

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0673101	(X3) Date Survey Completed 03/07/2023
Name of Provider or Supplier Cuero Regional Hospital	Street Address, City, State 2550 North Esplanade, Cuero, 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 the CLIA regulations. The condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
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 a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that the laboratory failed to have documentation of a competency assessment for one technical consultant in 2022. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 3/7/23) revealed the laboratory identified 1 technical consultant. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of a competency assessment for the technical consultant in 2022. 3. An interview with testing person #1 on 3/7/23 at 3:40 p.m. in the conference room, after review of the records, confirmed the above findings.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the</p>

performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel files, and staff interview, it was revealed that the technical consultant failed to perform a competency assessment on thirteen of fourteen testing personnel in 2022. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 3/7/23) revealed the laboratory identified 14 testing personnel performing moderate complexity testing. 2. A review of the laboratory's personnel records revealed no documentation of the technical consultant performing a competency assessment for the following testing personnel in 2022: - Testing person #2 - Testing person #3 - Testing person #4 - Testing person #5 - Testing person #6 - Testing person #7 - Testing person #8 - Testing person #9 - Testing person #10 - Testing person #11 - Testing person #12 - Testing person #13 - Testing person #14 *Further review of the personnel records for the above listed testing personnel revealed the competency assessments from 2022 were performed by Testing person #1, not the technical consultant. 3. An interview with testing person #1 on 3/7/23 at 3: 30 p.m. in the conference room, after review of the records, confirmed the above findings.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the education to determine the qualifications of testing personnel to perform moderate complexity testing (refer to D6065).

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that the laboratory failed to have documentation of education for five of fourteen testing personnel to qualify them to perform moderate complexity testing. Findings include: 1. A review of the CMS 209 form (signed by the laboratory director on 3/7/23) revealed 14 testing personnel who performed moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of education for the following testing personnel: - Testing person #1 - Testing person #3 - Testing person #11 - Testing person #12 - Testing person #14 3. An interview with testing person #1 on 3/7/23 at 2:40 p.m. in the conference room, after review of the records, confirmed the above findings.