

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:
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2. Product information

Kit name	Hereditary OncoKitDx (Without index)
Kit reference	IMG-326
Internal references	Without internal references
Reactions	48
Intended use	In vitro diagnosis use only

Components:

- **Fragmentation Buffer*¹**: Buffer required to DNA fragmentation and DNA preparation to Adapter ligation.
- **Fragmentation Enzyme**: Enzyme required to DNA fragmentation and DNA preparation to Adapter ligation.
- **Ligation Master Mix**: Buffer required to perform the ligation of the DNA to the Adaptors.
- **Ligation Enhancer**: Ligation enhancer molecule required to maximize the ligation of the DNA to the Adaptors.
- **Adaptors**: specific short DNA sequences which are ligated to DNA sample repaired tails and enable the DNA to become bound to the structures that are required for the sequencing (Index and sequencing adapters).
- **Ligase**: Ligation enzyme required to obtain the ligation of the DNA to the Adaptors.
- **PCR Master Mix**: PCR Master Mix containing MgCl₂, nucleotides, **DMSO***, enzyme and buffer solution, required for the PCR reaction that add the Indexes to the DNA fragments.
- **Cot-1-DNA**: DNA sequences of 50-300 bp with repeated sequences as Alu or Kpn. These sequences will bind to complementary DNA in the sample and prevent them from interfering with the capture process.

- **Blockers:** Oligonucleotides that complementary bind to the adapter sequences of the library to cut down the capture of non-target regions during the library enrichment process.
 - **Probes:** Biotinylated synthetic oligonucleotides complementary to the target regions of the 50 target genes. The probes hybridize to the target DNA and then are captured using streptavidin-conjugated magnetic beads by biotin-streptavidin linkage.
 - **Hybridization Buffer*:** Buffer for the hybridization of the target regions with the capture probes.
 - **Hybridization Buffer Enhancer*:** Enhancer for the hybridization of the target regions with the capture probes.
 - **Beads Wash Buffer:**
 - **Wash Buffer I*:**
 - **Wash Buffer II*:**
 - **Wash Buffer III:**
 - **Wash Buffer IV:**
- Buffers required to wash the streptavidin-conjugated magnetic beads and of the different reagents required for the capture, as well as of the DNA fragments remained uncaptured.
- **Streptavidin Beads:** Magnetic particles attached to streptavidin molecules that allow the capture of DNA fragments attached to biotinylated capture probes.
 - **Enrichment PCR Master Mix*:** PCR Master Mix containing MgCl₂, nucleotides, enzyme and buffer solution, required for the PCR reaction that amplify the captured DNA.
 - **Amplification Primer Cocktail:** Oligonucleotides complementary to Illumina adapters required to amplify the captured DNA.
 - **Elution Buffer (EB):** Buffer used in different steps of the protocol to elute the DNA.

*Note: see product safety data sheet KAPA HiFi HotStart ReadyMix PCR Kit ref:07958935001; xGen 2X Hybridization Buffer and wash kit, 96 rxn, ref: 1080584; xGen® 10x Wash 1 Buffer; xGen® Hybridization Buffer Enhancer.

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. 1272/2008 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 (IFU's).

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.

For any questions, please contact our technical department: 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