Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0694147	04/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Psoriasis And Eczema Treatment Center	597 Baldwin St, Jenison, MI	

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 record review and interview with the Office Manager, the laboratory failed to evaluate testing personnel competency in 2020 for 3 (Testing Personnel 1-3) of 3 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's "Personnel Competency Policy and Procedure" revealed a section stating, "All testing personnel must be reviewed for their ability to perform testing correctly and accurately. Testing personnel will be reviewed prior to testing patients' specimens to ensure that all personnel have the appropriate education and experience, have received that appropriate training for the type and complexity of services offered, and have demonstrated that they can perform all testing operations reliably, and can provide and report accurate results. Testing personnel must be reviewed every six months during the first year of testing and annually thereafter." 2. A review of the laboratory's competency records revealed a lack of a documented competency assessment for the following testing personnel in 2020: a. Testing Personnel #1 performing microscopic tissue examinations and scabies preparations. b. Testing Personnel #2 performing Potassium Hydroxide (KOH) preparations. c. Testing Personnel #3, hired 2/3/20, semiannual competency for the performance of KOH preparations. 3. An interview on 4/12/21 at 1:42 pm with the Office Manager confirmed the above findings.
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 record review and interview with the Office Manager, the laboratory failed to verify the accuracy of its Potassium Hydroxide (KOH) preparations, Scabies preparations, and microscopic tissue examinations at least twice annually for 1 (2020) of 2 years reviewed. Findings include: 1. A review of the laboratory's records revealed a lack of documentation of two verification of accuracy testing events performed for the following tests in 2020: a. KOH preparations, one of two events was performed. b. Scabies preparations, no events performed. c. Microscopic tissue examinations, no events performed. 2. An interview on 4/12/21 at 1:42 pm with the Office Manager confirmed the laboratory did not verify the accuracy of its testing twice annually for the tests listed above.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to ensure positive patient identification on test reports for 1 (Patient ME9) of 9 patient test records reviewed. Findings include: 1. A review of patient test records revealed Patient ME9 had a Potassium Hydroxide (KOH) preparation performed on 3/19/20. The test report did not include an identification number or a date of birth for positive patient identification. 2. An interview on 4/12/21 at 2:00 pm with the Office Manager confirmed the test report did not include an identification number or a date of birth for positive patient identification. ***This is a repeated deficiency from the 5/9/19 recertification survey***