

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D1067628	(X3) Date Survey Completed 01/16/2019
Name of Provider or Supplier Tms Bioscience Labs	Street Address, City, State 1441 Canal Street, Lab 305 - Nobic Bldg, 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	A Certification Survey was performed at January 16, 2019 at TMS Bioscience Labs, CLIA ID # 19D1067628. 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 record review and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess competency for the Clinical Consultant, Technical Supervisor, and General Supervisor. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the following: a) Personnel 2 serves as Clinical Consultant b) Personnel 3 serves as Technical Supervisor and General Supervisor 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for competency assessment of the Clinical Consultant, Technical Supervisor, and General Supervisor. 3. Review of personnel records revealed competency assessments for the duties of Clinical Consultant, Technical Supervisor, and General Supervisor were not performed. 4. In interview on January 16, 2019 at 11:15 am, Personnel 3 stated the Laboratory Director did not perform an assessment of his duties as Technical Supervisor and General Supervisor. Personnel 3 confirmed the laboratory did not have documentation of a competency assessment for Personnel 2's duties as Clinical Consultant. II. Based on record review and interview with personnel, the laboratory failed to establish complete policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's "Clinical Laboratory Scientist</p>

Proficiency Assessment" policy and "Proficiency Checklist" revealed it did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting of test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 3 serves as testing personnel. 3. Review of personnel records for Personnel 3 revealed the laboratory did not have documentation of an annual competency assessment for 2017 and 2018. 4. In interview on January 16, 2019 at 11:15 am, Personnel 3 stated the Laboratory Director did not perform a competency assessment for his duties as testing personnel.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:
I. Based on observation, record review, and interview with personnel, the laboratory failed to document the temperatures of the refrigerator and freezer utilized for Toxicology testing. Findings: 1. Observation by surveyor during laboratory tour revealed the laboratory maintains a Frigidaire refrigerator and freezer for storage of Toxicology reagents. 2. Review of the laboratory's temperature logs for the laboratory's freezer and refrigerator revealed the laboratory did not have documentation of temperatures from September 10, 2017 through January 16, 2019. 3. In interview on January 16, 2019 at 11:00 am, Personnel 3 stated he has not been documenting temperatures like he should. Personnel 3 confirmed the laboratory did not have documentation of refrigerator and freezer temperatures for the identified dates. II. Based on observation, record review, and interview with personnel, the laboratory failed to document maintenance performed on the Waters instrument for Toxicology testing. Findings: 1. Observation during the laboratory tour revealed the laboratory utilizes a Waters Quattro LC/MS analyzer for Toxicology testing. 2. Review of the laboratory's policy and procedure manual revealed a "Maintenance & Repair of System Protocol and Procedure" that includes sample cone cleaning and HPLC column replacement. 3. Review of the laboratory's records revealed the laboratory did not have documentation of maintenance for 2017 and 2018. 4. In interview on January 16, 2019 at 11:00 am, Personnel 3 stated he performs maintenance, but has not been documenting it. Personnel 3 confirmed the laboratory did not have documentation of maintenance for the Waters Quattro LC/MS instrument.

D6095

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(6)

The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Refer to D5413 I and D5413 II.

D6103

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(13)

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.

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 established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209 I and D5209 II.