Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2220614	03/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Kelsey-Seybold Clinic - The Woodlands Lab	106 Vision Park Blvd, Shenandoah, 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 certification 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.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the Operator's Guide for use for the CLINITEK Status+ Analyzer and manufacturer's instructions for use for the Multistix Reagent Strips for urinalysis testing, review of laboratory's policies and procedures, review of laboratory's temperature logs for January and February of 2023, review of laboratory test statistics and staff interview it was determined the laboratory failed to follow manufacturer's instructions for optimal urobilinogen testing temperature for 42 of 42 testing days reviewed. Findings included: 1. Review of the Operator's Guide for use for the CLINITEK Status+ Analyzer (10490853 Rev.2011-12) revealed: "Optimum

	Operating Temperature Range "22 to 26C (72 to 79F) ... Optimum ranges insure that the reagent results are optimized for performance. For example, at temperatures under 22C (72F), urobilinogen and leukocyte results might decrease, and at temperatures above 26C (79F), increase." 2. Review of the manufacturer's instructions for use for the Multistix Reagent Strips (11306391 Rev. A) for urinalysis testing revealed: "UROBILINOGEN ... Limitations: ...Strip reactivity increases with temperature; the optimum temperature is 22-26C (72-79F)." 3. Review of laboratory policy/procedure "Urinalysis by Clinitek Status+ Connect" (LU-005.1, Effective 12/10/2022) revealed: "6.9 Due to the nature of the urobilinogen and leukocytes reagents found on the strips, these two results may be decreased at temperatures below 22C (72F) and increased at temperatures above 26C (79F)." 4. Review of laboratory's temperature logs for January and February of 2023 revealed the following 42 of 42 testing day temperatures fell outside the optimal temperature range for urobilinogen testing: Date: Minimum Temperature: 01/03/2023 20.0C 01/04/2023 20.0C 01/05/2023 20.9C 01/06 /2023 21.0C 01/09/2023 21.5C 01/10/2023 20.0C 01/11/2023 20.0C 01/12/2023 20.1 C 01/13/2023 20.1C 01/16/2023 20.0C 01/17/2023 20.0C 01/18/2023 20.0C 01/19 /2023 20.0C 01/20/2023 20.0C 01/23/2023 21.0C 01/24/2023 20.0C 01/25/2023 20.0 C 01/26/2023 21.0C 01/27/2023 21.0C 01/30/2023 20.0C 01/31/2023 21.0C 02/01 /2023 21.1C 02/02/2023 20.4C 02/03/2023 20.0C 02/06/2023 20.0C 02/07/2023 20.4 C 02/08/2023 20.0C 02/09/2023 20.1C 02/10/2023 20.0C 02/13/2023 19.1C 02/14 /2023 20.0C 02/15/2023 19.8C 02/16/2023 19.6C 02/17/2023 19.5C 02/20/2023 19.1 C 02/21/2023 19.4C 02/22/2023 19.1C 02/23/2023 19.5C 02/24/2023 20.0C 02/27 /2023 20.0C 02/28/2023 19.8C Note: The laboratory utilized a minimum/maximum temperature reading system. During the day the temperature increased from the minimum temperature listed above to temperatures within the optimal testing range for urobilinogen. However, it was unclear at what time temperatures were within range, nor whether any testing occurred at the time when optimal temperature was out of range. 5. Review of laboratory test statistics revealed the laboratory performed 43 urobilinogen tests in January and February of 2023. 6. In an interview on 03/22/2023 at 1505 hours in the conference room, the laboratory's General Supervisor (as described on submitted Form 209), after review of the data, confirmed the findings. Legend: C = Degrees Celsius F = Degrees Fahrenheit
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 review of laboratory policies and procedures, review of Stat order transport logs from outside facilities for March of 2023 and staff interview it was determined the laboratory filed to follow its own protocols for monitoring transport temperature for 2 of 2 Stat samples received in March of 2023 from outside facilities. Findings included: 1. Review of laboratory's policy/procedure "Specimen Transport via Courier" (PRE-015.1, Effective 12/10/2022) revealed: "1.2 The purpose of this standard operating procedure is to ensure that all clinical diagnostic specimens submitted via courier are received at Kelsey-Seybold laboratories within acceptable

	temperature limits to ensure sample integrity." ... 2.1 Maintaining specimen integrity and quality are essential to obtaining accurate test results. A major influencer in specimen quality is temperature, hence the need to maintain correct temperature ranges." And, "5.7 Courier in Transit 5.7.1 Coolers will be temperature monitored. 5.7.2 GPS and Temperature will be sent real-time to Lab Logistics." ... 5.8.2 Courier and Processor will retrieve the cooler temperatures and logged [sic] temperatures onto log PRE-015.1F1 Temperature Log for Transported Specimens." 2. Review of Stat order transport logs from outside facilities for March of 2023 revealed there was no documentation of the sample transport temperature for the following 2 of 2 outside facility Stat samples delivered to the laboratory for testing: Date: 03/01/2023 Tracking list: 23-KR6734 Transport Type: KSC Refrigerated Container: 1000567831 Patient: 11530086 Test ordered: Creatinine Date: 03/08/2023 Tracking list: 23-KR7670 Transport Type: KSC Refrigerated Container: 1000630677 Patient: 11353447 Test ordered: BNP (B-Type Natriuretic Peptide) 3. In an interview on 03/22/2023 at 1000 hours in the conference room, the laboratory's Technical Supervisor (as described on submitted Form 209), stated thet the laboratory did not monitor transport temperatures for Stat samples from outside of the facility. This confirmed the findings.
