

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D1011466	<b>(X3) Date Survey Completed</b>  05/23/2023
<b>Name of Provider or Supplier</b>  Dept Of Path/Lab Med Kennett	<b>Street Address, City, State</b>  400 Mcfarland Road, Kennett Square, PA	
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>D5473</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's manual differential quality control (QC) log, procedure manual, and interview with technical consultant (TC) and testing personnel #1 (TP), the laboratory failed to establish criteria for intended reactivity to ensure acceptable staining characteristics for manual differentials stained using the 1 of 1 Midus III-Plus Stainer. QC log for 21 of 21 days of patient testing performed in January 2022 was reviewed on the day of survey (5/23/23). Findings: 1. On the day of survey, 05/23/2023 at 10:30 am, a review of manual differential QC logs and the laboratory's quality control procedure for manual differential staining revealed that the laboratory did not establish or document criteria for intended reactivity for acceptable staining characteristics of manual differentials stained using 1 of 1 Midus III-Plus Stainer for 21 of 21 days of patient testing performed in January 2022. 2. The TC stated that 872 manual differentials testing was performed in the last 1 year. 3. TC and TP #1 confirmed that the lab did not establish the criteria for the intended reactivity on 05/23/23 around 11:00 am.</p>