Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0495618	09/25/2020
Name of Provider or Supplier	**Street Address, City, State**	
Little Buddies Pediatrics Pa	2343 Town Center Dr Suite 2, Sugar Land, 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	The laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCY: D5400 - 42 C.F.R. 493.1250 Condition: Analytic Systems Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. 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.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's analytic records from October 2018 to August 2020 for the Sysmex pocH-100i hematology analyzer and confirmed in interview of facility personnel, it was revealed the laboratory failed to retain instrument background checks for 15 of 100 records checked. The findings included: 1. A review of the laboratory's analytic background check records from October 2018 to August 2020 for the Sysmex pocH-100i hematology analyzer revealed the following 15 of 100 days checked when the laboratory failed to provide documentation of retaining instrument background checks: 10-08-2018 10-24-2018 10-30-2018 11-08-2018 12-20-2018 08-24-2019 08-31-2019 09-02-2019 12-04-2019 12-05-2019 12-11-2019 12-

	18-2019 01-03-2020 01-10-2020 01-15-2020 2. The laboratory was asked to provide documentation of the missing background checks for surveyor review. No documentation was provided. 3. An interview with Testing Personnel #2 (as listed on Form CMS-209) on 09-25-2020 at 10:30 hours in the laboratory confirmed the findings when she was unable to retrieve the documents electronically. Key: CMS - Centers for Medicare and Medicaid Services
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) hematology proficiency testing records from 2018, 2019, and 2020, and confirmed in interview of facility personnel, the laboratory failed to retain proficiency testing results for 3 of 7 events. The findings were: 1. A review of the laboratory's API hematology proficiency testing records from 2018 (events 1, 2, and 3), 2019 (events 1, 2, and 3), and 2020 (event 1) revealed the laboratory failed to retain testing records, signed attestation statements, proficiency testing (PT) results and scores, and documentation of review for 3 of 7 events: 2018 Hematology (event 1) 2018 Hematology (event 2) 2018 Hematology (event 3) 2. An interview with the Administrative Assistant on 09-25-2020 at 10:00 hours in the break room confirmed the findings. She revealed that the records could not be located.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory's policies and procedures, laboratory records, test records and staff interview, it was revealed that the laboratory failed to monitor and evaluate the overall quality of the analytic systems (refer to D5405, D5417, D5429, and D5441).
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by:

	Based on review of the manufacturer's instructions for the Sysmex pocH-100i hematology analyzer, review of patient test records from October 2018 to August 2020, and staff interview, it was revealed the laboratory failed to have documentation of a procedure for addressing flags on CBC results prior to their release to the healthcare provider. The findings were: 1. This is a repeat deficiency from the survey conducted on March 19, 2018. 2. Review of the manufacturer's instructions for the pocH-100i hematology analyzer (Code No. 461-23877-2, Revised September 2006_NA) under, "Instructions for Use" stated, "Operate the instrument as instructed. Reliability of test results cannot be guaranteed if instructions in this manual are not followed ..." and; "Review of the manufacturer's instructions for the pocH-100i hematology analyzer (Code No. 461-23877-2, Revised September 2006_NA) under, "Histogram Flags" stated, "The pocH-100i extracts the characteristics of the histogram and displays them as histogram flags. If there are histogram flags, repeat analysis. If flags are still displayed, one of the following problems may apply ..." The manufacturer's instructions went on to list potential histogram flags, their probably cause, and corrective action. "Flag: T2 Probable sample cause: Aged sample, incomplete lysing of red blood cells, etc., causing the last two WBC populations in the WBC-Histogram not to be separated, presence of CML or other immature granulocytes Correction: Check smear. If cryoglobulins are suspected, first warm the sample and repeat analysis. If error message persists, perform a plasma replacement (remove plasma and replace with equal volume of diluent) and repeat analysis." 3. Review of 2 of 30 patient test records from October 2018 to August 2020 found the following patient results were released to the healthcare provider when flags on CBC results were not resolved: Patient Alias 1 Date: 11-26-2018 Flag: T2 Patient Alias 2 Date: 07-29-2019 Flag: T2 4. The laboratory was asked to provide documentation of a procedure to address these flags as required by the manufacturer. No documentation was provided. 5. An interview with the Administrative Assistant on 09-25-2020 at 11: 00 hours in the break room confirmed the findings. Key: CBC - Complete Blood Count WBC - white blood cell CML - Chronic myeloid leukemia
