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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 14D1063570 | (X3) Date Survey Completed 02/07/2018 |
| Name of Provider or Supplier Duly Health And Care - Westmont Asc | Street Address, City, State 815 Pasquinelli Drive, Westmont, 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 |
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| D6033 | <p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with laboratory testing personnel (TP) #1; the laboratory delegated responsibilities of the technical consultant to personnel who fail to meets the qualification requirements of 493.1411. Findings Include: 1. The laboratory director delegated the competency assessment duties to an individual who failed to meet the qualification requirements of a technical consultant. See D6035.</p> |
| D6035 | <p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant 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 in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for</p> |

example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
 Based on review of laboratory records and interview with laboratory testing personnel (TP) #1; the laboratory director failed to delegate the responsibilities of technical consultant to a qualified individual. Findings Include: 1. Review of laboratory personnel records found the document, "Laboratory Coordinator Competency Evaluation", which stated the following for TP#1: "Evaluates staff for competency." This document was signed and dated by the laboratory director on 1-29-2018. 2. Review of competency assessment records in 2017 through January of 2018 found that 5 of 7 currently employed testing personnel had competency assessments performed by TP#1. Testing Personnel Competency Date TP#5 01-29-2018 TP#2 05-05-2017 TP#3 11-15-2017 TP#4 07-10-2017, 01-09-2018 TP#6 07-21-2017, 01-07-2018 3. Review of laboratory personnel records for TP#1 found the highest degree on file was a high school diploma and therefore TP#1 failed to meet the qualification requirements as a technical consultant (TC) for a moderate complexity laboratory. 4. On survey date 02-07-2018, at 12:00 pm the findings were confirmed by the TP#1.

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#7, listed on line 2 of 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; the laboratory failed to employ testing personnel (TP) who met the qualification requirements of 493.1423. Findings Include: 1. Review of laboratory personnel records found no diploma or qualifying degree for TP#7, as listed on of the CMS-209. 2. On survey date 02-07-2018, at 12:00 pm TP#1 confirmed the laboratory failed to have qualifying documentation for TP#7.