

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2189668	(X3) Date Survey Completed 11/28/2023
Name of Provider or Supplier Lillie's Lab Solutions	Street Address, City, State 3901 East Stan Schlueter Loop Suite 103, Killeen, 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	<p>An unannounced complaint investigation was conducted on November 28,2023. The laboratory failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780. 493.1403 Condition: Laboratories Performing Moderate Complexity Testing; laboratory director 493.1415 Condition: Laboratories Performing Moderate Complexity Testing; clinical consultant. Complaint TX22087835 was substantiated based upon findings made during this investigation.</p>
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CMS Report 209 Laboratory Personnel Report, electronic mail submission and staff interview, the laboratory director failed to provide overall management and direction of the laboratory services. The Laboratory Director failed to ensure that the laboratory had a qualified clinical consultant for a laboratory performing moderate complexity testing. (See D 6065)</p>
D6028	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the</p>

appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Based upon review of the CMS report 209 Laboratory Personnel Report, electronic mail submission and interview of facility personnel, the Laboratory director failed to ensure the laboratory had employed a qualified clinical consultant to provide consultation for performing moderately complex chemistry procedures. (See D6065)

D6056

CLINICAL CONSULTANT

CFR(s): 493.1415

The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.

This CONDITION is not met as evidenced by:

Based on review of the CMS 209 Laboratory Personnel Report, electronic mail submissions and interview of facility personnel, the facility failed to employ an individual that met the minimum qualifications for the clinical consultant of a moderate complexity laboratory for thirteen of thirteen months. NOTE: This is a repeat deficiency from the January 2023 initial certification inspection. (See D6057) The findings included: 1. Review of the CMS Laboratory Personnel Report (provided by the laboratory director on November 28, 2023) found the laboratory identified an individual as the Clinical Consultant. (see attached CMS 209) 2. Review of electronic mail submissions dated November 28, 2023 from the individual defined as the Clinical Consultant found the laboratory had not entered into a contractual agreement for employment as the Clinical Consultant. 3. During interview of the Laboratory Director conducted on November 28, 2023 at 10:00 AM (conducted by telephone) she explained that she did not have anything to do with negotiating contracts for employment and that was the responsibility of the owner/operator.

D6057

CLINICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1417

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:

Based on review of the CMS 209 Laboratory Personnel Report, electronic mail submissions and interview of facility personnel, the facility failed to employ an individual that met the minimum qualifications for the clinical consultant of a moderate complexity laboratory for thirteen of thirteen months. NOTE: This is a repeat deficiency from the January 2023 initial certification inspection. (See D6057) The findings included: 1. Review of the CMS Laboratory Personnel Report (provided

by the laboratory director on November 28, 2023) found the laboratory identified an individual as the Clinical Consultant. (see attached CMS 209) 2. Review of electronic mail submissions dated November 28, 2023 from the individual defined as the Clinical Consultant found the laboratory had not entered into a contractual agreement for employment as the Clinical Consultant. 3. During interview of the Laboratory Director conducted on November 28, 2023 at 10:00 AM (conducted by telephone) she explained that she did not have anything to do with negotiating contracts for employment and that was the responsibility of the owner/operator. NOTE: This is a repeat deficiency from the January 2023 initial certification inspection.