

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0703841	<b>(X3) Date Survey Completed</b>  07/20/2021
<b>Name of Provider or Supplier</b>  Sonoma State University	<b>Street Address, City, State</b>  1801 E Cotati Ave, Rohnert Park, CA	
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>D6076</b>	<p><b>LABORATORY DIRECTOR</b> 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 Surveyor review of laboratory director's qualifications, training and experiences, and interview with the laboratory technical supervisor during an onsite survey of the laboratory on July 20, 2021, it was determined that the Condition: Laboratories performing high complexity testing laboratory director was not met. The laboratory's failure to have a qualified director has a consequence of potential erroneous test result reporting and thus causing patient harm. The findings include: The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests. See D6078.</p>
<b>D6078</b>	<p><b>LABORATORY DIRECTOR QUALIFICATIONS</b> 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 Surveyor review of laboratory director's qualifications, training and experiences, and interview with the laboratory technical supervisor during an onsite survey of the laboratory on July 14, 2021, it was determined that the laboratory director is not qualified to direct a laboratory performing high complexity testing and may cause inaccurate patients test reporting. The findings include: 1. The laboratory has a new director effective June 2020. The new director is a California licensed physician and had completed 20 CME for directing a moderate complexity laboratory which qualifies the director to direct a moderate complexity laboratory. The laboratory does high complexity testing in bacteriology and hematology. 2. The laboratory technical supervisor on July 20, 2021 at 12:30 pm, affirmed that the laboratory director had completed 20 CME for directing a moderate complexity laboratory. 3. The laboratory's testing declaration form, signed by the laboratory director on 7/20/2021, stated that the laboratory performs approximately 66 high complexity tests in bacteriology and hematology, annually.