Laboratory Tests performed at Foundation Medicine GmbH, Germany

Test	Analyte (Measurement Parameter)	Test Material (Matrix)	Test Technique	Version	Date Introduced
FoundationOne CDx[1]	See gene list in SPEC-0001	Tumor samples fixed (FFPE), DNA extracted from tumor cells	DNA extraction, library construction, hybrid capture, sequencing-by-synthesis (Illumina HiSeq)	N/A[2]	March 2019
FoundationOne Heme[1]	See gene list in SPEC-0003	Tumor samples fixed (FFPE), Extracted DNA and RNA from neoplastic cells isolated from peripheral blood, bone marrow aspirate	DNA/RNA extraction, library construction, hybrid capture, sequencing-by-synthesis (Illumina HiSeq)	N/A[2]	April 2020
FoundationOne Liquid CDx[4]	See gene list in SPEC-0004	Extracted cell-free DNA isolated from peripheral blood, blood plasma	cfDNA extraction, library construction, hybrid capture, sequencing-by-synthesis (Illumina NovaSeq)	N/A[2]	December 2020
PD-L1 Immunohistochemistry (IHC) Analysis (SP142, SP263)[3]	PD-L1 protein	Tumor samples fixed (FFPE)	Immunohistochemistry (Roche Ventana monoclonal primary rabbit antibody)	N/A[2]	January 2019

[1] In scope of ISO15189 Flexible Accreditation for DAkkS. Information on Analyte (Measurement Parameter), Test Material (Matrix), Test Technique, Version, as applicable, shall be made publicly available on Roche-FMI EU website at www.rochefoundationmedicine.com. Foundation Medicine's CE-IVD Tests are Self-declared IVD Medical Devices (IVDD)

[2] No versioning applied at Foundation Medicine; only current/latest version available. Analysis Software version, if applicable, documented on patient report.

[3] Not in scope of ISO15189 Flexible Accreditation for DAkkS; IHC analysis performed at Referral Laboratory, Patient Report provided by FMI.

[4] Certification approval pending by DAkkS

Next generation sequencing based Devices, CE-IVD, manufactured by Foundation Medicine Inc.

Product	Part Number	CE IVD Registration Number / GTIN	Risk Classification
FoundationOne®CDx	PN-00106	BE-CA01/1-90022-00004-IVD	Self-Declared (IVDD)
FoundationOne®Liquid CDx	PN-00108	BE-CA01/1-90022-00008-IVD	Self-Declared (IVDD)
FoundationOne®Heme	PN-00104	BE-CA02-182-16	Self-Declared (IVDD)

Specimen Collection Kits, CE-IVD, manufactured by Foundation Medicine Inc. [(1)]

Product	Part Number	CE-IVD Registration Number / GTIN	Risk Class
Cell-free DNA Collection Tube 2 Pack	PN-00101	BE-CA01/1-90022-00003-IVD	Self-declared (IVDD)
Cell-free DNA Collection Tube 2 Pack, set of 25	PN-00102		
FoundationOne Heme Specimen Transport Box (Fresh Liquid Samples)	PN-00107	BE-CA01/1-90022-00007-IVD	Self-declared (IVDD)
FoundationOne Liquid CDx Specimen Collection Kit (Configuration: F1LCDx Global IVDR kit PNZ return UN3373)	PSK0055	00850029315001	Class A (IVDR)
FoundationOne Liquid CDx Specimen Collection Kit (Configuration: F1LCDx Global IVDR kit PNZ return FedEx)	PSK0056	00850029315018	Class A (IVDR)
FoundationOne Liquid CDx Specimen Collection Kit (Configuration: F1LCDx Global IVDR kit PNZ return DHL)	PSK0057	00850029315025	Class A (IVDR)

[(1)] Importer into the EU for Specimen Collection Kits is Foundation Medicine GmbH, Penzberg, Germany.