

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0469039	(X3) Date Survey Completed 12/11/2024
Name of Provider or Supplier Johnson Regional Medical Center	Street Address, City, State 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
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Review of American Proficiency Institute (API) proficiency testing events in 2024, the correlated corrective action forms, and interview determined that the laboratory failed to identify corrective action or assure the effectiveness of corrective action in the event of errors and/or failures in proficiency testing challenges in two of the three proficiency testing events reviewed. Findings follow: A) Review of the first "AP Chemistry Core" event of 2024 revealed a score of 60% (unacceptable) for N-Terminal proB-Type Natriuretic Peptide (NT-proBNP) with sample CM-01 resulted as 4521 with acceptable results (3647 to 4480), and sample CM-03 resulted as 2092 with acceptable results (1728-2088). B) Review of the laboratory's "Corrective Action Checklist" revealed corrective action "calibration performed on 2/13/24, repeated samples were 100%". C) Review of the third "AP Chemistry Core" event of 2024 revealed a score of 0% (unacceptable) for N-Terminal proB-Type Natriuretic Peptide (NT-proBNP) with sample CM-1 resulted as 2385 with acceptable results (1935 to 2266), sample CM-12 resulted as 81 with acceptable results (57-78), sample CM-13 resulted as 5016 with acceptable results (4155 to 4748), sample CM-14 resulted as 1206 with acceptable results (970-1124) and, sample CM-15 resulted as 620 with acceptable results (499-578). D) Review of the API annual summary revealed "unsuccessful" performance for NT-proBNP for the year. E) In an interview on 12/11/24 at 11:55 a.m. , laboratory personnel (numbers 1 and 3 on form CMS 209) confirmed that there were problems with the NT-proBNP assays for a period of two</p>

years and corrective action had not been successful and a new chemistry analyzer has been ordered to replace the current analyzer used for that assay.