Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0670947	(X3) Date Survey Completed 01/30/2018
Name of Provider or Supplier Marietta Dermatology Associates Pa	**Street Address, City, State** 111 Marble Mill Road, Marietta, GA	
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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 30, 2018. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on policy and procedure manual (SOP) review, the laboratory failed to establish a written procedure for all tests, assays, and examinations performed by the laboratory. Findings include: 1. The laboratory failed to establish a written procedure for a sterility check of the mycology media. 2. The laboratory failed to establish a written procedure for quality control (QC) of the mycology media. 3. An interview with the laboratory quality supervisor on 1/30/18 at approximately 130 p.m. in lab#12 confirmed the laboratory SOP did not contain a procedure for mycology media sterility check or QC.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on observation and interview with the lead histotechnologist, the lab failed to calibrate/certify the vent (fume) hood, microscope, and timers per the procedure manual (SOP). Findings include: 1. Observation during the lab tour revealed the Airventronix hood located in the Histology lab has not been certified since installation. 2. Observation during the lab tour revealed the Premiere microscope #1206545 located in the Histology lab has not been serviced since 09/19/14. 3. Observation during the lab tour revealed the timers (S/N 150317607, 150317602, 122304384, 122097541) located in the Histology lab have not been certified since purchase. Timers expired 04/20/17, 06/01/14, 02/24/14 respectively. 2. Interview with lead histotechnologist on 1/30/18 in the histology lab at approximately 1:45 PM, confirmed the aforementioned equipment had not been calibrated as outlined in the SOP.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on quality control (QC) document review and staff interview, the laboratory failed to check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms, and to check each batch for sterility. Findings include: 1. QC document review revealed the laboratory failed to perform a sterility check for each batch of media for 2017, and 2018 thus far. 2. QC document review revealed the laboratory failed to check each batch of media for its ability to support growth. or, as appropriate, inhibit growth for each batch of media for 2017 and 2018 thus far. 2. An interview with the laboratory quality supervisor in lab #12 room on 1/30/18 at approximately 1:30 p.m. confirmed a sterility check for each batch of media had not been performed nor a check for each batch of media to support or, as appropriate, inhibit growth for 2017 and 2018 thus far.