

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2224368	(X3) Date Survey Completed 04/07/2022
Name of Provider or Supplier Pro Diametrics Corp DbA Prodi Lab	Street Address, City, State 9627 S Dixie Hwy, Pinecrest, 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	An initial survey was completed on 3/29/2022 to 4/07/2022 at Pro Diametrics Corp dba Prodi Lab. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Conditions were not met: D 6076-Laboratory Director D 6134-Clinical Consultant
D6076	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to have a laboratory director (LD) that was licensed to oversee the bacteriology, virology and parasitology specialties from 2/15/2022 to present. (see 6078)</p>
D6078	<p>LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443</p> <p>The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (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 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) Be a</p>

doctor of medicine, a 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)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; 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 and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:
 Based on record review and interview, the laboratory failed to have a laboratory director (LD) that was licensed to oversee the bacteriology, virology and parasitology specialties from 2/15/2022 to present. Findings included: Review of CMS-209 Laboratory Personnel Report revealed employee A was listed as the laboratory director and clinical consultant. Review of the LD personnel folder revealed the LD had a Doctor of Philosophy in Chemistry degree and State of Florida license as Clinical Laboratory Director in Clinical Chemistry. Review of the laboratory test menu displayed GI panel and Pneumonia panel tested with the Biofire listed as bacteriology, virology and parasitology. Review of Biofire validation for GI and Pneumonia panel revealed the LD had signed off on the validation as approved for use on 6/15/2021. During an interview on 3/29/2022 at 12:00 PM, the office manager stated that 2 patients were tested with the GI panel and 6 patients were test with pneumonia panel from 2/19/2022 to 3/28/2022. During an interview on 3/30/2022 at 2:00 PM, the office manager confirmed the LD was unqualified to oversee the bacteriology, virology and parasitology areas.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
 CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
 Based on record review, the laboratory director was not qualified to perform a competency assessment for 1 out 1 testing personnel in the areas of bacteriology, virology and parasitology. Finding Included: Review of CMS-209 Laboratory Personnel Report revealed employee A was listed as the laboratory director and

	<p>Clinical Consultant. Employee B is listed as technical supervisor. Refer to 6078 - Based on record review and interview, the laboratory failed to have a laboratory director that was licensed to oversee the bacteriology, virology and parasitology specialties from 2/15/2022 to present. Review of Personnel Competency Assessments revealed the testing personnel competency assessment was done by the laboratory director for GI and pneumonia panel on the bio fire on 8/30/2021. During an interview on 3/30/2022 at 2:00 PM, the office manager confirmed the laboratory director was not qualified to perform a competency assessment for 1 out of 1 testing personnel.</p>
<p>D6134</p>	<p>CLINICAL CONSULTANT CFR(s): 493.1453</p> <p>The laboratory must have a clinical consultant who meets the requirements of 493.1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to have a qualified clinical consultant (CC) in the laboratory for specialties of bacteriology, virology and parasitology from 2/15/2022 to present. (see D 6135)</p>
<p>D6135</p>	<p>CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455</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 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed 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 record review and interview, the laboratory failed to have a qualified clinical consultant (CC) in the laboratory for bacteriology, virology and parasitology from 2/15/2022 to present. Findings Included: Review of CMS-209 Laboratory Personnel Report revealed employee A was listed as the laboratory director and CC. Refer to 6078 - Based on record review and interview, the laboratory failed to have a laboratory director that was licensed to oversee the bacteriology, virology and parasitology specialties from 2/15/2022 to present. During an interview on 3/30/2022 at 2:01 PM, the office manager confirmed the CC was unqualified to oversee the bacteriology, virology and parasitology areas.</p>