EU Declaration of Conformity

In accordance with EU Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

Manufacturer:	**Roche Molecular Systems, Inc.** **1080 US Highway 202 South** **Branchburg, NJ 08876** **USA**
Single Registration Number (SRN) Manufacturer:	**US-MF-000018066**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Single Registration Number (SRN) Authorized Representative:	**DE-AR-000006262**

This declaration is issued under the sole responsibility of Roche Molecular Systems, Inc.

Product Information

Part Number:	Product Name:	Basic UDI-DI:
07001088190	**cobas**® DPX - 96	761333600859BE
09171126190	**cobas**® DPX - 192	761333602495BC
09040749190	**cobas**® DPX Control Kit	761333600860AX

Intended Purpose: The **cobas**® DPX test is an in vitro test for the direct quantitation of parvovirus B19 genotypes 1, 2, and 3 DNA and the direct qualitative detection of Hepatitis A virus (HAV) genotypes I, II, and III RNA in human plasma. This test is intended for use as an in-process test to quantify parvovirus B19 DNA alone or to simultaneously quantify parvovirus B19 DNA and detect HAV RNA in plasma intended for further manufacture collected from donors of whole blood, blood components, or plasma. Plasma from all donors or manufacturing pools may be tested as individual samples or in pools comprised of aliquots of individual samples.

	This test is not intended for use on samples of cord blood. This test is not intended for use as an aid in diagnosis for parvovirus B19 or HAV.
Risk Class and Classification Rule:	Class D, as per EU Regulation 2017/746, Annex VIII, Rule 1
Common Specifications:	At this time, the Commission Implementing Regulation (EU) 2022/1107 is not applicable for this product.
Name, Address and Identification number of the Notified Body:	BSI Group The Netherlands B.V. Notified Body Number: 2797 Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands

Conformity Assessment was established through the procedure described in Annex IX of EU Regulation 2017/746, including an assessment of the Technical Documentation as described in Annex IX, Chapter II. This declaration is supported by the following certificate(s):

EU Quality Management System Certificate: IVDR732732
First Issued: 2021-04-29 Valid until: 2026-04-28
EU Technical Documentation Assessment certificate: IVDR732829
First Issued: 2023-05-31 Valid until: 2028-05-30

Conformity of the product with EU Regulation 2017/746 and other applicable EU legislation has been established.

On behalf of Roche Molecular Systems, Inc.

Place: Rotkreuz, Switzerland

Date: 31 July 2023

DocuSigned by:
Nathalie Pankiw
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Nathalie Pankiw
Network Lead Molecular Lab
Pre-Market Quality

Place: Pleasanton, CA

Date: 07 August 2023

DocuSigned by:
Rita Hoady
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Rita Hoady
Network Lead
Global Head of Regulatory Affairs, Molecular Lab