Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0935897	03/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Frisco Pediatrics Pa	6930 Parkwood Blvd, Frisco, 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 representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, 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 certification 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.
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's American Proficiency Institute's proficiency testing records from 2021 and staff interview, it was revealed the laboratory failed to

	retain the instrument printouts of proficiency testing samples for 1 of 2 events. The findings include: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2021 (events 1 and 2) revealed the laboratory failed to retain the instrument printouts for the 5 samples tested for event 1. 2. The laboratory was asked to provide documentation of the instrument printouts. No documentation was provided. 3. An interview with the practice manager on 03/01 /2022 at 1040 hours in her office - after her review of the records- confirmed the findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2021 and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director reviewing the results for 1 of 2 events. The findings include: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2021 (events 1 and 2) revealed the laboratory failed to have laboratory director review for 2021 event 2. 2. The laboratory was asked to provide documentation of the review of the results. No documentation was provided. 3. An interview with the practice manager on 03/01/2022 at 1040 hours in her office - after her review of the records- confirmed the findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's quality control records from August 2021 to February 2022, and staff interview, it was revealed the laboratory failed to testing quality control material each day of patient testing for testing performed on the SLIGHT Dx OLO hematology analyzer. The findings include: 1. A review of the laboratory's test menu revealed the laboratory started performing hematology testing on the SLIGHT Dx OLO hematology analyzer in August 2021. 2. A review of the laboratory's quality control records from August 2021 to February 2022 revealed the laboratory did not test quality control material on the SLIGHT Dx OLO analyzer. 3. The facility was asked to provide documentation of testing quality control material. No documentation was provided. 4. The laboratory reported an annual hematology test volume of 2052 tests. 5. An interview with the practice manager on 03/01/2022 at 1100 hours in the break room revealed the facility had not tested quality control material since the instrument was placed into use. This confirmed the findings.

D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to have a written policy which defined the laboratory's critical values and the procedure to document the notification of the provider of the critical values. The findings include: 1. A review of the laboratory's policies revealed the laboratory failed to have a written policy which defined the laboratory's critical values and the procedure to follow to document the notification of the provider of the critical value. 2. The laboratory was asked to provide a policy for the notification of critical values. No documentation was provided. 3. An interview with the practice manager on 03/01 /2022 at 1148 hours in the laboratory confirmed the findings.
D6020	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 the quality control program is 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 quality control records and staff interview, it was revealed the laboratory director failed to ensure a quality control program was developed and followed (refer to D5447).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, and staff interview, it was revealed the laboratory director failed to ensure competency assessments were

	performed at a frequency and with the required information in order to ensure testing personnel were competent (refer to D6048, D6050, D6051, D6052, D6053 and D6055).
D6048	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's annual competency assessments performed in 2021 and staff interview, it was revealed the competency assessments failed to include the recording and reporting of test results for 2 of 2 annual competency assessments performed. The findings include: 1. A review of the annual competency assessments performed in 2021 for testing personnel number 1 and number 2 (as listed on Form CMS 209) did not include the recording and reporting of test results as part of the assessments. 2. The laboratory was asked to provide documentation of including this required information as part of the assessments. No documentation was provided. 3. An interview with the practice manager on 03/01/2022 at 0945 hours in the break room - after her review of the records- confirmed the findings.
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(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 laboratory's annual competency assessments performed in 2021 and staff interview, it was revealed the competency assessments failed to include the observation of instrument maintenance or function checks for 2 of 2 annual competency assessments performed. The findings include: 1. A review of the annual competency assessments performed in 2021 for testing personnel number 1 and number 2 (as listed on Form CMS 209) did not include the observation of instrument maintenance or function checks as part of the assessments. 2. The laboratory was asked to provide documentation of including this required information as part of the assessments. No documentation was provided. 3. An interview with the practice manager on 03/01/2022 at 0945 hours in the break room - after her review of the records- confirmed the findings.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's annual competency assessments performed in 2021 and staff interview, it was revealed the competency assessments failed to include the testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples for 2 of 2 annual competency assessments performed. The findings include: 1. A review of the annual competency assessments performed in 2021 for testing personnel number 1 and number 2 (as listed on Form CMS 209) did not include the testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples as part of the assessments. 2. The laboratory was asked to provide documentation of including this required information as part of the assessments. No documentation was provided. 3. An interview with the practice manager on 03/01/2022 at 0945 hours in the break room - after her review of the records- confirmed the findings.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of the laboratory's annual competency assessments performed in 2021 and staff interview, it was revealed the competency assessments failed to include the assessment of problem solving skills for 2 of 2 annual competency assessments performed. The findings include: 1. A review of the annual competency assessments performed in 2021 for testing personnel number 1 and number 2 (as listed on Form CMS 209) did not include the assessment of problem solving skills as part of the assessments. 2. The laboratory was asked to provide documentation of including this required information as part of the assessments. No documentation was provided. 3. An interview with the practice manager on 03/01/2022 at 0945 hours in the break room - after her review of the records- confirmed the findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the facility failed to have documentation of performing twice annual competency assessments for 1 of 1 testing personnel who required them. The findings include: 1. A review of the laboratory's personnel records revealed testing personnel number 2 (as listed on Form CMS 209) was hired by the laboratory in March 2020. Thus, documentation of two competency assessments were required by March 2021. 2. Further review of the personnel records revealed competency assessments on testing personnel number 2 were performed on: 12/03/2020 12/3/2021 3. The laboratory was asked to provide documentation of a second competency assessment being performed within 1 year of the hire date. No documentation was provided. 4. An interview with the practice manager on 03/01/2022 at 0945 hours in the break room - after her review of the records- confirmed the findings.

D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's instrumentation, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of performing competency assessments on personnel prior to the reporting of patient results for new test systems. The findings include. 1. A review of the laboratory's instrumentation revealed the laboratory placed a new analyzer (SLIGHT Dx OLO hematology analyzer) into use in August 2021. 2. A review of the laboratory's personnel records revealed the facility failed to have documentation of performing competency assessments on 2 of 2 testing personnel in August 2021 prior to the reporting of patient results. 3. The laboratory was asked to provide documentation of performing the competency assessments. No documentation was provided. 4. An interview with the practice manager on 03/01/2022 at 0945 hours in the break room - after her review of the records- confirmed the findings.