

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0864215	<b>(X3) Date Survey Completed</b> 01/31/2024
<b>Name of Provider or Supplier</b> Alere Toxicology Services, Inc	<b>Street Address, City, State</b> 450 Southlake Blvd, Richmond, VA	
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>D0000</b>	An announced CLIA Recertification survey was conducted at the Alere Toxicology Services, Inc on January 29-31, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
<b>D5775</b>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&amp;P), method comparison records, lack of documentation, and interviews, the lab failed to follow the established P&amp;P for performing a method comparison of the methodologies used for specific gravity and pH analysis twice annually from 01/01/22 up to dates of survey on 01/29/24-1/31/24 (22 months). Findings include: 1. Review of the P&amp;P revealed the following statements, "4.3 Instrument Comparison/Donor Comparison", "Donor Comparison is completed every 6 months for all NON-SAMHSA SVT assays with more than one validated instrument/method by the comparison of a minimum of 5 donor specimens or controls within the specified ranges." The P&amp;P provided step-by-step instructions for performing method comparison for the specific gravity, pH, creatinine, and oxidants analytes. 2. Review of the method comparison records on the dates of the survey (01/29/24-1/31/24) revealed a lack of documentation of the method comparisons as defined in the P&amp;P from January 2022 up to December 2023 as follows: Specific gravity- method comparisons performed in December 2023 between three Beckman Coulter AU 5400 (#21, 22 and 23), two Beckman Coulter AU 5800</p>

(#24 and 26) analyzers and the two 3-place hand-held Atoago Palette, five 4-place hand-held Atoago Palette refractometers and one Reicherts refractometer. No further documentation of method comparisons was observed. pH- method comparisons performed in December 2023 between three Beckman Coulter AU 5400 (#21, 22 and 23), three Beckman Coulter AU 5800 (#24, 25 and 26) analyzers and the four Mettler Toledos and one Orian pH meters. No further documentation of method comparisons was observed. 3. In an interview with technical supervisor #1 on 01/30/24 at 10:20 AM, the inspector requested to review method comparisons for the above-specified analytes. They stated, "we were not performing the comparisons every six months. We opened a QI [Quality Indicator] in December 2023 and will perform the comparisons every six months going forward." 4. An exit interview with the technical supervisors #1, #2 and #3, the lab director and quality assurance director on 01/31/24 at 10:15 AM confirmed the findings.