Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D0925302	05/16/2019
Name of Provider or Supplier	**Street Address, City, State**	
Dhillon Pediatrics	22811 Washington Street, Leonardtown, MD	

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
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: NOTE: This is a repeat deficiency. During the recertification survey on 04/18/19 the laboratory was cited for not individually listing the proficiency testing (PT) samples on the hematology patient log in the same manner as the patient specimens. The plan of correction (POC) that was submitted stated that the laboratory would list the PT samples on the hematology patient log in the same manner as the patient specimens. Based on review of the hematology patient log and interview with the testing personnel, the laboratory failed to implement the POC that was submitted and list the PT samples on the hematology patient log in the same manner as the patient specimens. Findings: 1. Review of the hematology patient logs for 2017 through May 2019 showed that the laboratory was not listing the PT samples on the hematology patient log in the same manner as the patient specimens. 2. During the survey on 05/16 /19 at 12:45 PM the testing personnel confirmed that the PT samples were not listed on the hematology patient log in the same manner as the patient specimens.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2)

	The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records from 2017 through 2019 and interview with the testing personnel, the laboratory failed to test the PT samples the same number of times as the patient samples were tested. Findings: 1. The PT records from the 2nd event of 2017 through the 1st event 2019 (six events) were reviewed. 2. The PT records showed that each of the PT sample was tested two times during 4 of the six events reviewed. (The 2nd event of 2017, 2nd and 3rd event of 2018 and the 1st event of 2019) 3. The daily patient log shows that the patient samples were only tested once. 4. During the survey on 05/16/19 at 12:45 PM the testing personnel confirmed that the PT samples were being tested in duplicated but that the patient samples were only being tested once.
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 hematology proficiency testing (PT) records and interview with the testing person, the laboratory failed to ensure that the all PT records were being saved for two years as required. Findings: 1. The PT records from the 2nd event of 2017 through the 1st event 2019 (six events) were reviewed. 2. The PT records showed that 3 of the 6 events did not include a copy of the signed attestation worksheets. (2nd and 3rd event of 2017 and 1st event of 2019) 3. The PT records showed that the original instrument printouts from the 3rd event of 2017 was not available. 4. During the survey on 05/16/19 at 12:45 PM the testing personnel confirmed that all the required PT records were not being saved for the required two years.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit

	of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: NOTE: This is a repeat deficiency. During the recertification survey on 04/18/19 the laboratory was cited for not performing calibration verification every 6 months per the manufacturer's instructions. The plan of correction (POC) that was submitted stated that the laboratory would perform calibration verification every 6 months per the manufacturer's instructions. Based on review of the calibration records and interview with the testing personnel, the laboratory failed to implement the POC and perform calibration verification every six months per the manufacturer's instructions. Findings: 1. The calibration records for 2017 through May 2019 were reviewed. The records show that calibration verification was performed on 03/14/17, 12/22/17, 07/18/18, 09 /05/18 and 05/07/19. 2. During the survey on 05/16/19 at 12:45 PM the testing personnel confirmed that the calibration verification was not being performed every six per the manufacturer's instructions.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: NOTE: This is a repeat deficiency. During the recertification survey on 04/18/19 the laboratory was cited for not documenting remedial actions when the hematology quality control (QC) materials were unacceptable. The plan of correction (POC) that was submitted stated that the laboratory would document remedial actions when QC materials were unacceptable and needed to be repeated. Based on review of the QC printouts and interview with the testing personnel, the laboratory failed to implement the POC and document remedial actions when QC materials were unacceptable and needed to be repeated. Findings: 1. The QC printouts from August 2018 through November 2018 were reviewed. 2. According to the testing personnel when QC results are unacceptable the remedial actions are to be recorded on the daily patient log along with the QC information. 3. On 08/15/18 level "L" was repeated; 09/13/18 Level "L" and "H" were repeated; 10/04/18 level "L" was repeated; 11/13/18 level "L"

	was repeated and on 11/16/18 level "N" was repeated. Review of the daily patient log showed that remedial actions were not documented on the days that QC was unacceptable and had to be repeated. 4. During the survey on 05/16/19 at 12:45 PM the testing personnel confirmed that when QC materials were unacceptable the remedial actions were not being documented on the daily patient log as required.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory director failed to provide oversight of the overall operation of the laboratory (D6004): failed to ensure that proficiency testing samples were tested in the same manner as patient samples and that PT records were saved for the required (D6016); and failed to oversee the quality control (QC) and quality assurance (QA) programs (D6022).
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the quality assurance (QA) activities and interview with the testing personnel, the laboratory director failed to provide oversight of the overall operation of the laboratory by ensuring that the QA activities are performed by the qualified person in compliance with the regulations. Findings: 1. The "Laboratory Personnel Report (CLIA)" form identifies the Laboratory Director, Clinical Consultant and Technical Consultant as the same person. 2. According to the testing personnel the items on the Monthly Quality Assurance Checklist" are reviewed by them. The testing personnel do not meet the minimum requirements a bachelor's degree and 2 years documented experience and are therefore not qualified to perform the QA review. 3. The qualified LD failed to perform and document the items listed on the "Monthly Quality Assurance Checklist." 4. During the survey on 05/16/19 at 12:45 PM the testing personnel confirmed that they complete the "Monthly Quality Assurance Checklist" for the LD to sign.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)

