Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0071559	03/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Northeast Dermatology Associates	111 Maplewood Ave, Ste A, Portsmouth, NH	

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
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have an adequate system in place to ensure mycology test results are sent accurately and reliably to the final report destination. Findings include: 1) Review on 3/12/18 of a final report for Accuderm Acu-DTM mycology testing reported on 2/20/17 revealed the laboratory sent mycology test results via an electronic intramail system to the provider. 2) Interview on 3/12/18 at 10:30 a.m. with testing personnel revealed that final patient mycology test reports could only be accessed and viewed in the laboratory by the testing personnel who sent the intramail report. 3) The laboratory performs 272 Acu-DTM patient tests annually.
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 record review and staff interview, the laboratory failed to include the name and location where mycology testing was performed on the final reports. Findings include: 1) Review on 3/12/18 of a final report for Accuderm Acu-DTM mycology testing reported on 2/20/17 revealed the laboratory sent mycology test results via an intramail electronic system to the provider. Further review of this final report revealed that the report did not include the name and address of the laboratory where the Acu-DTM test was performed. 2) Interview on 3/12/18 at 10:30 a.m. with testing personnel confirmed the above finding. 3) The laboratory performs 272 Acu-DTM patient tests annually.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to correct problems identified with mycology test reports from February 2017 to March 2018. Findings include: 1) Review on 3/12/18 of a final report for Accuderm Acu-DTM mycology testing reported on 2/20/18 revealed the laboratory sent mycology test results via an intramail electronic system to the provider. 2) Interview on 3/12/18 at 10:30 a.m. with testing personnel revealed that each mycology test report could only be viewed by the provider the intramail was sent to and the testing personnel who sent it. The testing personnel further revealed that the laboratory began using the current mycology test report in February 2017 and had requested more access to the electronic system so that laboratory personnel can review all patient Acu-DTM test reports. As of this survey date, no additional access or updates to the current reporting process has been made to address the problems the laboratory has identified over the last 13 months. 3) Cross reference deficiency tags D5801 and D5805.