Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1053338	10/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pediatrics Dr Seymour Goldberg	7900 Fannin, Suite 3250, 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.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory American Proficiency Institute (API) proficiency testing records from 2018 and 2019 and confirmed in interview, the laboratory failed to retain laboratory records 1 of 5 Hematology events. Findings were: 1. Review of the API proficiency testing records from 2018 and 2019 revealed 1 of 5 Hematology events with no documentation of the laboratory records (2018 API 2nd event). 2. Review of the API profieicney testing evaluation records revealed the laboratory received a 100% for 2018 API Hematology 2nd event, but no documentation of the corresponding laboratory records were available for review. 3. An interview with the

	technical consultant on 10/29/19 at 1120 hours in the break room confirmed the above findings.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing reports from 2018 and 2019, and confirmed in interview, the laboratory failed to provide documentation of evaluating proficiency testing results returned ungraded by the proficiency testing agency. Findings were: 1. Review of the API performance evaluation revealed "laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform self-evaluation using statistics presented in the Participation Data Summary for samples that have not been graded." 2. Review of the 2018 and 2019 API Hematology records revealed 1 of 5 events with a grade of not graded with no documentation of the self-evaluation. 2019 2nd event sample ID grade QBC - 06 not graded 3. An interview with the technical consultant on 10/29/19 at 1130 hours in the break room confirmed the above findings
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on review of laboratory 2018 and 2019 test logs and confirmed in interview, the facility failed to document the time and date it received specimens. Findings were: 1. Review of 2018 and 2019 test logs revealed no documentation of the time the facility collects specimens for CBC (complete blood count). Specimen time of collection/receipt into the laboratory is vital information in order to ensure specimens are tested within required storage time frames. 2. An interview with the technical consultant on 10/29/19 at 1120 hrs in the break room confirmed that the facility does not log the time of specimen collection/receipt. She acknowledged that the laboratory log has the option for the date and time, but testing persons do not document it. Review of the CMS116 form revealed an annual test volume of 3900 CBCs.
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 quality control records from September and October 2019, patient test records, and confirmed in interview, the laboratory failed to verify the CBC (complete blood count) quality controls for the QBC Star hematology analyzer prior to patient testing. Findings were: 1. Review of the laboratory records from September and October 2019 revealed no documentation of the laboratory verifying the following quality controls for the QBC Star hematology analyzer: lot Q558 exp 11/3/19 lot Q557 exp 10/13/19 2. Random review of patient records from September and October 2019 revealed the laboratory performed patient testing. Refer to patient alias list. 3. An interview with the technical consultant on 10/29/19 at 1110 hours in the break room confirmed the above findings. She stated that she instructed the testing persons to verify the quality control 5 times prior to use.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of the laboratory quality control records and confirmed in interview, the technical consultant failed to ensure that the quality control program had been established and maintained for the QBC Star. Refer to D5469
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of personnel files and interview, the technical consultant failed to include the direct observation of routine test performance including patient preparation, specimen handling, processing, and testing as part of the competency evaluation for 2 of 3 testing persons. Findings include: 1. Review of CMS209 revealed 3 testing persons. 2. Review of the personnel files for testing personnel 1 (hire date 12/2017) revealed competency performed on 2/25/19, but the specimen

	source "observed" was dated 11/5/18. 3. Review of the personnel files for testing personnel 2 (hire date 06/10/17) revealed competency performed on 2/25/19, but the specimen source "observed" was dated 2/14/19. 4. Interview with the technical consultant on 10/29/19 at 1005 hours in the break room confirmed the above findings. She acknowledged that she had no direct observation of specimen testing on the day the competency was documented.
D6124	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on review of the personnel files and confirmed in interview, the technical consultant failed to include, but are not limited to direct observation of performance of instrument maintenance and function checks for CBC (complete blood count) testing on the QBC Star hematology analyzer. Findings were: 1. Review of CMS209 revealed 3 testing persons (TP). TP #1 (hire date 12/2017) TP #2 (hire date 6/10/17) TP #3 (hire date 7/2016) 2. Review of the personnel files from 2018 and 2019 revealed no documentation of the direct observation of performance of instrument maintenance and function checks for the above testing persons. 3. Interview with the technical consultant on 10/29/19 at 1005 hours in the break room confirmed the above findings. She acknowledged that she should include maintenance on the competency forms.
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limted to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of the personnel files and confirmed in interview, the technical consultant failed to include, but are not limited to assessment of problem solving skills for the CBC (complete blood count) testing on the QBC Star hematology analyzer. Findings were: 1. Review of CMS209 revealed 3 testing persons (TP). TP #1 (hire date 12/2017) TP #2 (hire date 6/10/17) TP #3 (hire date 7/2016) 2. Review of the personnel files from 2018 and 2019 revealed no documentation of problem solving skills for the CBC (complete blood count) on the QBC Star hematology analyzer for the above testing persons. 3. Interview with the technical consultant on 10/29/19 at 1005 hours in the break room confirmed the above findings.