Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0680316	10/01/2020
Name of Provider or Supplier	**Street Address, City, State**	
Associated Skin Care Specialists Pa	18315 Cascade Dr Suite #150, Eden Prairie, MN	

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
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, document review, and interview with laboratory personnel, the laboratory failed to ensure a stain used for Histopathology tissue processing was not used after the expiration date had been exceeded in 2020. Findings are as follows: 1. The laboratory performed Mohs micrographic surgery and Histopathology slide examination as confirmed by the Laboratory Specialist (LS) during a tour of the laboratory at 10:10 a.m. on 10/01/20. 2. A requirement to inspect all date sensitive products was established in the Equipment Maintenance - Linistainer and Stains procedure found in the Policy and Procedure manual. 3. Expired Thermo Scientific Eosin-Y stain was observed as present and available for use during the tour. See below for detailed information. Stain Exp. Lot number Eosin-Y 05/2020 475731 3. The laboratory used the expired stain June through September 2020. 4. In an interview at 10:15 a.m. on 10/01/20, the LS confirmed the above finding. .
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 observation, document review, and interview with laboratory personnel, the laboratory failed to ensure 1 of 2 test reports reviewed on date of survey included complete test results. Findings are as follows: 1. The laboratory performed Mohs micrographic surgery and Histopathology slide examination as confirmed by the Laboratory Specialist (LS) during a tour of the laboratory at 10:10 a.m. on 10/01/20. 2. Case E-M-345, performed on 08/20/18, was 1 of 2 cases reviewed on date of survey. The Mohs map and associated slide labeling indicated the surgery was performed in two stages. Mohs map documentation indicated the tissue margins were clear of tumor after the second surgical stage. 3. The operative report (test report) included a description of the first surgical stage and indicated residual tumor was seen. The report did not include a description of the second surgical stage nor a statement indicating the final result of the surgery. 4. In an interview at 12:05 p.m. on 10/01/20, the LS confirmed the above finding.