

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0926680	(X3) Date Survey Completed 11/14/2019
Name of Provider or Supplier Bellaire Dermatology Associates, Pa	Street Address, City, State 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	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. 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.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory test list and staff interview, it was revealed the laboratory failed to have documentation of verifying the accuracy of all stains used at least twice annually in 2018. Findings include: 1. A review of the laboratory test list revealed the laboratory performed the following stains in 2018: a) Wade-Fite's Acid Fast Stain b) PAS stain- Periodic acid-Schiff 2. The laboratory was asked to provide documentation of performing the twice annual accuracy assessments for each of the special stains in 2018. No documentation was provided. 3. An interview with the head of laboratory operations on 11/14/19 at 10:20 a.m. in the conference room, after review of the records, confirmed the above findings.</p>

<p>D6029</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory director failed to ensure that testing personnel had documentation of the appropriate training to perform moderate complexity testing (refer to D6066).</p>
<p>D6046</p>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel files, and staff interview, it was revealed the technical consultant failed to perform competency assessments on 6 of 10 testing personnel for moderately complex testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 11/14/19), revealed the laboratory identified 10 testing personnel. 2. A review of the laboratory's personnel records revealed that there was no documentation of the technical consultant performing competency assessments for 6 of 10 testing personnel for moderately complex testing for the specialties Mycology and Parasitology. The testing personnel with no documentation of competency assessments: Testing person #2 Testing person #3 Testing person #4 Testing person #7 Testing person #8 Testing person #10 4. An interview with the head of laboratory operations on 11/114/19 at 10:00 a.m. in the conference room, after review of the records, confirmed the above findings.</p>
<p>D6066</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii)</p> <p>Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of training for 8 of 10 testing personnel to perform</p>

moderately complex testing. Findings include: 1. A review of the laboratory's CMS 209 form (signed by the laboratory director on 11/14/19) revealed the laboratory identified 10 testing personnel. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training for the following testing personnel (as indicated on the CMS 209 form) for moderately complex testing for the specialties Mycology and Parasitology: Testing Person #2 Testing Person #3 Testing Person #4 Testing Person #5 Testing Person #6 Testing Person #7 Testing Person #8 Testing Person #10 3. The laboratory was asked to provide documentation of the training for the above testing personnel. No documentation was provided. 4. An interview with the head of laboratory operations on 11/14/19 at 10:00 a.m. in the conference room, after review of the records, confirmed the above findings.