Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2054064	10/20/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology And M O H S Surgery Institute	100 Deerpath Rd, Charleston, IL	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the laboratory representative SB; the laboratory failed to follow their written policy to assess the competency of the clinical consultant, technical consultant and technical supervisor. Findings Include: 1. Review of the laboratory's policy and procedure manual identified the policy, "Competency Assessment Policy", which stated: "Documented competency is required for individual clinical consultants, technical consultants, technical supervisors, general supervisors, and/or testing personnel (if applicable) who perform testing on patient specimens are required to comply with the procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities. Results of each competency test will be entered in a log and kept in the laboratory management manual, as par of its records". 2. Review of competency records found no competency assessments for the individual listed as the clinical consultant, technical consultant and technical supervisor on the CMS-209 (Laboratory Personnel Report). 3. On survey date 10-20-2021, at 2:30 pm, the laboratory representative SB confirmed the laboratory failed to follow the competency assessment policy and document competency assessments for the clinical consultant, technical consultant and technical supervisor.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory representative SB; the laboratory failed to outline all required components of the ectoparasites test procedure. Findings Include: 1. Review of the policy and procedure manual identified the procedure, "Ectoparasites", which failed to outline the following required components: a. Microscopic examination, including the detection of inadequately prepared slides. b. The reportable range for test results for the test system as established or verified in 493.1253. c. Description of the course of action to take if a test system becomes inoperable. d. Reference intervals (normal values). 2. During survey date 10-20-2021, at 2:30 pm, the above findings were confirmed by the laboratory representative, SB.
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 direct observation, review of laboratory records, and interviews with laboratory testing personnel TC and the laboratory representative SB; the laboratory failed to ensure reagents used for ectoparasite testing were labeled to ensure accurate and reliable testing. Findings Include: 1. Direct observation of the laboratory facility on 10-20-2021 at 10:45 am identified an unlabeled bottle of solution used for ectoparasite testing. 2. Interview with testing personnel TC on 10-20-21 at 10:45 am confirmed the solution is mineral oil used for the ectoparasite wet prep testing. 3. Review of test volume records from October of 2020 through September of 2021 found the laboratory performed 22 ectoparasite tests. 4. On survey date 10-20-2021, at 2:30 pm, the laboratory representative SB confirmed the laboratory failed to label the

	mineral oil solution with the following criteria: (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.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory representative SB; the technical consultant failed to ensure annual competency assessments for ectoparasite testing were completed for two of two testing personnel in 2019 and 2020. Findings Include: 1. Review of the CMS-209 (Laboratory Personnel Report) identified two established testing personnel, TP#5 and TP#6. 2. Review of competency assessment records for TP#5 and TP#6 revealed the laboratory failed to document annual competency assessment for ectoparasite testing in 2019 and 2020. 3. On survey date 03-05-2020, at 2:30 pm the surveyor's findings were confirmed by the laboratory representative SB.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory representative SB; the laboratory director (LD) failed to specify, in writing, the examinations and procedures each individual is authorized to perform and if supervisory review is required for six of six testing personnel listed on the CMS-209 (Laboratory Personnel Report). Findings Include: 1. Review of the laboratory policy and procedure manual failed to identify documentation that specified, in writing, the examinations and procedures each individual is authorized to perform and if supervisory review is required for testing personnel #1, #2, #3, #4, #5, and #6, as identified on the CMS-209. 2. On survey date 10-20-2021, at 2:30pm, the laboratory representative SB confirmed the laboratory director failed to specify, in writing, the responsibilities and duties for six of six testing personnel listed on the CMS-209.