Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0991077	08/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laredo Pediatrics And Neonatology	3507 Jaime Zapata Memorial Hwy, Suite 5, Laredo, 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	An entrance conference was held 08/15/2018 with the laboratory staff. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 08/15/2018, this facility was found to be in substantial compliance for the specialties/subspecialties in which it was surveyed. An exit conference was held 08/15/2018 with the laboratory staff. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. An opportunity for questions and comments was provide
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 laboratory records, the laboratory's American Proficiency Institute (API) hematology proficiency test records from 2017 and 2018 and staff interview, it was revealed that the laboratory failed to test proficiency testing samples for Complete Blood Counts (CBC) in the same manner that the laboratory tests patient samples. Findings included: 1. The laboratory's policy titled "Policy for Repeating CBC Tests" (Signed by the Laboratory Director on 11/01/2014) stated "In an effort to ensure accuracy in patient CBC testing, it is the policy of this laboratory to repeat tests when patient results are outside of the following range:" "RBC Less than 4.00 or greater than 6.00 million WBC Less than 4.00 or greater than 20.00 thousand HCT Less than 30% or greater than 50% HGB Less than 10 or greater than 18 mg/% PLT Less than 150 or greater than 450 thousand" 2. The laboratory In-service record titled "In-Service/Continuing Education Form" (Date: 12/11/2014; Subject: CBC repeat Policy Out of Limits) stated "It is the policy of this laboratory to follow the CBC repeat policy implemented in the laboratory. The laboratory will repeat patients when

	performing CBC testing when the patients fall outside the ranges indicated in the CBC repeat policy." The form was signed by TP1, TP2, TP3, TP4, and the Technical Consultant on 12/11/2014. 3. The laboratory policy titled "Proficiency Testing" stated "PT specimens are to be treated the same as patient samples." 4. Review of the API records for 2017 (Events 1,2 and 3) and 2018 (Events 1 and 2) revealed the following proficiency test samples for Complete Blood Counts (CBC) with results outside of the laboratory's defined repeat range were not repeated. They were: API 2017 Event 1 Sample ID Result 2017 API Sample HSY01 WBC=3.1 RBC=2.33 HGB=6.0 HCT=16. 7 PLT=55 2017 API Sample HSY03 PLT=491 2017 API Sample HSY04 PLT=116 2017 API Sample HSY05 HCT=27.4 PLT=47 API 2017 Event 2 Sample ID Result 2017 API Sample HSY06 WBC=18.9 PLT=494 2017 API Sample HSY08 WBC=3.1 RBC=2.33 HGB=6.0 HCT=16.4 PLT=52 2017 API Sample HSY09 PLT=114 2017 API Sample HSY10 WBC=3.8 RBC=6.39 HGB=19.5 HCT=52.1 PLT=130 API 2017 Event 3 Sample ID Result 2017 API Sample HSY11 HGB=16.1 PLT=120 2017 API Sample HSY14 WBC=3.0 RBC=2.36 HGB=5.8 HCT=16.9 PLT=50 2017 API Sample HSY15 RBC= 3.70 HCT=27.3 API 2018 Event 1 Sample ID Result 2018 API Sample HSY01 WBC=18.3 PLT=535 2018 API Sample HSY03 WBC=3.2 RBC=2. 25 HGB=5.6 HCT=15.9 PLT=51 2018 API Sample HSY04 RBC=3.68 HGB=9.5 HCT=26.0 2018 API Sample HSY05 WBC=3.9 RBC=6.27 HGB=18.5 HCT=50.5 PLT=111 API 2018 Event 2 2108 API Sample HSY06 Result WBC=3.2 RBC=2.23 HGB=5.8 HCT=16.1 PLT=47 2018 API Sample HSY08 PLT=510 2018 API Sample HSY09 PLT=135 2018 API Sample HSY10 HGB=9.7 HCT=26.4 5. The laboratory was asked to provide documentation of testing proficiency samples in the same manner as patients for 2017 Hematology Events 1, 2 and 3 and 2108 Hematology Events 1 and 2. No documentation was provided. 6. During an interview with laboratory staff on 08/15/2018 at 1027 AM in the breakroom, Testing Person 1 stated "We are not repeating the Proficiency test when results are out of established limits. We do repeat patients." This confirmed the above findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED ON 10/12/2016. Word Key: CBC=Complete Blood Count HGB=Hemagloblin HCT=Hematocrit PLT=Platelet RBC=Red Blood Cell WBC=White Blood Cell
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, random review of patient test records, and staff interview, it was revealed that the laboratory failed to follow their own Complete Blood Count (CBC) policy to ensure that results with alerts or flags were verified prior to reporting these results to the provider. Findings included: 1. A review of the laboratory's policy titled "Policy for Handling Flagged CBC Differentials" (approved and signed by the laboratory director on 10/12/2016) revealed: "It will be the policy of this laboratory to rerun flagged CBC results. If the second run still shows flags, then the lab will evaluate flagged differentials according the procedures in the unit operator's manual. See that the sample requirements are met, that the unit is in good working order, and that the testing procedure in correctly followed. Sometimes the flags will disappear when the sample is allowed to equilibrate at room temperature

