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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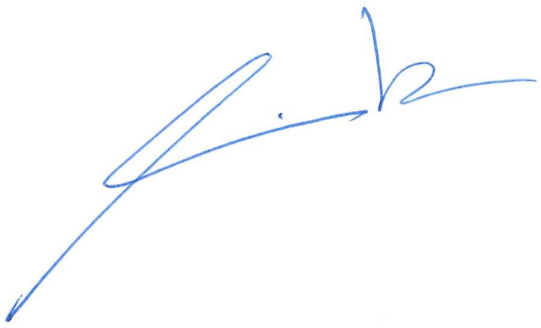
Cancer Genomics Laboratory (VHIO) declares that the device described in the accompanying table is only manufactured and used in VHIO and meets the applicable general safety and performance requirements (GSPR) of the in vitro diagnostic medical devices Regulation (EU 2017/746). A reasoned justification 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)
VHIO360	IVD	Class C (Rule 3h)	The VHIO360 test is a qualitative, next-generation sequencing-based IVD designed to analyse cell-free DNA (cfDNA) extracted from plasma samples of cancer patients. This integrated system automates genomic library preparation, gene enrichment, and sequencing through a high-throughput, hybrid capture-based targeted approach, allowing sensitive detection of genomic alterations in a 74-gene panel of cancer-related genes. The analysis detects single nucleotide variants (SNVs) and insertions/deletions (indels), with cfDNA alterations reflecting those present in the patient's tumour. The VHIO360 test include a bioinformatic pipeline that performs 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. The VHIO360 test is intended for use by trained healthcare professionals to support cancer patient screening,	Y

			monitoring, prognosis, and therapeutic outcome prediction, specifically in the following scenarios: - Before initiating first-line therapy when molecular testing is incomplete, limited, or unobtainable - At disease progression to avoid invasive biopsies when seeking new genomic targets for patients whose tissue testing was incomplete at the initial diagnosis	