Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0954398	(X3) Date Survey Completed 05/12/2022
Name of Provider or Supplier Duke Lightner Dermatology	**Street Address, City, State** 11081 Forest Pines Drive, Suite 110, Raleigh, 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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of laboratory records, review of patient testing logs and interview with laboratory director (LD) 5/12/22, the laboratory failed to establish and/or maintain verification of accuracy for the Dermatophyte Test Medium (DTM) testing, the Potassium hydroxide (KOH)/Wet Prep testing and the Tzanck stain testing since time of last survey, 2/14/19. A period of approximately 3 years and 3 months in which verifications of accuracy were not performed. 4 DTM tests, 4 KOH/Wet tests and 3 Tzanck stains were performed since February of 2019. Findings: 1. The laboratory failed to establish a verification of accuracy procedure for the DTM testing performed and failed to perform a verification of accuracy for the DTM test since time of last survey, 2/14/19. Review of laboratory procedures revealed no procedure for the verification of accuracy for the DTM testing performed. Review of laboratory records revealed no documentation of a verification of accuracy for the DTM test. Review of patient testing logs for DTM revealed 4 patients were tested. Interview with LD at approximately 10:50 a.m. confirmed the laboratory did not perform a verification of accuracy for the DTM test and the laboratory has no procedure for the verification of accuracy for the DTM test. She also confirmed 4 DTM tests were performed since time of last survey. 2. The laboratory failed to perform a verification of accuracy for the KOH/Wet Prep test since time of last survey, 2/14/19. Review of laboratory procedure "PEER SUPERVISED CLIA PROFICIENCY TESTING: KOH" revealed "...Duke is in the process of setting up Quality Control Testing for this procedure. The test will be taken twice a year....". Review of laboratory records revealed no documentation of "test" for the verification

	of accuracy of the DTM test. Review of patient testing logs for the KOH/Wet Prep revealed 4 patients were tested. Interview with LD at approximately 10:50 a.m. confirmed the laboratory did not perform a verification of accuracy for the KOH/Wet Prep test. She stated, due to COVID, Duke never set up the process as intended and she needed to get in touch with them as to the status. She also confirmed 4 KOH/Wet Preps were performed since time of last survey. 3. The laboratory failed to perform a verification of accuracy for the Tzanck stain since time of last survey, 2/14/19. Review of laboratory procedure "PEER SUPERVISED CLIA PROFICIENCY TESTING: TZANCK PREP" revealed "...a viral culture swab will be obtained from the same area of the skin. This will be sent to LabCorp in viral culture media for confirmation of Tzanck preps taken.". Review of laboratory records revealed no documentation of viral culture swabs sent to LabCorp and the corelation with the Tzanck stain. Review of patient testing logs for the Tzanck stain revealed 3 patients were tested. Interview with LD at approximately 10:50 a.m. confirmed the laboratory did not perform a verification of accuracy for the Tzanck stain. She also confirmed 3 Tzanck stains were performed since time of last survey, 2/14/19.
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 random patient test reports and interview with office staff 5/12/22, the patient test report failed to include the correct address of the laboratory. Findings: Review of random patient test reports, MR# PH5601 and MR# D3088324, revealed the laboratory address as 82 Wheaton Dr., Youngsville, NC 27596. The address where testing was performed is 11081 Forest Pines Drive, Suite 110, Raleigh, NC 27614. Interview with office staff at approximately 11:00 a.m. confirmed the laboratory address on the patient test reports were incorrect.