

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0185196	(X3) Date Survey Completed 10/27/2022
Name of Provider or Supplier Geisinger Mount Pocono	Street Address, City, State 126 Market Way, Mount Pocono, 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
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: Based on review of Manual Differential Stain Quality control (QC) and interview with the General Supervisor (GS) and Team Leader (TM), the laboratory failed to document the manual differential stain Quality Control for negative and positive reactivity each day of patient testing from 8/19/2020 to the day of survey. Finding Include: 1. At the time of the survey 10/27/2022 at 11:15 AM, a review of the manual differential QC record revealed that only checkmarks were documented for manual differential stain QC from 8/19/2020 to the day of survey. 2. The checkmark did not indicate the negative or positive reactivity of the control materials. 2. The GS and TM confirmed the findings above on 10/27/2022 at 12:15 PM.