Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1088233	05/24/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mcgee Dermatology Clinic	41 Macon Center Drive, Franklin, NC	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory policies, review of 2016, 2017 and 2018 laboratory records, and interview with laboratory director 5/24/18, the laboratory failed to verify the accuracy of the potassium hydroxide (KOH) preps at least twice a year. 1. Review of laboratory policy; "KOH-DMSO PROFICIENCY TESTING" revealed "....9. QC: During each 6 month period, #2 + (positive) and #2 - (negative) slides will be retained, sealed with nail polish around their cover slips, and critiqued for accuracy by Dr. ....., Pathologist, Angel Medical Center, Franklin, North Carolina. His findings will be recorded and saved." 2. Review of laboratory records revealed no documentation the laboratory verified the accuracy of the KOH preps in 2016, 2017 and 2018. 3. During interview with laboratory director at approximately 10:30 am, the laboratory director confirmed there was no documentation available to document the laboratory verified the accuracy of the KOH preps in 2016. 2017 and 2018 and stated "We are not doing that, it is impossible for us to do that." This deficiency was previously cited on 1/27/2016.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

	This CONDITION is not met as evidenced by: Based on review of laboratory policies, review of 2016, 2017 and 2018 laboratory records and interviews with laboratory director and laboratory staff 5/24/18, the laboratory director failed to provide overall management and direction for the laboratory. 1. The laboratory director failed to ensure the accuracy of KOH preps (see D5217). 2. The laboratory director failed to ensure the laboratory's quality assessment policy was maintained (see D6094).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of 2016, 2017 and 2018 laboratory records and interview with laboratory staff 5/24/18, the laboratory director failed to maintain the laboratory's quality assessment program. 1. Review of laboratory policy; "QUALITY ASSESSMENT" revealed...." B. Proficiency testing cases (DermPath Slide Review) are received 3-4 times each years. Diagnosis are submitted. Later, the official diagnoses and discussions are correlated with the initial diagnoses. Slides are held until feedback is received. A file of these cases is retained in the lab at McGee Dermatology Clinic." 2. Review of laboratory records revealed no documentation or "file" for the proficiency cases retained in 2016, 2017 and 2018. 3. During interview with laboratory staff at approximately 11:15, the laboratory staff stated "they were unsure where the file for the proficiency cases would be." She did pull a few "frozen section" cases that had been sent for confirmation. There was no documentation the cases were reviewed as part of the laboratory's quality assessment program.