Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0301578	05/19/2026
Name of Provider or Supplier	**Street Address, City, State**	
St Vincent's East Laboratory	50 Medical Park Drive East, Birmingham, AL	

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	A validation survey was performed on May 18-19,2026, with the following standard level deficiencies cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of the laboratory's mean of the normal patient range (MNPT) study and interview with Technical Consultant #3, the laboratory failed to retain their questionnaire to determine if normal patients were used when the laboratory changed thromboplastin in 2025 with 1 of 1 reviewed lot changeovers for coagulation as evidenced by: 1. The laboratory could not provide documentation of their questionnaire to determine if normal patients were being used when the laboratory changed thromboplastin on August 14,2025. 2. In interview with the technical consultant #3 on 5-19-2026 at 1201, she confirmed that they ask their patient questions to make sure they are not on anti-coagulants but could not provide any documentation for the lot change in 2025. 3. The laboratory performs 20,967 prothrombin times test (PT) per year.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory 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 general

	laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing documents, and interview with Technical Consultant #2, the laboratory failed to review the effectiveness of corrective actions to resolve problems with the API Chemistry event#1, 2026 proficiency testing failure of Ionized calcium with 1 of 1 chemistry event reviewed as evidenced by: 1. In a review of the laboratory proficiency testing document titled, Proficiency Testing Exception Investigation Worksheet, for Istat performance date of 1/26/26 (Ionized Calcium), the laboratory received a 60% score. The laboratory determined the problem was: "delay in testing." There was no corrective action performed and documented. 2.In review of the laboratory proficiency testing document titled, Proficiency Testing Exception Investigation Worksheet, for Istat Sodium Chemistry 1st event 2026 the laboratory received a score of 80%. The laboratory determined the problen was: "delayed in testing" and their corrective action was "staff educated." The laboratory could not provided documentation on how they educated staff. 3.In interview with Technical Consultant (TC) #2 on 5-18-2026, the TC confirmed further investigation of PT failures must be performed and documented.
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 review of manufacturer's instructions, laboratories policy, patient test reports, and interview with Technical Consultant #3, the laboratory failed to follow the manufacturer's instructions and their own policy for specimen collection and receiving of ammonia (Abbott Architect) within the 15-minute time frame to analysis for 8 of 67 patients reviewed, March 1, 2026 to March 14,2026. Finding are: 1. A review of the manufacturer's instructions for Abbott Architect Ammonia stated, "Rapid separation of plasma from blood cells is critical for obtaining reliable results. Timing is especially critical for patients with liver diseases. Delays exceeding 15 minutes have been shown to increase ammonia concentration even at 0 degrees C." 2. A review of the policy Ammonia Ultra Plasma Abbott Architect stated, "Rapid separation of plasma from blood cells is critical for obtaining reliable results. Timing is especially critical for patients with liver diseases. Delays exceeding 15 minutes have been shown to increase ammonia concentration even at 0 degrees C." 3. In review of patient test reports, the following 8 of 67 patients were not within the 15-minute time frame according to the laboratory's proceedure. a. patient # 25-26-060-0090 collection time: 3/1/2026 at 1720 received: 3/1/2026 at 1747, 12 minutes after the 15-minute time frame. b. patient#25-26-0017 collection time: 3/14/2026 at 0500 received 3/14/2026 at 0609, 54 minutes after the 15 minute time frame. c. patient #25-26-06-0019 collection time: 3/3/2026 at 0334 received: 3/3/2026 at 0406, 17 minutes after the 15-minute time frame. d. patient #25-26-065-0015 collection time:3/6/2026

	at 0510 received: 3/6/2026 at 0537, 12 minutes after the 15-minute time frame. e. patient #25-26-067-0033 collection time: 03/08/2026 at 0642 received: 3/08/2026 at 0807, 1 hour 10 minutes after 15-minute time frame. f. patient # 25-26-072-0010 collection time: 03/13/2026 at 0106 received: 3/13/2026 at 0125, 4 minutes after 15-minutes time frame. g. patient# 25-26-0015 collection time: 3/13/2026 at 0500 received: 3/13/2026 at 0602, 47 minutes after 15-minutes time frame. h. patient #25-26-0007 collection time: 03/14/2026 at 0419 received: 3/14/2026 at 0542, 68 minutes after the 15-minutes time frame. 4.In interview with Technical Consultant #3 on 5-18-2026 at 1031 confirmed that the 8 patients collection and received time in the laboratory exceeded the 15-minute time frame for ammonias.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Vitamin B12 Test A. Based on review of the manufacturer's instructions, direct observations, and interview with Technical Consultant #2, the laboratory failed to follow manufacturer's instructions (Abbott Architect) for 1 of 1 centrifuge observed, for B12 chemistry preparations as evidenced by: 1.In review of the manufacturer's instructions pg. 4 of the package insert for B12 Abbott Architect stated, " To ensure consistence in results, specimens must be centrifuged using an appropriate tube to obtain > 100,000 g-minutes before testing it. For example: 10 minutes, 10,000xg Relative Centrifugal force (RCF) 20 minutes, 5000Xg RCF or 40 minutes 2500xg RCFs." 2. In direct observation on Thermo Scientific Megafuge 8 at 1320, (where chemistries specimens were centrifuged) the centrifuge was set at 3200xg RCF for 5 minutes. 3. In interview with Technical supervisor #2 on 5-18-2026 at 1321 confirmed that the centrifuge was not set as per manufacturer's instruction for B12. 4.The laboratory performs 2,469 B12s a year annually. RPR B.Based on review of manufacturer's instructions, review of rapid plasma reagin (RPR) quality control documents, patient reports, and interview with Technical consultant #2, the laboratory failed to follow manufacturer's temperature requirements when preparing reagents and patient samples for RPR testing with 2 of 2 months reviewed as evidenced by: 1. In review of the Arlington Scientific manufacturer's instructions on pg. 3 stated, "Allow all reagents and samples to warm to room temperature (20-30 degrees C) before use." 2. In review of the laboratory quality control documentation for December 2025 and January 2026, the following were outside of the 20-30 degrees C range when tested. a. December 1, 2025 temperature recorded as 19.5 degrees C. b. January 8, 2026 temperature recorded as 19.5 degrees C. c. January 9,2026 temperature recorded as 19.4 degrees C. 3.The following patients were tested when the temperature was outside of the range: a. patient #25-25-334-0074 tested on December 1, 2025. b. patient #21-25-330-00169 tested on December 1,2025. c. patient # 29-26-007-00078 tested on January 8 and 9th, 2026. d. patient #25-26-009-00336 tested on January 8 and 9th, 2026. e. patient #21-26-007-00257 tested on January 8 and 9th, 2026. 4. In interview with Technical Consultant #3 on 5-19-2026 at 1237, the TC confirmed that the room temperature was outside of the ranges on those days.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, direct observation, and interview with Technical consultant #2, the laboratory failed to monitor room temperature where supplies (blood tubes) were stored in the phlebotomy room two of two supplies reviewed. Finding include: 1. In review of the manufacturer's instructions for Becton Dickinson (BD) ethylenediaminetetraacetic acid (EDTA) tubes stated, "store at 4-25 degrees C." 2. During a tour of the laboratory at 1205 on 5-18-2026 the following EDTA tubes in the phlebotomy room were not temperature monitored: a. 19-BD EDTA 3.0ml lot #6047522 expiration date: 06-30-2027 b. 41- BD EDTA 4.0ml lot#5317320 expiration date: 03-20-2027 3. In interview with Technical consultant #2 on 5-18-2026 at 1206, TC confirmed that they did not monitor room temperature and they could not provide documentation for the last two years.