

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  29D1106339	<b>(X3) Date Survey Completed</b>  12/06/2023
<b>Name of Provider or Supplier</b>  Primmed	<b>Street Address, City, State</b>  5741 S Fort Apache Rd Suite 120, Las Vegas, NV	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	<p>This Statement of Deficiencies was created as a result of an on-site initial CLIA survey conducted at your facility on December 6, 2023. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.</p>
<b>D6076</b>	<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 the number and severity of the deficiency cited herein, the Condition: Laboratory Director was not met. The laboratory failed to ensure that the director was qualified to direct high complexity testing between the dates of April 1, 2023 and November 21, 2023. (Refer to D6078)</p>
<b>D6078</b>	<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)</p>

(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 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 a review of the laboratory personnel records, and an interview with the laboratory technical supervisor, the laboratory failed to ensure that the laboratory director met the qualifications to direct high complexity toxicology testing between the dates of April 1, 2023 and November 21, 2023. Findings include: 1. The laboratory discontinued moderate complexity toxicology screen testing and began performing high complexity toxicology screen and confirmatory testing on April 1, 2023. 2. The Director of the laboratory between the dates of April 1, 2023 and November 21, 2023 failed to meet the qualifications for high complexity testing. The director was a physician licensed in the State of Nevada and had completed the required 20 continuing education credits to qualify as a director for moderate complexity testing only. 3. The findings were confirmed during a telephone interview with the technical supervisor on October 23, 2023, and re-confirmed during an interview conducted during the survey on December 6, 2023 at approximately 10:30 AM. The laboratory performs approximately 320,000 toxicology tests annually.