

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0495618	(X3) Date Survey Completed 01/11/2024
Name of Provider or Supplier Little Buddies Pediatrics Pa	Street Address, City, State 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the review of the manufacturer's package insert, the instrument instructions for use, CMS 116 application, and confirmed in an interview, the laboratory failed to document the open dates and revised expiration dates on one of one lot number in use for one of one Sysmex pocH-100i hematology Analyzer. The findings were: 1. Review of the manufacturer's instructions for use titled Sysmex AUTOMATED HEMATOLOGY ANALYZER pocH-100i INSTRUCTIONS FOR USE (Code No. 461-2387-2 PRINTED IN JAPAN Date of Last Revision: September 2006 Software Version: 00-23 and onwards) under EIGHTCHECK 3WP X-TRA revealed "Once opened, the product is stable for 14 days if returned to the refrigerator promptly after use." 2. Review of the manufacturer's package insert titled Sysmex EIGHTCHECK-3WP X-TRA Hematology control for Sysmex analyzers with 3-part differentials under Storage and shelf life after first opening revealed "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8C after being recapped." 3. Direct observation of the surveyor on 1/11/2024 at 10:11 am in the laboratory revealed no open dates and revised expiration dates documented on the</p>

pierced QC vials for one of one lot number in use for one of one Sysmex pocH-100i hematology Analyzer. EIGHTCHECK-3WP X-TRA L (low): Lot# 33330710 Exp. 3/6/2024 N (normal): Lot# 33330711 Exp. 3/6/2024 H (High): Lot# 33330712 Exp. 3/6/2024 4. An interview with the TP#2 on 1/11/2024 at 10:14 am in the laboratory confirmed the TP#2 did not know the opened dates of QC vials currently in use and stated QC vials were changed every 3 weeks. 5. Review of the CMS 116 application signed by the laboratory director on 1/10/2024 revealed the annual CBC volume was 2346. 6. Another interview with the manager on 1/11/2024 at 12:56 pm in the laboratory confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services C=Celsius Degree QC=Quality Control CBC=Complete Blood Count TP=Testing personnel

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 the review of the instrument instructions for use, the laboratory's maintenance logs from January 2023 to December 2023, Patient results from 11/17/2023 to 1/10/2024, and confirmed in an interview, the laboratory failed to document one of four Quarterly maintenance for one of one Sysmex pocH-100i hematology Analyzer. The findings were: 1. Review of the manufacturer's instructions for use titled Sysmex AUTOMATED HEMATOLOGY ANALYZER pocH-100i INSTRUCTIONS FOR USE (Code No. 461-2387-2 PRINTED IN JAPAN Date of Last Revision: September 2006 Software Version: 00-23 and onwards) under Cleaning revealed "Clean waste Chamber. Every 3 months or 1500 samples. 2. Review of the laboratory's maintenance logs from January 2023 to December 2023 revealed the laboratory failed to document one of four Quart maintenance for one of one Sysmex pocH-100i hematology Analyzer. Last quartly maintenance documented: 8/16/2023 Next quartly maintenance due: 11/16/2023 3. Review of the patient results from 11/17/2023 to 1/10/2024 revealed 12 patients had CBC testing performed. Date: 11/17/2023 Patient ID: 17806 Date: 11/29/2023 Patient ID: 18127 Date: 11/29/2023 Patient ID: 19357 Date: 12/01/2023 Patient ID: 19137 Date: 12/01/2023 Patient ID: 19274 Date: 12/05/2023 Patient ID: 17496 Date: 12/08/2023 Patient ID: 16427 Date: 12/11/2023 Patient ID: 18541 Date: 12/12/2023 Patient ID: 17306 Date: 12/12/2023 Patient ID: 18994 Date: 12/13/2023 Patient ID: 16449 Date: 12/22/2023 Patient ID: 18351 4. An interview with the manager on 1/11/2024 at 12:10 pm in the break room confirmed the above findings. Key: CBC=Complete Blood Count