Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0495618	05/11/2022
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 May 11, 2022 and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of personnel records, and confirmed in interview of laboratory personnel, the laboratory failed to follow the manufacturer's instructions to ensure testing persons were trained prior to performing SARS-CoV-2 testing for 1 of 3 testing personnel. The findings included: 1. Review of the manufacturer's instructions for the Sophia SARS-CoV-2 test kit stated, "All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling." 2. Review of personnel record for testing personne #1, #2, and #3 found no documentation of training for the Sophia SARS-CoV-2 test kit. 3. The laboratory was asked to provide documentation of following the manufacturer's instructions to ensure testing persons were trained prior to performing SARS-CoV-2 testing. No documentation was provided. 4. The findings were confirmed in interview with the office administrator on May 11, 2022 at 0920 hours in the break room.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)

	The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records and confirmed in interview of laboratory personnel, the laboratory failed to ensure 2 of 4 attestation statements were signed by required personnel for 2 of 4 events reviewed. The findings included: 1. Reverie of API's Attestation Statement stated, "Signatures Required: For all PT results, an attestation statement must by signed by the testing personnel and the laboratory director and retained for a minimum of 2 years. Either the attestation statement below or the form provided online may be used. Electronic signatures must have evidence that only the authorized persone can utilize the signature." 2. Review of the laboratory's API proficiency testing records for 2020 (event 3) and 2021 events (1, 2, and 3) found attestation statements were not signed by all required persons: 2021 (event 3) Hematology - not signed by laboratory director 2021 (event 2) Hematology - not signed by laboratory director - not signed by testing person 3. The findings were confirmed in interview with the office administrator on May 11, 2022 at 10:00 a.m. hours in the break room.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records and confirmed in interview of laboratory personnel, the laboratory failed to attain a score of at least 80% for White Blood Cell Differential resulting in unsatisfactory performance in 1 of 4 events reviewed. The findings included: 1. Review of the laboratory's API proficiency testing records for 2020 (event 3) and 2021 (events 1, 2, and 3) found the laboratory received the following unsatisfactory score: 2021 (event) White Blood Cell Score: 33% 2. The findings were confirmed in interview with the office administrator at 10:00 hours in the break room.
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) proficiency testing records from 2020 (event 3) and 2021 (events 1, 2, and 3) the laboratory failed to retain required proficiency testing records for 2 years in 1 of 4 events reviewed. The findings included: 1. Review of the laboratory's API proficiency testing records for 2020 (event 3), 2021 (events 1, 2, and 3) found the following records were not retained for a 2 years: 2021 (event 2) Hematology - Instrument records 2. The laboratory was asked to provide documentation of the retaining the instrument records for 2021 (event 2). No documentation was provided. 3. The findings were confirmed

	in interview of the office administrator on May 11, 2022 at 10:00 a.m. in the break room.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's environmental records for April and May 2022 and confirmed in interview of laboratory personnel, the laboratory failed to provide documentation of corrective action when the room humidity was documented out of range for 28 of 28 days reviewed. The findings included: 1. Review of the laboratory's environmental records found the laboratory had established a room humidity range of 30-85%. 2. Review of the laboratory's environmental records for April and May 2022 found the following 28 of 28 days when the room humidity was documented out of range: April 1, 2022 2% April 4, 2022 6% April 5, 2022 20% April 6, 2022 21% April 7, 2022 20% April 8, 2022 2% April 11, 2022 10% April 12, 2022 21% April 13, 2022 21% April 14, 2022 2% April 18, 2022 14% April 19, 2022 2% April 20, 2022 17% April 21, 2022 15% April 22, 2022 18% April 25, 2022 18% April 26, 2022 14% April 27, 2022 10% April 28, 2022 16% April 29, 2022 14% May 2, 2022 11% May 3, 2022 15% May 4, 2022 17% May 5, 2022 8% May 6, 2022 5% May 9, 2022 2% May 10, 2022 5% May 11, 2022 6% 3. The laboratory was asked to provide documentation of a policy when the room humidity was documented out of range for 28 of 28 days reviewed in April and May 2022. No documentation was provided. 4. The findings were confirmed in interview with the office manager on May 11, 2022 at 11:00 hours in the break room.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records and confirmed in interview of laboratory personnel, the laboratory director failed to ensure proficiency testing reports were reviewed and evaluated to

	identify problems for 1 of 4 testing events reviewed. The findings included: 1. Review of the Proficiency Testing Performance Evaluation form for 2021 (event 1) for Hematology, it stated, "After reviewing the evaluation reports, compete the information below and retain this form along with the enclosed reports for your records." a. The form was blank 2. Review of the laboratory's API records found the laboratory director failed to review and identify problems for 1 of 4 proficiency testing failures: 2021 (event 1) White Blood Cell Differential Score = 33% 2. The findings were confirmed in interview of the office administrator at 10:00 hours in the break room.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute (API) proficiency testing records and confirmed in interview of laboratory personnel, the laboratory director failed to ensure an approved corrective action plan is followed when proficiency testing was unsatisfactory for 1 of 4 events reviewed. The findings included: 1. Review of the laboratory's API records found the laboratory received the following unsatisfactory score: 2021 (event 1) White Blood Cell Differential Score = 33% 2. Review of the proficiency testing records found no documentation of corrective action for the analyte failure. 3. The laboratory was asked to provide documentation of a policy for corrective action when a proficiency testing score is unsatisfactory or unsuccessful. No documentation was provided. 4. The findings were confirmed in interview of the office administrator at 10:00 hours in the break room.