| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 51D0661760 | 06/10/2026 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Summers County Arh Hospital Laboratory | 115 Summers Hospital Road, Hinton, 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** | A routine recertification survey was performed at Summers County ARH Hospital Laboratory on June 9 & 10, 2026, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with 42 CFR 493, Requirements for Laboratories. Noncompliance was found and explained below. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Prothrombin time (PT) reagent validation documents for the Sysmex CA-660, laboratory International Normalized Ratio (INR) calculation verification for 2025, direct observation of the Sysmex CA-660 analyzer, Dade Innovin reagent manufacturer instructions for use (IFU), laboratory policies and procedures, interview with the general supervisor (GS), and exit interview with the laboratory administration team, the laboratory failed to follow the manufacturer's instructions for use and ensure the normal patient Prothrombin time mean (MNPT) established for the new lot of Innovin PT reagent was implemented when put into use for patient testing (September 2025 thru date of survey). Findings: 1. A review of the Sysmex CA-660 Dade Innovin PT reagent validation records for lot number 564677 (expiry 12/16/27) revealed the laboratory established a normal patient Prothrombin time mean (MNPT) of 10.51 in the laboratory population PT study performed in September 2025. 2. A review of the INR calculation verification, performed 9/3/2025 to manually check the calculation used by the Sysmex CA-660 analyzer for the new PT reagent, identified the laboratory used an MNPT of 10.70 to manually calculate the INR for Innovin lot 564677 when put into use. 3. During a tour of the hematology |

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| | laboratory, 6/9/26 at 3:30 PM, the state surveyor directly observed the normal patient Prothrombin time mean (MNPT) programmed as 10.7 and the ISI as 1.01 in the set parameters for Innovin lot 564677 on the Sysmex CA-660 analyzer. The IFU for the Dade Innovin reagent lot 564677 verified the ISI of 1.01 was correct. 4. A review of the Dade Innovin manufacturer IFU confirmed "the mean normal PT (MNPT) is defined as the mean value of the normal range. It must be determined specifically for each thromboplastin (Innovin) lot using the method used to analyze patient samples." 5. The laboratory "CA 660 Reagent and Lot Conversion" standard operating procedure, in effect 3/11/2021, states "The calculation of the INR is appropriately adjusted for every new lot of PT reagent" with the established MNPT from the normal laboratory population and the manufacturer ISI from the new reagent lot IFU. 6. During an interview 6/9/26 at 3:40 PM, the GS verified that the incorrect MNPT of 10.7 was programmed into the Sysmex CA-660 analyzer and used for the INR calculation in patient PT testing since implementation of the new lot of Innovin in September 2025. 7. An exit interview with the laboratory administration team, 6/10/26 at 2:00 PM, 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 review of environmental monitoring logs, Sysmex CA-660 manufacturer instructions for use (IFU), laboratory policies and procedures, interview with the general supervisor (GS1), and exit interview with the laboratory administration team, the laboratory failed to implement and document the corrective action (CA) taken when the humidity was outside the manufacturer acceptable range for the Sysmex CA-660 analyzer for 89 of 151 days of testing from January 1, 2026 thru May 31, 2026. Findings: 1. Review of the Sysmex CA-660 IFU identified the manufacturer established acceptable range for humidity as 30-85%. 2. Laboratory policy "Temperature and Humidity Monitoring", implemented 3/6/2024, states "If any humidity value is out of range, immediate corrective action will be performed and documented on the applicable humidity logs and corrective action sheets." 3. Review of the environmental monitoring logs (January 2026 thru May 2026) for the laboratory testing area of the Sysmex CA-660 analyzer revealed no documentation of corrective action for 89 testing days when humidity was recorded as below the manufacturer established acceptable range of 30-85%: 27 days in January, 26 days in February, 16 days in March, 7 days in April, 3 days in May 4. During an interview 6/10/26 at 10:30 AM, the GS verified that no documented corrective action could be located for the 89 testing days that humidity was outside the established manufacturer acceptable range. 5. An exit interview with the laboratory administration team, 6/10/26 at 2:00 PM, confirmed the findings. |