Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1015919	06/12/2019
Name of Provider or Supplier	**Street Address, City, State**	
Carolina Mountain Internal Medicine	902 Fleming Street, Suite C, Hendersonville, 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**
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 procedure manual review and interview with TP (testing personnel) 6/12/19, the laboratory's procedure manual was not complete and current for the testing performed. Findings: 1. The procedure manual did not include a written step-by-step procedure for the performance of scabies testing. During interview at approximately 10:40 a.m., TP #1 confirmed that the laboratory does perform scabies tests, but she stated they do not do them very often. 2. The procedure manual included procedures

	for the following instruments that were no longer in use: a. Cell-Dyn 1700 - discontinued 9/10/04; b. Coaguchek S - discontinued 10/26/06; c. Cell-Dyn 1800 - discontinued 4/23/09; d.. miniVidas - discontinued 2/19/16.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with TP (testing personnel) 6/12 /19, the laboratory director failed to ensure that 1 of 1 TP received training for all non-waived testing prior to testing patient specimens. Findings: Review of personnel records for TP #1 revealed TP #1 was trained July-September 2008. Each item on the "Laboratory Training Record" listed the date training was done, the TP initials, and the supervisor (trainer) initials. "N/A" (not applicable) was listed beside wet prep /KOH (potassium hydroxide) on the "Laboratory Training Record" for TP #1. During interview at approximately 10:40 a.m., TP #1 confirmed that she performs patient wet prep/KOH testing. She stated that she was trained by the former laboratory supervisor, and she was unsure why the training record was marked N/A.
D6047	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with TP (testing personnel) 6/12 /19, the technical consultant (laboratory director) failed to ensure that the 6 competency assessment criteria were evaluated for 1 of 1 TP performing non-waived testing. Review of personnel records for the TP revealed competency evaluations were completed in December 2017 and December 2018. The competency evaluations did not include direct observation of testing for wet prep/KOH(potassium hydroxide) and urine microscopics. During interview at approximately 10:40 a.m., the TP confirmed that direct observation was not included as part of her competency evaluation for wet prep/KOH and urine microscopic testing.