

変更箇所：青文字部（検査項目IBG保険収載）

CAP Laboratory Accreditation Program (LAP)			ISO15189_JAB (Japan Accreditation Board) RM205:2024v12				Test/Activity		
Discipline	Subdiscipline	Apply	大分類	中分類		適用	検査項目		
Molecular Pathology	Molecular Oncology - Solid Tumor	2021.08	17 Gene-related / Chromosome test 遺伝子関連/染色体 検査	a-2 Somatic gene test - Solid Tumor 体細胞遺伝子検査 (固形腫瘍等)	17 a-2	2019.03	RAS/BRaf 遺伝子変異検査	BRAF, Solid Tumor	D004-2 悪性腫瘍組織検査
Molecular Pathology	Molecular Oncology - Solid Tumor	2021.08	17 Gene-related / Chromosome test	a-2 Somatic gene test - Solid Tumor 体細胞	17 a-2	2018.03		KRAS, Solid Tumor	D004-2 悪性腫瘍組織検査
Molecular Pathology	Molecular Oncology - Solid Tumor	2021.08	17 Gene-related / Chromosome test	a-2 Somatic gene test - Solid Tumor 体細胞	17 a-2	2018.03		NRAS, Solid Tumor	D004-2 悪性腫瘍組織検査
Molecular Pathology	Molecular Oncology - Solid Tumor	2021.08	17 Gene-related / Chromosome test	a-2 Somatic gene test - Solid Tumor 体細胞	17 a-2	2018.03		Nucleic acid extraction (From FFPE)	D004-2 悪性腫瘍組織検査
Microbiology	Molecular Microbiology	適用外	17 Gene-related / Chromosome test 遺伝子関連/染色体 検査	b Identification of pathogen nucleic acid 病原体核酸同定	17 b	2024.03	M. genitalium, DR 23S rRNA M.ジェニタリウム・ 薬剤耐性変異検出検査 cA2071G, cA2071C, cA2071T, cA2072G, cA2072C, cA2072T	D023 微生物核酸同定	
Microbiology	Molecular Microbiology	適用外 (研究用)	17 Gene-related / Chromosome test 遺伝子関連/染色体 検査	b Identification of pathogen nucleic acid 病原体核酸同定		適用外 (研究用)			
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)	G&G Test Code: APU 2018.03 ~ (Angiogenesis Panel Test, 17 target Multiplex Assay)	ANG2 (Angiopoietin-2)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		HGF (Hepatocyte growth factor)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		PlGF (Placental growth factor)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		VEGF-A (Vascular endothelial growth factor A)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		VEGF-D (Vascular endothelial growth factor D)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		OPN (Osteopontin)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		sNRP-1 (Neuropillin-1, soluble)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		sVEGFR1 (Vascular endothelial growth factor receptor 1, soluble)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		sVEGFR2 (Vascular endothelial growth factor receptor 2, soluble)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		sVEGFR3 (Vascular endothelial growth factor receptor 3, soluble)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		TSP-2 (Thrombospondin-2)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		IFN-γ (interferon-gamma)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		IL-6 (Interleukin-6)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		IL-8 (Interleukin-8)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		sICAM-1 (intercellular adhesion molecule 1, soluble)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		sVCAM-1 (vascular cell adhesion molecule 1, soluble)	
Immunology	Immunology	適用外 (研究用)	15 Immunology	Immunology for plasma protein		適用外 (研究用)		TIMP-1 (Tissue Inhibitor of matrix metalloproteinases 1)	

<b>MSF-A 検査案内</b> Instructions for user of the Lab-services	更新	G&Gサイエンス株式会社 衛生検査所	管理：臨床検査室・品質保証室
<b>F2 臨床検査項目リスト Activity menu List</b>	Review: 2025.01.01	G&G SCIENCE CO., LTD. Clinical Laboratory	Quality Assurance Dep. Shoko Yanaka

注) IVD: In-vitro diagnostics 体外診断用医薬品  
 RUO: Research Use only, Test Reagents 研究用検査試薬  
 RUC: Certified test reagent confirmation 認定検査試薬

