

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0268163	(X3) Date Survey Completed 08/28/2020
Name of Provider or Supplier Tomoka Medical Laboratory Inc	Street Address, City, State 783 S Nova Rd, Ormond Beach, FL	
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 complaint investigation (2020014504) was conducted on 8/28/20. Tomoka Medical Laboratory Inc was found not in compliance with 42 CFR 493, requirements for clinical laboratories. Two CLIA Conditions were not met, all at the Immediate Jeopardy level: 42 CFR 493.1403 Laboratories Performing Moderate Complexity Testing: Laboratory Director, and 42 CFR 493.1415 Laboratories Performing Moderate Complexity Testing: Clinical Consultant. Immediate Jeopardy was identified as beginning on 8/28/20 and is presently ongoing.
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a director to provide sufficient over sight of the laboratory's specimen testing process since September 2019. The findings include: 1. The Laboratory failed to hire a qualified Laboratory Director to oversee the laboratory operations. Refer to D6003. .</p>
D6003	<p>LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406</p> <p>The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of</p>

osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board

of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

This STANDARD is not met as evidenced by:

Based on review of laboratory documents and interview with laboratory staff, the laboratory owner failed to appoint a qualified Laboratory Director after the September 2019 resignation of the Laboratory Director on record with CMS (Centers for Medicare & Medicaid Services). The findings include: Review of the laboratory's policy and procedure manual showed no review by a Laboratory Director since 9/12/18. Reviewed of laboratory requisitions from January 2020 - August 2020 showed the following testing were performed at the laboratory: WBC differential count, Red blood cell count (RBC), Hematocrit (Hct), Hemoglobin (Hgb), Mean corpuscular volume (MCV), Mean corpuscular hemoglobin (MCH), Mean corpuscular hemoglobin concentration (MCHC), Red cell distribution width (RDW), Platelet count, Mean Platelet Volume (MPV), Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), BUN (blood urea nitrogen), Calcium, Chloride, Carbon Dioxide, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin, Total Protein, Cholesterol, High-Density Lipoprotein Cholesterol, Low-Density Lipoprotein Cholesterol, Triglycerides, Uric Acid, Iron, Total Iron Binding Capacity, Ammonia, Prothrombin Time, Vancomycin, Urinalysis, Magnesium, Creatine kinase, Gamma-glutamyltransferase, Phosphorus, Valporic Acid, Direct Bilirubin, and Occult Blood. At the time of survey, the laboratory was unable to provide the number of each individual test performed. During an interview on 8/28/20 at 9:00am with the Office Manager, it was stated that the Laboratory Director removed his license from the wall in June 2019. During an interview on 8/28/20 at 12:00pm with the laboratory owner, it was stated that the facility has been looking for a new laboratory director but "it has been a challenge". When asked why the laboratory continued testing without a director on staff, the owner stated "We should not have done testing without a lab director. We should have it resolved in 30 days". During an

	<p>interview on 8/28/20 at 2:00pm with the Laboratory Director on file with CMS, it was stated that an official resignation letter was given to the laboratory owner on September 15th, 2019. A copy of the letter was sent to the Agency for Healthcare Administration in Florida on September 25th, 2019.</p>
<p>D6056</p>	<p>CLINICAL CONSULTANT CFR(s): 493.1415</p> <p>The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have a Clinical Consultant for the Diagnostic Immunology, Chemistry, and Hematology testing. The findings include: 1. The laboratory failed to have the position of Clinical Consultant filled. Refer to D6057. .</p>
<p>D6057</p>	<p>CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417</p> <p>The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located.</p> <p>This STANDARD is not met as evidenced by: Based on lack of records and staff interview, the laboratory failed to have a Clinical Consultant that provided consultation regarding laboratory patient's diagnosis, treatment, and management of care. The findings include: At the time of survey, the laboratory was unable to provide documentation of a Clinical Consultant on staff. The reviewed of the CMS 116 form from the CLIA recertification in October 2018 showed the Laboratory Director was listed as the Clinical Consultant. During the interview with the laboratory owner on 8/28/20 at 12:00pm, it was confirmed the laboratory did not have a Clinical Consultant on staff.</p>