

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2218184	(X3) Date Survey Completed 01/31/2022
Name of Provider or Supplier Pelican Plasma	Street Address, City, State 6917 Fairfield Ave, Shreveport, 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	An Initial survey was performed on January 31, 2022 at Pelican Plasma, CLIA ID # 19D2218184. 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:</p> <p>I. Based on review of the laboratory policy, personnel records and interview with personnel, the laboratory failed to follow their established competency policy for two (2) of two (2) testing personnel reviewed. Findings: 1. Review of the laboratory's competency assessment policy revealed the laboratory performs an initial assessment, six (6) month assessment and an annual assessment thereafter upon hiring of testing personnel. 2. Review of personnel records revealed the laboratory did not perform an initial or a six (6) month assessment for the following one (1) of two (2) testing personnel reviewed: a) Testing Personnel 2 3. Further review of personnel records revealed the laboratory did not have Laboratory Director/Technical Consultant approval/signature for the following one (1) of two (2) testing personnel reviewed: a) Testing Personnel 3 3. In interview on January 31, 2022 at 12:20 pm, Personnel 2 stated she was unaware that a competency assessment was required since she normally does not perform patient testing. Personnel 2 further stated that a competency assessment was completed for Personnel 3 but the assessment was not performed by qualified personnel. Personnel 2 confirmed the above identified testing personnel did not have completed competency assessments. II. Based on review of laboratory policy, personnel records and interview with personnel, the laboratory failed to ensure that a competency assessment policy was included for the assessment</p>

for the Technical Consultant. Findings: 1. Review of laboratory policy and procedure manual revealed the laboratory did not include a policy for the assessment of the duties and responsibilities along with the frequency of performance for the Technical Consultant. 2. Review of personnel records revealed the laboratory did not include a competency assessment for Personnel 4 who serves as the Technical Consultant. 3. In interview on January 31, 2022 at 12:20 pm, Personnel 2 confirmed the laboratory did not have a competency assessment policy or perform an assessment for the identified personnel.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

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 laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish a written, detailed procedure for all aspects of testing. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have written, detailed instructions for the following: a) Proficiency Testing: to include but not all inclusive of how to test proficiency samples, analyzer utilized for testing or a twice a year verification for other analyzers, who is responsible for proficiency testing reviews and assessment of unacceptable results, and how often proficiency testing samples are tested. 2. In interview on January 31, 2022 at 11:00 am, Personnel 2 confirmed the laboratory did not include the identified above policy.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's CMS-209 (Laboratory Personnel Report) and personnel records as well as interview with personnel, the Laboratory Director failed to ensure Testing Personnel had appropriate training documentation prior to patient testing. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) and personnel records revealed the following testing personnel did not have documentation of the Laboratory Director's approval/signature for patient testing: a) Personnel 2 b) Personnel 3 2. In interview on January 31, 2022 at 12:20 pm, Personnel

2 confirmed the laboratory did not have documentation of initial training for the identified testing personnel approved/signed by the Laboratory Director prior to performing patient testing.

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 review of laboratory policy, personnel records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established. Findings: 1. The laboratory failed to follow their established competency policy for two (2) of two (2) testing personnel reviewed. Refer to D5209 I. 2. The laboratory failed to ensure that a competency assessment policy was included for the assessment for the Technical Consultant. Refer to D5209 II. 3. The Technical Consultant failed to evaluate competency annually for two (2) of two (2) testing personnel reviewed. 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 review of laboratory policy and procedure manual and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5403.

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 laboratory policy, personnel records and interview with personnel, the Technical Consultant failed to evaluate competency annually for two (2) of two (2) testing personnel reviewed. Findings: 1. Review of laboratory policy revealed the laboratory performs testing personnel competency assessments upon initial hire, at six (6) months and then annually thereafter. 2. Review of personnel records revealed the laboratory did have documentation of an initial and six (6) month assessment for Personnel 3; however, the personnel records did not have documentation to show Laboratory Director/Technical Consultant approval/signature for Personnel 3. 3. Further review of personnel records revealed the laboratory did not have documentation of initial and six (6) month competency assessment with Laboratory Director/Technical Consultant approval for Personnel 2. 4. In interview on January 31, 2022 at 12:20 pm, Personnel 2 confirmed the initial and six (6) month competency assessments were not performed or completed by qualified personnel.