

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0921152	(X3) Date Survey Completed 08/05/2020
Name of Provider or Supplier Molecular Diagnostcs Dept Of Dermatology	Street Address, City, State 233 South 10th Street, Philadelphia, PA	
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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the testing personnel (TP), the laboratory failed to document test requisitions for 7 of 7 patient specimen analyzed for pseudoxanthoma elasticum ABCC6 mutation gene in 2019. Findings include: 1. On the day of survey, 08/05/2020, the TP could not to provide test requisitions for 7 of 7 patient specimen analyzed for pseudoxanthoma elasticum ABCC6 mutation gene in 2019. 2. TP confirmed the above finding on 08/05/2020 around 11:00 am.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the testing personnel (TP),</p>

the laboratory failed to document patient test report for 3 of 7 patient specimen analyzed for pseudoxanthoma elasticum ABCC6 mutation gene in 2019. Findings include: 1. On the day of survey, 08/05/2020, the TP could not to provide test reports for 3 of 7 patient specimens analyzed for pseudoxanthoma elasticum ABCC6 mutation gene in 2019. 2. the TP confirmed the above finding on 08/05/2020 around 11:00 am.