

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  46D0687836	<b>(X3) Date Survey Completed</b>  09/21/2022
<b>Name of Provider or Supplier</b>  Richard White Parkinson Md	<b>Street Address, City, State</b>  5314 N 250 W, Suite 220, Provo, UT	
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>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the laboratory failed to have written procedures for Dermatophyte Test Medium (DTM) testing. The laboratory performs approximately 150 DTM tests annually. Findings include: 1. The laboratory failed to have a written procedure for DTM testing. 2. Medical Assistant not listed on the Laboratory Personnel Report (CMS-209) confirmed during an interview on 09/21 /2022 at approximately 2:30 p.m., the laboratory did not have a written procedure for DTM testing.</p>
<b>D6021</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with staff, the Laboratory Director</p>

failed to ensure a quality assessment plan was established to assure quality of laboratory services through the pre-analytical, analytical, and post-analytical phases. The laboratory performs approximately 4,900 histopathology and 150 mycology tests annually. Findings include: 1. The procedure manual failed to include a written Quality Assessment (QA) plan. 2. Medical Assistant confirmed during an interview on 09/21/2022 at approximately 2:30 p.m., the laboratory did not have a written QA plan.