

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D2129912	<b>(X3) Date Survey Completed</b>  05/14/2019
<b>Name of Provider or Supplier</b>  Alden Estates Of Orland Park	<b>Street Address, City, State</b>  16450 S 97th Ave, 2nd Floor - Vent Unit, Orland Park, IL	
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>D5445</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to ensure the SRC quality control (QC) cassette was ran as required by the manufacturer each day of patient testing for 1 of 6 patient testing dates reviewed. Findings Include: 1. Review of the laboratory policy, "QC Purpose &amp; Frequency" states: "SRC (per manufacturers recommendation) should be performed levels 1 &amp; 3; 1 x/day. We perform SRC Q8 hours/daily; levels 1, 2, &amp;3." 2. Review of "ABG LAB QC Log Sheet: SRC" found the laboratory failed to run the SRC cassette as recommended by the manufacturer on 11-17-2018 through 11-19-2018. a. November 17, 2018 - Shift 1 - Level 1 - Pass Shift 2 - Level 2 - Pass Shift 3 - Level 3 - Not performed b. November 18, 2018 - Shift 1 - Level 1 - Not performed Shift 2 - Level 2 - Not performed Shift 3 - Level 3 - Not performed c. November 19, 2018 - Shift 1 - Level 1 - Not performed Shift 2 - Level 2 - Not performed Shift 3 - Level 3 - Pass 3. Review of patient testing results identified 3 patients (Patient Identifiers - P6, P7, &amp; P8) were tested when SRC controls were not performed per the manufacturer's recommendations and the laboratory's QC policy on November 18, 2019. 4. On survey date 5-14-09, at 4:15 pm, TP#1 confirmed the above findings.</p>

**D5537**

**ROUTINE CHEMISTRY**

CFR(s): 493.1267(b)(d)

For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to ensure one sample of external quality control (QC) material was tested each 8 hours of laboratory operation that included both low and high values for 1 of 6 patient testing dates reviewed. Findings Include: 1. Review of the laboratory policy, "QC Purpose & Frequency" stated: "We perform 1 level of Opticheck Q8 hours /daily; levels 1, 2, & 3." 2. Review of "ABG LAB QC Liquid Log Sheets" found the laboratory failed to run external liquid Opticheck QC as the procedure states on 11-17-2018 through 11-19-2018. a. November 17, 2018 - Shift 1 - Level 1 - Pass Shift 2 - Level 2 - Pass Shift 3 - Level 3 - Not performed b. November 18, 2018 - Shift 1 - Level 1 - Not performed Shift 2 - Level 2 - Pass Shift 3 - Level 3 - Not performed c. November 19, 2018 - Shift 1 - Level 1 - Not performed Shift 2 - Level 2 - Pass Shift 3 - Level 3 - Pass 3. Review of patient testing results identified 3 patients (Patient Identifiers - P6, P7, & P8) were testing when external QC was not performed each 8 hours of testing on November 18, 2019. 4. On survey date 5-14-09, at 4:15 pm, TP#1 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 review of laboratory records and interview with testing personnel (TP) #1; the laboratory failed to employ testing personnel (TP) who met the qualification requirements of 493.1423. Findings Include: 1. TP#4, listed on the CMS-209, failed to meet the qualification requirements for moderate complexity testing. 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 review of laboratory records and interview with testing personnel (TP) #1; TP#4 failed to meet the qualification requirements of 493.1423. Findings Include: 1. Review of laboratory personnel records found TP#4, as listed on the CMS-209, failed to have qualifying educational documents. 2. On survey date 05-14-2019, at 4:15 pm, TP#1 confirmed the laboratory failed to have qualifying educational documentation for TP#4.