Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2219591	**(X3) Date Survey Completed** 05/16/2023
Name of Provider or Supplier Kelsey-Seybold Clinic / Main Campus Lab	**Street Address, City, State** 2727 West Holcombe Blvd, 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	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.
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: Based on review of laboratory's policies/procedures, review of random patient test records and final Laboratory Information System (LIS) reports, and staff interview, the laboratory failed to follow its own policy for calculating semiquantitative indicators for presence of atypical cell morphologies for 3 of 25 reviewed patient records. Findings included: 1. Review of the laboratory's policy "Manual Differential Criteria" (document LH-011.1, effective December 2022) revealed: "6.6.2.Evaluate and report RBC (red blood cell) morphology using the chart below. Percentages indicate findings per field. 0-2% Trace 2-9% 1+ 10-25% 2+ >25% 3+" Legend: % - Percent 2. Review of random patient test records and final LIS reports revealed the following Manual Differential annotations by technologists, and corresponding final reports: Sample No (number): 1000611773 Patient ID (Identification): 93553790 Tested: 03/06/2023 15:18 Manual Differential LIS MICRO 2+ Microcytes 2+ HYPO 2+ Hypochromia 2+ POLY 1+ Polychromasia 1+ OVAL 2+ Ovalocytes 2+ Teardrop 1+ Teardrop Cells 1+ Schistocytes 1+ Schistocytes 1+ Anisocytosis 2+ Anisocytosis 2+ There was no evidence of technologist's calculations of cell percent per field to establish semiquantitative (Trace, 1+, 2+, 3+) designation. The final LIS report did not define the meaning of semiquantitative designation. Sample No (number):

	1000639660 Patient ID (Identification): 07729049 Tested: 03/09/2023 10:59 Manual Diff LIS MICRO 2+ Microcytes 2+ HYPO 2+ Hypochromia 2+ OVAL 1+ Ovalocytes 1+ Teardrop Trace Teardrop Cells Trace Rouleaux 1+ Rouleaux 1+ Anisocytosis 2+ Anisocytosis 2+ There was no evidence of technologist's calculations of cell percent per field to establish semiquantitative (Trace, 1+, 2+, 3+) designation. The final LIS report did not define the meaning of semiquantitative designation. Sample No (number): 1000868058 Patient ID (Identification): 22354534 Tested: 04/11 /2023 04:37 Manual Diff LIS Smud 1+ Smudge Cells 1+ per 100 WBCs Note: The policy did not define semiquantitative designation of white blood cells (WBCs), or how to calculate it. The final LIS report did not define the meaning of semiquantitative designation. 3. In an interview on 05/15/2023 at 1605 hours in the conference room, the laboratory's Technical Consultant (as evident on submitted form CMS 209), after review of the data, confirmed the findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the manufacturer's package inserts, and confirmed in an interview, the laboratory failed to document revised expiration dates on thawed opened QC for seven of 10 lot numbers in use for two of two Ortho Vitros 5600 chemistry analyzers. The findings were: 1. Review of the manufacturer's package insert titled Liquid Assayed Multiqual Level 1, 2, and 3 (English. 2022-02. 5351-00S) under STORAGE and STABILITY revealed, "Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8C, this product will be stable as follows: -All Analytes: 14 days Except -Alkaline Phosphate, AST/SGOT, Bilirubin (Neonatal) and Bilirubin (Total): 9 days -Bilirubin (Direct), Cholesterol (HDL), Cholinesterase, Creatine Kinase (CK), Phosphorus, and Triglycerides: 7 days." 2. Review of the manufacturer's package insert titled Liquichek Immunoassay Plus Control Level 1, 2, and 3 (Enligsh. 2023-02. 4203-00S) under STORAGE and STABILITY revealed, "Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8C, this product will be stable as follows: -All Analytes: 14 days" 3. Review of the manufacturer's package insert titled Liquichek Cardiac Markers Plus Control Level 1, 2, and 3 (English. 2021-06.5523-00S) under STORAGE and STABILITY revealed, "Thawed Opened: Once thawed, opened, and stored tightly capped at 2 to 8C, this product will be stable as follows: -N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) and B-type Natriuretic Peptide (BNP): 5 days." 4. Direct observation of the surveyor on 5/16/2023 at 11:00 am in the laboratory revealed no revised expiration dates documented on the thawed opened QC for seven of 10 lot numbers in use. BioRad Liquid Assayed Multiqual Level 1 Lot#: 45931 Original Exp. 2024-07-31 Opened date: 5/16/23 Level 3 Lot#: 45933 Original Exp. 2024-07-31 Opened date: 5/16/23 BioRad Liquichek Immunoassay Plus Control Level 1 Lot#: 85321 Original Exp. 2024-05-31 Opened date: 5/12/23 Level 2 Lot#: 85322 Original Exp. 2024-05-31 Opened date: 5/12/23 Level 3 Lot#: 85323 Original Exp. 2024-05-31 Opened date: 5/12/23 BioRad Liquichek Cardiac Markers Plus Control Level 1 Lot#: 87841 Original Exp. 2024-09-30 Level 3 Lot#: 87843 Original

