| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 51D0233527 | 10/28/2020 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Wvu Med Princeton Community Hospital Bluefield | 500 Cherry St, Bluefield, 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, recertification survey was conducted at Princeton Community Hospital Bluefield on October 27 and October 28, 2020, 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. |
| **D2025** | BACTERIOLOGY<br>CFR(s): 493.823(c)<br><br>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of laboratory proficiency testing (PT) records from the College of American Pathologists (CAP) and an interview with the general supervisor (GS), the laboratory failed to return PT results to CAP within the timeframe specified for the CAP D6-B 2020 event. Findings: 1. Review of laboratory CAP PT records identified an unsatisfactory score of 0% for the CAP D6-B 2020 bacteriology event. 2. Review of laboratory PT records identified an investigation into the unsatisfactory score and documentation of the laboratory self-evaluation. 3. During an interview with the GS, on 10/27/2020 at approximately 8:45 AM, the GS stated the results were not returned in time to CAP because the delivery of the specimens was after the due date. |
| **D2123** | HEMATOLOGY<br>CFR(s): 493.851(c)<br><br>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended |

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| | during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory proficiency testing (PT) records from the College of American Pathologists (CAP) and an interview with the general supervisor (GS), the laboratory failed to return the results to the CAP VPBS-B 2020 testing event within the time frame required. Findings: 1. Review of CAP PT records identified a 0% unsatisfactory score for the VPBS-B 2020 virtual peripheral blood smear event. 2. The PT investigation identified a failure to participate in the VPBS-B 2020 virtual peripheral blood smear event within the specified time frame by CAP. 3. During an interview with the GS, on 10/27/2020 at approximately 9:00 AM, the GS stated that there were some issues during the transition of the laboratory and the event did not get performed in time. |
| **D5433** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(1)<br><br>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of laboratory preventative maintenance (PM) logs for August and September 2020 of the Sysmex XS-100i and the Sysmex EX-2100 analyzers, and an interview with the general supervisor (GS), the laboratory failed to document weekly and monthly maintenance of the hematology analyzers. Findings: 1. Review of August 2020 and September 2020 PM logs for the Sysmex XS-100i, identified no documentation of the weekly or monthly maintenance being performed for the months reviewed. 2. Review of August 2020 and September 2020 PM logs for the Sysmex XE-2100, identified no documentation of the weekly or monthly maintenance being performed for the months reviewed. 3. Review of the October 2020 PM logs (thru October 27th) for the Sysmex XS-100i and the Sysmex XE-2100, identified the documentation of the weekly and monthly maintenance of the analyzers for the month. 4. During an interview with the GS, on 10/27/2020 at approximately 3:30 PM, the GS stated she was aware of the weekly and monthly maintenance not being documented for the Sysmex XE-2100 and the Sysmex XS-100i hematology analyzers for August 2020 and September 2020. |