

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2256605	(X3) Date Survey Completed 11/13/2023
Name of Provider or Supplier Hallman Care Llc	Street Address, City, State 1213 Butterfield Rd - 2nd Flr, Downers Grove, IL	
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	<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 review of laboratory records and lack of documentation the laboratory failed to meet the requirements of this condition. The laboratory failed to have a qualified laboratory director from 10-12-2023 through the date of survey, 11-13-2023 (See D6078).</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 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</p>

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 laboratory records and lack of documentation the laboratory failed to have a qualified laboratory director from 10-12-2023 through the date of survey, 11-13-2023. Findings include: 1. A written resignation request by the laboratory director was received by the Illinois (IL) State Agency (SA) Clinical Laboratory Improvement Amendments (CLIA) program on 10-11-2023, confirming the resignation of the laboratory director effective 10-11-2023. 2. The IL SA on 10-13-2023 formally issued via email and certified mail a request for the laboratory to submit a Center for Medicare & Medicaid Services (CMS) CMS-116 application and credentials for a new qualified laboratory director within 30 days as codified in the federal regulations by 11-10-2023. 3. The IL SA failed to receive a CMS-116 and credentials for a qualified laboratory director as requested by 11-10-2023.