

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0415981	<b>(X3) Date Survey Completed</b>  02/26/2020
<b>Name of Provider or Supplier</b>  Duly Health And Care - Glen Ellyn Lab	<b>Street Address, City, State</b>  430 Pennsylvania Ave, Glen Ellyn, 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>D6086</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory procedure's manuals and verification records, the laboratory director failed to ensure that verification procedures used are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method used to determine cortisol levels. Findings: 1. There were no procedures that described the processes used to determine performance characteristics for cortisol testing. 2. Review of verification records revealed that there was no documentation that identifies which records were used for the following performance characteristics: a. Accuracy b. Precision c. Reportable Range d. Reference intervals 3. There was no documentation to show that the laboratory director reviewed and approved the results of the verification studies. 4. In an interview at 1:30 PM on February 26, 2020, the Technical Supervisor told the surveyor that the laboratory went live with Cortisol testing on January 22, 2019. 5. Review of patients' test results revealed cortisol results were reported on March 27, 2109. 6. At 2:30 PM on February 26, 2020, the Technical Supervisor confirmed the surveyor's findings</p>
<b>D6120</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain</p>

their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of Laboratory Personnel Report (FORM CMS 209) and personnel records and interview with the technical supervisor, the technical supervisor failed to be responsible for evaluating the competency of all testing personnel to ensure that they maintained their competency to perform test procedures and report test results promptly, accurately and proficiently. Findings: 1. There were a total of 14 testing personnel listed on FORM CMS 209. One of the 14 testing personnel was the Technical Supervisor. 2. Review of personnel records revealed that the Technical Supervisor failed to perform the competency assessments of 13 of 14 testing personnel from March 1, 2018 through February 26, 2020. 3. At 11:30 AM, on February 26, 2020, the Technical Supervisor confirmed the surveyor's findings.