

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0893118	(X3) Date Survey Completed 01/09/2025
Name of Provider or Supplier Christus St Michael Laboratory	Street Address, City, State 2600 St Michael Drive, Texarkana, TX	
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	The laboratory was found to be out of compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a validation survey completed on 1/8 /2025. The following conditions were not met: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel;
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>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:</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory patient reports, and confirmed in interview, the laboratory failed to ensure access to patient test record on the Vitek 2 microbiology analyzer, used in the identification and susceptibilities of selected organisms, for records reviewed in February 2024. The findings included: 1. Review of the laboratory policy titled "Guidelines for Retention of Clinical Laboratory Records" stated the following: "For Laboratory Disciplines: Hematology, Coagulation, Urinalysis, Chemistry, Microbiology, Serology & Pathology. Item: Patient results, Log Books (w/ pt results), Test Requisitions, QC Records, Quality Management Records, Proficiency Testing Records, Associate Training and Competency Records. CAP Retention: 2 Years Christus Retention: 5 Years" 2. In an interview on 1/8/2025 at 14:45, in the supervisors' area, technical supervisor (TS) 3 stated the laboratory implemented a new Vitek 2 analyzer on June 24, 2024. Surveyor asked for the analytic record of the Vitek 2 susceptibility and or identification results for patient final reports reviewed in February 2024, on the previous analyzers software system, and none could be provided. 3. In an interview on 1/8/2025 at 16:15 hours, in the supervisor area, TS 3 confirmed the Vitek 2 patient analytic records for</p>

the identification and susceptibility of bacteria isolated from patients could not be accessed on the computer back up system the laboratory had in place.

D5431

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(2)

(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:

This STANDARD is not met as evidenced by:

Based upon observations, review of policies and procedures, manufacturer's instructions and interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for verifying the dispense volume of the needle used for delivering the carbon antigen when testing 1423 patient samples for RPR (Rapid Plasma Reagin) between January 1, 2024 and September 30, 2024. The findings included: 1. During a mock demonstration of the RPR antigen needle check by testing person 7 conducted January 8, 2025 at 2:58 PM, she used deionized water to dispense 0.5 ml. She said she should get 30 + 1 drops to be acceptable for use. 2. Review of the laboratory's own written procedure (approved by the laboratory director 02/09/2024) found on page 1 under the heading QUALITY CONTROL: " The accuracy of the needle used to dispense RPR antigen must be verified monthly, when a new needle is used, when control patterns cannot be reproduced, or when the antigen drop does not fall cleanly from the tip. Remove the needle from the RPR antigen vial and place it on the end of a 1 ml syringe. Fill the syringe with distilled water. Hold the syringe in a vertical position over the sink and count the number of drops delivered in 0.5 ml. The needle is considered satisfactory if 30 + 1 drops is obtained in 0.5 ml." 3. Review of the Sure-View Rapid Plasma Reagin (RPR)instructions for use (Rev. 09-2021) found on page 1 under the heading HANDLING AND PROCEDURAL NOTES: "1. In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for reagents or samples. 4. The needle should deliver 60 + 2 drops of antigen suspension per milliliter when held in a vertical position. To perform accuracy check on the needle, attach the needle to a 1 or 3 ml syringe. Fill the syringe with the antigen suspension and, holding the syringe in a vertical position, count the number of drops delivered in 0.5 ml. The needle is considered satisfactory if 30 + 1 drops are obtained in 0.5 ml." 4. Review of patient test records found the laboratory tested and reported results for 1423 patients tested for RPR between January 1, 2024 and September 30, 2024 as follows: January 2024 - 165 February 2024 - 180 March 2024 - 164 April 2024 - 137 May 2024 - 139 June 2024 - 142 July 2024 - 166 August 2024 - 180 September 2024 - 150 5. During interview of testing person 7 conducted January 8, 2025 at 2:58 PM, she confirmed the laboratory did not follow the manufacturer's instructions for verifying the dispensed volume of carbon antigen from the needle.

