

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D2096354	<b>(X3) Date Survey Completed</b>  11/05/2024
<b>Name of Provider or Supplier</b>  Kedplasma Llc	<b>Street Address, City, State</b>  444 Martin Luther King Blvd, Youngstown, OH	
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>D6031</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(13)</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 and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interviews with the Center Manager (CM) and Quality Assurance Manager (QAM), the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the total protein (TP) testing procedures performed in the subspecialty of Routine Chemistry. This deficient practice had the potential to affect 2,803 out of 2,803 patient TP tests performed in this laboratory upon the change of Laboratory Director from 10/02/2024 through 11/05/2024. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, found them to be unapproved by the current Laboratory Director. 2. The Inspector requested the laboratory's policies and procedures, approved by the current Laboratory Director, to include all aspects of TP testing from the CM and QAM. The CM and QAM confirmed the current Laboratory Director did not approve any policy and procedure for any aspect of TP testing procedures under this CLIA certificate and were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 11/05/2024 at 10:30 AM.</p>