Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0926680	03/29/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bellaire Dermatology Associates, Pa	6565 West Loop South, Suite 800, Bellaire, TX	

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
D0000	The laboratory was found to be in compliance with the CLIA regulations at 42 C.F.R. and recertification is recommended, Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representative was given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
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 a review of patient logs from 2016 and 2017, quality control logs from 2016 and 2017, and confirmed in interview of facility personnel, it was revealed the laboratory failed to have documentation of verifying the accuracy of the following special stains at least twice annually: PAS - Periodic acid-Schiff GMS - Grocott-Gomori's methenamine silver stain AFB - Acid Fast Bacilli The findings were: 1. A review of patient test logs from 2016 and 2017 revealed the laboratory performed the following special stains at least once annually for 2016 and 2017: PAS - Periodic acid-Schiff GMS - Grocott-Gomori's methenamine silver stain AFB - Acid Fast Bacilli 2. A review of special stain quality control logs from 2016 and 2017 revealed the laboratory performed the following special stains at least once annually for 2016 and 2017: PAS - Periodic acid-Schiff GMS - Grocott-Gomori's methenamine silver stain

	AFB - Acid Fast Bacilli 3. The laboratory was asked to provide documentation of performing twice annual accuracy assessments for each of the special stains in 2016 and 2017. No documentation was provided. 4. An interview with the laboratory operations manager on 03/29/2018 at 1100 hours in the break room confirmed the findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow manufacturer's instructions for proper storage of reagents. The findings were: 1. Direct observation on 03/29/2018 at 0915 hours in the laboratory during the initial tour of the laboratory revealed the following items stored in the refrigerator: a. 1 container "Gold Chloride 1% w/v aqueous solution" Lot #6217 (expiration date: 08-04-2018) b. 1 container "Sodium Thiosulfate" Lot #31165 (expiration date: 11-2015) 2. Review of the laboratory's policy titled, "13.3.5 Reagents, Preparation, Supplies, and Locations" stated: "1% Gold Chloride - Refrigerator" "Sodium Thiosulfate - Cabinet under hood" 3. Review of the manufacturer's labeling instructions on the outside of the container for "Gold Chloride" stated, "Store at Room Temperature." 4. Review of the manufacturer's labeling instructions on the outside of the container for "Sodium Thiosulfate" stated, "Store at 18-25 degrees Celsius." 5. The laboratory was asked to provide documentation of following the manufacturer's instructions for storage of the reagents. No documentation was provided. 6. An interview with testing personnel two (as listed on Form CMS-209) on 03/29/2018 at 1045 hours in the laboratory confirmed the findings. Key: w/v - weight per volume CMS - Centers for Medicare and Medicaid Services
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 policy, and confirmed in interview of facility personnel, the laboratory failed to ensure reagents were identified. The findings were: 1. Direct observation in the laboratory on 03/29/2018 at 0915 hours during the initial tour of the laboratory revealed a glass jar filled with a liquid. The jar was not identified with the identity or the lot number. High complexity testing personnel number two (as listed on Form CMS-209) later identified the reagent as Silver Nitrate, but when asked to provide the original container to verify the lot

	number, it could not be located. 2. Review of laboratory policy, "13.2.5 Reagents, Preparation, Supplies, and Locations" stated, "Label should contain: name of reagent, dated poured into Coplin jar, expiration date, any related hazards (see MSDS located in Appendix B). 3. The laboratory was asked to provide documentation of labeling the container with the appropriate information. No documentation was provided. 4. An interview with the laboratory director, laboratory operations manager, and testing personnel two (as listed on Form CMS-209) on 03/29/2018 at 1100 hours in the conference room confirmed the findings. Key: MSDS - material safety data sheet CMS - Centers for Medicare and Medicaid Services
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 surveyor observations and confirmed in staff interview, it was revealed the laboratory failed to ensure that expired materials were not available for use in patient testing. The findings were: 1. A surveyor observation on 03/29/2018 at 0915 hours in the laboratory during the initial tour of the laboratory revealed the following expired items: a. 1 open container of "Schiff's Reagent" Lot #615103-16 - expiration date: 06-2016 b. 1 open container of "Sodium Thiosulate" Lot #31165 - expiration date: 11-2015 c. 1 open container of "10% Silver Nitrate" Lot # (not identified) - expiration date: 12-18-2016 d. 1 open container of "10% KOH" Lot # (not identified) - expiration date: 06-15-2017 2. The laboratory was asked to provide documentation of ensuring expired items were not available for patient testing. No documentation was provided. 3. An interview with testing personnel two (as listed on Form CMS-209) at 1045 hours in the laboratory confirmed the findings. She revealed that new reagents were on order.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the ThermoFisher Shandon Varistain Gemini stainer (A780104702 Issue 4), review of the laboratory's maintenance records from 2016 and 2017, and confirmed in staff interview, it was revealed the laboratory failed to have documentation of annual performance maintenance on the ThermoFisher Shandon Varistain Gemini stainer. The findings were: 1. A review of the manufacturer's instructions for the ThermoFisher Shandon Varistain Gemini stainer (A780104702 Issue 4) on page 64 stated, "5.2 MAINTENANCE: The Shandon Varistain Gemini stainer requires annual servicing by a qualified engineer." 2. The laboratory was asked to provide documentation of the

	annual performance maintenance records for 2016 and 2017. No documentation was provided. 3. An interview with the laboratory operations manager on 03/29/2018 at 1210 hours in the laboratory director's office confirmed the findings.
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 random review of patient final reports and confirmed in interview of facility personnel, the laboratory failed to have the facility's address on Mohs maps as part of the final report. The findings were: 1. Review of two patient Mohs cases, one from 2016 and one from 2017, revealed the laboratory's address was not included on the Mohs maps. The cases reviewed were: Patient 1 Mohs #M160105 Date: 11-30-2016 Patient 2: Mohs: M17-352 Date: 10/17/2017 2. The laboratory was asked to provide documentation that the address was included on the Mohs maps. No documentation was provided. 3. Interview with the laboratory director, the laboratory operations manager, and testing personnel two and three (as listed on Form CMS-209) on 03/29 /2018 at 1220 hours in the laboratory's director's office confirmed the findings. CMS - Centers for Medicare and Medicaid Services
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on direct observation and confirmed in interview of facility personnel, the laboratory director failed to ensure a safe working environment for employees. The findings were: 1. Direct observation made on 03/29/2018 at 0915 hours in the laboratory during the initial tour of the laboratory revealed a laboratory refrigerator labeled as infectious. Inventory of the contents of the refrigerator in the bottom drawer revealed one container of "Oikos" brand yogurt and one small jar of "Blossom Honey." 2. The above findings were confirmed in interview of the laboratory operations manager and the laboratory director on 03/29/208 at 0915 hours in the laboratory. They confirmed they did not know the items were stored in the refrigerator.