D5447

CONTROL PROCEDURES

CFR(s): 493.1256(d)(3)(i)(g)

(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;

This STANDARD is not met as evidenced by:
 Based on review of laboratory policy, Food and Drug Administration (FDA) in-vitro diagnostic device database, quality control and patient records, and interview with laboratory personnel, the laboratory failed to ensure two levels of quality control materials were performed each day of patient testing for 18 patients tested between June 14, 2024, and September 25, 2024. The findings included: 1. Based on review of the laboratory policy "Verify Now: PRU (PRU) Test Procedure (Plavix)", under the section Reagent Quality Control, stated the following: "1. The manufacturer recommends a Level 1 and Level 2 Quality Control procedures be run once each time a new lot or a new shipment of Test kits is received. 2. Level 1 and Level 2 Quality Control Test Devices must also be performed at the frequency specified. Please refer to the Quality Control section below for additional instructions." Under the section Quality Control Procedures, the policy stated the following: "Wet Quality Control. The Wet Quality Control (WQC) procedure must be performed whenever a program is suspected with the temperature indicator of a newly received lot of Test Devices, whenever a problem is suspected with the VerifyNow System, and as part of the laboratory quality control program. CSMHS Laboratory Policy dictates that West Quality Control (WQC) levels I and II, will also be performed on a monthly basis, upon receipt of a new lot or a new shipment of test devices, and may also be used in correlation and competency assessments." 2. Based on a review of the Food and Drug Administration (FDA) in-vitro diagnostic device database on 1/8/2025 at 12:26 pm, (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm>), the surveyor observed the VerifyNow PRU test has a moderate complexity rating for all assays except the VerifyNow Aspirin Assay, which is Waived complexity. 3. Based on a review of quality control and patient testing records from June 2024 to October 2024, the laboratory failed to run two levels of quality control material each day of patient testing on the following dates: June 2024 Two levels of quality control were performed on 6/6/2024. Patient testing on days without two levels of quality control: 6/14/2024 - MRN 102411399 6/21/2024 - MRN 100418917 6/25/2024 - MRN 102219669 July 2024 Two levels of quality control were performed on 7/11/2024. Patient testing on days without two levels of quality control: 7/4/2024 - MRN 101317991 7/5/2024 - MRN 103101748 7/31/2024 - MRN 100416670 August 2024 Two levels of quality control were performed on 8/12/2024. Patient testing on days without two levels of quality control: 8/2/2024 - MRN 100416670 8/14/2024 - MRN 101171520 8/20/2024 - MRN 100947961 8/22/2024 - MRN 100717992 8/23/2024 - MRN 100922281 8/29/2024 - MRN 101804295 September 2024 Two levels of quality control were performed on 9/11/2024. Patient testing on days without two levels of quality control: 9/13/2024 - MRN 101968508 9/13/2024 - MRN 101699307 9/13/2024 - MRN 101701400 9/22/2024 - MRN 100948209 9/25/2024 - MRN 100969222 9/25/2024 - MRN 100872938 4. In an interview at 13:56 hours on 01/08/2025, the Hematology Supervisor stated the lab believed this test system to be waived complexity and had not established an individualized quality control plan to reduce quality control frequency. The Hematology Supervisor stated the laboratory ran quality control as described in the laboratory policy, which was monthly and each new lot or shipment.

D5783

CORRECTIVE ACTIONS
 CFR(s): 493.1282(b)(2)

