PRODUCT SAFETY DATA SHEET

1. Company/Undertaking Identification

Supplier:

Health in Code, S.L.
Calle de la Travesía s/n, 15E Base 5, Valencia, 46024, España.
https://www.healthincode.com

Emergency Response:

National Institute of Toxicology:
+34 91 562 04 20

2. Product information

Kit name	DPYD PharmaKitDx
Kit reference	IMG-413
Internal references	Without internal references
Reactions	4x48
Intended use	In vitro diagnosis use only

Components:

- **DPYD*2A Master Mix:** Specific oligonucleotides, FAM and VIC TaqMan probes, and nuclease-free water to detect the DPYD*2A genetic variant.
- **DPYD*13 Master Mix:** Specific oligonucleotides, FAM and VIC TaqMan probes, and nuclease-free water to detect the DPYD*13 A>C genetic variant.
- **DPYD*hapB3 Master Mix:** Specific oligonucleotides, FAM and VIC TaqMan probes, and nuclease-free water to detect the IVS10 G>C genetic variant.
- **DPYD D949 Master Mix:** Specific oligonucleotides, FAM and VIC TaqMan probes, and nuclease-free water to detect the D949 T>A genetic variant.
- **General Master Mix*:** Hotstart DNA polymerase for the real-time PCR assay containing 10-30% glycerol and buffers.
- **Positive Control:** Heterozygous positive control for the targets of interest.

*Note: see safety data sheet for TaqMan™ Environmental Master Mix 2.0 (200 reactions), ref: 4396838.

Identification of hazards:

Health in Code S.L. declares that the following product, in accordance with the following declarations, complies with the applicable legislation:

- Commission Delegated Regulation (EU) 2022/692 of 16 February 2022 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No. 1272/2088 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.
- Commission Regulation (EU) 2022/586 of 8 April 2022 amending Annex XIV to Regulation (EC) 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
- Not regulated for transport by road (ADR), air (IATA) and sea (IMDG).

According to Regulation (EU) 2022/692 components containing no more than 1% of a component classified as hazardous and no more than 0.1% of a component classified as carcinogenic do not require a Material Safety Data Sheet (MSDS). Components marked with an asterisk "*" do, on the other hand, require an SDS.
*1 These reagents contain 1-10 % of a mixture of ingredients of unknown toxicity.

For these reasons, Health in Code S.L. shall not be liable for any damages, direct or indirect, resulting from harm caused using this product by the purchaser or user.

However, when working with products manufactured by Health in Code S.L., we always recommend following the warnings and precautions included in Section 4 of the product's Instructions for Use (IFUs).

Disclaimer

IMPORTANT: The information provided in this MSDS is based on our present knowledge as of the issue date (or subsequent revision date, if any), and is to be used only as a guidance for safe handling, use, processing, storage, transportation, disposal, and release, and is not to be considered a guarantee (express or implied) for any specific product features and shall not establish a legally valid contractual relationship. This information relates only to the designated material as shipped and may not be valid for such material used in combination with any other materials or in any other procedures, unless specified in our instructions for use. It is the responsibility of the user to ensure that its activities comply with all applicable legislation and requirements.

If you have any questions, please contact tech.support@healthincode.com

Edition history:

Edition	Date	Description of change
03	NOV 2022	Change of manufacturer's address: Health in Code S.L., Calle de la Travesía s/n, 15E Base 5, Valencia 46024, Spain. New contact for the toxicological information service.
02	SEP 2022	Change of the manufacturer's identification: from imegen S.L. to Health in Code S.L.

		Update of regulatory information.
01	JAN 2019	N/A