

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2219814	(X3) Date Survey Completed 04/12/2023
Name of Provider or Supplier Kelsey-Seybold Clinic Fort Bend Lab	Street Address, City, State 11555 University Blvd, Sugar Land, 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.
D5461	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(g)</p> <p>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-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the manufacturer's instructions, the laboratory's reagent replace logs from 2/7/2023 to 4/7/2023, patient records, and confirmed in an interview, the laboratory failed to document a quality control run after a change in a reagent for 3 of 10 days reviewed on one of one Sysmex XN-430 hematology instrument. The findings were: 1. Review of the manufacturer's instructions titled Sysmex Automated Hematology Analyzer XN-530/XN-430/XN-330 General Information (North American Edition) (Code No. BV237179 en-am. Date of Last Revision: 08/2019. Software Version: Ver. 3 onwards.) in Chapter 7. Reagents revealed four reagents were used in the XN-430 Hematology analyzer (SN: 11473). Cellpack DCL Fluorocell WDF Lysercell WDF Sulfolyser 2. Random review of the reagent replace logs from 2/7/2023 to 4/7/2023 revealed 3 of 10 days reviewed had no documentation of a quality control run after the following reagent change on the Sysmex XN-430 hematology analyzer. 2/8/2023 at 2:14pm Fluorocell WDF Lot#: A2004 Exp: 05/19/2023 2/17/2023 at 12:16pm Lysercell WDF Lot#: A2008 Exp: 06/14/2023 3/2/2023 at 9:44am Sulfolyser Lot#: Y2005 Exp:06/15/2023 3. Review of</p>

the laboratory's QC logs for the above dates revealed the next QC was performed on the following date and time after reagent changes: Reagent change 2/8/2023 at 2:14pm Fluorocell WDF Next QC 2/9/2023 at 7:54am Reagent change 2/17/2023 at 12:16pm Lysercell WDF Next QC 2/17/2023 at 4:12pm Reagent change 3/2/2023 at 9:44am Sulfolyser Next QC 3/3/2023 at 7:51am 4. Random review of the patient records for the above dates revealed the laboratory performed 40 patient CBC testing after the reagent change with no documentation of a quality control run after a change in a reagent. 2/8/2023 at 2:55pm Sample NO:1000417016 2/8/2023 at 2:59pm Sample NO:1000416995 2/8/2023 at 3:12pm Sample NO:1000417341 2/8/2023 at 3:24pm Sample NO:1000417458 2/8/2023 at 4:03pm Sample NO:1000418109 2/8/2023 at 4:09pm Sample NO:1000417868 2/8/2023 at 4:12pm Sample NO:1000417835 2/8/2023 at 4:21pm Sample NO:1000418504 2/8/2023 at 4:24pm Sample NO:1000418500 2/8/2023 at 5:51pm Sample NO:1000419730 2/17/2023 at 12:40pm Sample NO:1000485730 2/17/2023 at 1:07pm Sample NO:1000487901 2/17/2023 at 2:52pm Sample NO:1000488372 2/17/2023 at 2:59pm Sample NO:1000488270 2/17/2023 at 3:33pm Sample NO:1000488539 2/17/2023 at 3:53pm Sample NO:1000489005 2/17/2023 at 4:00pm Sample NO:1000489117 2/17/2023 at 4:04pm Sample NO:1000489606 2/17/2023 at 4:06pm Sample NO:1000490201 2/17/2023 at 4:10pm Sample NO:1000490677 3/2/2023 at 10:03am Sample NO:1000581026 3/2/2023 at 10:07am Sample NO:1000581658 3/2/2023 at 10:21am Sample NO:1000581793 3/2/2023 at 10:23am Sample NO:1000581942 3/2/2023 at 10:30am Sample NO:1000581620 3/2/2023 at 10:37am Sample NO:1000581172 3/2/2023 at 10:52am Sample NO:1000581114 3/2/2023 at 11:01am Sample NO:1000582899 3/2/2023 at 11:10am Sample NO:1000583116 3/2/2023 at 11:21am Sample NO:1000583603 3/2/2023 at 11:26am Sample NO:1000584031 3/2/2023 at 11:43am Sample NO:1000583526 3/2/2023 at 11:57am Sample NO:1000583615 3/2/2023 at 12:29pm Sample NO:1000584488 3/2/2023 at 12:40pm Sample NO:1000585503 3/2/2023 at 1:14pm Sample NO:1000585785 3/2/2023 at 1:16pm Sample NO:1000585496 3/2/2023 at 2:46pm Sample NO: 1000588171 3/2/2023 at 3:00pm Sample NO: 1000588589 3/2/2023 at 3:24pm Sample NO: 1000589266 5. An interview with the clinical compliance manager on 4/12/2023 at 11:30 am in the conference room confirmed the laboratory did not perform at least a level of quality control run after a change in a reagent.