Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D0049580	11/05/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mena Regional Health System	311 North Morrow Street, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (b)The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based upon a review of American Proficiency Institute (API) proficiency testing preformance evaluation for Immunology/Immunohematology proficiency testing events in 2025, and interviews with laboratory staff, the laboratory did not test compatability for samples SER-07 and SER-08 in the 2nd proficiency testing event in 2025 in the same manner as patient testing. Findings follow: A) Review of the API Immunology/Immunohematology Antibody Screen result comparative evaluation for the second event in 2025 revealed samples SER-07 and SER-08 were resulted as "unexpected antibody detected" and the results were evaluated as acceptable. B) Review of the API Immunology/Immunohematology Compatability result comparative evaluation for the second event in 2025 revealed samples SER-07 and SER-08 were resulted as compatible and the results were evaluated as unacceptable. C) In an interview on 11/5/25 at 02:30 p.m., when asked what caused the failure for compatability testing on the 2nd API Immunology/Immunohematology event in 2025, the laboratory staff member (#10 on the form CMS 209) stated that samples SER-07 and SER-08 had positive antibody screens and the testing personnel performed and reported the samples as compatible based upon an immediate spin crossmatch. The laboratory's policy is to refer compatibility testing for all patients with positive

	antibody screens to a reference laboratory, but "the techs thought because it was proficiency testing they had to report it" and they did not treat the proficiency testing samples in the same manner as patients.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the 2025 CMS Casper Reports 0153D and 0155D, and the American Proficiency Institute (API) proficiency testing results, the laboratory failed to have successful participation in proficiency testing for the test compatibility testing. Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance as cited at D2181.
D2181	COMPATIBILITY TESTING CFR(s): 493.863(e) (e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of 2025 CMS Casper Reports 0153D and 0155D, and the American Proficiency Institute (API) proficiency testing results, the laboratory failed to achieve satisfactory performance in two consecutive proficiency testing events for the test compatibility testing as evidenced by: A) The Laboratory received a score of 0.0% for compatibility testing in the third proficiency testing event of 2024. B) The Laboratory received a score of 60% for compatibility testing in the second proficiency testing event of 2025. C) The scores identified above resulted in a "long term" evaluation of "unsuccessful" by the API proficiency testing agency.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d)

	(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual, lack of documentation, and interviews with laboratory staff, the laboratory director failed to approve, sign, and date all the laboratory procedures. Survey findings include: A. During a review of the laboratory procedures, it was determined the laboratory director failed to sign the procedure manual and individual policies (Titled procedures NOT signed by the Laboratory Directory: Guidelines for Manual Differential & Scanning a Peripheral Blood Smear, Blood Cell Differential & Smear Review, Red Blood Cell Indices, Platelet Clumping Cold Agglutinin Procedure, Policy & Procedure for Hematology Analyzer, Corrected Reference Laboratory Report, MMA Corrected report, Hematology QC Lot Verification, Quality Assessment Plan, Quality Assessment Report Criteria, Specimen Collection Manual, HcG Dipstick rapid Test, Quickvue RSV, Stat Flu A&B, Coagulation Quality Control and Corrective, Coagulation Sysmex CA-620, Coagulation Sysmex 2500, Coag Lot Rollover, Coag IRN Calculation Verification.) B. In an interview at 1:54 pm on 11/03/2025, Technical Consultant (TC) as listed on the 209 form, confirmed the laboratory director's written approval of the laboratory procedures was not available.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) (e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based upon the review of the laboratory policy and procedure "Quality Assurance of Blood Bank Procedures", and interview with laboratory staff, the laboratory did not document the discontinuance of performing AHG crossmatches on IgG cards on patients with positive antibody screens. Findings follow: A) Review of the policy and procedure "Quality Assurance of Blood Bank Procedures" effective 6/14/24, reviewed and approved by the laboratory director on 9/25/24, revealed that patients with a positive antibody screen will have samples sent to the reference blood bank for antibody identification and the provision of antigen negative blood units. "After receiving the antidody negative units the units will be retyped, immediate spin crossmatched in buffer cards and AHG crossmatched in IgG cards". B) In an interview on 11/5/25 at 02:00 p.m., the laboratory staff member (# 10 on the form CMS 209) stated that policy is no longer in use and that all patients with positive antibody screens are referred to the reference blood bank who performs the crossmatches.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

	This STANDARD is not met as evidenced by: Based upon review of the package insert for Dade Innovin reagent for Prothrombin Time (PT) assays, lack of documentation, observation of instrument settings, and interview, the laboratory failed to determine the normal patient mean (MNPT) value for the laboratory's patient population used in the calculation of International Normalized Ratio (INR) values in accordance with manufacturer's instruction. Findings follow: A) Review of the package insert for Dade Innovin revealed that the MNPT used in the calculation of the INR "must be determined specifically for each thromboplastin lot using the method to analyze the patient samples using the coagulation analyzer used for the analysis. Follow appropriate laboratory guidelines for establishing MNPT for US customers the appropriate CLSI guideline is recommended". B) When asked to present the data used to establish the MNPT with the change to Dade Innovin lot # 564677, the data was available with no demographic presented of 20 normal health subjects. Laboratory could not provide the number of males and females, free of known illnesses and medications. C) In an interview at 01: 22 pm on 11/4/25, the Technical Consultant (TC), listed on the CMS 209 form, stated the data could not be located.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based upon a review of chemistry quality control (QC) documentation for September 2025, the laboratory policy for "General Quality Control", and interview with laboratory staff, the laboratory documented running only one level of quality control on one of thirty-one days of testing in September 2025. Survey findings follow: A) Review of the laboratory policy and procedure for "General Quality Control" revealed "for each quantitative procedure include at least two levels of control material of different concentrations". B) The surveyor reviewed quality control for September 2025. On 9/4/25 the laboratory documented quality control results for the High chemistry Control (lot #3923) for the analyte Thyroid Stimulating Hormone (TSH) but did not document results for the Normal (lot # 3921) C) A review of patient TSH test results for 9/4/25 revealed sixteen patients (identified as number 1 through 16 on a separate patient identification list) had TSH assays performed and reported on the day that only one control was documented. D) During an interview at 01:00 p.m.on 11 /5/2025, laboratory staff member (#11 on the form CMS 209) confirmed that sixteen patients were tested on 9/4/25 when only one control was documented for TSH assays.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of 2024 and 2025 proficiency testing results, the laboratory director failed to ensure that the proficiency testing samples are tested as required under Subpart H of this part. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on the 2024 and 2025 proficiency testing event results, the laboratory director failed to ensure the laboratory successfully participated in proficiency testing for the immunohematology analyte compatability testing. Refer to D2181.