

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  42D2189565	<b>(X3) Date Survey Completed</b>  05/17/2024
<b>Name of Provider or Supplier</b>  Vitrologic, Inc	<b>Street Address, City, State</b>  1704 Old Towne Road, Charleston, SC	
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 initial survey was conducted at Vitrologic, Inc on 05/17/2024 by the South Carolina Department of Environmental Control (SCDHEC). The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. The facility was found to be out of compliance with the standards of the CLIA program. The following <b>CONDITION LEVEL DEFICIENCIES</b> were found to be out of compliance:
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This <b>CONDITION</b> is not met as evidenced by: During an announced initial survey on 05/17/2024, direct observations, proficiency testing record review, and staff interview, the laboratory failed to enroll in proficiency testing for specialty of Chemistry. 16 out of 16 proficiency testing (PT) records were reviewed. Findings included: 1. During the entrance conference on 05/17/2024 at 11:01 am, the surveyor requested proficiency testing records for the moderately complex testing performed. The staff provided records from American Association of Bioanalysis (AAB) from 2018 thru 2024. 2. While reviewing PT records from AAB it was discovered that the records were from a different CLIA #42D1056115. Vitrologic, CLIA # 42D2189565 is not enrolled in PT program. 3. A Certification and Survey Provider Enhanced Reporting systems (CASPER) was used 06/14/2024 revealed a validation error, certification number (CCN) "CCN entered was not found".</p>

	<p>4. In an interview on 05/17/2024 at 11:01 am with staff in the office, provided PT records for CLIA #42D1056115 as existing records.</p>
<p><b>D5407</b></p>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation, staff interview, the laboratory failed to ensure that the laboratory procedures and changes in procedures were approved, signed, and dated by the laboratory director before use. Findings included: 1. Documentation of the laboratory director ' s approval for the use of the laboratory ' s standard operating procedures regarding all pre-analytic, analytical, and post-analytical phases of testing, quality assurance, quality control, patient test management, and personnel activities were unavailable for review on the day of the survey. 2. Staff interviewed during onsite interview on 05/17/2024 at 1:30pm in office that the laboratory had failed to ensure the reviewed procedures were approved, signed, and dated by the laboratory director.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a standard operating procedures (SOP), lack of 0155D CASPER record, graded American Association of Bioanalysts (AAB) reports and staff interviewed, the laboratory has failed to ensure proficiency testing for total protein was performed as required by 42 CFR, Part 493.801. see D2000 Findings included: 1. No 0155D CASPER record of CLIA #42D2189565 can be found in the system. 2. A review of proficiency testing results from AAB for 2019, 2020, 2021, 2022, 2023, Events 1, 2, 3, and Event 1 for 2024 revealed testing of total protein was for CLIA #42D1056115. 3. A review of policy and procedures titled "Quality Systems" revealed in section 201.7.5.1 "Each year the screening laboratory will enroll in a CMS approved Proficiency Testing Program." No proficiency testing records for total protein for CLIA #42D2189565 available on 05/17/2024 day of survey. 4. In an interview on 05/17/2024 with staff at 1:30 pm the above findings were confirmed.</p>
<p><b>D6033</b></p>	<p><b>TECHNICAL CONSULTANT-MODERATE COMPEXITY</b> CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by:</p>

	<p>Based on records reviewed (CMS 209), lack of documentation, and staff interviewed, the laboratory has failed to fill a position as technical consultant for a moderately complex laboratory. Findings included: 1. A review of CMS 209 PERSONNEL FORM ON 05/17/2024 revealed no technical consultant for a moderately complex laboratory. 2. A review of policies and procedures revealed the laboratory failed to employ a technical consultant who is qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service. 3. In an interview on 05/17/2024 at 1:30 pm with staff in the office, the above findings were confirmed.</p>
<p><b>D6046</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b>  CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by:  Based on records reviewed (CMS 209), lack of documentation, personnel records, and staff interview during onsite visit on 05/17/2024, the laboratory failed to ensure the staff maintain their competency to perform test procedures accurately and proficiently. Findings included: 1. A review of CMS 209 personnel form on 05/17/2024 revealed two testing personnel. 2. A review of personnel records revealed the competency assessment failed to include six competency assessment criteria for 2 of 2 testing personnel. 3. In an interview with TP2 on 05/17/2024 at 1:30 pm confirmed the findings above.</p>
<p><b>D6066</b></p>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b>  CFR(s): 493.1423(b)(4)(ii)</p> <p>Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.</p> <p>This STANDARD is not met as evidenced by:  Based on lack of documentation, and testing personnel interviewed, the laboratory failed to ensure documentation of training appropriate for the testing performed prior to analyzing patient specimens. 1 of 2 testing personnel (TP) lacked documentation. Findings included: 1. Review of testing personnel ' s records on 05/17/2024 revealed that TP2 lacked documentation of any training records. 2. During an interview with TP2 on 05/17/2024 at 1:30pm in the office the findings above were confirmed.</p>