

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2264730	(X3) Date Survey Completed 11/06/2024
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 laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, surveyor observation, the laboratory's records, and staff interview, the laboratory failed to follow their policy for centrifuging patient samples for 42 of 42 urine microscopic examinations performed from October 1, 2024 to November 6, 2024. Findings include: 1. A review of the laboratory's policy titled 'Urinalysis Microscopic Examination' revealed the following: "Centrifuge for 5 minutes at 1500 rpm/450 rcf." 2. Surveyor observation of the laboratory on 11/6/24 at 12:40 p.m. revealed the laboratory staff used the following centrifuge for urine microscopic examinations: -Medline Model 642E Serial number (SN): 220913IG483 3. A review of the laboratory's Service Request Detail records for the Medline centrifuge (SN: 220913IG483) revealed the Revolutions per Minute (RPMs) and timing were tested on 8/29/24 with the following results: 3173 rpm 10 minutes 4. A review of the laboratory's records revealed the laboratory had performed 42 urine microscopic examinations using the Medline centrifuge (SN: 220913IG483)</p>

from October 1, 2024 to November 6, 2024. 5. In an interview on 11/6/24 at 12:50 p. m. in the conference room, after review of the records, the laboratory compliance manager confirmed the above findings.