

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0686649	(X3) Date Survey Completed 01/31/2020
Name of Provider or Supplier Southeast Dermatology, Pa	Street Address, City, State 11914 Astoria Blvd Suite 570, Houston, 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	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.
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: A. Based on a review of the laboratory's policies, a review of the laboratory's Quality Assurance records from 2018 and 2019, and staff interview, it was revealed the laboratory failed to have documentation of verifying the accuracy of H&E Histopathology slides at least twice annually in 2018 (only one accuracy assessment was done in 2018). Findings include: 1. A review of the laboratory's policy titled 'Histopathology and Special Stains Quality Assurance' revealed the following: "The following measures are implemented to maintain a high level of quality in the interpretation of histopathology specimens: - Second review of five specimens every 6 months by another CLIA certified laboratory (include both conventional H&E histopathology and special stains). 2. A review of the Quality Assurance records for</p>

2018 revealed the following dates when an accuracy assessment was performed for H&E Histopathology: 6/25/18 3. The laboratory was missing the documentation of a second accuracy assessment being performed in 2018. 4. An interview with the laboratory director on 1/31/2020 at 11:05 a.m. in the break room, after review of the records, confirmed the above findings. B. Based on a review of the laboratory's Quality Assurance records from 2018 and 2019, and staff interview, it was revealed the laboratory failed to have documentation of verifying the accuracy of Tzanck Stain Preparations at least twice annually in 2018 and 2019. Findings include: 1. A review of the Quality Assurance records for 2018 and 2019 revealed the laboratory failed to have documentation of assessing the accuracy of the Tzanck stain preparation at least twice annually. 2. An interview with the laboratory director on 1/31/2020 at 11:05 a. m. in the break room, after review of the records, confirmed the laboratory did not know that an assessment on the Tzanck stain was needed. C. Based on a review of the laboratory's policies, a review of the laboratory's Quality Assurance records from 2018 and 2019, and staff interview, it was revealed the laboratory failed to have documentation of verifying the accuracy of Mohs slides at least twice annually in 2018 and 2019 (only one accuracy assessment was done each year). Findings include: 1. A review of the laboratory's policy titled 'Proficiency Testing' revealed the following: "Purpose: This is done for the evaluation of diagnoses of the Mohs surgeon and dermatopathologist. Frequency: January & June of the calendar year. Procedure: Ten Mohs cases are randomly selected to be pulled and put on the slide trays and given to the Dermatopathologist. They will evaluate the slides and list if they concurs with diagnoses." 2. A review of the Quality Assurance records for 2018 and 2019 revealed the following dates when an accuracy assessment was performed for Mohs slides: 1/4 /18 12/3/19 3. The laboratory was missing the documentation of a second accuracy assessment being performed in 2018 and 2019. 4. An interview with the laboratory director on 1/31/2020 at 11:05 a.m. in the break room, after review of the records, confirmed the above findings.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
 CFR(s): 493.1413(b)(8)

(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.

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 1 of 8 testing personnel for moderately complex testing in 2018. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 1/27/20), revealed the laboratory identified 8 testing personnel who performed moderately complex testing (Potassium Hydroxide Preparation, Mineral Oil Preparation, Tzanck Stain Preparation). 2. A review of the laboratory's personnel records revealed that there was no documentation of the technical consultant performing competency assessments for 1 of 8 testing personnel for moderately complex testing in 2018. The testing personnel with no documentation of a competency assessment: Testing person #5 3. An interview with the laboratory director on 1/31/20 at 11:05 a.m. in the break room, after review of the records, confirmed the above findings.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

The laboratory director must 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.

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 laboratory director failed to ensure documentation of site-specific training (demonstrating that they can perform all testing operations for this laboratory) for 1 of 2 testing personnel performing high complexity testing (Mohs). Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 1/27/20) revealed the the laboratory identified 2 testing personnel performing high complexity testing (Mohs). 2. A review of the laboratory's personnel records revealed testing person #2 had no documentation of site-specific training, demonstrating that they can perform all testing operations for this laboratory. 3. An interview with the laboratory director on 1/31/20 at 11:05 a.m. in the break room, after review of the records, confirmed the above findings.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

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 laboratory director failed to have documentation specifying the responsibilities and duties of the clinical consultant and the general supervisor. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 1/27/20) revealed the laboratory identified 1 clinical consultant and 1 general supervisor. 2. A review of the laboratory's personnel files revealed the records failed to have documentation specifying the responsibilities and duties of the clinical consultant and the general supervisor. 3. An interview with the laboratory director on 1/31/20 at 11:05 a.m. in the break room, after review of the records, confirmed the above findings.