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Test/Activity 検査項目		Type of Samples 検体種	G&G Test code	SOP No. 手順書No.	Method 測定原理	Reagents, manufacturer 主要な検査試薬, 製造販売業者	Proficiency testing 技能試験	Start 適用年月	変更概要	
RAS/BRAF 遺伝子変異検査	BRAF, Solid Tumor	D004-2 悪性腫瘍組織検査	IRB	MSF-PS01	PCR-rSSO, Luminex (xMAP)	MEBGEN RASKET-B kit, MBL MEBGEN BRAF kit, MBL	IVD	CAP-PT_MTP	2023.02 試薬追加 (MEBGEN BRAF)	
	KRAS, Solid Tumor	D004-2 悪性腫瘍組織検査	IRB	MSF-PS01	PCR-rSSO, Luminex	MEBGEN RASKET-B kit, MBL	IVD	CAP-PT_MTP	2020.08 試薬変更 (RASKET中止)	
	NRAS, Solid Tumor	D004-2 悪性腫瘍組織検査	IRB	MSF-PS01	PCR-rSSO, Luminex	MEBGEN RASKET-B kit, MBL	IVD	CAP-PT_MTP	2020.08 試薬変更 (RASKET中止)	
	Nucleic acid extraction (From FFPE)	D004-2 悪性腫瘍組織検査	IRB	MSF-OP01	(Heat De-waxing) Phenol-choroform	Laboratory developed test (LDT), Nucleic acid extraction Reagent	RUO	CAP-PT_MHO5	2018.03 ISO15189認定で新規登録	
<i>M. genitalium</i> , DR 23S rRNA M.ジェニタリウム・ 薬剤耐性変異検出検査 <i>c.A2071G, c.A2071C, c.A2071T, c.A2072G, c.A2072C, c.A2072T</i>		D023 微生物核酸同定	IBG	MSF-PS09	qPCR  Proteinase K, chaotropic salts, Magnetic particle	MEBRIGHT M.genitalium plusDR, MBL  Maxwell RSC Blood DNA Kit, AS1400, Promega	IVD  RUO	CAP-PT_MGEN	2024.03 New 製造販売承認2023.12.18 保険収載2025.01.01	
G&G Test Code: APU 2018.03~ (Angiogenesis Panel Test, 17 target Multiplex Assay)	ANG2 (Angiopoietin-2)	Plasma	-	PMM-A-1	MSF-OP10	Luminex (xMAP)	MILLIPLEX* MAP Human Angiogenesis /Growth Factor Magnetic Bead Panel - Cancer Multiplex Assay, HAGP1MAG-12K	RUO	2018.12	試薬/検査範囲 変更 (←SPR939)
	HGF (Hepatocyte growth factor)	Plasma	-	PMM-A-2	MSF-OP10	Luminex (xMAP)		RUO	2018.12	試薬/検査範囲 変更 (←SPR939)
	PIGF (Placental growth factor)	Plasma	-	PMM-A-3	MSF-OP10	Luminex (xMAP)		RUO	2018.12	試薬/検査範囲 変更 (←SPR939)
	VEGF-A (Vascular endothelial growth factor A)	Plasma	-	PMM-A-4	MSF-OP10	Luminex (xMAP)		RUO	CAP-PT_CTKN	2018.12 試薬/検査範囲 変更 (←SPR939)
	VEGF-D (Vascular endothelial growth factor D)	Plasma	-	PMM-A-5	MSF-OP10	Luminex (xMAP)		RUO	2018.12	試薬/検査範囲 変更 (←SPR939)
	OPN (Osteopontin)	Plasma	-	PMM-B-1	MSF-OP10	Luminex (xMAP)	MILLIPLEX* MAP Human Angiogenesis Panel 2, HANG2MAG-12K	RUO	2018.12	検査範囲変更
	sNRP-1 (Neuropillin-1, soluble)	Plasma	-	PMM-B-2	MSF-OP10	Luminex (xMAP)		RUO	2018.12	検査範囲変更
	sVEGFR1 (Vascular endothelial growth factor receptor 1, soluble)	Plasma	-	PMM-B-3	MSF-OP10	Luminex (xMAP)		RUO	2018.12	検査範囲変更
	sVEGFR2 (Vascular endothelial growth factor receptor 2, soluble)	Plasma	-	PMM-B-4	MSF-OP10	Luminex (xMAP)		RUO	2018.12	検査範囲変更
	sVEGFR3 (Vascular endothelial growth factor receptor 3, soluble)	Plasma	-	PMM-B-5	MSF-OP10	Luminex (xMAP)		RUO	2018.12	検査範囲変更
	TSP-2 (Thrombospondin-2)	Plasma	-	PMM-B-6	MSF-OP10	Luminex (xMAP)		RUO	2018.12	検査範囲変更
	IFN-γ (interferon-gamma)	Plasma	-	PMM-C-1	MSF-OP10	Luminex (xMAP)	MILLIPLEX* Human Cytokine/Chemokine /Growth Factor Panel A - Immunology Multiplex Assay, HCYTA-60K	RUO	2023.06	試薬/検査範囲 変更 (←HCYTO)
	IL-6 (Interleukin-6)	Plasma	-	PMM-C-2	MSF-OP10	Luminex (xMAP)		RUO	CAP-PT_CTKN	2023.06 試薬/検査範囲 変更 (←HCYTO)
	IL-8 (Interleukin-8)	Plasma	-	PMM-C-3	MSF-OP10	Luminex (xMAP)		RUO	CAP-PT_CTKN	2023.06 試薬/検査範囲 変更 (←HCYTO)
	sICAM-1 (intercellular adhesion molecule 1, soluble)	Plasma	-	PMM-MP2-1	MSF-OP10	Luminex (xMAP)	MILLIPLEX* MAP_My panel SPR931, From: Human Cardiovascular	RUO	2018.09	検査範囲変更 (希釈200倍)
	sVCAM-1 (vascular cell adhesion molecule 1, soluble)	Plasma	-	PMM-MP2-2	MSF-OP10	Luminex (xMAP)	Disease (CVD) Magnetic Bead Panel 2, HCVD2MAG-67K	RUO	2018.09	検査範囲変更 (希釈200倍)
TIMP-1 (Tissue Inhibitor of matrix metalloproteinases 1)	Plasma	-	PMM-MP2-3	MSF-OP10	Luminex (xMAP)	MILLIPLEX* MAP_My panel SPR931, From: Human Kidney Injury Panel 5, HKI5MAG-99K	RUO	2018.09	検査範囲変更 (希釈200倍)	