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 the laboratory's policies and procedures, review of laboratory's temperature logs for January to February of 2023 and staff interview, it was determined the laboratory failed to follow its own policy for documenting minimum and maximum temperature during closure for 9 of 9 closure intervals reviewed. Findings included: 1. Review of laboratory's policy/procedure "Room, Refrigerator, and Freezer Temperature Monitoring" (LG-001.1, effective 12/10/2022) revealed: "6.4 If the laboratory is closed, there must be a method to measure the low and the high temperature/humidity for the days the laboratory is closed. This temperature /humidity are recorded on the log and the source noted and initialed." 2. Review of laboratory's temperature/humidity logs for January to February of 2023 revealed there was no documentation of the low and high temperatures/humidity during the following closure intervals: 01/01/2023 to 01/02/2023 01/07/2023 to 01/08/2023 01/14 /2023 to 01/15/2023 01/21/2023 to 01/22/2023 01/28/2023 to 01/29/2023 02/04/2023 to 02/05/2023 02/11/2023 to 02/12/2023 02/18/2023 to 02/19/2023 02/25/2023 to 02 /26/2023 Note: Temperature was noted as "Closed" for the above dates. 3. In an interview on 03/24/2023 at 1510 hours via telephone, the laboratory's Clinical Compliance Manager (as documented on submitted Entrance/Exit Conference Form), after discussion of the data, confirmed the findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of laboratory's temperature logs for January and February of 2023, review of laboratory's corrective action documents and staff interview, it was determined the laboratory failed to document corrective action for 8 of 8 instances laboratory's room temperature was documented outside of laboratory defined acceptable range. Findings included: 1. Review of laboratory's policy/procedure "Room, Refrigerator, and Freezer Temperature Monitoring" (LG-001.1, effective 12/10/2022) revealed: "DEFINITIONS 3.1 Room Temperature -temperature of a room ranging from 20-25C (68 - 77F) (based on the most restrictive temperature range for equipment and supplies)." And, "6.6 When the acceptable range has been exceeded... 6.8 Document all actions taken in detail on the log." 2. Review of the laboratory's "Daily Room Temperature & Humidity Monitoring" log revealed the expected room temperature range was defined as 20-24C. Note: The policy and temperature log definitions of acceptable range did not correlate. 3. Review of laboratory's temperature logs for January and February of 2023 revealed the following days the laboratory's room temperature exceeded expected temperature range (20-24C) withoud documentation of corrective action: Exceeded lower limit: Date: Temperature 02/16/2023 19.6C. 02 /20/2023 19.1C. 02/21/2023 19.4C. 02/22/2023 19.1C. 02/23/2023 19.5C. 02/28/2023 19.8C. Exceeded upper limit: Date: Temperature 02/08/2023 24.5C. 02/10/2023 24.8 C. 4. Review of laboratory's corrective action logs revealed there was no corrective action documented for the above out of range temperatures. 5. In an interview on 03 /22/2023 at 1535 hours in the conference room, the laboratory's Technical Supervisor (as described on submitted Form 209), after review of the data, confirmed the findings. Legend: C = Degrees Celsius F = Degrees Fahrenheit