Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0877152	12/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Hospital Plaza Foot & Ankle Sc	1228 Ogden Ave, Downers Grove, IL	

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 unannounced revisit survey was performed on 12-05-2024 as a follow-up to the 10-01-2024, recertification survey. The Illinois Department of Public health has evaluated this facility and determined it remains out of compliance with the following Conditions CFR(s): 493.1203 Condition: Mycology CFR(s): 493.1403 Condition: Laboratories performing moderately complexity testing; laboratory director
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, and interview with laboratory director (LD); the laboratory failed to follow manufacturer's instructions for the storage of Kwik-STIK quality control reagent for mycology testing for one of one month in 2024. 1. Interview with LD, on 12-05-2024, at 10:30 am, revealed the laboratory had purchased Kwik-STIK quality control reagent used for mycology testing. 2. Review of the manufacturer's instructions for Kwik-STIK states under "storage and expiration" to "Store LYFO DISK and KWIK-STIK microorganisms at 2o C to 8o C in original seal vial or seal foiled pouch containing a desiccant." 3. Interview with LD, on 12-05-2024, at 11:20 am, revealed the Kwik-Stick reagents had been stored in the cabinet prior to use and surveyors confirmed that the laboratory failed to store Kwik-STICK quality control reagent in the required storage conditions in December of 2024.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory records, direct observation, and interview with laboratory director (LD), the laboratory failed to demonstrate they can obtain performance specification comparable to those established by the manufacturer for Dermatophyte Test Medium (DTM) testing. Findings Include: 1. Direct observation of laboratory testing supplies on 12-05-2024 at 10:00 am identified the Hardy Diagnostics Dermatophyte Test Medium (DTM) (Catalog No. L27) 10ml vial used for mycology testing. 2. Review of laboratory records revealed the laboratory was using BD BBL Dermatophyte Test medium during previous survey on 10-01-2024. 3. Review of laboratory records titled "Quality Control Process (Each DTM Lot)" revealed the laboratory was using ACU-DTM for DTM testing prior to May of 2023. 4. Interview with LD, on 12-05-2024, at 10:00 am, confirmed that the laboratory failed to demonstrate they can obtain performance specifications comparable to those established by the manufacture for DTM for the change in test system in May of 2023 and the change in test system in November of 2024.