



BUILDING IVDR COMPLIANT PANELS FOR HAEMATOLOGICAL DISORDERS

DIAGNOSTIC PURPOSE OF THE IVDR CONJUGATED ANTIBODIES



The new IVDR (EU IVDR 2017/746) will ensure that IVD (in vitro diagnostics) products, achieve the highest levels of safety and efficacy possible. Laboratory-developed tests (LDT)/in-house devices (IH-IVD), which constitute a majority of the clinical flow cytometry tests, will now be regulated by the new IVDR.

Under the new regulation, flow cytometry laboratories willing to build their own cocktail of conjugated antibodies for diagnostic purposes can either use :

- Non CE-marked monoclonal antibodies (mAb) Cocktail (RUO, and/or off-label use of CE marked mAb) and bring their cocktail in compliance with IVDR or ensure all article 5.5 requirements are met, including among others compliance with Annex I General Safety & Performances requirements, ISO15189 or other national provision related to accreditation, justify the absence of equivalent devices commercially available, plus adaptations to the QMS to make it appropriate for design and manufacture.

OR

- A CE-marked mAb Cocktail in line with each mAb Instruction for Use (IFU) and intended purpose. The laboratories are not affected by the IVDR and might only have to perform either performance verification or validation, very similar to the current process.

The use of CE-marked mAb cocktails necessitates that all mAbs have Intended Purposes that are consistent with the application (article 5.1*).

Description	Clone (Isotype species)	SNV428	Pacific Blue*	Krome Orange	SNV605	SNV786	FITC	PE	ECD	PC5	PC5.5	PC7	APC	APC-A700	APC-A750	Differential diagnosis of hematologically abnormal patients. Monitor patients with known hematopoietic neoplasm	Hematological disorders (non cancers included)	Prognosis of patients having hematopoietic neoplasm/hematological disorder	Diagnosis of patients with suspected immunodeficiency. Monitor patients with known immunodeficiency	Monitor patients with known autoimmune disease or disorder	Monitor transplantation process or results	Diagnosis of in vitro activation of basophils in response to allergens (allergic reactions)	Differential diagnosis of hematologically abnormal patients suspected of having thrombocytopenic disorder. Monitor patients with known thrombocytopenic disorder	Monitor patients on allergen specific immunotherapy
CD1a	BL6 (IgG1 mouse)																							
CD2	39C1.5 (IgG2a rat)																							
CD3	UCHT1 (IgG1 mouse)	*												*										
CD4	13B8.2 (IgG1 mouse)			*							*													
CD5	BL1a (IgG2a mouse)	*												*										
CD7	8H8.1 (IgG2a mouse)		*			*								*										
CD8	B9.11 (IgG1 mouse)		*	*		*								*										
CD10	ALB1 (IgG1 mouse)	*			*						*			*										
CD11b	Bear1 (IgG1 mouse)		*											*										
CD11c	BU15 (IgG1 mouse)										*			*										
CD13	SJID1 (IgG1 mouse)													*										
CD14	Immu103.44 (IgG1 mouse)	*												*										
CD14	RM052 (IgG2a mouse)										*	*		*										
CD15	80H5 (IgM mouse)		*											*										
CD16	3G8 (IgG1 mouse)													*										
CD19	J3-119 (IgG1 mouse)	*												*										
CD20	B9E9 (IgG2a mouse)	*		*							*			*										
CD22	B9E9 (IgG2a mouse)	*		*		*					*			*										
CD23	9P25 (IgG1 mouse)	*		*		*					*			*										
CD24	ALB9 (IgG1 mouse)													*										
CD25	BI.49.9 (IgG2a mouse)	*		*							*			*										
CD27	1A4CD27 (IgG1 mouse)	*												*										
CD33	D3HL60.251 (IgG1 mouse)	*												*										
CD34	5B1 (IgG1 mouse)	*												*										
CD36	FA6.152 (IgG1 mouse)			*		*								*										
CD38	LS198-4-3 (IgG1 mouse)	*	*	*		*		*	*	*	*	*	*	*										
CD38	T16 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD41	P2 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD43	DFT1 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD45	J33 (IgG1 mouse)	*	*	*		*		*	*	*	*	*	*	*										
CD45RA	ALB11 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD45RO	2H4LDHILDB9 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD55	UCHL1 (IgG2a mouse)			*		*		*	*	*	*	*	*	*										
CD55	JS11KSC2.3 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD56	N901 (IgG1 mouse)	*		*		*		*	*	*	*	*	*	*										
CD57	NC1 (IgM mouse)	*	*	*		*		*	*	*	*	*	*	*										
CD59	P282E (IgG2a mouse)			*		*		*	*	*	*	*	*	*										
CD61	SZ21 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD62P	CLB-Thromb/6 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD63	CLB-Gran/12 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD64	22 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD65	88H7 (IgM mouse)			*		*		*	*	*	*	*	*	*										
CD69	TP1.55.3 (IgG2b mouse)			*		*		*	*	*	*	*	*	*										
CD71	YD.J1.2.2 (IgG1 mouse)	*		*		*		*	*	*	*	*	*	*										
CD79a	HM47 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD79b	CB3-1 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD103	2G5 (IgG2a mouse)			*		*		*	*	*	*	*	*	*										
CD105	TEA3/171.1 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD117	104D2D1 (IgG1 mouse)	*		*		*		*	*	*	*	*	*	*										
CD127	R34.34 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD138	B-A38 (IgG1 mouse)	*		*		*		*	*	*	*	*	*	*										
CD200	OX-104 (IgG1 mouse)	*		*		*		*	*	*	*	*	*	*										
CD203c	97A6 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD235a	11E4B-7-6 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
FMC7	FMC7 (IgM mouse)	*	*	*		*		*	*	*	*	*	*	*										
HLA-DR	Immu-357 (IgG1 mouse)	*	*	*		*		*	*	*	*	*	*	*										
κ Chain	Polyclonal (Goat)			*		*		*	*	*	*	*	*	*										
λ Chain	Polyclonal (Goat)			*		*		*	*	*	*	*	*	*										
Myeloperoxidase	CLB-MPO-1 (IgG2a mouse)			*		*		*	*	*	*	*	*	*										
NG2	71 (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
TCR PAN α/β	IP26A (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
TCR PAN γ/δ	IMMU510 (IgG1 mouse)	*		*		*		*	*	*	*	*	*	*										
TdT	HT1 + HT4 + HT8 + HT9 (IgG mouse)			*		*		*	*	*	*	*	*	*										
CD3/CD4	UCHTI-FITC/13B8.2-PE (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD3/CD8	UCHTI-FITC/B9.11-PE (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD3/CD16+CD56	UCHTI-FITC/3G8+N901-PE (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD3/CD19	UCHTI-FITC/J3-119-PE (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD3/HLA-DR	UCHTI-FITC/Immu-357-PE (IgG1 mouse)			*		*		*	*	*	*	*	*	*										
CD45/CD14	Immu19.2-FITC/RM052-PE (IgG1 / IgG2a mouse)			*		*		*	*	*	*	*	*	*										

APC-A700: APC-Alexa Fluor** 700
APC-A750: APC-Alexa Fluor** 750

* IVDR compliance intended
** Alexa Fluor and Pacific Blue are registered trademarks of Molecular Probes, Inc.