

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D1079617	<b>(X3) Date Survey Completed</b> 06/28/2022
<b>Name of Provider or Supplier</b> Laboratorio Clinico Capa	<b>Street Address, City, State</b> Plaza Quintana Carr Pr-111 Km 11 Hm 5, Moca, PR	
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>D5445</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the Urinalysis microscopic quality control review and laboratory supervisor interview; it was determined that the laboratory did not include and not document the negative microscopic control material when 1,267 patient were processed and reported from January 2022 to May 2022. The findings include: 1. The Urinalysis quality control was review on June 28, 2022 at 9:50 am. No negative quality control material was documented. 2. The laboratory supervisor confirmed on June 28, 2022 at 10:00 am that no microcopy negative control was included from January 2022 to May 2022 when 1,267 patient were processed and reported under the microscope.</p>
<b>D5471</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and</p>

negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:  
Based on hematology quality control for wright stain records review and laboratory general supervisor interview; it was determined that the laboratory failed to check, each day of use, the Wright's stain used in hematology for intended reactivity to ensure predictable staining characteristics. The finding includes: 1. During interview with the laboratory supervisor, on June 28, 2022 at 10:45 am, the supervisor stated that every week three differential smears were stained, read and reported. 2. Review of the wright stain quality control records on June 28, 2022 at 10:37 am, showed that the laboratory did not document the wright stain control since February 3, 2022. 3. The Laboratory supervised confirmed on June 28, 2022 at 10:48 am that the laboratory fail to check each day of used the wrights stain for Hematology smear when 3 patients were process and reported weekly.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:  
Based on Urinalisys microscopic and Hematology wright stain quality control records review and laboratory supervisor interview on June 28, 2022 at 10:42 AM, it was determined that the laboratory director did not fulfill her responsibilities to ensure that the control material was run each day of patient testing from January 2021 to June 28, 2022. Refer D5449 and D5471.

**D6177**

**TESTING PERSONNEL RESPONSIBILITIES**  
CFR(s): 493.1495(b)(3)

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:  
Based on Urinalysis microscopic and Hematology wright stain quality control records review from January 2021 to June 2022 and laboratory supervisor interview on June 28, 2022 at 11:00 AM, it was determined that testing personnel failed to follow quality control procedures. Refer to D5445 and D5471.