Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2220613	06/02/2023
Name of Provider or Supplier	**Street Address, City, State**	
Kelsey-Seybold Clinic / North Houston Campus	15655 Cypress Woods Medical Drive, Houston, 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 out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found in compliance with applicable CLIA conditions, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor's observations in the laboratory, review of instrument test printouts, patient test records, laboratory's policies and staff interview, the laboratory failed to follow specimen collection requirements for collection volume for 8 of 27 samples tested for coagulation factors on May 30 and 31, 2023. Findings included: 1. Surveyor's observations on 06/01/2023 at 0920 hours in the laboratory revealed the

	following 8 of 27 samples collected in blue top (sodium citrate) tubes tested on May 30 and 31, 2023, stores in a refrigerator(at 2-8 C), had collection volumes 1/4 to 1/3 below the minimum required level (indicated by a line on the tube): Sample: 1001229833 Tested on: 05/30/2023 Tested for: PT (prothrombin time) Tube sample level: 3/4 full Sample: 1001232677 Tested on: 05/30/2023 Tested for: PT Tube sample level: 3/4 full Sample: 1001242535 Tested on: 05/31/2023 Tested for: PT Tube sample level: 3/4 full Sample: 1001242546 Tested on: 05/31/2023 Tested for: PT Tube sample level: 3/4 full Sample: 1001242545 Tested on: 05/31/2023 Tested for: PT Tube sample level: 2/3 full Sample: 1001242552 Tested on: 05/31/2023 Tested for: PT Tube sample level: 3/4 full Sample: 1001242536 Tested on: 05/31 /2023 Tested for: PT Tube sample level: 3/4 full Sample: 1001242555 Tested on: 05 /31/2023 Tested for: PT Tube sample level: 2/3 full 2. Review of the Sysmex CS-2500 System Quick Reference Guide (Version 01-70) revealed: "Preanalytical sample integrity Hemolysis, lipemia, tube volume check ... Vol Sample tube fill out of range" Note: Preanalytic sample integrity flags displayed under "Sample Info. (information)" on the instrument test printouts. 3. Review of laboratory's instrument test printouts for the above samples revealed all the above samples had the "Vol" flag displayed. 4. Review of laboratory's patient test records for the above samples revealed the obtained results flagged with the "Vol" indicator under sample information were reported to provider. 5. Review of laboratory's policy Prothrombin Time and Activated Partial Thromboplastin Time (document LH-013.2, effective December 2022) revealed: "Collection tubes must be filled to completion to ensure a proper blood to anticoagulant ratio." 6. In an interview on 06/01/2023 at 1050 in the conference room, the laboratory's Technical Consultant (as indicated on submitted form CMS 209), after review of the data, confirmed the findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on surveyor's observations in the laboratory, review of manufacturer's quick reference guide for the hemostasis analyzer, laboratory's instrument printouts and patient test records, laboratory's policies/procedures and staff interview, the laboratory's quality assurance failed to identify and correct issues with collection of required sample volume for hemostasis testing. Refer to D5311.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on review of laboratory's quality control (QC) records, policies/procedures and staff interview, the laboratory failed to follow its own policy for verification of

	new lots of controls for 3 of 3 new hematology controls implemented in February 2023. Findings included: Review of laboratory's QC records for the Sysmex XN 1000 hematology analyzer from January to March 2023, revealed the following new lots of controls were placed in use on 02/13/2023: XN Check L1: Level 1 Lot: 30331101 Expiration: 2023-04-23 XN Check L2: Level 2 Lot: 30331102 Expiration: 2023-04-23 XN Check L3: Level 3 Lot: 30331103 Expiration: 2023-04-23 2. Further review of the QC records revealed the new lot establishment studies contained 10 points for each of the 3 levels of controls, tested over a span of 7 days (02/13/2023 to 02/20 /2023). 3. Review of laboratory's policy "Quality Control and Corrective Action (document LQ-002.1, effective December 2022) revealed: "5.1 Quantitative QC Procedure 5.2 Establish statistical quality control on a new instrument or on new lots of control material. The different levels of control material must be analyzed for at least ten (10) days, collecting a total of twenty (20) QC data points." 4. In an interview on 06/01/2023 at 1410 hours in the training room, the laboratory's Technical Consultant (as indicated on submitted for CMS 209), after review of the data, confirmed the findings. B. Based on surveyor's observations in the laboratory, review of laboratory's policies/procedures and staff interview, the laboratory failed to follow its own policies/procedures for calibration of pipettes for 4 of 9 pipettes in use. Findings included: 1. Surveyor's observations on 06/01/2023 at 0940 hours in the laboratory revealed the following 4 of 9 pipettes in use had expired calibration dates: Pipette serial number: 811520 Volume: 50 uL (microliters) Calibration expiration date: 03/31/2023 Pipette serial number: 811156 Volume:100 uL Calibration expiration date: 03/31/2023 Pipette serial number: 810674 Volume: 200 uL Calibration expiration date: 02/02/2023 Pipette serial number: 811730 Volume: 500 uL Calibration expiration date: 03/17/2023 2. Review of the laboratory's the policy "Ancillary Equipment Maintenance and Use" (document LG-002.1, effective December 2022) revealed: "5.4.1 Pipettes are to be calibrated annually." 3. In an interview on 06/01/2023 at 1050 hours in the training room, the laboratory's Technical Consultant (as indicated on submitted for CMS 209), after review of the data, confirmed the findings.