

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0930340	(X3) Date Survey Completed 09/13/2021
Name of Provider or Supplier Desoto Regional Family Medicine Logansport	Street Address, City, State 808 Main Street, Logansport, LA	
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	A Recertification survey was performed on September 13, 2021 at DeSoto Regional Family Medicine-Logansport, CLIA ID # 19D0930340. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
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 the laboratory's policy and procedure manual, Laboratory Personnel Report and personnel records as well as interview with personnel, the laboratory failed to ensure written policies and procedures to address competency for Technical Consultant were complete. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did have a policy which includes competency assessment criteria for the position of Technical Consultant; however, the policy did not include the frequency of performance assessment for personnel serving as Technical Consultant. 2. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed that Personnel 2, 3, and 4 serves as Technical Consultants. 3. Review of personnel records for Personnel 2, 3, and 4 revealed the Laboratory Director did perform an annual competency assessment for their duties as Technical Consultant for 2020 and 2021. 4. In interview on September 13, 2021 at 2:40 pm, Personnel 3 confirmed the laboratory did not include the frequency at which the Technical Consultant has a competency assessment performed.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p>

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have a complete policy and procedure manual.

Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include the following: a) Reporting of SARS COV-2 test results to state public health agency, to include but not limited to frequency and who is responsible. b) Detailed, written instructions for SARS CoV-2 testing platform 2. In interview on September 13, 2021 at 3:02 pm, Personnel 3 confirmed the laboratory did not have the above identified policies.

D6030

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(12)

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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Findings: 1. The laboratory failed to ensure written policies and procedures to address competency for Technical Consultant were complete. Refer to D5209. 2. The Technical Consultant failed to evaluate competency annually for one (1) of six (6) Testing Personnel for the years of 2019 and 2020. Refer to D6054.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(13)

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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel. Refer to D5401.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the 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 review of personnel records and interview with personnel, the Technical Consultant failed to evaluate competency annually for one (1) of six (6) Testing Personnel for the years of 2019 and 2020. Findings: 1. Review of personnel records revealed the laboratory did not have documentation of an annual competency assessment for 2019 and 2020 for Testing Personnel 7. 2. In interview on September 13, 2021 at 2:40 pm, Technical Consultant 1 stated Personnel 7 is a part time employee who only worked when available during the years of 2019 and 2020. Technical Consultant 1 confirmed that no competency assessments were performed for Personnel 7 for 2019 and 2020.