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

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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,

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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 (Internal catalog 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 (Internal catalog 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 (Internal catalog 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
Estudio mutacional y de genes de fusión de neoplasias mieloides por NGS, médula ósea o sangre periférica (Internal catalog 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	Y

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			professionals to support cancer patient screening, monitoring, prognosis, and therapeutic outcome prediction.	
Cribado de glucosaminoglicanos, orina (Internal catalog code: 16199)	IVD	C	The dimethylmethylene blue (DMB) assay is a spectrophotometric method used for the quantitative determination of total glycosaminoglycans (GAGs) in urine samples. It enables the measurement of urinary GAG excretion and is commonly used as a biochemical screening tool for mucopolysaccharidoses (MPS) and other lysosomal storage disorders associated with abnormal GAG metabolism. The principle of the method is based on the interaction between the cationic dye 1,9-dimethylmethylene blue (DMB) and negatively charged sulfated glycosaminoglycans present in urine. The formation of dye–GAG complexes produces a measurable change in absorbance, which is determined spectrophotometrically. GAG concentrations are calculated using a calibration curve generated with an appropriate GAG standard and are typically normalized to urinary creatinine concentration. The test is intended for use by trained healthcare professionals as an aid in the biochemical screening and assessment of patients with suspected mucopolysaccharidoses. Results should be interpreted in conjunction with clinical findings and, when appropriate, confirmed by specific enzymatic and/or molecular genetic testing.	Y
Determinación de heparán sulfato, líquido cefalorraquídeo, plasma, orina	IVD	C	Heparan sulfate (HS) assay is a quantitative method based on enzymatic digestion followed by liquid chromatography–tandem mass spectrometry (LC-MS/MS). It enables the detection and quantification of heparan sulfate-derived disaccharides in biological fluid and is used as a biochemical tool for the evaluation of mucopolysaccharidoses (MPS) associated with abnormal heparan sulfate metabolism. The principle of the method is based on the enzymatic depolymerization of heparan sulfate using heparinase/heparitinase enzymes, which cleave the glycosaminoglycan chains into characteristic unsaturated disaccharides. These digestion products are subsequently separated by liquid chromatography and detected and quantified using tandem mass spectrometry (MS/MS), based on their specific mass-to-charge ratios and fragmentation patterns. The test is intended for use by trained healthcare professionals to support the screening, biochemical diagnosis, and monitoring of patients with suspected or confirmed mucopolysaccharidoses, particularly MPS types I, II, III, and VII. Results should be interpreted in conjunction with clinical findings and, when appropriate, confirmed by specific enzymatic activity assays and/or molecular genetic testing. The heparan sulfate measurement can be done in urine, plasma and cerebrospinal fluid (CSF).	Y
Determinación de Heparán-N-sulfatasa (E. Sanfilippo A), leucocitos, fibroblastos, líquido cefalorraquídeo	IVD	C	The heparan N-sulfatase (sulfamidase, SGSH) enzyme activity assay is a fluorometric method used for the quantitative determination of lysosomal heparan N-sulfatase activity in biological samples. It enables the detection of deficient enzyme activity and is used as a biochemical diagnostic test for mucopolysaccharidosis type IIIA (MPS IIIA), also known as Sanfilippo syndrome type A. The principle of the method is based on the enzymatic hydrolysis of a synthetic substrate derived from 4-methylumbelliferone (4-MU). Heparan N-sulfatase catalyzes the removal of the N-sulfate group from the substrate, followed by a second enzymatic reaction that releases fluorescent 4-methylumbelliferone. The fluorescence intensity is measured using a fluorometer	Y

HOSPITAL CLÍNIC DE BARCELONA. CENTRE DE DIAGNÒSTIC BIOMÈDIC

			and is proportional to the enzymatic activity present in the sample. Enzyme activity is calculated using a 4-MU calibration curve and expressed relative to the protein content of the sample. The test is intended for use by trained healthcare professionals to support the biochemical confirmation of Sanfilippo syndrome type A (MPS IIIA) in patients with suspected mucopolysaccharidosis. Reduced or absent heparan N-sulfatase activity is indicative of MPS IIIA. Results should be interpreted in conjunction with clinical findings and, when appropriate, confirmed by molecular genetic testing of the SGSH gene. The enzyme activity can be measured in leukocytes, fibroblasts and in cerebrospinal fluid (CSF).	