

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2161808	(X3) Date Survey Completed 10/28/2019
Name of Provider or Supplier Opteo Laboratory, Llc	Street Address, City, State 1441 Canal Street, Suite 401, New Orleans, 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 October 28, 2019 at Opteo Laboratory, LLC, CLIA ID # 19D216808. 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 record review and interview with personnel, the laboratory failed to follow their competency assessment policy for Testing Personnel. Findings: 1. Review of the laboratory's "Quality Management Plan," under the "Training and Competency; Continuing Education" section, revealed "all personnel that process, test, and /or report patient samples are trained prior to being approved to perform the aforementioned tasks. They must successfully show initial competency and be approved by their Technical Supervisor (or supervisor in the case of accessioning) before performing tasks without direct supervision." 2. Review of the laboratory's CMS-209 Form (Laboratory Personnel Report) revealed the Technical Supervisor and General Supervisor also served as Testing Personnel. 3. In interview on October 28, 2019 at 9:14 am, the Technical Supervisor stated the laboratory began patient testing on September 18, 2019. 4. Review of personnel records revealed the two (2) Testing Personnel did not have documentation of an initial orientation/training. 5. In interview on October 28, 2019 at 9:47 am, the General Supervisor stated the laboratory did not have documentation of competency assessments for their duties as Testing Personnel.</p>
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p>

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the laboratory failed to follow their specimen rejection policy for three (3) of seven (7) patients reviewed. Findings:
1. Review of the laboratory's "Sample Acceptance and Rejection Criteria Policy" under the "Policy I. Required Acceptability Criteria for Specimen/Samples" section revealed the following for test requisitions: a) "The approved test requisition must have the following information: The name and address or other suitable identifiers of the authorized person(s) , or laboratory requesting the test and, if appropriate, the name and address of the individual responsible for using the test results." b) "The date of specimen/sample collection" c) "3. In addition to the testing system, to the above requisition requirements, the following is MANDATORY: a. ICD codes." 2. Review of the laboratory's "Instructions for DNA Kit Submission" document given to providers revealed "Requisition must be filled out by the provider COMPLETELY." 3. Review of patient requisitions from September 2019 revealed the following three (3) of seven (7) patients did not have the required information: a) Patient 1: Requesting provider's information not included b) Patient 2: Collection date, ICD code, and requesting provider's information not included c) Patient 3: ICD code not included 4. In interview on October 28, 2019, the General Supervisor confirmed the identified patient requisitions did not include the required information indicated in the laboratory's policy.

D6087

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5311.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must 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:

	<p>Based on record review and interview with personnel, the Laboratory Director failed to ensure Testing Personnel met training requirements prior to patient testing. Refer to D5209.</p>
<p>D6112</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451</p> <p>The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Refer to D5311.</p>
<p>D6120</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor failed to have documentation of initial training/orientation for Testing Personnel per laboratory policy. Refer to D5209.</p>