

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0189568	(X3) Date Survey Completed 02/15/2023
Name of Provider or Supplier Gmg Pottsville	Street Address, City, State 529 Terry Reiley Way, Pottsville, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Laboratory Director (LD), the laboratory failed to evaluate twice annually the relationship between the automated blood differential (Sysmex XS1000i) and the manual blood differential from 12/21/2020 to 02/15/2023. Findings: 1. On the day of Survey 02/15/2023 at 12:35 pm, the laboratory could not provide comparison of test results between the automated blood differential (Sysmex XS1000i) and the manual blood differential from 12/21/2020 to 02/15/2023. 2. Review of the CMS116 form showed annual testing for hematology was 13000. 3. The LD confirmed the above finding on 02/15/2023 around 01:35 pm.</p>