

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0686649	(X3) Date Survey Completed 01/30/2018
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.
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 review of laboratory records for accuracy assessment, and confirmed in interview, the laboratory failed to verify, at least twice annually, the accuracy of 8 special stain tests. Findings were: 1. No documentation was available for review for the accuracy assessment for the 7 special stains the laboratory performed for the years 2016 and 2017. FITE (laboratory performed 92 tests in 2016 and 85 tests in 2017) Colloidal Iron (laboratory performed 192 tests in 2016 and 224 tests in 2017) Gram stain (laboratory performed 87 tests in 2016 and 94 tests in 2017) Perl's Iron (laboratory performed 45 tests in 2016 and 69 test in 2017) Fontana-Masson (laboratory performed 40 tests in 2016 and 31 tests in 2017) Elastic Tissue (laboratory performed 13 tests in 2016 and 12 tests in 2017) Von Kossa Calcium (laboratory performed 4 tests in 2016 and 10 tests in 2017) 2. Review of Consecutive Specimens twice yearly by second CLIA-certified laboratory revealed the laboratory performed an accuracy assessment for PAS on 2/15/16. The laboratory was asked for the 2nd accuracy assessment for PAS in 2016. No documentation was provided. No documentation was available for review for the accuracy assessment for PAS for 2017. PAS (laboratory performed 470 tests in 2016 and 590 tests in 2017) 3. An</p>

interview with the lab director on 01/30/18 at 1120 hours in the office confirmed the laboratory does not perform an accuracy assessment twice a year for all of the above stains. Key FITE - type of staining method to detect the presence of either Nocardia sp. or Mycobacterium leprae sp. (causative agent of leprosy) in tissue Colloidal Iron - type of staining method for histological visualization of acid mucopolysaccharides gram stain - method of staining used to differentiate bacterial species into two large groups (gram-positive and gram-negative) PAS - type of Periodic acid-Schiff (PAS) staining method Perl's Iron - staining method to detect the presence of ferric iron in tissue (normally occurring or from ruptured red blood cells) Fontana-Masson - silver based histochemical stain used for two purposes: (1) to demonstrate melanin and (2) to demonstrate argentaffin granules in neuroendocrine cells Elastic Tissue - staining elastic fibres (blue/black) and collagen (red/pink) in formalin fixed paraffin tissues. Muscle and other tissues appear yellow. Von Kossa Calcium - staining method to quantify mineralization in cell culture and tissue sections

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and records, the laboratory quality assessment failed to identify that laboratory did not perform twice annual accuracy assessment for all tests performed in the laboratory. (special stains) Findings were: 1. Review of the laboratory quality assurance policy (updated December 2015) state "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 hisopathology and special stains.) 2. Review of Consecutive Specimens twice yearly by second CLIA-certified laboratory revealed no documentation of the twice annual accuracy assessment for the following 8 special stains: FITE Colloidal Iron Gram stain Perl's Iron Fontana-Masson Elastic Tissue Von Kossa Calcium PAS 3. An interview with the laboratory director on 1/30/18 at 1120 hours in the office confirmed the above findings. Key FITE - type of staining method to detect the presence of either Nocardia sp. or Mycobacterium leprae sp. (causative agent of leprosy) in tissue Colloidal Iron - type of staining method for histological visualization of acid mucopolysaccharides gram stain - method of staining used to differentiate bacterial species into two large groups (gram-positive and gram-negative) PAS - type of Periodic acid-Schiff (PAS) staining method Perl's Iron - staining method to detect the presence of ferric iron in tissue (normally occurring or from ruptured red blood cells) Fontana-Masson - silver based histochemical stain used for two purposes: (1) to demonstrate melanin and (2) to demonstrate argentaffin granules in neuroendocrine cells Elastic Tissue - staining elastic fibres (blue/black) and collagen (red/pink) in formalin fixed paraffin tissues. Muscle and other tissues appear yellow. Von Kossa Calcium - staining method to quantify mineralization in cell culture and tissue sections