Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D1033208	02/14/2023
Name of Provider or Supplier	**Street Address, City, State**	
Somerset Skin Centre	255 Kirts Blvd Suite 100, Troy, 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: . A. Based on record review and interview with Testing Personnel #2 (TP2), the laboratory failed to establish a policy for personnel serving as the Clinical Consultant, Technical Supervisor, or General Supervisor for 2 (February 2021 to February 2023) of 2 years reviewed. Findings include: 1. A review of the laboratory's "Personnel Competency Testing" policy revealed it only addressed "Technical Personnel". 2. A review of the laboratory's competency assessment records revealed a lack of competency assessments performed for personnel serving the roles of Clinical Consultant, Technical Supervisor, or General Supervisor. 3. An interview on 2/14/23 at 1:09 pm with Testing Personnel #2 confirmed the laboratory had not established a policy for assessing competency for personnel serving as a Clinical Consultant, Technical Supervisor, or General Supervisor. B. Based on record review and interview with Testing Personnel #2, the laboratory failed to follow its established policy to assess testing personnel competency for 1 (Testing Personnel #2) of 2 testing personnel listed on Form CMS-209. Findings include: 1. A review of the laboratory's "Quality Assurance" policy revealed a section titled "Personnel Assessment" stating, "If the Laboratory has employees, the Laboratory Director will use personal observation to perform an ongoing evaluation of all employees of the laboratory to ensure competence in job performance. After 90 days upon hire, annually thereafter." 2. A review of the laboratory's competency assessment records revealed Testing Personnel #2 was hired in January 2022 and had one competency assessment performed on 4/11/22. 3. An interview on 2/14/23 at 1:09 pm with Testing Personnel #2 confirmed their competency was not assessed and documented according to the

	laboratory's policy. ***This is a repeated deficiency from the 7/19/21 recertification survey***
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #2, the laboratory failed to perform and document its assessment of staining intended reactivity each day of use for 476 of 476 patients that had been prepared at an outside laboratory prior to testing. Findings include: 1. A review of the laboratory's patient test records revealed all patient specimens were sent to an outside laboratory to be processed between November 2021 and January 2022. Slides were made and sent back for testing and reporting of results. A total of 476 patients were tested in this manner. 2. The surveyor requested documentation of stain quality assessed for the dates when the 476 patients had been tested on 2/14/23 at 11:30 pm and it was not made available. 3. An interview on 2/14/23 at 11:32 pm with Testing Personnel #2 revealed the laboratory had not performed and documented staining intended reactivity each day of use for slides that had been prepared at an outside laboratory.
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 Testing Personnel #2, the laboratory failed to include the name and address of the laboratory where tissue specimen gross examinations were performed for 1 (Patient 22-53) of 13 patient test reports reviewed. Findings include: 1. A review of patient test records revealed Patient 22-53 had testing performed on 1/13/23 using a specimen that had been prepared and grossed at a reference laboratory. The test report included the grossing results from the reference laboratory but did not list the name and address of the laboratory where testing was performed. 2. An interview on 2/14/23 at 11:32 am with Testing Personnel #2 revealed patients that had specimens prepared at an outside laboratory between November 2021 and January 2022 had not included the grossing laboratory's information on the test report. ***This is a repeated deficiency from the 1/9/17 recertification survey***