

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0117604	<b>(X3) Date Survey Completed</b>  04/20/2021
<b>Name of Provider or Supplier</b>  Minniti Center For	<b>Street Address, City, State</b>  174 Democrat Road, Mickleton, NJ	
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>PROCEDURE MANUAL 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 surveyor review of the Procedure Manual (PM), Patient work records and interview with the Testing Personnel (TP), the laboratory failed to follow their PM policy for "Act Diff #2 Flags and Codes" for Hematology tests ran on the Beckman Coulter AcT diff 2 from November 2019 to the date of survey. The finding includes: 1) The PM stated "X flag indicates that one of the multiple Alert criteria was not met. 1. Thoroughly mix and rerun the sample. 2. If the flag does not repeat report result. 3. If flag repeats, clean the aperture as instructed in zapping the aperture. 4. If after cleaning, problem persists contact your Beckman Coulter Representative". a) Patient number 8314 run on 11/05/19 with "X" flagged results was not rerun. b) Patient number 3535 run on 11/14/19 with "X" flagged results was not rerun. 2) The TP #1 on CMS form 209 confirmed on 4/20/21 at 11:05 am the above mentioned procedure was not followed.</p>