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation and confirmed in interview of facility personnel, the laboratory failed to ensure that expired specimen collection tubes were not available for use. The findings were: 1. Surveyor observation on September 25, 2020 at 10:15 hours in the laboratory found the following expired items: 3 purple top specimen collection tubes Lot # 6029878 Expiration date: 2017-06 2. An interview with Testing Personnel #2 (as listed on Form CMS-209) on September 25, 2020 at 10:15 hours confirmed the findings. She revealed the laboratory was not using the tubes. Key: CMS - Centers for Medicare and Medicaid Services
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 manufacturer's instructions, review of the laboratory's Sysmex pocH-100i hematology analyzer maintenance logs from January 2019 to August 2020, and confirmed in interview of facility personnel, the laboratory failed to have documentation of performing required maintenance. The findings were: 1. Review of the manufacturer's instructions for the Sysmex pocH-100i hematology analyzer (Code No. 461-2387-2) under, "Cleaning and Maintenance" it stated, "Clean transducer: Every 2 weeks or 150 samples." Note: The laboratory's test volume is such that the transducer maintenance should be performed and documented every 2 weeks. 2. A review of the laboratory's maintenance records for the Sysmex pocH-100i from January 2019 to August 2020 revealed the laboratory failed to provide documentation of performing transducer maintenance every two weeks for the following 4 of 20 months reviewed: July 2019 - every two week maintenance documented 1 out of 4 weeks March 2020 - every two week maintenance documented 1 out of 4 weeks April 2020 - every two week maintenance documented 1 out of 4 weeks May 2020 - every two week maintenance documented 1 out of 4 weeks 3. An interview with the Administrative Assistant on 09-25-2020 at 11:20 hours in the break room confirmed the findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from June 2018 to August 2020, and confirmed in interview of facility personnel, it was revealed the laboratory failed to have documentation of a policy that ensured the laboratory could detect quality control errors over time. The findings were: 1. Review of laboratory quality control records from June 2018 to August 2020 revealed the laboratory had no documentation of evaluating quality control statistics over time. 2. The laboratory failed to have a policy for monitoring quality control statistics over time. 3. An interview with the Administrative Assistant on September 25, 2020 at 11:40 hours in the break room 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 quality control records, patient test records, and confirmed in interview of facility personnel, the laboratory failed to have documentation of performing at least two levels of quantitative quality control each day of patient testing for two patient testing days in September 2018. The findings were: 1. Review of quality control records from June 2018 to August 2020 found the following two patient testing days when the laboratory failed to provide documentation of performing at least two levels of quality control: September 11, 2018 September 13, 2018 2. Review of patient test records for September 11, 2018 and September 13, 2018 found the laboratory performed testing on the following patients when there was no documentation of performing at least two levels of quality control: Patient 1 September 11, 2018 Patient 2 September 11, 2018 Patient 1 September 13, 2018 Patient 2 September 13, 2018 3. The laboratory was asked to provide documentation of the missing quality control records. No documentation was provided. 4. An interview with the Administrative Assistant on 09-25-2020 at 11:50 hours in the break room confirmed the findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, review of the laboratory's policies, and staff interview, it was revealed the laboratory director failed to specify, in writing, the responsibilities of the laboratory director, clinical consultant, technical consultant, and testing personnel. The findings were: 1. A review of the laboratory's personnel records revealed the files did not contain job descriptions for the personnel. 2. A review of the laboratory's policies revealed the laboratory did not have documentation of a policy for personnel job descriptions. 3. The laboratory was asked to provide documentation of the laboratory director specifying the responsibilities of personnel. No documentation was provided. 4. An interview with the Administrative Assistant on 09-25-2020 at 09:30 hours in the break room confirmed the findings.