	Exp. 2024-09-30 Opened date: 5/16/23 5. An interview with the clinical compliance manager on 5/16/2023 at 11:11 am in a conference room confirmed the above findings Key: QC=Quality Control
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for use for the laboratory's ASI RPR Card Test for Syphilis, laboratory's quality control records from December 12, 2022, to May 15, 2023, patient test records and staff interview, the laboratory failed to document manufacturer required end of shift ASI RPR Card Test needle cleaning each day of use for the five months the test was in use. Findings included: 1. Review of manufacturer's instructions for use for the laboratory's ASI RPR Card Test for Syphilis (document 6004-900 CLSI, revision 03/17) revealed: "HANDLING AND PROCEDURAL NOTES 6.1 In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed." And, "6.3 The needle assembly must be thoroughly washed in distilled or deionized water and air dried after each shift." 2. Review of laboratory's ASI RPR Card Test quality control records from December 12, 2022, to May 15, 2023, revealed the laboratory did not document end of shift needle cleaning. 3. Review of the laboratory's patient test records from December 12, 2022 to May 15, 2023 revealed the laboratory performed 1,372 ASI RPR Card Tests within the five month testing interval. Note: The test was implemented on December 12, 2022. 4. In an interview on 05/16/2023 at 1405 hours in the conference room, the laboratory's Technical Consultant (as evident on submitted form CMS 209), after review of the data, confirmed the findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's equipment maintenance logs from December 12, 2022, to May 15, 2023, laboratory's policies/procedures and staff interview, the laboratory failed to document laboratory required maintenance for Sysmex XN-1000 hematology analyzer 10 times within the reviewed five-month period. Findings included: 1. Review of the laboratory's Sysmex XN-1000 Hematology Analyzer (SN 80665) maintenance logs for December 12, 2022, to May 15, 2023, revealed the laboratory failed to document required maintenance as follows: No documentation of "Daily Cleaning CELLCLEAN AUTO" on: 05/01/2023 05/02/2023 05/03/2023 05/04

/2023 05/05/2023 05/09/2023 05/10/2023 05/11/2023 05/15/2023 No documentation of "Daily Cleaning CELLCLEAN AUTO" and "WEEKLY SHUT DOWN: XN 1000 IPU" on: 05/08/2023 2. Review of laboratory's policy/procedure for the Sysmex XN-1000 Hematology Analyzer operation (document LH-004.1, effective December 2022) revealed: "7.3 Maintenance 7.3.1. XN 1000 - performed daily 7.3.1.1. CELLCLEAN AUTO..." 3. In an interview on 05/15/2023 at 1135 hours in the conference room, the laboratory's Technical Consultant (as evident on submitted form CMS 209), after review of the data, confirmed the findings. B. Based on review of the laboratory's equipment maintenance logs from December 12, 2022, to May 15, 2023, laboratory's policies/procedures and staff interview, the laboratory failed to document laboratory required maintenance for Sysmex XN-430 hematology analyzer 48 times within the reviewed five month period. Findings included: 1. Review of the laboratory's Sysmex XN-430 Hematology Analyzer (SN 11684) maintenance logs for December 12, 2022, to May 15, 2023, revealed the laboratory failed to document required maintenance as follows: No documentation of "VERIFY XB DATA AFTER SHUTDOWN" on: 02/02/2023 02/03/2023 02/06/2023 02/07/2023 02/08/2023 02/09 /2023 02/10/2023 02/13/2023 02/14/2023 02/15/2023 02/16/2023 02/17/2023 02/20 /2023 02/21/2023 02/22/2023 02/23/2023 02/24/2023 02/27/2023 02/28/2023 03/07 /2023 03/08/2023 03/09/2023 03/10/2023 03/13/2023 03/14/2023 03/15/2023 03/16 /2023 03/20/2023 03/21/2023 03/22/2023 03/23/2023 03/24/2023 No documentation of "PLACE IN SAMPLE RACK PRESS START" on: 04/05/2023 04/10/2023 04/11 /2023 04/12/2023 04/13/2023 04/14/2023 04/21/2023 No documentation of "Daily Cleaning CELLCLEAN AUTO" on: 05/02/2023 05/03/2023 05/04/2023 05/05/2023 05/08/2023 05/09/2023 05/10/2023 05/11/2023 No documentation of "WEEKLY SHUT DOWN: XN 1000 IPU" on: 05/05/2023 2. Review of the laboratory's policy /procedure for the Sysmex XN-430 Hematology Analyzer operation (document LH-003.1, effective December 2022) revealed the policy maintenance steps did not reflect the maintenance log's documentation rubrics/requirements. The filled maintenance logs could not be reconciled with the policy in regard to task performance or frequency. The policy stated: "7.4 Maintenance 7.4.1 XN-450/XN-430 Shutdown - performed daily ... 