

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D1048934	<b>(X3) Date Survey Completed</b> 02/06/2025
<b>Name of Provider or Supplier</b> Wrmc Medical Complex Laboratory	<b>Street Address, City, State</b> 195 Hospital Drive, Suite E, Cherokee Village, AR	
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>D5311</b>	<p><b>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL</b> CFR(s): 493.1242(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the manufacturer's instruction, the laboratory's procedure manual, patient test records, and interview with staff the laboratory failed to ensure 9 of 42 patient lactate samples were centrifuged within 15 minutes of collection from 1/28/25 through 2/5/25. A) Manufacturer's instructions ("Instructions for Use Vitros Chemistry Products LAC Slides" Lactate, REF 843 3880, 815 0112, ver 13.0, Pub. No. C-212_EN) for the lactate analysis performed in the laboratory, stated:"centrifuge specimens and remove the plasma from the cellular material within 15 minutes of collection time." B) The Laboratory's QC Policy manual did not contain specific policies for lactate, but referred to "following manufacturer's instructions and/or package inserts". C) A query of Lactate sample turnaround time records from 1/28/25 through 2/5/25 revealed 9 of 42 samples took longer that 25 minutes from collection to result. Centrifuge times were not documented. D) During interview 2/6/25 at 3:23pm, the Technical Consultant (as listed on the CMS-209 form) confirmed that the lab documented collection times and report times; but not centrifuge times.</p>
<b>D5791</b>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an</p>

ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policy and procedure for "Quality Control" (QC), review of quality control Levy-Jennings charts for March 2024 through December 2024, review of QA review notes, lack of documentation, and interview it was determined that the laboratory failed to recognize or take corrective action on one of one month reviewed when the trend met the labs definition of a shift. Findings follow: A) Review of the laboratory's policy and procedure for "Analysis Trends / Shifts in Chemistry" (effective date 6/17/2014) revealed that "A shift is seven points on a Levy-Jennings Chart that go progressively outward." "When a shift is noted remediation should be started using the Algorithm for Resolving Unacceptable Controls. All remediation efforts should be documented." B) Review of Levy Jennings reports from March 2024 through December 2024 for Cholesterol assays performed in the lab showed seven points that went progressively outward from 6/17/24 thru 6/23/24. C) Upon request, the laboratory was unable to provide documentation that the shift identified above had been identified and corrective action taken. D) In an interview on 2/6/25 at 3:17pm the technical consultant confirmed that the cholesterol controls had seven or more points trending upward in the month of June 2024 and no corrective actions were taken or documented.