

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0305141	<b>(X3) Date Survey Completed</b>  03/05/2025
<b>Name of Provider or Supplier</b>  Mizell Memorial Hospital	<b>Street Address, City, State</b>  702 N Main Street, Opp, AL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records, and an interview with the Laboratory Manager, the laboratory failed to implement a mechanism to verify the accuracy of the following non regulated analytes: DAT (direct antiglobulin test) IgG (Immunoglobulin G), CRP ( C-reactive protein), and MALB (Micro-albumin). The surveyor noted the PT evaluation failures occurred in two consecutive events out of six events from 2023-2024. The findings include: 1. A review of the API PT records revealed the laboratory's DAT IgG, CRP, and MALB evaluation scores were unsuccessful due to the following unacceptable scoring events: a) DAT IgG: 2023 Immunohematology 2nd Event 50% and Immunohematology 2023 3rd Event 0%. b) CRP: 2023 Immunology 3rd Event 50% and 2024 Immunology 1st Event 50%. c) MALB: 2023 Chemistry Miscellaneous 2nd Event 0% and 2024 Chemistry Miscellaneous 2nd Event 0%. 2. The Laboratory Manager confirmed the above findings during the exit conference on 03-4-2025 at 11: 59 AM.</p>
<b>D5445</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493. 1261 through 493.1278. (d)(2) For each test system, perform control procedures using</p>

the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:

Based on a review of the ESR (Erythrocyte Sedimentation Rate) QC (Quality Control) records and an interview with the Laboratory Manager, the Laboratory failed to ensure daily normal and abnormal QC on the ESR eXcyte 20 analyzer were within manufacturer's ranges prior to patient testing. The surveyor noted six out of thirty days in September 2023 when QC exceeded manufacturer's ranges, or was not documented, and patient testing was performed. The findings include: 1. A review of the ESR eXcyte 20 QC records revealed daily abnormal QC exceeded manufacturer's ranges for the following days in September 2023: a) 9/1; 1 patient affected, b) 9/2; 4 patients affected, c) 9/13; 6 patients affected, d) 9/16; 2 patients affected f) 9/27; 3 patients affected. 2. A review of the ESR eXcyte 20 QC records revealed daily normal QC was not documented for September 20, 2023; 5 patients were affected. 2. During an interview on March 4, 2025 at 12:57 PM, the Laboratory Manager confirmed the above findings.