

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0906636	(X3) Date Survey Completed 09/10/2025
Name of Provider or Supplier Family Practice Assocs Of Clarksville	Street Address, City, State 23 Professional Park Drive, 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
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based upon review of Levey-Jennings graphs for quality control (QC) Detail reports for sodium (NA) testing performed on the Cobas Integra chemistry analyzer, 'corrective action log', "epidemiology report", and interview with laboratory staff, the laboratory failed to evaluate patient results back to the last successful QC performance when QC for NA testing failed to meet the laboratory's criteria for acceptability on one of one occasions reviewed. Findings follow A) Review of the QC Statistic Report Levey-Jennings graphs for control level 1 lot# 46011 performed on the Cobas Integra chemistry analyzer revealed that the level 1 control was unacceptable on three successive runs on 5/6/25 @ 08:39 a.m., 09:24 a.m., and 10:02 a.m. before being acceptable at 11:50 a.m. B) Review of statements of corrective action revealed that the corrective action was listed "sodium calibrated 3 times". C) Review of the QC Statistic Report Levey-Jennings graphs revealed that the last successful QC for NA assays was performed on 5/5/25 at 08:44 a.m. D) Review of the "epidemiology report" revealed that NA assays were performed and reported on nineteen patients (identified as numbers 1 through 19 on a separate patient identification list) on 5/5/25 from 08:55 a.m. until 5/5/25 at 4:30 p.m. E) Upon request the laboratory was unable to provide evidence that NA results were evaluated for NA assays performed on 5/5</p>

/25. F) In an interview on 9/10/25 at 09:33 a.m., the laboratory staff member (# 4 on the form CMS 209) confirmed that NA assays performed and reported on 5/5/25 had not been evaluated.