(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the

unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, quality control records, and interview with laboratory personnel, the laboratory failed to document all corrective actions taken when quality control values exceeded laboratory limits for nine quality control values for the fibrinogen assay between July 2024 and September 2024. The findings included: 1. Based on review of the laboratory policy "ACL TOP 750 LAS Coagulation Procedure", under QUALITY CONTROL, stated the following: "Follow established rules for QC (Quality Control) outliers and document accordingly in either Laboratory Communication Log and/or Analyzer QC log. Instrument will not run testing on patient's parameters, if QC fails. " 2. Based on a review of quality control records from July, August, and September 2024, the laboratory failed to document corrective actions taken when the following quality control values exceeded acceptability limits: Low Fibrinogen Control - July 2024 7/31/2024 at 06:37 hours - The value was -3.6 standard deviations below the expected mean. 7/31/2024 at 06:46 hours, the value was -3.7 standard deviations below the expected mean. 7/31/2024 at 07:16 hours - The value was -3.3 standard deviations below the expected mean. The low fibrinogen control was in-range at 10:28 hours on 7/31/2024. There was no documentation as to what steps were taken to correct the out-of-control assay on 7/31/24. Fibrinogen Normal Control - August 2024 8/10/2024 at 07:34 hours - The normal fibrinogen control is 4.2 standard deviations above the expected mean - Status: FAILED The quality control is within limits on 8/10/2024 at 09:15 hours. There was no documentation as to what steps were taken to correct the out-of-control assay on 8/10/24. 8/22/2024 at 06:45 hours - The normal fibrinogen control is 3.3 standard deviations above the expected mean - Status: FAILED The quality control is within limits on 8/22/2024 at 07:32 hours. There was no documentation as to what steps were taken to correct the out-of-control assay on 8/22/24. Low Fibrinogen Control - August 2024 8/29/2024 at 06:21 hours, the value was 2.2 standard deviations above the expected mean. This was the second value in a row that was greater than 2 standard deviations above the mean, making it a 2-2S failure. The QC Status was FAILED for this event. The low fibrinogen control was in-range at 08:05 hours on 08/29/2024. There was no documentation as to what steps were taken to correct the out-of-control assay on 08/29/24. Low Fibrinogen Control - September 2024 9/10/2024 at 06:37 hours - The low fibrinogen control was -3.5 standard deviations below the expected mean. The QC status was FAILED. 9/10/2024 at 06:46 hours, the low fibrinogen control was -2.6 standard deviations below the expected mean. The QC status was FAILED. The low fibrinogen control was within expected limits at 07:37 on 9/10/2024. There was no documentation as to what steps were taken to correct the out-of-control assay on 9/10/2024. Normal Fibrinogen Control - September 2024 09/18/2024 at 07:35 hours, the normal control was 3.5 standard deviations above the expected mean. The QC status was FAILED. The normal control was within expected limits at 07:49 hours on 9/18/2024. There was no documentation as to what steps were taken to correct the out-of-control assay on 9/18/2024. 3. In an interview at 14:27 hours on 01/08/2025, the Hematology Supervisor confirmed documentation of corrective actions taken for the values that exceeded acceptability limits were not present in the analyzer quality control log or the laboratory communication log for the values listed above.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, laboratory documents, microbiology worksheets, and confirmed in interview, the laboratory failed have a mechanism in place to ensure the identification of aerobic gram negative bacilli (rods), identified without the use of the Vitek 2 microbiology analyzer, included the appropriate biochemical reactions to support the identification of the bacteria reported for three of five patient reports reviewed in February 2024. The findings included: 1. Review of the laboratory microbiology policy titled "Aerobic Gram-Negative Bacilli" included the following instructions: "Procedure: Observe growth on MacConkey agar. A. Lactose fermenter (pink pigment) 1. Mucoïd growth: report GNR and set up Vitek GNID/N806 as indicated. 2. Growth not mucoïd: perform indole i. Indole positive a. If beta hemolytic: Perform oxidase a. Oxidase negative: report E. coli and set up a Vitek N806. b. Oxidase positive: report GNR and set up Vitek GNID/N806. b. If gamma hemolytic: perform PYR a. PYR negative: report E coli and set up Vitek N806 b. PYR positive: report GNR and set up Vitek GNID/N806. ii. Indole negative: report GNR and set up Vitek GNID/N806. Note that it is possible for E coli to be indole negative, however a vitek GNID will be required for identification of indole negative E coli. B. Non-lactose fermenter (clear, unpigmented) 1. Rapid grower, swarming on blood agar. This is a Proteus species. Report GNR and set up Vitek GNID/N806 ... 2. Rapid grower, no swarming on blood agar: perform oxidase. i. Oxidase positive, indole negative, flat growth, fruity or corn tortilla odor, typically beta hemolytic with a green/metallic sheen: report Pseudomonas aeruginosa and set up a Vitek N806. If oxidase positive but other parameters are questionable, report GNR and set up a Vitek GNID/N806. ii. Oxidase negative: report GNR and set up Vitek GNID/N806." 2. Review of five random urine cultures from February 2024 with aerobic gram-negative organisms identified included the following three patients with deviation from laboratory policy: Patient 101040053: Urine culture collected on 02/01/2024. A preliminary result of "Proteus species" was reported, instead of a preliminary report of GNR as policy instructs. Patient 102921097: Urine culture collected on 2/3/2024 A preliminary report as pseudomonas aeruginosa was provided. Review of the laboratory testing personnel worksheet did not include any biochemical reactions to support the identification, no Vitek GNID was performed. Patient 100323767: Urine Culture collected on 2/25/2024. A preliminary report for the following three organisms were resulted: ">= 100,000 CFU/mL Pseudomonas aeruginosa 50,000 - 100,000 CFU/mL Escherichia coli 50,000 - 100,000 CFU/mL Proteus spp." Review of the laboratory testing personnel work card included the following biochemical reactions to support the organism identification: Pseudomonas aeruginosa: Testing personnel indicated the following: Gram negative rod, non-lactose fermenter, oxidase negative. Laboratory policy states a that a GNR, non-lactose fermenter, that is oxidase negative indicates a preliminary result of "GNR" and a setup of Vitek GNID for the identification. No Vitek GNID was performed. Escherichia coli: Testing personnel indicated the following: Gram negative rod, non-lactose fermenter, oxidase positive, indole positive. Laboratory policy states that a GNR, non-lactose fermenter, that is oxidase positive and indole positive indicates a preliminary result of GNR and the setup of a Vitek GNID for the identification. No Vitek GNID was performed. Proteus spp: Testing personnel indicated the following: Gram

