Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0928432	01/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Alexander City Dermatology	125 Alison Drive Suite 8, Alexander City, AL	

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 a review of the quality control (QC) records and procedure for the Acu-DTM (Dermatophyte Test Medium) media, and a phone interview with the Clinic RN (Registered Nurse), the surveyor determined the facility failed to retain documentation on the DTM QC kits utilized to assess the acceptability of each new lot number of Acu-DTM media. The findings include: 1. A review of the Quality Control procedure in the manufacturer's package insert for the Acu-DTM media revealed the requirement to perform QC on each new lot number or batch of media utilizing a DTM QC kit with four organisms. The package insert included the following instructions: "... Maintain a log of the QC labels with lot number enclosed in each box. Retain log for inspection purposes. ...". 2. A review of the Acu-DTM QC records revealed the laboratory performed QC on three different lot numbers of Acu-DTM media on 12/3/2015, 12/6/2016, and 8/3/2017. However, the records failed to include any information (manufacturer's package insert, lot numbers or expiration dates) on the DTM QC kit utilized to assess the acceptability of each new lot number of media. 3. In a phone interview on 1/16/2018 at 11:20 AM, the Clinic RN stated she had been the one to set up the QC for each new lot number of Acu-DTM media, however she confirmed she had not retained any documentation or information about the DTM QC kits used. .
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d)

	Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the laboratory policy and procedure manual and an interview with the Clinic Manager, the surveyor determined the laboratory failed to ensure the Laboratory Director documented his review and approval (as indicated by his signature and date) of procedures in use for on-site testing since the previous survey. The findings include: 1. A review of the laboratory policy and procedure manual revealed no Laboratory Director's signature and date. There was no evidence the procedures had been reviewed and approved by the Laboratory Director in use for patient testing since the previous survey on 11/2/2015. 2. During a review of the manual with the Clinic Manager on 1/16/2018 at 11:30 AM, this observation was confirmed.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the quality control (QC) records and procedure for the Acu-DTM (Dermatophyte Test Medium) media, and a phone interview with the Clinic RN (Registered Nurse), the surveyor determined the facility failed to ensure QC results were in agreement with the manufacturer's criteria for acceptability for one out of four organisms used in QC performance. The findings include: 1. A review of the Quality Control procedure in the manufacturer's package insert for the Acu-DTM media revealed the requirement to perform QC on each new lot number or batch of media utilizing a DTM QC kit with four organisms. The package insert specified the culture for one organism, Candida albicans should be read one to two days after set up, and the cultures should have a cream-colored, pasty smooth appearance with the media possibly turning red 48 hours after set-up. 2. A review of the Acu-DTM QC records revealed the laboratory had performed QC on three different lot numbers of Acu-DTM media on 12/3/2015 (Thursday), 12/6/2016 (Tuesday), and 8/3/2017 (Thursday) since the previous survey. The QC results for all three lot numbers were documented as NEGATIVE for the Candida albicans cultures. The QC records failed to include any documentation of investigation or corrective actions taken when the laboratory's negative QC results were not in agreement with the manufacturer's criteria for acceptability (growth for the Candida albicans cultures). 3. In a phone interview on 1/16/2018 at 11:20 AM, the Clinic RN stated she had been the one to set up the QC organisms for each new lot number of Acu-DTM media, however only the Laboratory Director read and reported culture results for the QC and patients. When asked if she was aware of any investigation or corrective actions taken when the laboratory's QC results were not in agreement with the manufacturer's criteria for acceptability for the Candida albicans cultures, the Clinic RN said she was not aware of any additional action taken. After confirming the clinic's closure on weekends, the surveyor then asked if the Candida albicans cultures had been set up again (to allow reading at one to two days as per manufacturer's instructions) on a weekday (instead of a Saturday as would have been required for the 12/3/2015 and 8/3/2017 cultures), the RN stated she

	did not think so. Thus the above findings were confirmed. SURVEYOR:Laura T. Williams, BS, MT (ASCP) Licensure and Certification Surveyor