Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0891461	08/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
Vitalant - Pittsburgh Pc5	875 Greentree Road, Ste 134, Pittsburgh, PA	

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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (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. This STANDARD is not met as evidenced by: Based on general supervisor interviews and written preanaltyic policies and procedures record review on August 19, 2025 at 02:15 pm, the laboratory failed to establish written policies and procedures for the conditions for specimen transportation. Findings included: a. It was the practice of the laboratory to use a courier service to transport patient specimens from referring facilities to the laboratory. b. The laboratory maintained no written policies and procedures detailing the conditions for specimen transportation for these referred patient specimens. c. According to laboratory records, the laboratory performed and reported 102,711 patient tests annually.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified

	by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on general supervisor interviews and BacT/ALERT Culture Bottle quality control record review on August 20, 2025 at 11:50 am, the laboratory failed to establish statistical parameters for an unassayed positive quality control material over time through concurrent testing of the quality control material having previously determined statistical parameters. Findings included: a. It was the practice of the laboratory to use BacT/ALERT Culture Bottles on the Biomerieux BacT/ALERT test system. b. According to the laboratory's written protocol, each batch/lot of BacT /ALERT Culture Bottles received were to be checked for its ability to support growth prior to using the culture bottles to test patient specimens using an unassayed quality control material such as saline diluted saliva. c. For the lot of BacT/ALERT Culture Bottles in use on August 20, 2025 (lot number 1062987, expiration date December 13, 2025), laboratory records indicated that quality control procedures were performed and completed on March 24, 2025. The general supervisor confirmed on August 20, 2025 at 11:50 am that the quality control procedure completed on March 24, 2025 included the use of unassayed saline diluted saliva quality control material to ensure the lot of BacT/ALERT Culture Bottles supported growth prior to using this lot of culture bottles to test patient specimens. d. The general supervisor confirmed on August 20, 2025 at 11:50 am that the laboratory maintained no documentation to indicate that the statistical parameters for the unassayed saline diluted saliva used to complete the March 24, 2025 quality control procedures had been established over time by the laboratory through concurrent testing of the quality control material having previously determined statistical parameters. e. According to laboratory records, the laboratory performed 35,982 tests on patient specimens using BacT /ALERT Culture Bottles on the Biomerieux BacT/ALERT test system annually.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by:
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on general supervisor interviews and written postanalytic systems quality

	assessment policies record review on August 19, 2025 at 02:55 pm, the laboratory failed to document all postanalytic systems quality assessment activities. Findings included: a. According to the laboratory's written postanalytic systems quality assessment policy and procedure "PHS Report (Document Number: SOP-0001829, Document Version: 12.0), "pending tests should be reviewed in PHS at least daily, and prior to scheduled downtimes." b. The general supervisor confirmed on August 19, 2025 at 02:55 pm that the review of "pending tests" occurred daily as established by the laboratory's written protocol "PHS Report," but was not documented. c. According to laboratory records, the laboratory performed and reported 102,711 patient tests annually.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on general supervisor interviews and hematology records, policies, and procedures record review on August 20, 2025 at 11:00 am, the laboratory director, high complexity testing, failed to ensure that hematology quality control programs were established to assure the quality of laboratory services provided to to identify failures in quality as they occur. Findings included: a. It was the practice of the laboratory to use the Sysmex XN-1000 test system to perform and report patient hematology test results. b. On the laboratory's Sysmex XN-1000 document titled "Sysmex XN-1000BB Startup, QC and Shutdown Log" it states: "Verify no QC data shift/trends in L-J Charts." c. The general supervisor confirmed on August 20, 2025 at 11:00 am that the laboratory maintained no written quality control document defining a "shift" and/or a "trend" even though hematology quality control test results were to be reviewed for "shifts/trends." In addition, the laboratory maintained no documentation to indicate the remedial/corrective actions to be taken in the event hematology quality control results displayed a "shift" or "trend." d. According to laboratory records, the laboratory performed 35,800 patient hematology tests annually.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on general supervisor interviews and written competency policies record review on August 19, 2025 at 10:30 am, the laboratory director, high complexity testing, failed to ensure that procedures were established for monitoring individuals who conduct preanalytical, analytical, and post analytical phases of testing to assure

	that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Findings included: a. Although the laboratory maintained documentation to indicate that it had met the requirement at 42 CFR 493.1451(b)(8), the laboratory maintained no written procedures detailing the laboratory's process for determining an individuals' documented competency. b. These findings were confirmed by a technical supervisor on August 19, 2025 at 10:30 am c. According to laboratory records, the laboratory performed and reported 102,711 patient tests annually.