Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2182395	06/03/2025
Name of Provider or Supplier	**Street Address, City, State**	
Tdcj Montford Unit-Clinical Laboratory	8602 Peach St, Lubbock, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based upon review of policies and procedures, personnel records and interview of facility personnel, the laboratory failed to have a procedure to assess the competency of the clinical consultant. The findings included: 1. Review of the policy titled Competency Assessment Policy found on page one under the heading Oversight and Compliance: "The Laboratory Director is responsible for the approval and oversight of the competency assessment program and ensuring compliance with all applicable CLIA regulations. The Director must ensure that the policy is implemented consistently and that the qualifications of the Technical Consultant and assessors are maintained. The policy will be updated as necessary to reflect changes in regulatory standards, test methods, or laboratory structure." 2. Review of personnel records found no documentation of competency assessment for the clinical consultant (hired 04/11/2023). 3. During interview of the Technical Consultant conducted June 3, 2025 at 09:19 AM, she confirmed there was no competency assessment completed for the clinical consultant.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) (e)(8) Ensure that reports of test results include pertinent information required for interpretation;

	This STANDARD is not met as evidenced by: Based on review of patient test records, verification records, manufacturer's instructions for use and interview with facility personnel, the laboratory director failed to ensure that Chemistry final test results included the appropriate reference intervals were included on three of three reports reviewed. The findings included: 1. Review of patient test records found the reference ranges provided were not the same as those defined in the verification study completed in February of 2024, and did not match those in the manufacturer's instructions for use. 2. During interview of the Technical Consultant conducted June 3, 2024 at 2:42 PM, she confirmed that the laboratory used the reference ranges provided by their associate hospital instead of verifying the manufacturer's ranges, and they did not match the defined ranges in the verification study.