	for 15 to 20 minutes or by re-drawing the patient. If the flags disappear, then report that result. If the flags persist, then the laboratory will confirm the abnormal differential by sending out to a reference laboratory." This policy does not ensure that the results with alerts or flags are verified prior to reporting the results to the provider. The manual differential results did not verify all results that were flagged on the Complete Blood Count. 2. A random review of patient medical records from 2017 and 2018 revealed the following patient results with alerts and flags on both the initial and repeated runs were reported to the provider before being verified. Both the initial and repeated test reports were included in the patient's medical record. Date ID Flag(s) 08 /07/2017 Y1612018 T2 10/16/2017 Y1702015 T2 12/20/2017 Y0510006 AG 01/09 /2018 Y1708017 AG 04/26/2018 Y1101116 AG 05/29/2018 Y1511011 AG 07/30 /2018 Y1804018 AG,WL 08/13/2018 Y1709031 AG,T2 3. A review of patient medical records for the results listed above revealed the results with flags were sent out to a reference laboratory for manual differential testing but the flagged results were still reported to the physician prior to being verified. 4. During an interview with laboratory staff on 08/15/2018 at 12:30 PM in the laboratory, Testing Person 1 stated "We attached both result printouts to the chart before we receive the manual differential results." This confirmed the above findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual and staff interview, the laboratory failed to ensure that the current laboratory director signed and dated the procedures before use. Findings included: 1. A review of the laboratory's procedure manual revealed procedures that had a been signed by an individual OTHER than the current laboratory director. Examples are: Title of Policy: "Control Policy" "Controls not Within Range" "Quantitative Control Policy" "Reporting Laboratory Results" "Reporting Panic Values" "Panic Values" "Corrective Action for an Error in the Test Result Report" 2. An interview on 08/15/2018 at 0145 PM in the breakroom with laboratory staff confirmed the 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 manufacturer's instructions for the Sysmex XP-300 hematology analyzer, review of patient records and staff interview, it was revealed the laboratory failed to follow manufacturer's instructions to verify results with alerts or flags. Findings included: 1. A review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer (Revised July 2012) under the section titled "8.3 Histogram Flags" revealed: Section 8.3 "Histogram Flags" stated: A. "Flag:WL-Incomplete

	lysing of red blood cells, presence of nucleated red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction (reference): 1) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis. 2) Check smear, etc." B. "Flag: AG-Presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction (reference) 1) Check smear, etc. 2. A random review of patient medical records from 2017 and 2018 identified the following patient results with alerts and flags on both the initial and repeated runs. Manual differentials were ordered for each sample. The manual differential results failed to provide White Blood Count (WBC) or Platelet (Plt) estimates to determine the accuracy of the CBC flagged results for WBC and/or Platelets. Date ID Flag(s) 12/20/2017 Y0510006 AG (Platelet result flagged) 01/09 /2018 Y1708017 AG (Platelet result flagged) 05/29/2018 Y1511011 AG (Platelet result flagged) 07/30/2018 Y1804018 AG,WL (WBC and Platelet result flagged) 3. An interview on 08/15/2018 at 0145 PM in the breakroom with laboratory staff confirmed the findings.
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 the laboratory's policy manual, the Sysmex SP-300 operator's manual, the Sysmex XP-300 hematology analyzer maintenance records from October 2016 through July 2018 and staff inteview, it was revealed that the laboratory failed to have documentation of performing required maintenance. Findings included: 1. The laboratory's policy titled "Instrument Operation and Maintenance" stated "Maintenance of each piece of laboratory instrumentation shall be in accordance with the manufacturer's recommendations. Document all maintenance performed on the test systems in use." 2. The Sysmex SP-300 operator's manual (January 2012) Section 12 titled "Cleaning and Maintenance" stated the following maintenance requirements: A. Daily Clean TD (Transducer) chambers and diluted sample lines Check trap chamber level and discard B. Weekly Clean SRV (Sample Rotor Valve) tray C. Every month (or every 1500 samples) Clean TD Clean waste chamber D. Every 3 months (or every 4500 samples) Clean SRV 2. Review of the laboratory's maintenance records titled "SYSMEX XP-300 MAINTENANCE LOG" from October 2016 through July 2018 revealed no documentation for the following analyzer maintenance: A. March 2017 Monthly / Clean RBC&WBC Transducer B. April 2017 Quarterly/ Clean Sample Rotor Valve (SRV) C. May 2017 Monthly / Clean RBC&WBC Transducer D. July 2017 Monthly / Clean Waste Chamber E. September 2017 Monthly / Clean RBC&WBC Transducer F. October 2017 Quarterly/ Clean Sample Rotor Valve (SRV) 3. An interview on 08/15/2018 at 0145 PM in the breakroom with laboratory staff 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's quality assurance policy, it was revealed that the laboratory failed to have an effective process to monitor, access, and correct problems in the analytic system. Findings included: 1. The laboratory failed to have complete documentation of verifying Complete Blood Count (CBC) results with alerts or flags. (Refer to D5403) 2. The laboratory failed to ensure that the current laboratory director signed and dated the procedures before use. (Refer to D5407) 3. The laboratory failed to follow manufacturer's instructions for the Sysmex XP-300 to verifying results with alerts or flags. (Refer to D5411) 4. The laboratory failed to have documentation of performing required maintenance on the Sysmex XP-300 hematology analyzer. (Refer to D5429)