

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D0426602	<b>(X3) Date Survey Completed</b>  05/24/2021
<b>Name of Provider or Supplier</b>  Northshore Clinical Laboratories,	<b>Street Address, City, State</b>  4751 N Kedzie Ave, Chicago, 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>D6090</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)(ii)</p> <p>The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on record review, CASPER Report 0155D, and interview with technical supervisor (TS1); the laboratory director (LD) failed to ensure proficiency testing (PT) results are returned within the timeframes established by the proficiency testing programs. Findings include: 1. The Report 0155D, American Proficiency Institute (API) and WSLH PT reports for the years 2019, 2020, and 2021, and the laboratory's PT policies and procedures were reviewed. 2. The Report 0155D revealed the following scores for Event #3 of 2020: General Immunology: Antinuclear Antibody (ANA) = 0* Hematology: Cell Identification (I.D) or White Blood Cell (WBC) differential (Diff) = 0* Red Blood Cell Count (RBC) = 0* Hemoglobin (HGB) = 0* Hematocrit (HCT) = 0* White Blood Cell Count (WBC) = 0* Platelets = 0* Endocrinology: Human chorionic gonadotropin (HCG) - 0* 3. The API and WSLH PT reports showed the above "0*" scores were due to late or failed submissions of PT results to the proficiency programs. 4. The LD failed to ensure the laboratory followed its PT policies and procedures to submit all PT results before the PT programs' deadlines. 5. On a Recertification survey conducted on 05/24/2021 at 2:45 PM, the TS1 confirmed the above findings.</p>