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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 34D0860277 | (X3) Date Survey Completed 06/14/2018 |
| Name of Provider or Supplier Hickory Dermatology | Street Address, City, State 1899 Tate Boulevard Se, Suite 2110, Hickory, 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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| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and interview with staff 6/14/18, the laboratory failed to follow policies and procedures for evaluating the competency of the providers who read KOH (potassium hydroxide) and scabies preps, Tzanck smears, and DTM (dermatophyte test medium) fungal cultures. Review of personnel records for 3 of 3 providers who read KOH (potassium hydroxide) and scabies preps, Tzanck smears, and DTM (dermatophyte test medium) fungal cultures revealed there was no documentation of competency evaluations for any of the providers since the last survey on 3/24/16. During interview at approximately 11:00 a.m., histotechnician #1 confirmed there were no competency evaluations available for 3 of 3 providers.</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 review of 2016, 2017, and 2018 patient logs and interview with TP (testing personnel) 6/14/18, the laboratory failed to verify the accuracy of the scabies preps, DTM (dermatophyte test medium) fungal cultures, and Tzanck smears at least twice a year during 2016, 2017, and 2018. Findings: 1. Review of patient logs revealed the</p> |

laboratory had not documented any patient scabies preps since 12/10/15. During interview at approximately 12:40 p.m., TP #3 (the former laboratory director) stated that they had performed some scabies preps since then. He stated that they might have been documented as KOH preps, so it would be difficult to tell how many were actually done. He confirmed there was no documentation that the laboratory had verified the accuracy of the scabies preps at least twice a year during 2016, 2017, and 2018. 2. Review of patient logs revealed the laboratory documented verifying the accuracy of the DTM fungal cultures 1 time in 2016. The laboratory failed to document verifying the accuracy of the DTM fungal cultures during 2017, and had not documented verifying the accuracy of the DTM fungal cultures from 1/1/18 - 6/14/18. 3. Review of patient logs revealed the laboratory performed 2 patient Tzanck smears during 2016, 3 patient Tzanck smears in 2017, and 1 patient Tzanck smear from 1/1/18 - 6/14/18. The laboratory verified the accuracy of the Tzanck smears by having two testing personnel read and document their results only 1 time in 2016 and 2017, and 1 time in 2018 from 1/1/18 - 6/14/18.

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions and procedure manual review 6/14/18, the laboratory's procedure manual was not complete and current for the DTM (dermatophyte test medium) fungal culture testing performed. Findings: 1. Manufacturer's instructions for HealthLink "DERMATOPHYTE TEST MEDIUM" require inspection of each lot number/shipment of media to ensure acceptability for use. The instructions state on page 1 "... VI. STORAGE/SHELF LIFE ... Do not use vials that exhibit evidence of drying, cracking, discoloration, microbial contamination or any other signs of deterioration. ..." Review of the laboratory's procedure manual revealed the DTM Fungal Culture procedure did not include instructions for inspection of each lot number/shipment of DTM on receipt to ensure acceptability for use, including how and where the inspection should be documented. 2. The laboratory's DTM Fungal Culture procedure states "Storage, Use, and Handling of Media Manufacturer's control checks of media are not provided; therefore, the laboratory will check each lot of DTM media for their ability to support growth and as

appropriate selectively inhibit non-pertinent organisms by using commercially available dermatophyte test samples and controls. All information will be properly documented. ... Quality Control Procedures Quality control test specimens will be used as controls (both (+) and (-)) periodically. ..." The DTM Fungal Culture procedure did not include step-by-step instructions for performing quality control growth checks, including what organisms are used, the expected reactions for each organism, the incubation times, how and where the results are documented, and what steps should be taken if the growth check results are not acceptable.

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 review of a random patient test report (MR #164655) and interview with staff 6/14/18, the test report did not include all required information. 1. Review of a random KOH (potassium hydroxide) prep test report (MR# 164655) revealed the KOH prep test result was documented in the patient's electronic medical record under "Visit Findings". The test report printed from the electronic medical record did not include the laboratory's name and address. During interview at approximately 2:10 p. m., histotechnician #1 confirmed that the laboratory's name and address was not included on the patient test report. She stated they were unsure whether the report could be printed in another format to include the name and address of the laboratory.