

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 (Code 80201) | IVD | C | <p>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).</p> <p>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.</p> <p>The test is intended for use by trained healthcare professionals to support cancer patient screening, monitoring, prognosis, and therapeutic outcome prediction.</p> | Y |
| Análisis Genómico (DNA + RNA) tumor sólido 50 genes (Code 80200) | IVD | C | <p>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.</p> <p>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.</p> <p>The test is intended for use by trained healthcare professionals to support cancer patient screening, monitoring, prognosis, and therapeutic outcome prediction.</p> | Y |
| Análisis Genómico (DNA) tumor sólido 22 genes (Code 5916) | IVD | C | <p>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.</p> <p>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.</p> | Y |