

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2264730	(X3) Date Survey Completed 06/17/2026
Name of Provider or Supplier Kelsey-Seybold Clinic / Memorial Villages Lab	Street Address, City, State 9110 Katy Freeway, 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 Kelsey-Seybold Clinics/Memorial Villages laboratory was surveyed in response to complaint TX00562643 for compliance with CLIA CMS 42 CFR regulations. The complaint TX00562643 was substantiated. Standard level deficiencies were cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, patient test records, and staff interview, the laboratory failed to ensure one of three patient's urine specimen was collected according to the laboratory's procedure, ensuring the collection time was accurate, for testing in November 2025. Findings include: 1. A review of the laboratory's policy titled 'Urine Specimen Processing and Management' revealed the following: "Urine In-Office Collection for Satellite Sites - If a patient can void at site: a) Print a visit label b) Verify patient name with patient c) Place label on the cup. - Give patient clear instructions on urine collection: a) Inform patient urine collection instructions are also posted on the restroom wall. b) Instruct the patient to place their urine collection in the pass-through window. - The PST (Patient Services Technician) should retrieve the collected urine from the pass-through window and perform: a) Collect the urine in EPIC. b) Print the label. c) Deliver the urine to the processing area. - PSTs and Processors are responsible for routinely checking the urine pass-through window throughout the day. a) The pass-through window should be checked at a minimum every 10-15 minutes to prevent buildup of urine cups." 2. A review of patient test

record revealed the time the following patient checked in and checked out of the Laboratory Services Department for routine urinalysis testing: - Patient ID: 92010115 Date: 11/6/25 Check in time: 08:01 a.m. Check out time: 08:07 a.m. 3. Further review of the patient test record revealed the laboratory documented the following collection time for the urine specimen: - Patient ID: 92010115 Documented urine collection time: 09:55 a.m. Elapsed time from check out to documented collection time: 1 hour 48 minutes 4. In an interview on 6/17/26 at 11:40 a.m. in the office, after review of the records, the compliance manager confirmed that if the samples are ordered as routine, the samples are batched and tested when time allows. For this patient specimen, the documented collection time was actually the time the urine was tested and resulted.

D5801

TEST REPORT
CFR(s): 493.1291(a)

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on a review of test requisitions, a review of patient final reports, and staff interview, the laboratory failed to ensure the final test report reflected the correct collection time for one of ten patient reports reviewed from March 2026. Findings include: 1. A review of the test requisition for Patient ID: 89634638 revealed the following tests were ordered on 3/24/26: a) Cortisol - AM, Total Order comments: 8 am lab draw to be collected BEFORE Cosyntropin administration b) Cortisol Order comments: 8:30 lab draw to be collected 30 minutes AFTER Cosyntropin administration c) Cortisol- AM, Total Order Comments: hour draw d) Cortisol 2. A review of the patient's final report revealed the following collection times for the Cortisol tests: a) Cortisol 8:00 a.m. b) Cortisol 8:46 a.m. c) Cortisol 12:19 p.m. 3. Further review of the patient's final report revealed, the 'Cortisol- AM, Total order comments: hour draw', was collected at 3/24/26 9:46 a.m. but then canceled as a duplicate test. The results for the hour draw were then resulted under the 'Cortisol' test order with a collection time of 12:19 p.m. 4. In an interview on 6/17/26 at 12:33 p.m. in the office, after review of the records, the compliance manager confirmed the hour draw should have been ordered as a 'Cortisol' test, not a 'Cortisol- AM, Total' test. When the laboratory identified the error, the order was canceled, however, the collection time was not entered correctly for the hour draw.