Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0686969	07/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
South Florida Dermatology Group, Inc	401 Coral Way Ste 207, Coral Gables, FL	

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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, record review and interview with office manager, the histopathology mycology subspecialty laboratory: A- Had expired reagents in use. B- Had no log of checking the expiration date of reagents on monthly basis. C- Had no error monitoring log sheet for DTM quality control. The findings include: Observation and record review on July 18, 2018 at 11:00 AM revealed that: 1- DTM Healthlink Dermatophyte test medium (DTM), lot # 1706104, expiration date- 2018/3/2 was in use for; Patient ID# 36884, test date 7/10/18, to be read on 7/24/18 Patient ID# 57034, test date 7/12/18 to be read on 7/26/18. 2- Record review did not show any records for DTM expiration date check on monthly basis. 3- There was no error monitoring log sheet for DTM quality control. During an interview on July 18, 2018 at 4:00 PM, office manager confirmed that: a) The DTM Healthlink Dermatophyte test medium (DTM), Lot# 1706104, expiration date- 2018/3/2 was in use for; Patient ID# 36884, test date 7/10/18, to be read on 7/24/18 Patient ID # 57034, test date 7/12/18 to be read on 7/26/18. b) There was no log of checking the expiration date of reagents on monthly basis. c) There was no error monitoring log sheet for DTM quality control, for expired reagent in use.
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, record review and interview with office manager, the laboratory failed to have the microscope preventive maintenance records for the years 2016 to July18, 2018 two-year review period (2016 - 2018) for the subspecialty of histopathology mycology testing. The findings include: On 7/18/18 at 11:30AM, surveyor observed Nikon Alpha phot YS microscope that had Robert microscope services sticker with an original date erased with whiteout and new date of 4/19. Instrument maintenance records from July 2016 to July 18, 2018 showed documentation of microscope maintenance that did not include the service contract-invoices from Robert microscope services. During an interview on 7/18/18, at 4:00 PM, the office manager confirmed that: 1) Laboratory did not have records for any service contract and / or invoices from July 2016 to July 18, 2018 from Robert microscope services that would include microscope maintenance. 2) The microscope had Robert microscope services sticker with an original date erased with whiteout and new date of 4/19.
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 record review and interview, the laboratory failed to check each batch of Dermatophyte Test Medium for its ability to support growth and produce a biochemical response from July 2016 to July 18, 2018- two year record review period. The findings include: Review of Dermatophyte Test Medium quality control documentation records from July 2016 to July 18, 2018, showed that the laboratory had not checked each batch or lot number of Dermatophyte Test Medium for its ability to support growth and produce a biochemical response from July 2016 to July 18, 2018. During an interview on 7/18/18 at 4:00 PM, the office manager confirmed that the laboratory had not checked each batch or lot number of Dermatophyte Test Medium for its ability to support growth and produce a biochemical response from July 2016 to July 18, 2018- two year record review period.