

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0117604	<b>(X3) Date Survey Completed</b>  06/27/2023
<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>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Calibration (C) records, Manufactures Instructions (MI) and interview with the Testing Personnel (TP), the laboratory failed to follow MI for "Calibration Procedure" for Hematology Tests performed on the Beckman coulter Hematology analyzer on 8-25-21. The findings include: 1. A review of C records revealed that the laboratory failed to correctly perform and document "Calibration". a) on 08/25/21 Calibration failed for White blood Cell Count (WBC). b) The MI states "If FAILED appears, the % diff value and/or CV% exceeds the high acceptable limit. You cannot save FAILED calibration results. Call your local Coulter Service Representative for assistance." 2. There was no documented evidence that the laboratory followed the aforementioned procedure. 3. The TP confirmed on 6/27/23 at 1:00 pm that the laboratory failed to follow the MI.</p>