

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0488596	(X3) Date Survey Completed 05/07/2025
Name of Provider or Supplier Hillcrest Medical Centers	Street Address, City, State 2201 Macarthur Suite 30, Waco, 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	Based on an announced validation survey, the laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based upon observations, review of policies and procedures and interview of facility personnel, the laboratory failed to have written procedures for the collection, storage and handling and transportation of Bacteriology, Hematology, Chemistry, and Urinalysis specimens submitted by outside providers for testing in 2024 and 2025. The findings included: 1. Observations made in the laboratory on May 5, 2025 at 10:32 AM found the laboratory received specimens from outside sources via courier. The specimens were transported from the vehicle to the laboratory in a compartmentalized cooler. 2. Review of the laboratory's own written policy titled Collection of Blood by Venipuncture (BSWH.LAB.PHL.003.R_V5) found on page 7 under the heading Specimen Collection Notes: "Some specimens may require special collection instructions, refer to Collection Manual." Review of the notebook provided as the collection manual found no instructions to the referring provider for the collection, storage, handling and transportation of specimens submitted for testing. 3. During</p>

interview of the Technical Consultant conducted May 6, 2025 at 12:32 PM, she confirmed the laboratory did not have instructions available to outside clients for the collection, storage, handling and transportation of specimens submitted for testing.

D5441

CONTROL PROCEDURES
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance.

This STANDARD is not met as evidenced by:

Based upon observations, review of policies and procedures, manufacturer's instructions, quality control records and interview of facility personnel, the laboratory failed to establish a quality control procedure to ensure that negative and positive quality control materials were tested on each of the two Solana analyzers used for testing patient 7935 specimens for GAS (Group A Strep) and 28 specimens for Influenza A+B Between March and December 2024. The findings included: 1. Observations made in the laboratory on May 6, 2025 found the laboratory used two Solana instruments for testing patient specimens for GAS and Influenza A+B. Serial numbers for the two analyzers were 17020983 and 16020534. 2. Review of the Solana GAS and Influenza A+B Instructions for use found under the heading Quality Control: "It is recommended that the reactivity of each new lot and each new shipment of the Solana GAS and Influenza A+B Assays be verified on receipt and before use. External control tests should be performed thereafter in accordance with appropriate federal, state and local guidelines." 3. Review of the Solana quality control records for 2024 found the laboratory performed quality control testing in 2024 as follows: GAS: 02/26/2024 - lot 245905 exp. 11/6/2025 (new lot) 03/15/2024 - lot 247158 exp. 12/7/2025 (new lot) 03/21/2024 - lot 247158 exp. 12/7/2025 (new shipment) 04/04/2024 - lot 247158 exp. 12/7/2025 04/22/2024 - lot 247158 exp. 12/7/2025 (new shipment) 05/10/2024 - lot 247530 exp. 12/17/2025 (new lot) 06/05/2024 - lot 247158 exp. 12/7/2025 (new lot) 06/18/2024 - lot 247530 exp. 12/7/2025 (new lot) 07/02/2024 - lot 243157 exp. 9/18/2025 08/07/2024 - lot 247158 exp. 12/7/2025 09/03/2024 - lot 245905 exp. 11/6/2025 09/13/2024 - lot 252979 exp. 04/01/2026 09/24/2024 - lot 245905 exp. 11/6/2025 10/15/2024 - lot 247158 exp. 11/6/2025 10/22/2024 - lot 245905 exp. 11/6/2025 11/01/2024 - lot 247158 exp. 11/6/2025 11/06/2024 - lot 245905 exp. 11/6/2025 11/13/2024 - lot 248937 exp. 1/11/2026 (new lot) 11/19/2024 - lot 243157 exp. 9/18/2025 11/21/2024 - lot 252152 exp. 3/19/2026 12/04/2024 - lot 252152 exp. 3/19/2026 (new shipment) 12/20/2024 - lot 252152 exp. 3/19/2026 12/24/2024 - lot 248937 exp. 01/11/2026 Influenza A+B: 03/20/2024 - lot 245270 expiration 10/24/2025 (30 days) 03/26/2024 - lot 245270 expiration 10/24/2025 (Student) 05/03/2024 - lot 245270 expiration 10/24/2025 (QC due) 06/12/2024 - lot 245270 expiration 10/24/2025 (QC due) 07/16/2024 - lot 245270 expiration 10/24/2025 (30/Student) 08/15/2024 - lot 245270 expiration 10/24/2025 09/16/2024 - lot 245270 expiration 10/24/2025 11/12/2024 - lot 245270 expiration 10/24/2025 (30 days) 12/17/2024 - lot 245270 expiration 10/24/2025 (new kit) 4. Review of patient

test records found the laboratory tested and reported results for 7935 GAS and 28 Influenza A+B between March 1, 2024 and December 31, 2024. 4. During interview of the Technical Consultant conducted May 6, 2025 at 3:43 PM, she confirmed quality control specimens were not tested on both Solana analyzers with each new lot, shipment and every 30 days for GAS and Influenza A+B and there was no means to determine what analyzer was used for quality control testing on the dates performed.