

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0722888	(X3) Date Survey Completed 09/15/2022
Name of Provider or Supplier Laboratorio Clinico Miraflores	Street Address, City, State Ave Los Dominicos # 6 Bloque 14, Bayamon, PR	
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
D5445	<p>CONTROL PROCEDURES 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 it was determined that the laboratory did not include the negative microscopic control material when 4,300 patient were processed and reported from January 4, 2021 to December 30, 2021. The findings include: 1. The Urinalysis microscopic quality control was review on September 15, 2022 at 11:13 am. No negative quality control material was documented. 2. The laboratory director confirmed on September 15, 2022 at 11:20 am that no microcopy negative control was included from January 2022 to May 2022 whn 1,267 patient were processed and reported under the microscope.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p>

This STANDARD is not met as evidenced by:

Based on Urinalysis microscopic quality control records review from January 4, 2021 to December 30, 2021 and laboratory director interview, it was determined that the laboratory director failed to comply with the analytic system requirements. Refer 5445.