

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0961471	(X3) Date Survey Completed 11/12/2019
Name of Provider or Supplier Alden Lakeland	Street Address, City, State 820 W Lawrence Ave 3rd Floor Vent, Chicago, 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
D6000	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on record review and an interview with the general supervisor (GS), the laboratory failed to have a director who meets the qualification requirements of 493.1405 and provide overall management and direction in accordance with 493.1407 for testing performed in the subspecialty of Routine Chemistry. Findings: 1. The laboratory failed to ensure the laboratory employed a qualified laboratory director (LD) for the Blood Gas laboratory, after the previous LD resigned. See D6003.</p>
D6003	<p>LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406</p> <p>The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (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)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State</p>

in which the Laboratory is located; and (b)(2)(ii) Have had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); 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 by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical 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; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for

the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

This STANDARD is not met as evidenced by:
 Based on record review, the Laboratory Personnel Report (CMS 209), and an interview with the general supervisor (GS), the laboratory failed to employ a qualified director who provides overall management and direction for the Blood Gas testing performed in the laboratory. Findings: 1. The CMS 209, the personnel files, and patient Blood Gas test logs were reviewed. 2. The CMS 209 lists and personnel files revealed the following: *The laboratory director (LD) over the Blood Gas laboratory resigned on 10/31/2019. *No other qualified personnel had been designated to act as LD, since the previous LD ceased employment. *None of the LD responsibilities had been performed since the previous LD resigned. 3. The patients' test logs showed that Blood Gas testing had ceased the next day after the LD resigned, November 1, 2019. 4. On a Recertification survey conducted on 11/12/2019 at 11:45 AM, the GS confirmed the above findings.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
 CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
 Based on record review and an interview with the general supervisor (GS), the laboratory failed to have a technical consultant (TC) who meets the qualification requirements of 493.1411 and provide technical oversight in accordance with 493.1413 for testing performed in the subspecialty of Routine Chemistry. Findings: 1. The laboratory failed to ensure a qualified TC was employed for the Blood Gas laboratory after the LD resigned. See D6034.

D6034

TECHNICAL CONSULTANT QUALIFICATIONS
 CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:
Based on record review, the Laboratory Personnel Report (CMS 209), and an interview with the general supervisor (GS), the laboratory failed to employ a technical consultant (TC) for the Blood Gas testing performed in the laboratory. Findings: 1. The CMS 209, the personnel files, and patients' Blood Gas test logs were reviewed. 2. The CMS 209 lists and personnel files revealed the following: *The laboratory director (LD) resigned on 10/31/2019. *The previous LD also functioned as the TC. *No other personnel had been designated to be the TC since the previous LD ceased employment. 3. The patients' test logs showed that Blood Gas testing had ceased after the LD resigned. 4. On a Recertification survey conducted on 11/12/2019 at 11:45 AM, the GS confirmed the above findings.

D6056

CLINICAL CONSULTANT
CFR(s): 493.1415

The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part.

This CONDITION is not met as evidenced by:
Based on record review and an interview with the general supervisor (GS), the laboratory failed to have an employee who meets the qualification requirements of 493.1417 and provide clinical consultation (CC) in accordance with 493.1419 for testing performed in the subspecialty of Routine Chemistry. Findings: 1. The laboratory failed to ensure the laboratory employed a qualified CC in the Blood Gas laboratory after the LD resigned. See D6057.

D6057

CLINICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1417

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 493.1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license 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 record review, the Laboratory Personnel Report (CMS 209), and an interview with the general supervisor (GS), the laboratory failed to employ a clinical consultant (CC) for the Blood Gas testing performed in the laboratory. Findings: 1. The CMS 209, the personnel files, and patients' Blood Gas test logs were reviewed. 2.

The CMS 209 lists and personnel files revealed the following: *The laboratory director (LD) resigned on 10/31/2019. *The previous LD also functioned as the CC. *No other personnel had been designated to be the CC since the previous LD ceased employment. 3. The patients' test logs showed that Blood Gas testing had ceased after the LD resigned. 4. On a Recertification survey conducted on 11/12/2019 at 11:45 AM, the GS confirmed the above findings.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on record review and an interview with the general supervisor (GS), the laboratory failed to ensure individuals meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the complexity of tests performed in the subspecialty of Routine Chemistry. Findings: 1. The laboratory failed to ensure that laboratory personnel meet the education requirement for moderately complex testing, prior to testing patients. See D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on record review, the Laboratory Personnel Report (CMS-209) and an interview with the general supervisor (GS); the laboratory failed to ensure laboratory employees meet the qualification requirements for performing moderately complex testing in the specialty of Chemistry for 1 out of 18 testing personnel (TP). Findings: 1. The CMS 209 and the employee files were reviewed. 2. The CMS 209 lists 18 TP performing Blood Gas testing (a moderate complexity test). 3. The personnel education credentials revealed that TP-X1B had education documentation from a foreign country. These documents had not been evaluated for United States equivalency. 4. The laboratory failed to ensure the foreign documents of TP-X1B met the education requirements for moderately complex testing, prior to testing patients. 5. On a Recertification survey conducted on 11/12/2019 at 11:45 AM, the GS confirmed the above findings.