Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0685179	05/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
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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 the laboratory quality assurance (QA) plan, the quality control (QC) program policy, the lack of quality assurance and quality control documentation, and interview with the office manager, the laboratory failed to verify the accuracy of MOHS testing at least twice annually in 2021, 2022, and 2023. The findings include: 1. Review of the QA plan revealed the following: a) The laboratory will evaluate one system quarterly. b) System three titled "Proficiency Testing" says the laboratory will send cases to an outside facility for comparison. 2. Review of the QC program policy states "For MOHS: Every 4 months" the laboratory will send slides on a case to an outside dermatopathologist for review. 3. Review of the quality assurance and quality control records revealed no documented outside MOHS case reviews for 2021, 2022, and 2023. 4. Interview on May 11, 2023 at 11:35 am with the office manager confirmed no MOHS cases were sent for outside review in 2021, 2022 and 2023.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

	This STANDARD is not met as evidenced by: Based on the observation during laboratory tour, review of the Dermatology Practice Administration procedure manual, and interviews with the office manager, the laboratory failed to label reagents used in staining of tissues for MOHS testing and media used in fungal culture testing with appropriate information required for proper use. The findings include: 1. Observation of the laboratory revealed: a) The laboratory performed hematoxylin and eosin (H&E) staining of MOHS tissues and fungal culture evaluation for patient testing. b) The reagent cabinet contained "100% Reagent Alcohol", "70% alcohol", and "95% Alcohol". c) The 100% Reagent Alcohol container had manufacturers label. The 70% and 95% alcohol containers were hand labeled and did not list the lot number, preparation date, or expiration date. d) Refrigerator 1 contained a bin labeled "current fungal media" which included individual vials of media slants. None of the 15 media slants reviewed were labeled with name of reagent, preparation date, or expiration date. 2. An interview with the office manager at 9:00 am on the date of survey (5/11/23) revealed: a) The laboratory prepares the 70% and 95% alcohol solutions from the 100% reagent alcohol stock that is purchased. b) The laboratory prepares the fungal media slants in-house from dehydrated BBL Mycosel Agar. 3. Review of the laboratory's Dermatology Practice Administration procedure manual revealed the following: a) The quality control section (3) page 4 states all reagents, including solutions and culture media, will be labeled to indicate identity, preparation dates, expiration dates and any other pertinent information. b) Section 4.2 (page 18) states "reagents prepared by the laboratory or transferred from the manufacturers' containers to smaller containers must be labeled. Labels include: name of reagent, preparation date, expiration date, warning, strength or concentration, and storage requirements. 4. Interview on May 11, 2023 at 1130 a. m. confirmed the 70% and 95% alcohol solutions used for H&E staining of patient tissues and fungal culture media slants prepared in-house were not labeled appropriately.
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 of the laboratory, review of the Dermatology Practice Administration procedure manual, and staff interview, the laboratory failed to ensure collection material used by the laboratory for reference testing were not used past the expiration. The findings include: 1. Observation of the laboratory on May 11, 2023 at 8:30 am revealed the following: a) 25 of 25 EDTA whole blood collection tubes (Lot# 2338462) in patient rooms with expiration date of 4/2014. b) 15 of 29 SST blood collection tubes (Lot# 1041809) in patient rooms with expiration date 2/28/2020. c) 22 of 22 Copan BD sterile culturette swabs (Lot# 18053326001601) in patient rooms with expiration date 9/30/2020. d) 1 of 1 Remel Mycobiotic Agar (Lot # 444930) with an expiration date of 2/14/2023. 2. Review of the Dermatology Practice Administration procedure manual revealed the following statement: "Reagents, solutions, culture media, controls, calibration materials and other supplies are not used when they have exceeded their expiration dates". 3. Interview with the office manager on May 11, 2023 at 11:30 am confirmed the specimen collection supplies in patient rooms were used for collecting patient specimens and used for the following patient

	reference testing: a) EDTA whole blood collection tubes (Lot# 2338462) for complete blood counts (CBC) testing. b) SST blood collection tubes (Lot# 1041809) for long term drug use monitoring including tests for urea nitrogen, Creatinine, protein, albumin, total bilirubin, alkaline phosphatase, LDH, SGOT, SGPT. c) Copan BD sterile culturette swabs (Lot# 18053326001601) and Remel Mycobiotic Agar (Lot # 444930) for culture and sensitivity testing.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the BBL Mycosel Agar package insert and quality control (QC) records, and interview with the laboratory's office manager, the laboratory failed to follow manufacturer's specifications for user quality control of prepared BBL Mycosel agar. The Findings include: 1. Observation of the laboratory on May 11, 2023 at 9:00 am revealed the laboratory prepared fungal culture media for patient testing using dehydrated BBL Mycosel agar. 2. Review of the BBL Mycosel Agar package insert revealed under "User Quality Control" that the "reaction of 3.6% solution at 25 degrees Celsius (C)" should yield pH 6.9 +/- 0.2. 3. Review of the 2020, 2021, and 2022 fungal media QC logs revealed no pH results recorded for 3 of 3 batches prepared by the laboratory. 4. Interview with the office manager on May 11, 2023 at 11:35 am confirmed the laboratory did not record pH results for batches of BBL Mycosel Agar prepared by the laboratory.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance (QA) Plan, review of laboratory records, interview with the office manager, the laboratory failed to follow the procedure for review of quality assurance systems in 2021, 2022, and 2023. The findings include: 1. Review of the laboratory's QA plan revealed the following: a) System 10. Quality Assurance Review states "we will perform a quality review at least monthly and review the results with the laboratory director or technical consultant for their approval" b) the laboratory "will keep written records of our reviews, findings, and actions" 2. Review of laboratory records for QA review revealed a single Quality Assurance Audit encompasing the entire year for 2021 and 2022. 3. Interview with the office manager on May 11, 2023 at 11:30 am confirmed the laboratory failed to follow its' own procedure for QA review by not performing a quality review at least monthly and maintaining documentation of quality review outcomes in 2021, 2022, and 2023.