

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D0909740	(X3) Date Survey Completed 02/12/2018
Name of Provider or Supplier Spectrum Veterinary, Llc DbA Spectrum Labs	Street Address, City, State 2801 S 35th St, Phoenix, AZ	
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
D5205	<p>COMPLAINT INVESTIGATIONS CFR(s): 493.1233</p> <p>The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with the facility personnel, the laboratory failed to have a policy and procedure in place that indicates how the laboratory would address complaints that may be reported to the laboratory. Findings include: 1. A policy and procedure regarding the process of addressing complaints was not presented for review during the survey. 2. The facility personnel indicated that there were no complaints related to the testing of human specimens received by the laboratory, but acknowledged that there was no written policy and procedure to address complaints that may be received by the the laboratory in the future. 3. The laboratory's annual test volume under the sub-specialty of General Immunology is approximately 163,878.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on interview of the laboratory personnel and direct review of the procedure, the laboratory failed to have a procedural change signed and dated by the current director at the time of the change for the laboratory's plate making protocol due to a dispenser</p>

update. Findings include: 1. There was no indication of approval by the director at the time of the effective date on 03/28/2017 of the procedural change described above. 2. The director at the time has since retired and a new director has since signed the procedure manual.

D6076

LABORATORY DIRECTOR

CFR(s): 493.1441

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.

This CONDITION is not met as evidenced by:

The Condition of Laboratory Director was found to be not met based on the failure to provide evidence of qualifications (See D6078 for findings).

D6078

LABORATORY DIRECTOR QUALIFICATIONS

CFR(s): 493.1443

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 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 review of the credentials for the individual recently designated as laboratory director and interview with the laboratory director, the laboratory director is not qualified to direct a high complexity lab due to no evidence of being board certified by a board approved by HHS. Findings include: 1. The individual designated as director does hold a PhD degree in a biological science from an accredited institution, but has not obtained board certification by one of the HHS approved boards. 2. The director acknowledged that he was not board certified by an HHS approved board. 3. The individual assumed the responsibilities of the director of a CLIA high complexity testing lab in January 2018.