

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2219814	(X3) Date Survey Completed 12/05/2024
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	An onsite recertification survey conducted December 5, 23, 2024 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, proficiency testing records from 2023 and 2024, and interview with laboratory personnel, the laboratory failed to ensure six of six consecutive routine chemistry proficiency testing events were analyzed by personnel who routinely perform chemistry testing in the laboratory. The findings included: 1. Based on review of the laboratory's policy "Proficiency Testing" (Version 3.0, LQ-006.1), on page 3 of 14, the policy stated the following: "2.4.4 All testing personnel must participate in handling and testing of PT samples. If multiple personnel perform patient testing for the same analyte, testing of proficiency samples should be rotated among all testing personnel." 2. Based on review of American Proficiency Institute (API) proficiency testing records from 2023 and 2024, Testing Person 3 (as listed on the CMS-209 Laboratory Personnel report) attested to the analyzing six of six proficiency testing challenges for routine chemistry. 2023 - Chemistry Core - 1st event Testing Person 3 analyzed CH01-05 2023 - Chemistry Core - 2nd event Testing Person 3 analyzed CH06-10 2023 - Chemistry Core - 3rd event Testing Person 3 analyzed CH11-15 2024 - Chemistry Core - 1st event Testing Person 3 analyzed CH01-05 2024 - Chemistry Core - 2nd event Testing Person 3 analyzed CH06-10 2024 - Chemistry Core - 3rd event Testing Person 3 analyzed CH11-15 3. In an interview at 11:30 am on 12/05/2024 in the board room, the Compliance Manager confirmed the findings.</p>

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on surveyor observations and interview with laboratory personnel, the laboratory failed to ensure five of five pre-chilled grey top sodium fluoride blood collection tubes were not available for use beyond the expiration date. The findings included: 1. During a tour of the laboratory at 09:40 am on 12/05/2024, the surveyor observed five of five pre-chilled grey top sodium fluoride blood collection tubes in the refrigerator across from the chemistry instrument that had exceeded their expiration date. Lot: 3194791 Expiration date: 2024-11-30 Elapsed time: Expired by five days. 2. In an interview at 09:40 am on 12/05/2024 in the laboratory, the General Supervisor 2 (as listed on the CMS-209 Laboratory Personnel report) confirmed the blood collection tubes had exceeded the expiration date.

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on a review of laboratory policy, review of patient final reports, and confirmed in an interview of laboratory personnel, the laboratory failed to ensure normal reference intervals were available to health care providers for six of six relative test count results included on male and female Complete Blood Count (CBC) tests. The findings included: 1. A review of the laboratory's policy titled, "Sysmex XN-430 (SN 11473) Verification Summary under, "Reference Range" stated, "Table 6.4: Sysmex XN-430 (SN11473) Female Reference Interval Verification" and "Table 6.5: Sysmex XN-430 (SN11473) Male Reference Interval Verification". The tables did not include a patient normal range for: - % Neutrophils - % Lymphocytes - % Monocytes - % Eosinophils - % Basophils 2. A review of one female patient's final report and one male patient's final report found that the laboratory included the automated CBC relative counts on patient final reports available to healthcare providers. Specimen ID: 24FD-340H00002 (male) Final Report Date: 12/05/2024 Component Value Reference Range Neutrophils 88 Not estab. % Lymphs 7 Not estab. % Monocytes 3 Not estab. % Eos 0.0 Not estab. % Basos 0.0 Not estab. % Specimen ID: 24FD-340H00003 (female) Final Report Date: 12/05/2024 Component Value Reference Range Neutrophils 56 Not estab. % Lymphs 39 Not estab. % Monocytes 4 Not estab. % Eos 0.7 Not estab. % Basos 0.3 Not estab. % The final reports did not include a patient normal range for: - % Neutrophils - % Lymphocytes - % Monocytes - % Eosinophils - % Basophils 3. In an interview at 4:30 p.m. with the Compliance Manager and Director (as listed on the Entrance/Exit Conference Sheet) in the board room confirmed the findings.

D6066

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on direct observation, a review of personnel records, and confirmed in an interview with laboratory personnel, one of three testing personnel reviewed did not have documentation of training on the Vitros 3400 chemistry analyzer used for patient testing. The findings included: 1. A tour of the laboratory on December 5, 2024, at 9:15 hours, found the laboratory used one Vitros 3400 chemistry analyzer for patient testing. 2. A review of personnel records for testing personnel 4 (as listed on Form CMS-209) found no documentation of training for the Vitros 3400. The testing person's hire date was documented as 07/10/2023. Further review of the personnel records for testing personnel #4 found a training record from a satellite location for a different analyzer (Vitros 5600) signed off on 09/06/2023 by the testing person and the trainer. 3. In an interview at 11:10 a.m. with the Compliance Manager (as listed on the Entrance/Exit Conference Sheet) in the board room confirmed the findings. She confirmed the laboratory used a Vitros 3400, but the training records were for a Vitros 5600.