

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0489693	<b>(X3) Date Survey Completed</b> 03/06/2025
<b>Name of Provider or Supplier</b> Medical Clinic Of Houston/Laboratory	<b>Street Address, City, State</b> 1701 Sunset Boulevard, Houston, TX	
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>	A validation survey was completed on 02/06/2025. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the manufacturer's instructions, the laboratory's ACL Elite maintenance logs from January 2024 to December 2024, CMS 116 applications, and confirmed in an interview, the laboratory failed to have documentation of monthly maintenance for 12 of 12 months reviewed for ACL Elite Coagulation analyzer. The findings were: 1. Review of the manufacturer's instruction titled ACL ELITE/ELITE PRO Quick Reference Guide (Revision 0 (August 2014) under ACL ELITE and ELITE PRO Maintenance Procedure revealed "Monthly: 1 Clean the air filter with vacuum or rinse with water (dry filter before placing back in unit)." 2. Review of the laboratory's ACL Elite (SN: 14071711) maintenance logs from January 2024 to December 2024 revealed no documentation of monthly maintenance for 12 of 12 months reviewed. 3. Review of the laboratory's CMS 116 application revealed the annual volume of hematology was 70,642. 4. An interview on 03/05/2025 at 2:15 pm in a conference room, the lab manager and the general supervisor (indicated on the CMS 209 form) confirmed the above findings. Key: CMS=Center for Medicare and Medicaid Services</p>
<b>D5447</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p>

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

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's IQCP Lists, QC records from 10/01/2024 to 12/10/2024, patient results, and confirmed in an interview, the laboratory failed to perform two quantitative QC materials with different concentrations prior to patient testing for 45 of 51 days reviewed on Verify Now for Plavix resistance coagulation tests. The findings were: 1. Review of the laboratory's IQCP list revealed Plavix resistance coagulation test did not have IQCP established. 2. Review of the laboratory's QC records for Plavix resistance coagulation test from 10/01/2024 to 12/10/2024 revealed the laboratory failed to perform two quantitative QC materials with different concentrations prior to patient testing for 45 of 51 days reviewed on Verify Now (SN: 52639). 10/01/2024 10/02/2024 10/03/2024 10/04/2025 10/07/2024 10/08/2024 10/09/2024 10/10/2024 10/11/2024 10/14/2024 10/15/2024 10/17/2024 10/18/2024 10/21/2024 10/22/2024 10/23/2024 10/24/2024 10/25/2024 10/28/2024 10/29/2024 10/30/2024 10/31/2024 11/01/2024 11/04/2024 11/05/2024 11/06/2024 11/07/2024 11/08/2024 11/12/2024 11/13/2024 11/14/2024 11/15/2024 11/18/2024 11/19/2024 11/20/2024 11/21/2024 11/22/2024 11/25/2024 11/26/2024 12/02/2024 12/03/2024 12/04/2024 12/05/2024 12/06/2024 12/09/2024 12/10/2024 3. Review of the patient results for above dates revealed 148 Plavix Resistance Coagulation tests were performed. Refer to Plavix Tests Patient List. 4. An interview on 03/06/2025 at 10:50 am in the lab, the lab manager and the general supervisor (indicated on the CMS 209 form) confirmed the above findings. Key: IQCP=Individualized Quality Control Plan QC=Quality Control CMS= Center for Medicare and Medicaid Services

**D5545**

**HEMATOLOGY**

CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's coagulation reagent rollover study completed on 09/13/2024 and confirmed in an interview, the laboratory failed to ensure 18 of 18 normal patient study donors for new lots of Prothrombin Time reagent, Recombiplastin 2G, had medication questionnaire documentation for ACL Elite Coagulation Analyzer. The findings were: 1. Review of the laboratory's coagulation reagent rollover study completed on 09/13/2024 for Prothrombin time revealed no medication questionnaire documentation for 18 of 18 normal patient study donors for ACL Elite Coagulation Analyzer (SN: 14071711). 09/10/2024 SID: N1-SJ 09/10/2024 SID: N2-BK 09/10/2024 SID: N5-JV 09/10/2024 SID: N6-CU 09/10/2024 SID: N7-TP 09/10/2024 SID: N8-MV 09/10/2024 SID: N9 09/10/2024 SID: N10 09/10/2024 SID: N11 09/10/2024 SID: N12 09/10/2024 SID: N13 09/10/2024 SID: N14 09/10/2024 SID: N15 09/10/2024 SID: N16 09/10/2024 SID: N17 09/10/2024 SID: N18 09/10/2024 SID: N19 09/10/2024 SID: N20 2. An interview on 03/05/2025 at 2:15 pm in a conference room, the lab manager and the general supervisor (indicated on the CMS 209 form) confirmed the above findings.