

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0713365	(X3) Date Survey Completed 03/28/2024
Name of Provider or Supplier Bayonet Point Foot Health Center	Street Address, City, State 7117 Sr 52, Hudson, FL	
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
D0000	An announced CLIA recertification survey was conducted at Lawrence J Kales DPM PA D/B/A Bayonet Point Foot Health Center on 03/28/24. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level 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 laboratory record review and interview with Testing Personnel #A, the laboratory failed to perform quality control (QC) on 8 of 29 Accu-Dermatophyte Test Medium (DTM) shipments received from 2022-2024. Findings included: -Record review of DTM QC logs revealed that the laboratory did not perform QC on DTM shipments with a lot number previously QC'd by the lab. The laboratory did not perform QC on the following shipments: Lot D1474-0822; date received 01/27/23 Lot D1499-0523; date received 08/24/23 Lot D1505-0923; date received 11/03/23 Lot D1505-0923; date received 12/21/23 Lot D1439-1021; date received 03/04/22 Lot D1439-1021; date received 04/01/22 Lot D1454-0122; date received 06/30/22 Lot D1471-0822; date received 11/15/22 -Record review of both the DTM package insert</p>

and the laboratory SOP state that QC must be performed on each DTM shipment (or batch) received by the laboratory. -At 12:41, Testing Personnel #A confirmed that QC was not performed on these lots.