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))
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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, 29/10/2024

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 3h)	The VHIO-CARD-300 test is a qualitative, next-generation sequencing-based IVD designed to analyse DNA extracted from formalin-fixed, paraffin-embedded tumour tissues. It targets over 430 cancer-related genes, enriched using biotinylated custom probes, and sequenced on Illumina high- or mid-output instruments. The panel covers approximately 1.4 Mb of exonic regions of pan-cancer-related genes, allowing analysis of somatic single nucleotide variants (SNVs), insertions/deletions (indels), and copy number alterations (CNAs) across all genes. Additionally, the panel size enables the assessment of genomic instability biomarkers, such as tumour mutation burden (TMB) across tumour types and homologous recombination deficiency (HRD) in primary or metastatic ovarian and fallopian tube cancers. The VHIO-CARD-300 test includes a bioinformatic pipeline for sequencing data monitoring, sample quality control, and variant calling. Downstream steps of variant curation, classification, and reporting are performed manually, using public databases (COSMIC, cBioPortal, ClinVar, VarSome, OncoKB) for classification and interpretation.	Y

			Intended for use by trained healthcare professionals, the VHIO-CARD-300 test supports cancer patient screening, monitoring, prognosis, and prediction of therapeutic outcomes.	