

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0503616	(X3) Date Survey Completed 07/08/2019
Name of Provider or Supplier Stephen Schwartz Md	Street Address, City, State 1919 Ed Carey Dr, Harlingen, TX	
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
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of manufacturer's instructions, review of environmental records, and confirmed in interview of facility personnel, the laboratory's quality assurance program failed to identify when temperatures were documented out of control for DTM cultures. The findings were: 1. Review of the laboratory's Quality Control policy stated, "1) Temperature log of laboratory days when DTM cultures are incubating." The policy did not state establish procedures to be followed when the temperature is out of the manufacturer's specified range. 2. Review of the manufacturer's instructions for DTM (Dermatophyte Test Medium) (Revision No. 04) stated under "Procedure" the following, "...Incubate the inoculated media at 22-30 degrees Celsius for up to 14 days." 3. Review of the laboratory's environmental records from January 2018 to December 2018 revealed the laboratory had an acceptable range of 72-86 degrees Fahrenheit. 4. Further review of the environmental records revealed the following dates when temperatures were documented below the manufacturer's acceptable range: Date Unacceptable Temperature 01-08-2018 70 01-15-2018 70 01-16-2018 70 01-17-2018 66 01-24-2018 68 02-09-2018 70 02-15-2018 70 02-19-2018 70 02-20-2018 70 02-21-2018 70 02-27-2018 70 02-28-2018 70 03-22-2018 70 11-13-2018 69.4 11-14-2018 66.6 11-15-2018 67.5 11-16-2018 68.0 5. Interview with the office manager on July 8, 2019 at 14:15 hours in the exam room confirmed the findings.</p>