

DECLARATION OF CONFORMITY

The declaration of conformity is issued by:

Company business name:	Abbott Rapid Diagnostics Jena GmbH, Orlaweg 1, 07743 Jena, Germany
Headquarters:	Abbott Rapid Diagnostics Jena GmbH, Orlaweg 1, 07743 Jena, Germany
ID(registration number):	29133068

as a manufacturer of the in vitro diagnostic medical device for self-testing:

Name:	Panbio™ COVID-19 Antigen Self-Test
Model:	41FK51 C = 1Test configuration 41FK71C = 10 test configuration 41FK81C = 20 Test configuration
Brand:	Abbott Panbio™

Based on the exemption granted by the Ministry of Health of the Czech Republic pursuant to Section 4, Paragraph 8 of Government Decree No. 56/2015 Coll., on technical requirements for in vitro diagnostic medical devices, the intended use is self-testing on the basis of self-collection (by a lay person).

Ref. Decision of the Ministry of Health of the Czech Republic:	<i>will be filled in by the applicant only after receiving a new decision of the Ministry of Health</i>
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We declare that the properties of the above-mentioned in vitro diagnostic medical device meet the basic requirements of Government Decree No. 56/2015 Coll., on technical requirements for in vitro diagnostic medical devices (Council Directive 98/79/EC), which determines technical requirements for diagnostic in vitro medical devices.

Place and Date: Jena, Germany 16 April 2021

Name, surname and Position: Claudia Christner-Albrecht, Manager Regulatory Affairs

Signature: _____




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