

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D1020065	<b>(X3) Date Survey Completed</b>  01/27/2020
<b>Name of Provider or Supplier</b>  Duly Health And Care - New Lenox Oncology	<b>Street Address, City, State</b>  668 Cedar Crossings Dr, New Lenox, 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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of Laboratory Personnel Report (CMS 209); laboratory policies and procedures manual; personnel records; and interview with the laboratory manager, the laboratory failed to establish and follow written policies and procedure to assess consultant competency. Findings: 1. There were a total of 2 technical consultants listed on form CMS 209. One of them being the laboratory director. 2. The laboratory's policies and procedures manual show the assignment, as well as responsibilities and duties of the following positions: a. Laboratory Director b. Clinical Consultant c. Technical Consultant d. Testing Person 3. The responsibilities of the technical consultant includes the following: a. Evaluating the competency of all testing personnel on an on-going basis. b. Evaluating and documenting performance of individuals responsible for testing. 4. Review of personnel records revealed that there was no documentation to show that the laboratory director assessed the competency of 1 of 2 technical consultants, based on the technical consultant responsibilities. 5. On January 27, 2020 at 11:15 AM, the laboratory manager confirmed the surveyor's findings.</p>
<b>D6032</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(14)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently</p>

and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:  
Based on review of Laboratory Personnel Report (CMS 209); laboratory policies and procedures manual; personnel records; and interview with the laboratory manager, the laboratory director failed to specify, in writing, the duties and responsibilities to each consultant. Findings: 1. Review of form CMS 209 revealed that the laboratory director listed himself, as well as 1 other person, as technical consultants of the laboratory. 2. There are 3 persons listed on form CMS 209 as moderate complexity testing personnel. 2. The laboratory policies and procedures manual shows that the laboratory director is assigned to the positions of technical consultant and clinical consultant, and no one else. 3. Review of personnel records revealed that the laboratory director was not responsible for observing the competency of 3 of 3 testing personnel. 4. On January 27, 2020 at 11:00 AM, the laboratory manager told the surveyor that a medical technologist from one of their other sites assessed the competency 3 of 3 testing personnel. This person was not listed on the CMS 209. This person was, later, added to form CMS 209. 5. On January 27, 2020 at 11:15 AM, the laboratory manager confirmed the surveyor's findings.

**D6052**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(vi)

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures manual and personnel records and interview with testing personnel and laboratory manager; the procedures for evaluation of the competency of staff failed to include assessment of problem-solving skills. Findings: 1. The laboratory's policy states that there are three parts to the competency evaluation which include: a. Check List b. Unknown /Blind Sampling c. Problem Solving 2. There is a Cell-Dyn QC Troubleshooting Flow Chart, in the procedure manual, that the laboratory uses to assess and troubleshoot QC failures. 3. Review of personnel competency assessments revealed that the performance of Calibration verification was not included in the assessment of 3 of 3 testing personnel. In a column labeled "NA", a check mark was entered. 3. The surveyor asked 1 of 3 testing personnel what they would do if 2 control levels failed? Testing personnel gave an answer that was not on the troubleshooting flow chart. He did not know that all the controls should be rerun. 4. Testing personnel did not know if and when the CBC analyzer should be recalibrated. 5. On January 27, 2020 at 1:30 PM, the laboratory manager confirmed the surveyor's findings.