

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0278349	<b>(X3) Date Survey Completed</b>  05/07/2025
<b>Name of Provider or Supplier</b>  Homestead Hospital Laboratory	<b>Street Address, City, State</b>  975 Baptist Way, Homestead, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An unannounced CLIA complaint survey was conducted at HOMESTEAD HOSPITAL LABORATORY from 05/05/2025 to 05/07/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D2000 CFR 493.801 Condition: Enrollment And Testing of Samples. D6000 CFR 493.1403 Condition: Moderate Complexity Laboratory Director.
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> 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 instrument printouts review of one out of one event of Proficiency Testing (PT) and staff interview, the laboratory (Lab B) tested two American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency samples (S1 and S2) from another laboratory (Lab A) (that has its own Clinical Laboratory Improvement Amendments Certificate of Compliance) before the PT testing results due date of 02/23/2024. Refer to D2013.</p>
<b>D2013</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(4)</p>

(b)(5) The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

Based on review of procedure manual, test menu, Proficiency Testing (PT) documents and staff interview, the laboratory (Lab B) tested two of two American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) samples (S1 and S2) for the first event 2024 from another laboratory (Lab A) that has its own Clinical Laboratory Improvement Amendments Certificate of Compliance. Findings included: 1-Review of the test menu for Lab B revealed that the laboratory performs High Sensitivity C Reactive Protein C (HsCRP) on the analyzer Siemens Vista 500. 2-Based on direct observation on 05/05/2025 at 11:15 AM, the laboratory has two analyzers for the Chemistry area with Serial Number DV370176 (Vista1) and DV370179 (Vista2). 3-Review of laboratory PT records, revealed that Lab B is enrolled in College of American Pathologist (CAP) PT and date first event of 2024 (03/30/2024) for Siemens Vista 500 instrument prints out High Sensitivity C Reactive Protein (HsCRP). 4-Review of instrument printouts found at Lab A revealed that two of two PT samples (S1 and S2) for the first event 2024 for American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) were performed on Lab B analyzer with Serial Number DV370176 under "Admin" user with no Initials on the date tested (02/21/2024). . 5-Review of the analyzer at Lab B for the day of PT testing revealed that the analyzer only retained samples for two days and duplicate results printouts for the PT events could NOT be retrieved on site at Lab B. 6-During an interview on 05/07/2025 at 11:20 AM, the Chemistry Supervisor stated that for HsCRP testing of PT samples, they do not use the Autoverification System; the laboratory manually enters PT orders into the instrument and retains a copy of the analyzer result prints out; and that they track which analyst performed testing based on their Laboratory Tech Schedule.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and staff interview, the Laboratory Director failed to

effectively oversee the laboratory and to ensure this laboratory (Lab B) did not test samples of Proficiency Testing from another laboratory (Lab A) (that has its own Clinical Laboratory Improvement Amendments Certificate of Compliance) on the Siemens Vista 500 for two of two samples before the PT testing results due date of 02/23/2024. Refer to D6016.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(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 Siemens Vista 500 instrument printouts review of one out of one event of Proficiency Testing (PT) and staff interview, the Laboratory Director (LD) failed to ensure PT samples were tested as required by Subpart H. The laboratory (Lab B) failed to stop testing two American Association of Bioanalysts Medical Laboratory Evaluation (AAB-MLE) proficiency samples (S1 and S2) from another laboratory (Lab A) (that has its own Clinical Laboratory Improvement Amendments Certificate of Compliance) on 02/21/2024 and the submission date for AAB-MLE 1st event was 02/23/2024 and failed to report it. Refer to D2013.