

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2264730	(X3) Date Survey Completed 03/29/2023
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 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 recertification 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.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's submitted Form 209 (Laboratory Personnel Report), review of laboratory's policies/procedures, review of personnel records and staff interview, it was determined the laboratory failed to follow its own policy for documenting competency assessment for 1 of 1 technical supervisor/technical consultant. Findings included: 1. Review of laboratory's submitted Form 209 revealed the laboratory employed one technical supervisor. That same individual also held the title of technical consultant. 2. Review of laboratory's policy "Clinical Laboratory Employee Training and Competency" (LQ-008.1, effective: 12/10/2022) revealed:</p>

"2.4. The competency of each individual is evaluated within ninety (90) days of hire, at least semi-annually during the first year, and annually thereafter." And, "2.9.1. Clinical Consultants, Technical Supervisors, General Supervisors, Testing Personnel, and personnel performing certain non-testing tasks such as data entry, specimen accessioning, etc. will all undergo competency assessment." Note: The policy did not address competency assessment for technical consultant (moderate complexity testing). 3. Review of personnel records revealed the technical supervisor/technical consultant was hired in September of 2022. There was no documentation of competency assessment for the technical supervisor/technical consultant. 4. In an interview on 03/29/2023 at 1135 hours in the conference room, the laboratory's Technical Consultant/Technical Supervisor, after review of the data, confirmed the findings.