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	Inherited CardioKitDx
Kit reference	IMG-390
Internal references	Without internal references
Reactions	16
Intended use	In vitro diagnosis use only

Components:

- **Fragmentation Buffer**: Buffer used for DNA fragmentation, prior to NGS libraries preparation.
- **Fragmentation Enzyme:** Enzyme used for DNA fragmentation, prior to NGS libraries preparation.
- **Reagents Plate***1: Plate with all the reagents required to perform the DNA end repair, the Illumina adapters linkage, and amplifications done during the library preparation protocol.
- **Beads and Buffers plate:** Plate with magnetic particles and wash buffers, required for the DNA capture and its purification during the library preparation protocol.
- **Index:** Oligonucleotides with a unique 8 nucleotides identifier sequence compatible with the illumina adapters required to identify each sample during library preparation and NGS sequencing. The kit includes 16 different indexes, prepared in single-use strips.
- **Cardiovascular Probes Strips***1: Biotinylated synthetic oligonucleotides complementary to the target regions of the target genes.
- **Elution Buffer**: Buffer used to elute the DNA.

*Note: see product safety data sheet SureSelect XT HS and XT Enzymatic Fragmentation Kit, automated 96 rxs, ref: 5191-6764; Magnis SureSelect XT HS Index Plate, ILM, ref: 5190-9880; Qiagen Buffer EB (Tris-HCl pH8.5) 250mL, ref: 19086; SureSelect XT HS and XT Enzymatic Fragmentation Kit, automated 96 rxs, ref: 5191-6764.

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
05	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.
04	SEP 2022	Update of regulatory information
03	JUN 2022	Content review
02	OCT 2021	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