

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0457328	(X3) Date Survey Completed 07/17/2019
Name of Provider or Supplier Alere Toxicology Services, Inc	Street Address, City, State 1111 Newton Street, Gretna, 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 Certification survey was conducted at Alere-CLIA ID # 19D0457328 on July 17, 2019. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(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;</p> <p>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 maintained. Refer to D6046 and D6053.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(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 Consultants failed to ensure procedures to assess personnel competency were complete. Findings: 1. Review of personnel records revealed the laboratory utilized a "Certifying Technician" form for competency assessments. The forms included the minimum required six (6) procedures for assessing competency of testing personnel. 2. Review of the competency assessment forms for 2018 and 2019 revealed the Technical Consultants did not perform the competency assessments for the following Testing Personnel: Personnel 8 Personnel 9 Personnel 10 Personnel 11 Personnel 12 Personnel 13 Personnel 14 Personnel 15 Personnel 16 Personnel 17 Personnel 18 Personnel 19 Personnel 20 Personnel 21 Personnel 22 Personnel 23 Personnel 24 3. In interview on July 17, 2019 at 11:15 am, the RP non-negative Production Manager stated the Technical Consultants did not perform the competency assessments for Testing Personnel. The RP non-negative Production Manager further stated Testing Personnel observe each other perform the tasks.</p>
<p>D6053</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultants failed to document the performance of individuals at least semi-annually during the first year for one (1) of five (5) testing personnel reviewed. Findings: 1. Review of personnel records for Personnel 23 revealed a competency form, "Certifying Technician" signed June 19, 2018 by the observer, Testing Personnel 19. 2. Further review of the identified competency form for Personnel 23 revealed no documentation of the assessment. 3. In interview on July 17, 2019 at 11:15 am, the RP non-negative Production Manager confirmed the semi-annual competency assessment for Personnel 23 was not completed.</p>
<p>D6103</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must 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.</p> <p>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 were maintained for assessing personnel competency. Refer to D6120.</p>
<p>D6120</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES</p>

CFR(s): 493.1451(b)(7)(8)

(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.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the Technical Supervisor failed to perform competency assessments for testing personnel. Findings: 1. Review of personnel records revealed the laboratory utilized a "Certifying Technician" form for competency assessments. The forms included the minimum required six (6) procedures for assessing competency of testing personnel. 2. Review of the laboratory's personnel records revealed the Technical Supervisors did not perform competency assessments for 2018 and 2019 for the following high complexity testing personnel: Personnel 2 Personnel 5 Personnel 6 Personnel 7 3. In interview on July 17, 2019, the RP non-negative Production Manager stated Testing Personnel observe each other perform the tasks for competency. The RP non-negative Production Manager confirmed the Technical Supervisors did not perform competency assessments for the identified personnel.