Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D1082336	09/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Footcare Specialists Of Arizona	10503 W Thunderbird Blvd Ste #109, Sun City, AZ	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on lack of quality control (QC) documentation for review and interview with the laboratory director, the laboratory failed to retain documentation of the Quality Control (QC) that is performed for Dermatophyte Test Medium (DTM) testing. Findings include: 1. The laboratory performs DTM testing, with an approximate annual test volume of 300. 2. The laboratory's established policy titled, "Quality Control" states, "This is to be done for each batch of DTM's. We are to order positive and negative cultures from our DTM manufacturer and test each batch of DTM's for a positive and negative. The batch is not to be used for patient samples until we have accurate results. A log will be in place that will have the lot# of the batch being tested, date, personnel conducting the test, and control information". 3. No QC documentation was presented for review during the survey for testing that occurred from the date of the previous survey conducted on 7/26/16 through the date of the survey conducted on 09/10/18. 4. The laboratory director stated that QC was performed as indicated above, but the QC documentation could not be located at the time of the inspection.