Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0495618	03/19/2018
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 surveyed on March 19, 2018 and found to be in compliance with the CLIA regulations. Recertification is recommended. 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.
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 manufacturer's instructions, patient results, and confirmed in interview of facility personnel, the laboratory failed to follow manufacturer instructions to ensure CBC results with flags were resolved prior to their release to the healthcare provider. The findings were: NOTE: THIS IS A REPEAT DEFICIENCY 1. 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 ..." 2. 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: F1, F2, F3 Probable sample cause: Presence of CMS or other immature granulocytes, incomplete lysing of red blood cells, aged sample, etc. Correction: (1) Check smear, etc. (2) Centrifuge sample and replace the plasma with equal volume of saline or CELLPACK and repeat analysis, warm sample at 37 degrees Celsius for 30 minutes and repeat analysis, etc. Flag: AG (*) Probable sample cause: 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: Check smear, etc. 3. Review of patient results from December 21, 2017 to March 5, 2018 revealed the following 9 patient results with flags that had not been resolved prior to their release to the healthcare provider (see patient alias list): Patient 1 Date 03/05/2018 Flag: F2, F3 Patient 2 Date: 01/30/2018 Flag: * Patient 3 Date: 01/10/2018 Flag: * Patient 4 Date: 01/03/2018 Flag: * Patient 5 Date: 01/03/2018 Flag: * Patient 6 Date: 01/03 /2018 Flag: * Patient7 Date: 01/02/2018 Flag: * Patient 8 Date: 12/27/2017 Flag: * Patient 9 Date: 12/27/2017 Flag: * 4. The laboratory was asked to provide documentation of following the manufacturer's instructions to resolve flags prior to their release to the healthcare provider. No documentation was provided. 5. An interview with testing personnel 1 (as listed on Form CMS-209) on 03/19/2018 at 1530 hours in the break room confirmed the findings. Key: CBC - complete blood count CMS - Centers for Medicare and Medicaid Services
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the pocH-100i hematology analyzer, review of laboratory environmental records, and confirmed in interview of facility personnel, the laboratory failed to define an acceptable temperature range for the laboratory. The findings were: 1. Review of the manufacturer's instructions for the pocH-100i hematology analyzer (Code No. 461-23877-2, Revised September 2006_NA) under, "Specifications" stated, "Ambient temperature: 15-30 degrees Celsius / 59-86 Fahrenheit" and "Humidity: 20% to 85%." 2. Review of the laboratory's environmental records from January 2017 to February 2018 revealed the laboratory had established an ambient temperature range of 20 to 32 degrees Celsius and a humidity range of 10% to 95%." 3. The laboratory was asked to provide documentation of establishing an acceptable temperature and humidity range for the laboratory based on the manufacturer's instructions. No documentation was provided. 4. An interview with testing personnel one (as listed on Form CMS-209) on 03/19 /2018 at 1530 hours in the break room confirmed the findings.

D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies, quality control records, patient results, and confirmed in interview, the laboratory's quality assurance program failed to detect problems in analytic systems The findings were: 1. The laboratory's quality assurance program failed to detect that the laboratory didn't follow manufacturer instructions to resolve flags prior to their release to the healthcare provider. (refer to D5405) 2. The laboratory's quality assurance program failed to detect that the laboratory had not defined an acceptable room temperature and humidity range for the laboratory. (refer to D5413) 3. The laboratory's quality assurance program failed to detect that the laboratory failed to detect errors over time. (refer to D5441)