Vall d'Hebron Instituto de Oncología	VALL D'HEBRÓN INSTITUTE OF ONCOLOGY
	Public declaration regarding the manufacture and use of in-house devices by health institutions

Information of the manufacturing health institution

Name:	Cancer Genomics Laboratory (Vall d'Hebron Institute of Oncology (VHIO))
Address:	Cellex Center, Carrer de Natzaret, 115-117, 08035 Barcelona
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Cancer Genomics Laboratory (VHIO) declares that the device described in the accompanying table is only manufactured and used in VHIO and meets the applicable general safety and performance requirements (GSPR) of the in vitro diagnostic medical devices Regulation (EU 2017/746). A reasoned justification is provided in case applicable general safety and performance requirements are not fully met.

Barcelona, 08/04/2024

Dr. Ana Vivancos, Head of Cancer Genomics Laboratory

Device Identification	Device type (IVD/MD)	Risk class of the device	Intended purpose	Applicable GSPR fully met? (Y/N)
VHIO-CARD-300	IVD	Class C (Rule 3f)	The VHIO-CARD-300 panel is a custom targeted capture assay compatible with formalin-fixed, paraffin-embedded derived genomic DNA samples. Over 430 cancer-related genes are enriched through specific capture with biotinylated probes, followed by sequencing in Illumina high or mid output instruments. The panel covers approximately 1.4Mb of exonic regions of pan-cancer-related genes for the study of their **somatic single nucleotide variants** and **indels**, as well as to study **copy number alterations** (**CNA**) for all of them. On the other hand, its design is big enough in size to allow a **tumour mutation burden** (**TMB**) Moreover, the panel relies on capturing a backbone of single nucleotide polymorphisms (SNPs) spread along the whole genome and with an average population frequency of 0.5. Such backbone allows to draw a genomic landscape of all the chromosomes for ulterior analysis of loss of heterozygosity anomalies (LOH) and for the assessment of **DNA repair mechanism deficiency by homologous recombination (VHIO-HRD score)** in primary or metastatic ovarian cancer. VHIO-HRD score is composed of LOH, TAI and LST scores.	Y