5.4.1.5.2 IPU will automatically shut off..." And, "7.4.2 XN-450 /XN-430 Routine Cleaning - performed weekly CELLCLEAN AUTO is used to shut down the entire system." The policy did not mention verification of XB DATA after shutdown. 3. In an interview on 05/15/2023 at 1215 hours in the conference room, the laboratory's General Supervisor (as evident on submitted form CMS 209), stated that the correct maintenance log/form was used, and confirmed the findings. She also confirmed that the maintenance log/form did not reflect the policy. C. Based on review of the laboratory's equipment maintenance logs from December 12, 2022, to May 15, 2023, laboratory's policies/procedures and staff interview, the laboratory failed to document laboratory required maintenance for Sysmex UN-2000 Automated Urinalysis analyzer 6 times within the reviewed five month period. Findings included: 1. Review of the laboratory's Sysmex UN-2000 Automated Urinalysis Analyzer (SN 003594) maintenance logs for December 12, 2022, to May 15, 2023, revealed the laboratory failed to document required maintenance as follows: No documentation of "DAILY MAINTENANCE Perform Shutdown" on: 12/22/2022 12/23/2022 12/27 /2022 12/28/2022 12/29/2022 12/30/2022 2. Review of the laboratory's policy /procedure for the Sysmex UN-2000 Automated Urinalysis Analyzer operation (document LU-002.1, effective December 2022) revealed: "10. MAINTENANCE 10.1 Daily Maintenance 10.1.1. Shutdown entire system." 3. In an interview on 05/16 /2023 at 0945 hours in the conference room, the laboratory's Technical Consultant (as evident on submitted form CMS 209), after review of the data, confirmed the findings. D. Based on review of the laboratory's equipment maintenance logs from April 1 to May 15, 2023, review of laboratory's policies/procedures and staff interview, the

	laboratory failed to document laboratory required maintenance for Hematek Slide Stainer 9 times within the reviewed one and half month period. Findings included: 1. Review of the laboratory's Hematek Slide Stainer (Serial Number [SN] 372410) maintenance logs for April 1 to May 15, 2023, revealed the laboratory failed to document maintenance as follows: No documentation of "END OF SHIFT" ; "CLEAN STYLUS"; "CLEAN PLATEN DRAIN HOLE";"EMPTY WASTE RINCE W/H2O" on: 05/02/2023 05/03/2023 05/04/2023 05/05/2023 05/08/2023 05/09/2023 05/10/2023 05/11/2023 2. Review of laboratory's policy/procedure Hematek Slide Stainer (document LH-020.1, effective April 2023) revealed: "8.2 Daily Cleaning 8.2.1 Clean the platen ...8.2.3 Empty the waste tank" 3. In an interview on 05/15/2023 at 1105 hours in the conference room, the laboratory's Technical Consultant (as evident on submitted form CMS 209), after review of the data, confirmed the findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the laboratory's records in March 2023, patient results, and confirmed in an interview, the laboratory failed to perform two quantitative QC materials with different concentrations prior to patient testing on one of two Ortho Vitros 5600 chemistry analyzers for two of six days reviewed. The findings were: 1. Reviewed of the laboratory's records in March 2023 revealed the following dates did not have documentation of two quantitative QC materials with different concentrations prior to patient testing on one of two Ortho Vitros 5600 chemistry analyzers for two of six days reviewed. Ortho Vitros 5600 chemistry analyzer, SN: J56004146 3/10/23 From 11:06 am to 3:30 pm 3/23/23 From 1:21 pm to 3:45 pm 2. Reviewed of the laboratory's patient results for the dates above revealed 24 patients had chemistry testing performed on Ortho Vitros 5600 chemistry analyzer (SN: J56004146) 3/10/23 at 1:13 pm Patient ID: 11845336 3/10/23 at 1:14 pm Patient ID: 39098850 3/23/23 at 1:48 pm Sample ID: 1000740668 3/23/23 at 1:50 pm Sample ID: 1000725907 3/23/23 at 1:52 pm Sample ID: 1000718253 3/23/23 at 1:52 pm Sample ID: 1000735385 3/23/23 at 1:52 pm