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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>04D0469039  | <b>(X3) Date Survey Completed</b><br><br>09/24/2026 |
| <b>Name of Provider or Supplier</b><br><br>Johnson Regional Medical Center                                                 | <b>Street Address, City, State</b><br><br>1100 East Poplar, Clarksville, AR |                                                     |
| 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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| D5311              | <p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br/>CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of the manufacturer's instruction, patient test records, and interview with staff the laboratory failed to establish a policy to ensure 10 of 10 patient lactate samples were centrifuged within 15 minutes of collection on 9/21/26. A) Laboratory Policy ("Lactate Gen.2", Effective 5-12-25) for the lactate analysis performed in the laboratory, stated:"Centrifuge within 15 minutes of collecting the specimen." B) A query of Lactate sample turnaround time records for 9/21/26 revealed 10 of 10 samples took longer than 15 minutes from collection to result. Centrifuge times were not documented. C) During interview 9/23/26 at 10:17am, Technical Supervisor #1 (as listed on the CMS-209 form) confirmed that the lab documented collection times and report times; but not centrifuge times.</p> |
| D5791              | <p>ANALYTIC SYSTEMS QUALITY ASSESSMENT<br/>CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |

This STANDARD is not met as evidenced by:

Based on policy, lack of documentation and an interview, the laboratory failed to follow established written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in analytic systems. Findings include:

A. Policy titled "Quality Control (QC)" states " VI. Warning 8x: this rule is violated when 8 consecutive controls fall on the same side of the mean, either above or below. The rule could also apply if 4 consecutive controls fall on the same side of the mean with both controls. This rule detects a systemic error. Without a 12 rule violation the run may not be rejected, but any violation should be reported to the supervisor." and "Weekly Quality Control - All QC is evaluated for 4-1S and 8x any investigation is documented and the supervisor is notified." B. Chemistry records showed control results below the mean for Human Immunodeficiency Virus (HIV) level two controls in 27/28 runs for February 2026. For Hepatitis C Virus (HCV) level one controls were below the mean 31/31 days for July 2026 and 28/28 days for February 2026. HCV level two controls were above the mean for 23 consecutive days from July 8 to July 31 2026 and 14 consecutive days from February 14 to February 28 2026. N-terminal pro-B-type natriuretic peptide (NT-proBNP) level one and level three controls were above the means for 30/31 days in July 2026. Troponin T (Trop T) level 3 controls were above the mean for 30/31 days in July 2026 and Trop T level one controls were below the mean everyday from July 4th through July 25th 2026. Creatine Kinase-Myocardial Band (CK-MB) level 3 controls were below the mean for 27/28 days in February 2026 C. Quality assurance records failed to note any 8x shifts during the above time frames for the given analytes. D. Upon request, documentation noting the above 8x shifts were not available. C. At 9:51am on 9/23/26, the technical supervisor #1 (as noted on the CMS-209 form) confirmed that investigations of the 8x rule violations noted above had not been permanently documented.