

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2209172	(X3) Date Survey Completed 01/24/2023
Name of Provider or Supplier Genophyll Enterprises	Street Address, City, State 1 Deer Park Drive, Monmouth Junction, NJ	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Patient Requisition (PR), Final Report (FR) review of the Manufacture Instructions for Use (MIU) and interview with the General Supervisor (GS), the laboratory failed to follow the MIU for Virology testing performed on the Atila BioSystems analyzer from 12/12/22 to the date of survey. The findings include: 1. The MIU stated under "Specimens", "Acceptable Specimens", "Specimen Handling and Storage", "Specimens can be stored at room temperature for up to 12 hours". 2. 1 out of 10 patients FR had the sample received by the laboratory greater than 12 hours. 3. The GS confirmed on 1/24/23 at 11:40 am the laboratory failed to follow the MIU.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on surveyor review of Personnel Records (PR) and interview with the General Supervisor (GS), the Laboratory Director failed to ensure that the education records were available on the date of the survey. The finding includes: 1. Education records were not available for three out of three TP. 2. The GS confirmed on 1/24/23 at 10:00 am that education records were not available.