	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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records and interview with the testing personnel, the laboratory director failed to ensure that PT samples were tested in the same manner as patient samples and that PT records were saved for the required 2 years as required under Subpart H and be routinely performed by the testing personnel. Cross refer to Tags, D2006, D2010 and D2015.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: NOTE: This is a repeat deficiency. During the recertification survey on 04/18/19 the laboratory was cited for not monitoring the overall operation of the laboratory to identify quality control (QC) failures and ensure corrective actions are taken when failures are identified. The plan of correction (POC) that was submitted stated that the laboratory would ensure that quality assurance (QA) and QC plans would be monitored. A. Based on review of the QC records, QA plan, and interview with the laboratory director (LD), the LD failed to implement the POC that was submitted. Findings: 1. The "Monthly Quality Assurance Checklist" lists the QA tasks that the LD performs as part of the QA review each month. The last column on the checklist is labeled as "YES/NO NOT APPLICABLE." 2. The "Monthly Quality Assurance Checklist" for 2017 through April 2019 were reviewed. "YES" was written for all of the tasks listed. 3. The LD's QA review indicates that each month "Our Personnel Policies were followed" and that "Personnel evaluations were performed as necessary." The PT agency only provides PT samples three times a year. 4. There are two testing personnel listed on the "Laboratory Personnel Report (CLIA)" (CMS-209). Personnel evaluations were performed on both testing personnel on 01/16/18, 06 /01/18 and 01/01/19. The laboratory replaced the hematology analyzer on 12/22/17. There is no documentation showing that the LD had been trained on the new analyzer and was qualified to perform the evaluation. 5. The LD's QA review indicates that each month "Our Proficiency Testing Policies have been followed" and that "Proficiency tests were handled in the same manner as patient specimens. 6. The LD's QA review failed to identify that PT samples were not recorded like patients in the testing records. Cross refer to Tag D2006. 7. The LD's QA review failed to identify that PT samples were not being tested in the same manner as patient samples. Cross refer to Tag D2010. 8. The LD's QA review failed to ensure that all PT records were being saved for the required 2 years. Cross refer to Tag D2015. 9. The "Monthly

	Quality Assurance Checklist" from 2017 through April 2019 lists the date of review at the end of the checklist, but does not identify the month that was reviewed. 10. During the survey on 05/16/19 at 12:45 PM the testing personnel and LD confirmed that the QA review was not being performed as required. B. Based on review of the QC records, QA plan, and interview with the testing personnel and laboratory director (LD), the LD failed to evaluate the QC results on a monthly basis. Findings: 1. The laboratory installed a new hematology analyzer on 12/22/17. QC materials used on the new analyzer are good for three months. The QC materials for the previous hematology analyzer were good for only one month. 2. The QC summary printouts show the shifts and trends of the QC materials. Review of the QC summary printouts from December 22, 2017 through May 7, 2019 show that the QC results were not printed on a monthly basis as with the old analyzer. The QC results are printed approximately every 11 weeks for review by the LD. 3. The "Monthly Quality Assurance Checklist" for January 2018 through April 2019 were reviewed. "YES" was written for all of the tasks listed. 4. The LD's QA review indicates that each month "Our Quality Control Policies were performed as specified", "Any necessary remedial action was performed and documented", "All quality control/calibrations were performed and accepted before patient test results were reported", and "Quality control results were examined for possible problems." 5. The LD's QA review failed to ensure that remedial actions were performed and documented as required. Cross refer Tag D5783. 6. The LD's QA review failed to ensure that calibration was performed every six months and accepted before patient test results were reported. Cross refer Tag D5439. 7. The LD's QA review failed to ensure that QC summary printouts that show shifts and trends were actually reviewed on a monthly basis. Cross refer to #2 listed above. 8. The "Monthly Quality Assurance Checklist" for 2017 through April 2019 were reviewed. "YES" was written for all of the tasks listed. 9. The LD's QA review indicates that each month "Our Quality Assurance Program is monitored for compliance" and "The above information has been reviewed to determine whether errors that occurred could have been prevented by changing our policies and procedures." 10. According to the testing personnel the items on the Monthly Quality Assurance Checklist" are reviewed by them. The testing personnel do not meet the minimum requirements a bachelor's degree and 2 years documented experience and are therefore not qualified to perform the QA review. 11. The qualified LD failed to perform and document the items listed on the "Monthly Quality Assurance Checklist." 12. During the survey on 05/16/19 at 12:45 PM the testing personnel confirmed that they complete the "Monthly Quality Assurance Checklist" for the LD to sign.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the testing personnel, the laboratory director acting as the technical consultant failed to have the required training on the new hematology analyzer so that he was qualified to perform the annual evaluations of the testing personnel (D6034); and the laboratory director acting as the technical consultant failed to ensure scientific oversight of the laboratory (D6036).

D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on review of the training records for the new hematology analyzer and interview with the testing personnel, the laboratory director acting as the technical consultant failed to have the required training on the new hematology analyzer so that he could actually perform the annual evaluations of the testing personnel. Findings: 1. The laboratory installed a new hematology analyzer on 12/22/17. 2. Review of the annual evaluations for 2018 through 2019 show that the laboratory director signed the annual evaluation forms. Personnel evaluations were performed on both testing personnel on 01/16/18, 06/01/18 and 01/01/19. There is no documentation showing that the LD had been trained on the new analyzer and was qualified to perform the annual evaluation. 3. According to the testing personnel the laboratory director had not been trained on the new analyzer when it was installed on December 22, 2017. 4. During the survey on 05/16/19 at 12:45 PM the testing personnel confirmed that the LD had not been trained on the new hematology analyzer.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: The laboratory director acting as the technical consultant failed to provide technical and scientific oversight of the laboratory. Cross refer to Tag D6022.