

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D0534773	(X3) Date Survey Completed 04/01/2025
Name of Provider or Supplier Vitalant - Albuquerque	Street Address, City, State 1515 University Boulevard Ne, Albuquerque, NM	
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
D0000	An onsite complaint investigation conducted on April 1, 2025, at Vitalant - Albuquerque found the laboratory to be not in compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with the following conditions out. 42 C.F.R. 493.801 Condition: Enrollment and Testing of Samples 42 C.F.R. 493.1441 Condition: High Complexity Laboratory Director
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES 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 CONDITION is not met as evidenced by: Based on review of the Laboratory Proficiency Testing Survey policy, a SBAR document (Situation, Background, Assessment, Recommendation), an email chain, email PDF attachment, and interview with the Director of Reference and Transfusion Services (DRTS) and General Supervisor #2 (GS2), the laboratory failed to ensure no inter-laboratory communication of proficiency testing (PT) results for immunohematology proficiency testing occurred for 1 testing event in 2025. Refer to D2012.</p>
D2012	<p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(4) Laboratories that perform tests on proficiency testing samples must not engage</p>

in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

This STANDARD is not met as evidenced by:
Based on review of the Laboratory Proficiency Testing Survey policy, a SBAR document (Situation, Background, Assessment, Recommendation), an email chain, email PDF attachment, and interview with the Director of Reference and Transfusion Services (DRTS) and General Supervisor #2 (GS2), the laboratory failed to ensure no inter-laboratory communication of proficiency testing (PT) results for immunohematology proficiency testing occurred for 1 testing event in 2025. Findings included: 1. A review of the Laboratory Proficiency Testing Survey policy stated, "For laboratories with centralized management of multiple testing locations it is recommended that review of multiple PT survey results does not occur. If it is necessary to review PT submissions from multiple sites the following rules must be adhered to ... PT records must not be accessible to testing personnel of other laboratories, including an affiliated laboratory until after submission deadline. Every effort to keep PT records secure must be taken by management." 2. A review of a SBAR document submitted to CMS (Centers for Medicare and Medicaid) revealed that on 02/18/2025 the Director of Reference and Transfusion Services (DRTS) discovered PT results were sent via email to a sister location in Denver. 3. A Review of an email chain sent from General Supervisor #2 (GS2) revealed on 02/17/2025 at 10:14 am GS2 sent an email with a PDF attachment of their facility's PT results to the DRTS and a group email for their Denver location. On 2/18/2025 at 10:00 am the DRTS responded to GS2 requesting them to recall the email with the PT results. On 2/18/2025 at 10:51 am GS2 responded that the email had been recalled. 4. A request was made for a copy of the PDF that was attached to the email. A review of the PDF revealed test results for immunohematology PT for 2025 event 1 for PT samples J-01R/J-01S, J-02R/J-02S, J-03R/J-03S, J-04R/J-04S, and J-05R/J-05S. Results for the PT samples included ABO group, Rh (rhesus factor) type, antibody screening, antibody identification, and cross match and compatibility testing. 5. During an interview on 02/01/2025 at 11:16 am with the DRTS they stated, their policy is never to send PT results to other locations, GS2 was only supposed to submit the results to the DRTS for review then to the Laboratory director for final review and sign off. 6. An interview on 04/01/2025 at 11:40 am with General Supervisor #2 confirmed the above findings.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on review of the Laboratory Proficiency Testing Survey policy, College of American Pathologist (CAP) Proficiency Testing (PT) records, a SBAR document

(Situation, Background, Assessment, Recommendation), an email PDF attachment, and interview with General Supervisor #2 (GS2) the laboratory director failed to provide leadership and overall guidance as evidence by: 1. The laboratory director failed to ensure no inter-laboratory communication of proficiency testing (PT) results for immunohematology proficiency testing occurred for 1 testing event in 2025. Refer to D6089

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(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 review of the Laboratory Proficiency Testing Survey policy, College of American Pathologist (CAP) Proficiency Testing (PT) records, a SBAR document (Situation, Background, Assessment, Recommendation), an email PDF attachment, and interview with General Supervisor #2 (GS2), the laboratory director failed to ensure no inter-laboratory communication of proficiency testing (PT) results for immunohematology proficiency testing occurred for 1 testing event in 2025 Findings included: 1. A review of the Laboratory Proficiency Testing Survey policy stated, " ... Signatures by the CLIA LD (laboratory director) or designee and testing personnel, if present on the survey report, designate the survey samples are handled and tested appropriately." 2. Review of the J-A Comprehensive Transfusion Medicine CAP PT forms for event 1 in 2025 revealed the laboratory director signed the attestation form designating the survey samples were handled and tested appropriately. 3. A review of a SBAR document submitted to CMS (Centers for Medicare and Medicaid) revealed that on 02/18/2025 the Director of Reference and Transfusion Services (DRTS) discovered PT results were sent via email to a sister location in Denver. 4. A request was made for a copy of the PDF that was attached to the email. A review of the PDF revealed test results for immunohematology PT for 2025 event 1 for PT samples J-01R /J-01S, J-02R/J-02S, J-03R/J-03S, J-04R/J-04S, and J-05R/J-05S. Results for the PT samples included ABO group, Rh (rhesus factor) type, antibody screening, antibody identification, and cross match and compatibility testing 5. An interview on 04/01 /2025 at 11:40 am with General Supervisor #2 confirmed the above findings.