negative rod, non-lactose fermenter on MAC; TSA swarming, indole negative. Laboratory policy indicates a preliminary result of GNR and the setup of a Vitek GNID for identification. 3. In an interview on 1/8/2025 at 14:05 hours, in the supervisor area, general supervisor (GS) 1 confirmed that the laboratory did not have a mechanism in place to identify and correct for errors in laboratory personnel workups for bacterial identification without the use of the Vitek. Key: GNID - Gram Negative Identification GN - Gram Negative spp - species CFU/mL - colony forming units per milliliter PYR - detection of pyrolydonyl-aryl-amidase activity MAC - MacConkey agar TSA - Tryptic Soy Agar

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on review of laboratory personnel records, laboratory policy, and confirmed in interview, the laboratory failed to ensure seven of seven testing personnel met the qualifications in 493.1243(b)(6)(i)(ii) to perform moderate complexity testing. Refer to D6066.

D6066

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(4)(ii)

(b)(6)(ii) Have documentation of laboratory training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has- (b)(6)(ii)(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation, and storage of specimens; (b)(6)(ii)(B) The skills required for implementing all standard laboratory procedures; (b)(6)(ii)(C) The skills required for performing each test method and for proper instrument use; (b)(6)(ii)(D) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(6)(ii)(E) A working knowledge of reagent stability and storage; (b)(6)(ii)(F) The skills required to implement the quality control policies and procedures of the laboratory; (b)(6)(ii)(G) An awareness of the factors that influence test results; and (b)(6)(ii)(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory test menu, the laboratory provided Centers for Medicare and Medicaid (CMS) personnel form 209, laboratory personnel records, laboratory policy, and confirmed in interview, the laboratory failed to ensure documentation of training appropriate for testing patient before analyzing patient specimens for seven of seven "non-laboratory testing personnel" qualified at 493.1243(b)(6)(i) for point of care (POC) testing. The findings included: 1. Review of the laboratory test menu included the following two moderate complexity testing being performed by "non-laboratory testing personnel" for point of care (POC) patient testing: iSTAT Chem8+ cartridge iSTAT CG8+ cartridge 2. Review of the laboratory

provided CMS personnel Form 209 included the following sampling of testing personnel (TP) qualified with under 493.1243(b)(6)(i) with a high school level education: TP 37 TP 38 TP 42 TP 43 TP 48 TP 55 TP 65 2. Review of the following two laboratory policies did not include information for the documentation of training for personnel qualified for moderate complexity testing under 493.1243(b)(6)(i), high school diploma: Competency Assessments Quality Management Policy 3. Surveyor asked for documentation of training for the above testing personnel, and none was provided. In an interview on 1/7/2025 at 14:35 hours, in the supervisor's area, technical consultant (TC) 1 confirmed that the laboratory did not have documentation of training for the above testing personnel who were performing patient testing.