

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0236331	(X3) Date Survey Completed 06/15/2021
Name of Provider or Supplier Upc - Bridgeport Pediatrics	Street Address, City, State 900 Lodgeville Road, Bridgeport, WV	
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 announced, on site, initial certification survey was conducted at UPC Bridgeport Pediatrics on June 15, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures (P&P), lack of documentation, and interview the laboratory failed to perform and document the daily, monthly, and as needed maintenance on the Horibas Micros 60 hematology analyzer for 3 of 3 months. Findings: 1. Review of P&P Tab 5 Instrument Maintenance identified a defined routine daily maintenance, weekly maintenance, and as needed maintenance according to the manufacturer. 2. No documentation of daily, weekly, or as needed maintenance for the analyzer could be located for April 2021, May 2021, and June 2021. 3. The laboratory director confirmed the findings during an exit interview 6/15 /21 at approximately 12:30 PM.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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-- Establish or verify the criteria for acceptability of all control materials. (i) When</p>

control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review, laboratory policies and procedures (P&P), lack of documentation, and interview the laboratory failed to (ii) verify the manufacturer stated values of quality control for 1 of 1 new lot for the Horibas Micros 60 hematology analyzer. Findings: 1. Review of P&P identified an "Analytic Policy and Procedure" stating "At least one day before the current lot of controls expires, verify the acceptability of the new lot number of controls: Run the current quality control material as usual and use these QC results to judge whether or not to accept patient test results. During the same run, run all 3 levels of the new control material, five times each." 2. Review of quality control (QC) records April 2021 thru June 2021 revealed a lack of documentation verifying ranges for 1 of 1 new lot of control material. Lot MX428 (3 levels) in use thru 5/5/2021 Lot MX429 (3 levels) was put into use on 5/6/2021 No documentation of the verification of the manufacturer ranges for lot MX429 prior to being put into use could be located. 3. During an interview with testing personnel 1 (TP1), 6/15/21 at approximately 10:30 AM, TP1 stated that MX429 had not been verified before being put into use. 4. The laboratory director confirmed the findings 6/15/21 at approximately 12:30 PM during the exit interview.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on lack of documentation and interview, the laboratory failed to document a complete initial competency assessment on 5 of 5 testing personnel (TP) for 2021. Findings: 1. Review of the 2021 initial competency forms revealed no documented competency for the hematology analyzer Horibas Micro 60 methodology for 4 of 5 TP (TP2, TP3, TP4, TP5). 2. Review of the 2021 initial competency forms identified no documented assessment of problem solving skills for 5 of 5 TP. (TP1, TP2, TP3, TP4, TP5) 3. The findings were confirmed by the laboratory director during the exit interview 6/15/2021 at approximately 12:30 PM.

D6064

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:

Based on record review and interview the laboratory failed to ensure that 4 of 5 testing personnel had a current West Virginia Laboratory license to perform patient testing from 4/15/2021 thru 5/28/2021 as required by WV 64 CSR 57 Clinical Laboratory Technician and Scientist Licensure and Certification Rule. Findings: 1. Review of personnel files and CMS 209 form identified 5 current testing personnel (TP). 2. Review of the WV Licensure Verification database revealed the following: TP1 (03139) reinstated 5/1/2021 (previous license held 1/1/2000 to 1/1/2015) TP2 (12831) issued new 6/1/2021 TP3 (12830) issued new 6/1/2021 TP4 (12832) issued new 6/1/2021 TP5 (12834) issued new 6/1/2021 3. Review of analyzer quality control and patient test result documentation identified the following: 4 of 5 unlicensed TP (TP2, TP3, TP4, TP5) released patient results on 9 days of patient testing in April 2021. 4 of 4 unlicensed TP (TP2, TP3, TP4, TP5) released patient results on 20 days of patient testing in May 2021. 4. The laboratory director confirmed the findings during the exit interview 6/15/2021 at 12:30 PM.