

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0721589	(X3) Date Survey Completed 09/15/2026
Name of Provider or Supplier Mena Regional Health System Respiratory Care	Street Address, City, State 311 North Morrow, Mena, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based upon a review of the American Proficiency Testing Institute (API) proficiency test attestation records for three events in 2025 and two events in 2026, lack of documentation, and interviews with laboratory staff, it was determined that failed to obtain required signatures to attest to the routine integration of proficiency test samples in the patient workload on 5 of 5 events reviewed. Survey findings follow: A) Review of the attestation forms for API Chemistry Core proficiency test events, 1st event 2025, 2nd event 2025, 3rd event 2025, 1st event 2026, and 2nd event 2026 revealed that they were not signed by the lab director or designee or the testing personnel performing the test. B) In an interview, at 02:40 p.m.on 9/15/26, the laboratory staff member (number 1 on the form CMS 209) confirmed the API proficiency testing attestation forms identified above were not signed by the required personnel.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by:

Based upon a review of the CMS 209 form, review of laboratory documentation of competency assessment, lack of documentation and interview with laboratory staff the laboratory failed to assess clinical consultant competency on an annual basis for one of one clinical consultant listed on the form CMS 209. Findings follow: A) Review of the CMS 209 form revealed that the laboratory staff (number 12 on the form CMS 209) was acting as the clinical consultant for the laboratory. B) Review of competency assessment records revealed that the clinical consultant (number 12 on the CMS 209 form) had no record of competency evaluation. C) Upon request, the laboratory was unable to provide competency assessments for clinical consultant (number 12 on the CMS 209 form). D) In an interview on 9/15/26 at 2:30 p.m., the laboratory staff member (# 1 on the form CMS 209) confirmed that competency assessments for the clinical consultant identified above were not performed.

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(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.

This STANDARD is not met as evidenced by:

Through a review of the manufacturer's user manual for the Radiometer ABL 800 arterial blood gas analyzer, laboratory temperature records for January 2026, and through interview with laboratory staff, it was determined the laboratory failed to document corrective actions when humidity was outside of the specified performance specifications on 5 of 31 days in January 2026. Survey findings include: A) A review of the manufacturer's user manual for the Radiometer ABL 800 arterial blood gas analyzer revealed an operating humidity requirement of 20% to 80%. B) Through a review of environmental logs for January 2026, it was shown that humidity was below 20% for five of 31 days in January 2026. Corrective actions were not documented for any of the failures. C) Upon request, the laboratory could not provide documentation of the corrective action taken when humidity was below the manufacturer's specifications for the Radiometer ABL 800 arterial blood gas analyzer. D) During an interview at 2:55 on 9/15/26, the laboratory staff member #1 (as listed on the form CMS-209) confirmed that the humidity was documented outside of specified acceptable ranges and that no corrective actions were documented.