Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0933268	07/27/2018
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(s) at the exit conference. The facility representative(s) were 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.
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 2016, 2017 and 2018 American Proficiency Institute (API) proficiency testing (PT) records and confirmed in interview, the laboratory failed to obtain at least 80% for the hematology analyte Red Cell Count (RBC) for 2017 1st event and lymphocytes for the 2016 3rd event. Findings were: 1. Review of PT records for 2017 for red blood cells revealed the laboratory received the following scores for the 2017 Hematology 1st event: API 1st event 2017 = 60% sample lab result (x10E12/L) Hem-01 4.41 acceptable result 3.86 - 4.36 Hem-03 5.54 acceptable result 4.89 - 5.52 2. Review of PT records for 2016 for lymphocytes revealed the laboratory received the following scores for the 2016 Hematology 3rd event: API 3rd event 2016 = 60% sample lab result (%) acceptable result Hem-11 18.7 9.2 - 17.3 Hem-13 14.7 11.9 - 14.6 3. An interivew with the technical consultant on 7/27/18 at 1040 hours in the office confirmed the above 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 the manufacturer's instructions, laboratory policy, patient records, and confirmed in interview, the laboratory failed to follow the manufacturer's instructions to ensure system flags were verified prior to reporting patient results from the Medonic M-series hematology analyzer. Findings were: 1. Review of the Medonic M-series user manual revealed the following corrective action for the following flags. flags corrective action SE Reanalyze sample OM Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended. Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. 2. Review of the laboratory policy Medonic M-Series CBC Analyzer (effective date 2/1 /18) revealed the following actions for the corresponding flags. flags corrective action SE Reanalyze sample OM Blood sample too old or may be an abnormal pathological sample. 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. Re-analyze the sample. If the flags are not resolved, DO NOT REPORT PATIENT RESULTS. Refer the sample to send out lab. 3. Random review of patient records from April 2018 to July 2018 revealed 3 of 12 patient final reports with flags and no documentation of a repeat analysis or a manual differential from a reference lab per the laboratory policy. date sequence flag 4 /26/18 3843 OM 7/6/18 4287 SE 7/14/18 4337 OM 4. An interview with the technical consultant on 7/27/18 at 1030 hours in the office confirmed the above findings. She stated that the testing personnel is still getting used to the flags for the new analyzer. key: SE - The rate of cell pulses per time unit varies too much. Possible reasons might be clogging, air bubbles, electrical disturbances or difficult to lyse cells. OM - There was only one mode in the WBC distribution between the LYM-L and GRAN-H settings.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing (PT) records from 2016, 2017, and 2018, and confirmed in interview, the laboratory director failed to ensure the laboratory performed remedial action for proficiency testing failures. Findings were: 1. Review of the laboratory PT records from 2017 revealed no remedial action for the PT failures for the 2017 1st event. API 1st event 2017 - 60% RBC (red blood cells) 2. Review of the 2016 and 2017 patient test logs revealed the laboratory performed CBC (complete blood count) patient testing from

	November 2016 to February 2017. Refer to patient alias list. 3. An interview with the technical consultant on 7/27/18 at 1010 hours in the office confirmed the above findings.