufacturer's instructions for the Medonic M-series hematology analyzer (SN27451) under Section 7 "Calibration" states "It is recommended to calibrate the instrument every 6 months." 2. A review of the laboratory's calibrations records from October 2018 until October 2020 revealed calibrations were performed in October 2018 and July 2019. 3. The laboratory was asked to provide printing documentation of the calibration for March 2019 and January 2020 by the manufacturer prior to performing calibrations. No documentation was provided. 4. An interview with the technical consultant on 10/08/2020 at 1112 hours in the conference 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 verification records, laboratory quality control records, and confirmed in interview, the laboratory quality assurance policies failed to monitor and correct problems in the analytic systems. Refer to D5415, D5429, D5437