

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 18D0325229	<b>(X3) Date Survey Completed</b> 03/27/2024
<b>Name of Provider or Supplier</b> Hazard Arh Regional Medical Center	<b>Street Address, City, State</b> 100 Medical Center Drive, Hazard, KY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Recertification Survey was initiated on 03/26/2024 and concluded on 03/27/2024. The facility was found not to be in compliance with the laboratory requirements of 42 CFR Part 493 with deficiencies cited.
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on policy review, document review, and confirmed in staff interview; the laboratory failed to retain documentation of calibration for 1 of 54 chemistry test methods for 4 of 4 required calibration events in 2022 and 2023. Findings included: A review of a facility policy titled "Osmolality (Advanced Instruments Model 3320 Micro-Osmometer Osmolality)," adopted in 09/2018, revealed, "CALIBRATION: Re-calibration will need to be performed every six months." A review of calibration records for performance of osmolality revealed a lack of required documentation for 4 of 4 required calibration events in 2022 and 2023. During an interview on 3/27/2024 at 11:15 AM, Testing Personnel #4 stated osmolality calibration records were not printed off at the time of performance and that, because the instrument only retained results in memory for the last 1000 cycles, the calibration records could not be retrieved.</p>
<b>D5215</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance</p>

(that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on policy review, document review and confirmed in staff interview; the laboratory failed to perform a self-evaluation of 3 of 11 proficiency testing results from 01/25/2022 to 03/26/2024 that were returned as "Not Graded" by the proficiency testing provider because of a lack of required level of agreement within the test method peer group. Findings included: A review of a facility policy titled, "Proficiency Testing," adopted in 12/96 and last reviewed in 02/20, revealed, "4. Ungraded proficiency results are evaluated, whether from lack of consensus, less than 20 participants, results submitted after the cut-off date, results not submitted, or incorrect testing information recorded" and "5. For lack of consensus or less than 20 participants, the results are reviewed against the findings of the proficiency testing service. If the results are comparable with the majority of the other participants the results are accepted as being valid. If not the test(s) are repeated, slides reviewed with other testing personnel for consensus, Director review and other steps as deemed necessary by the Director." A review of an American Proficiency Institute (API) report titled, "Proficiency Testing Performance Evaluation" for the "2023 Hematology/Coagulation - 1st Event," signed by the Lab Director or designee on 04/18/2023, revealed the laboratory failed to notate the ungraded analyte/sample on the performance evaluation page or a participant summary sheet. A review of an API report titled, "Comparative Evaluation 2023 Hematology/Coagulation - 1st Event" revealed the "Body Fluid Crystals" for sample "CYS-02" was not graded. Further review of the report revealed the "Body Fluid Microscopy" for sample "BFM-02" was not graded. A review of an API report titled, "Proficiency Testing Performance Evaluation" for the "2023 Hematology/Coagulation - 3rd Event," signed by the Lab Director or designee on 12/20/2023, revealed the laboratory failed to notate the ungraded analyte/sample on the performance evaluation page or a participant summary sheet. A review of an API report titled, "Comparative Evaluation 2023 Hematology/Coagulation - 3rd Event" revealed the "PMN (CSF/body fluid) (%)" for sample "BFL-04" was not graded. During an interview on 03/26/2024 at 12:45 PM, Technical Supervisor #2 confirmed the above findings.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 policy review, document review and confirmed in staff interview; a technical supervisor failed to perform annual competency assessments for performance of arterial blood gases for 28 (respiratory therapy staff) of 28 testing personnel in 2022. Findings included: A review of a facility policy titled, "Assessing Job Performance," adopted in 12/93 and last reviewed in 02/18, revealed under a "B.

Competencies" section, "c. Technical Staff Performing Non-Waived Testing; i. Competencies for technical staff reporting non-waived testing is performed at least semi-annually the first year and yearly thereafter" and "c. iv. The laboratory director has delegated competency assessments to the laboratory administrative director and the senior medical technologists who possess the educational requirements to function [as] technical and/or general supervisors in the clinical laboratory and for blood gas analysis performed by nursing and cardiopulmonary staff." A review of competency assessment records for the performance of arterial blood gases revealed a lack of required documentation for 28 respiratory therapy testing personnel in 2022. During an interview on 03/26/2024 at 3:45 PM, Technical Supervisor #2 confirmed the above findings.