Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2168886	(X3) Date Survey Completed 09/14/2023
Name of Provider or Supplier Helix Specialty Diagnostics	**Street Address, City, State** 11829 Dorsett Rd, Maryland Heights, MO	

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
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: Based on lack of laboratory personnel credentials and interview, the laboratory failed to employ a laboratory director (LD) who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction of the laboratory. The laboratory failed to employ a qualified LD since August 31, 2023. The laboratory ceased all laboratory testing on August 31, 2023. (Refer to D6078)
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 interview with the technical supervisor (TS) the laboratory failed to ensure a qualified laboratory director is employed. Findings: 1. Interview with the TS on September 12, 2023 at 9:30 AM stated the previous laboratory director resigned on August 31, 2023. The laboratory ceased all laboratory testing on August 31. 2023. 2. Interview with the TS on September 12, 2023 at 9:30 AM confirmed the laboratory failed to ensure the laboratory employed a qualified laboratory director.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 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. This CONDITION is not met as evidenced by: Based on review of laboratory personnel credentials and interview, the laboratory failed to employ a clinical consultant who meets the requirements of 493.1455 of this subpart and provides clinical consultation to the laboratory. The laboratory failed to employ a qualified clinical consultant since August 31, 2023. The laboratory ceased testing on August 31, 2023. (Refer to D6135)
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 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.

	This STANDARD is not met as evidenced by: Based on interview with the technical supervisor (TS) the laboratory failed to ensure a qualified clinical consultant is employed. Findings: 1. Interview with the TS on September 12, 2023 at 9:30 AM stated the previous laboratory director (whom is also the clinical consultant) resigned on August 31, 2023. The laboratory ceased all laboratory testing on August 31, 2023. 2. Interview with the TS on September 12, 2023 at 9:30 AM confirmed the laboratory failed to ensure the laboratory employed a qualified clinical consultant.