Clínic Barcelona | Centre de Diagnòstic Biomèdic

HOSPITAL CLÍNIC DE BARCELONA. CENTRE DE DIAGNÒSTIC BIOMÈDIC

Public declaration regarding the manufacture and use of in-house devices by health institutions

Information about the manufacturing health institution

Name: Hospital Clínic de Barcelona. Centre de Diagnòstic Biomèdic

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Centre de Diagnòstic Biomèdic (CDB) declares that the device described in the accompanying table is only manufactured and used in CDB 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,

Miguel Ángel Benítez Merelo - DNI 38447852V (TCAT)

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Dr. Miguel Ángel Benítez

CDB Manager

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Device Identification	Device type (IVD/MD)	Risk class of the device	Intended purpose	Applicable GSPR fully met? (Y/N)
Análisis Genómico (DNA + RNA) tumor sólido 161 genes (Code 80201)	IVD	C	Oncomine™ Comprehensive Assay (OCA) v3 GX (ThermoFisher Scientific) is a targeted NGS assay that enables the detection of SNVs, CNVs, gene fusions, and relevant indels in 161 unique genes. It analyzes point mutations in hotspots, whole-gene analysis (full exon coverage), CNVs, and fusion drivers (inter- and intragenic). The principle of the method is the analysis of the commercial Oncomine Comprehensive Assay (OCA) massive sequencing (NGS) panel using IonTorrent chemistry and sequencing technology (ThermoFisher Scientific) on a Genexus sequencer, based on tumor DNA and RNA samples from paraffin-embedded tissue. The test is intended for use by trained healthcare professionals to support cancer patient screening, monitoring, prognosis, and therapeutic outcome prediction.	Y
Análisis Genómico (DNA + RNA) tumor sólido 50 genes (Code 80200)	IVD	C	Oncomine™ Precision Assay (OPA) GX (ThermoFisher Scientific) is a targeted NGS assay that enables the simultaneous detection of biomarkers in 50 genes. It analyzes point mutations in hotspots, CNVs, and intergenic and intragenic fusion drivers. The principle of the method is the analysis of the commercial Oncomine Precision Assay (OPA) massive sequencing (NGS) panel using IonTorrent chemistry and sequencing technology (ThermoFisher Scientific) in a Genexus sequencer, based on tumor DNA and RNA samples from paraffin-embedded tissue. The test is intended for use by trained healthcare professionals to support cancer patient screening, monitoring, prognosis, and therapeutic outcome prediction.	Y
Análisis Genómico (DNA) tumor sólido 22 genes (Code 5916)	IVD	C	The Oncomine Colon and Lung panel (ThermoFisher Scientific) is a targeted NGS assay based on Ion Torrent technology that enables the detection of point mutations in hotspot regions of 22 genes relevant to solid tumors. The principle of the method is the analysis of the commercial Oncomine Colon and Lung mass sequencing (NGS) panel using IonTorrent chemistry and sequencing technology (ThermoFisher Scientific) in a S5 sequencer, based on tumor DNA samples from paraffin-embedded tissue or cytology. The test is intended for use by trained healthcare professionals to support cancer patient screening, monitoring, prognosis, and therapeutic outcome prediction.	Y

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Estudio mutacional y de genes de fusión de neoplasias mieloides por NGS, médula ósea o sangre periférica (Code 6605, 6490)	IVD	C	The Oncomine Myeloid Assay GX v2 (ThermoFisher Scientific) is a targeted next-generation sequencing (NGS) assay designed for rapid and sensitive detection of key relevant myeloid mutations. For use on the Ion Torrent Genexus Integrated Sequencer, the assay enables automated DNA and RNA variant detection. The assay detects key DNA mutations and RNA fusion transcripts associated with disorders such as: • Acute myeloid leukemia (AML) • Myelodysplastic syndromes (MDS) • Myeloproliferative neoplasms (MPNs) • Chronic myeloid leukemia (CML) • Juvenile myelomonocytic leukemia (JMML) The test is intended for use by trained healthcare professionals to support cancer patient screening, monitoring, prognosis, and therapeutic outcome prediction.	Y