| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 51D0683776 | 05/24/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Broaddus Hospital | # 1 Health Care Drive, Philippi, 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 |
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| **D0000** | An announced, on site, routine recertification survey was conducted at Broaddus Hospital on May 23 and May 24, 2023. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to document the competency of 9 of 9 testing personnel (TP) in hematology for 2022. Findings: 1. Review of personnel records revealed no documented competency in hematology for 9 of 9 TP in 2022. 2. An interview with the technical supervisor, 5/23/23 at approximately 9:10 AM, confirmed the lack of hematology competencies for the 9 TP in the laboratory. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The |

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| | laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview, the laboratory failed to perform external quality control (QC) on each day of patient testing on the MicroScan for two of two months reviewed. Findings: 1. Review of MicroScan QC records for December 2022 and January 2023 identified external QC being performed on a weekly basis. 2. No IQCP to allow for equivalent quality testing on a weekly basis could be located. 3. An interview with the technical supervisor, 5/23/23 at approximately 11:00 AM, confirmed that QC was not being run each day of patient testing on the MicroScan and no IQCP could be located. 4. An exit interview with the laboratory director, 5/24 /23 at approximately 10:45 AM, confirmed the findings. |
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(g)<br><br>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 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview the laboratory failed to document the verification of the MultiChem S Plus quality control (QC) material before being put into use for patient testing in Chemistry. Findings: 1. Review of manufacturer instructions for assayed QC material in Chemistry identified a current lot 011007210 with an expiration date of 12/31/23. 2. Review of QC records established lot 011007210 to have been put into use April 2022. No documentation of the verification of the MultiChem S Plus assayed, stated values could be located. 3. An interview with the technical supervisor, 5/24/23 at approximately 8:30 AM, confirmed no documentation for the verification of the new lot of QC values could be located. 4. An exit interview with the laboratory director, 5/24/23 at approximately 10:45 AM, confirmed the findings. |
| **D5477** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(4)(g)<br><br>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the |

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| | manufacturer. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview the laboratory failed to document the quality control (QC) performed on microbiology media when a new lot or new shipment is put into use for two of two months reviewed. Findings: 1. Review of December 2022 and January 2023 QC records identified no documentation for (i)sterility checks and (ii)ability to support growth checks for Macconkey, SBA, Chocolate media plates and Bactec blood culture bottles. 2. An interview with the technical supervisor, 5/23/22 at approximately 12:00 PM, confirmed that no external QC for growth or sterility were being performed on new lots/shipments of media plates and blood culture bottles. 3. An exit interview with the laboratory director, 5/24/23 at approximately 10:45 AM, confirmed the findings. |
| **D5781** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(1)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review, written policies and procedures (P&P) and interview the laboratory failed to document the corrective action taken when platelet clump error codes are resulted by the Sysmex 450 hematology analyzer for one of one patient result reviewed. Findings: 1. Review of patient results for May 2023 identified one analyzer printout with a platelet clump error code. The patient result was released with no documentation of corrective action. 2. Review of P&P could not locate a procedure on corrective action to take for a platelet clump error code on the Sysmex 450. 3. An interview with the technical supervisor, 5/24/23 at approximately 8:00 AM, confirmed there was no written procedure for the corrective action process when handling a platelet error code on the Sysmex 450. 4. An exit interview with the laboratory director, 5/24/23 at approximately 10:45 AM, confirmed the findings. |
| **D5787** | TEST RECORDS<br>CFR(s): 493.1283(a)<br><br>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). |

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| | This STANDARD is not met as evidenced by:<br>Based on record review and interview the laboratory failed to include all required information on Microbiology worksheets documenting manual testing for 26 of 26 reviewed. Findings: 1. Review of January 2022 patient worksheets for manual testing identified 26 of 26 had no testing personnel (TP) identified for each step of testing performed. 2. An interview with the technical supervisor, 5/23/23 at approximately 12: 42 PM, confirmed the lack of TP identifiers on the Microbiology worksheets for each testing process performed. 3. An exit interview with the laboratory director, 5/24/23 at approximately 10:45 AM, confirmed the findings. |