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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 34D0245307 | (X3) Date Survey Completed 12/13/2018 |
| Name of Provider or Supplier Southeastern Dermatology, Pa | Street Address, City, State 4390 Fayetteville Rd, Lumberton, NC | |
| 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 |
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| 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 policy and procedures, review of test verification records and office manager interview 12/13/18, the laboratory failed to verify the accuracy of fungal culture testing at least twice annually. The laboratory participates in split specimen testing with a reference laboratory to verify the accuracy of fungal culture testing. Review of laboratory policy "Verification of Accuracy for Fungus cultures using DTM" revealed the following..."Discrepancies in split specimen results....The results will be compared. If one is positive and one is negative, a repeat culture may be ordered. The physician can elect not to repeat culture if clinical findings suggested a positive result and patient was treated with clearing of condition." The laboratory policy for discrepancies in split sample results fails to include a review of the testing process that could possibly cause a discrepancy in results. For example: It does not include review of quality control. It does not include a review of clerical errors. It does not include a review of specimen transport problems. It does not include media storage problems. Review of fungal culture verification record "Quality Control Log: Worksheet" revealed the following split samples had discrepancies and failed to verify the accuracy of the laboratory's fungal culture testing: 1. Chart #47106, 2/5/18, laboratory results were positive; reference laboratory results were negative. "Corrective action/Comment" for result discrepancy states "pt denied ty". 2. Chart #31263, 3/29/18, laboratory results were positive, reference laboratory results were negative. "Corrective action/Comment" for result discrepancy is blank. "Treatment" column states "Oifocan, Lamisil, Ciclopirox". Exit interview with office manager at approximately 12:30 p.m. confirmed the split samples failed to verify the accuracy of fungal culture testing performed. She stated</p> |

the patient was treated so they could not retest the sample and she did not know what else could they do in regards to discrepancies, but would do whatever was required for compliance.