

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0903471	<b>(X3) Date Survey Completed</b>  10/05/2021
<b>Name of Provider or Supplier</b>  Clinical Lab - Cellular Therapy	<b>Street Address, City, State</b>  1100 Walnut Street Mob, Suite 801, Philadelphia, PA	
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>D5429</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the laboratory service manager, the laboratory failed to perform maintenance/ function checks on 2 of 2 Sorval centrifuges in 2020. Findings Include: 1. On the day of survey, 10/05/2021, observation of the laboratory revealed , 2 of 2 sorval RC 3BP Plus centrifuges service stickers stated, "maintenance due on 12/2020". - H1: 41259558 - H2: 41259557 2. The laboratory could not provide maintenance records performed on the centrifuges after 12/2020. 3. The laboratory service manager confirmed the findings above on 10 /05/2021 around 9:50 am.</p>
<b>D6091</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the College of American Pathologist (CAP) proficiency testing (PT) records and interview with the laboratory service manager, the laboratory director (LD) failed ensure all PT reports were reviewed by the appropriate staff in</p>

2020. Findings Include: 1. On the day of survey, 10/05/2021, review of the CAP PT attestation statements revealed, the LD did not sign the following attestation forms: - 2020 CAP PT FL1-C. - 2020 CAP PT FL4-B. - 2020 CAP PT FL1-B. 2. The laboratory service manager confirmed the findings above at 10/05/2021 around 9:30 am.

**D6094**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
Based on review of the procedure manuals and interview with the a laboratory service manager, the laboratory director failed to ensure a quality assessment (QA) programs were maintained from 2019 to the day of survey. Findings Include: 1. On the day of survey, 10/05/2021, the laboratory could not provide documentation of lab specific QA activities performed to assess the laboratory's pre-analytic, analytic and post analytic phases of testing in 2019, 2020 and 2021. 2. The laboratory service manager confirmed the finding above on 10/05/2021 around 11:00 am.