Sample ID: 1000736249 3/23/23 at 1:53 pm Sample ID: 1000734141 3/23/23 at 1:53 pm Sample ID: 1000736462 3/23/23 at 1:54 pm Sample ID: 1000734034 3/23/23 at 1:54 pm Sample ID: 1000734960 3/23/23 at 1: 55 pm Sample ID: 1000734129 3/23/23 at 1:55 pm Sample ID: 1000735186 3/23/23 at 1:55 pm Sample ID: 1000735965 3/23/23 at 1:56 pm Sample ID: 1000735583 3/23 /23 at 1:56 pm Sample ID: 1000734593 3/23/23 at 1:57 pm Sample ID: 1000735254 3 /23/23 at 1:58 pm Sample ID: 1000734369 3/23/23 at 1:58 pm Sample ID: 1000735070 3/23/23 at 1:59 pm Sample ID: 1000734526 3/23/23 at 1:59 pm Sample ID: 1000734711 3/23/23 at 1:59 pm Sample ID: 1000734870 3/23/23 at 2:00 pm Sample ID: 1000735358 3/23/23 at 2:09 pm Sample ID: 1000741838 3. An interview with the clinical compliance manager on 5/16/2023 at 11:20 am in a conference room confirmed the above findings. Key: QC=Quality Control
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)

	Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer instructions for use for the Dade Actin FSL Activated PTT Reagent, review of laboratory's policies/procedures, activated partial thromboplastin time (APTT) quality control (QC) records for January to May 2023 and staff interview, the laboratory failed to document one of one required new lot establishment studies for the APTT reagent. Findings included: 1. Review of the manufacturer instructions for use for the Dade Actin FSL Activated PTT Reagent (document B4219G1E11 Re. 10-en 2020-03, page 5) revealed: "Reference intervals vary from laboratory to laboratory depending on the population served, and the technique, method, equipment and reagent lot used. Therefore each laboratory must establish its own reference intervals, or verify them whenever one or more of the aforementioned variables are changed." 2. Review of the laboratory's "Sysmex CS-2500 Quality Control Policy" (document LH-014.1 effective December 2022) revealed: "7. TOLERANCE LIMITS ... 7.3 To establish initial target values when new lots of controls are introduced or whenever lots of reagents are changed, no fewer than 20 data points are obtained for each control over a minimum period of 7 days." 3. Review of APTT QC records for January to May 2023 revealed no evidence of multiple QC (20 points per control over 7 days) for the establishment of new target values. 3. In an interview on 05/16/2023 at 0920 hour in the conference room the laboratory's Technical Consultant (as evident on submitted form CMS 209), when asked, stated there was a new lot of APTT reagent implemented on May 2, 2023 (Lot 562734), however, no new reagent lot establishment studies were undertaken at the time of reagent lot transition. This confirmed the findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on review of laboratory's quality control (QC) and corrective action records for the SQA-Vision Automated Sperm Quality Analyzer from January to May of 2023, policies/procedures and staff interview, the laboratory failed to document corrective actions for 3 of 9 failed QC within the five-month interval. Findings included: 1. Review of laboratory's quality control (QC) and corrective action records for the SQA-Vision Automated Sperm Quality Analyzer from January to May of 2023 revealed the following 3 of 9 failed QC that did not have documentation of corrective action: Control 1 Lot: 100722001 Expiration: 07/2023 Tested: 02/01/2023 Result: 4.4 M/ml (Mol /milliliter) Expected result: 41.3 - 54.7 M/ml No corrective action was documented either within the instrument's comments or laboratory's QC Corrective Action Log. Control 2 Lot: 100722002 Expiration: 07/2023 Tested: 02/13/2023 Result: 33.5M/ml Pass ranges: 20-30 M/ml No corrective action was documented either within the instrument's comments or laboratory's QC Corrective Action Log. Negative control Lot: 100722003 Expiration: 07/2023 Tested: 04/07/2023 Result: 5.1 /0.0 M/ml Pass ranges: 0.0 - 0.0 M/ml No corrective action was documented either within the instrument's comments or laboratory's QC Corrective Action Log. 2. Review of laboratory's policy "Quality Control and Corrective Action" (document LQ-002.1, effective December 2022) revealed: "5.5 Corrective Action for Quality Control ... 5.5.1.6.Document all corrective actions on the appropriate QC Corrective Action Log (see Appendix)." 3. In an interview on 05/16/2023 at 1045 hours in the conference room, the laboratory's Technical Consultant (as evident on submitted form CMS 209), after review of the data, confirmed the findings.