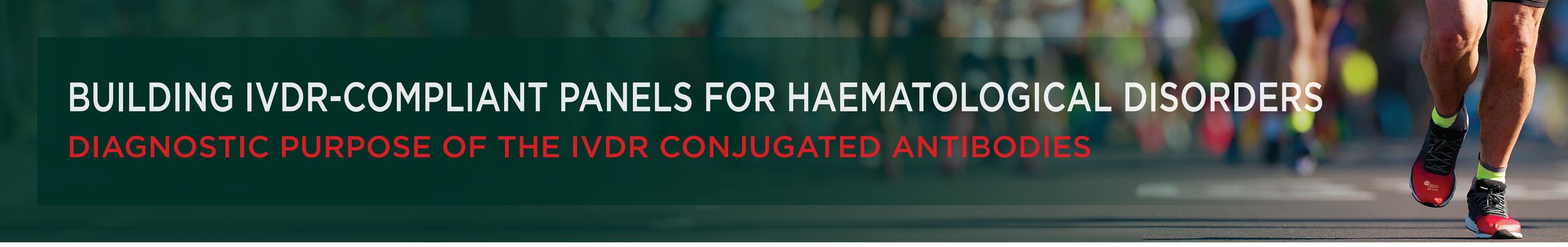

# BUILDING IVDR-COMPLIANT PANELS FOR HAEMATOLOGICAL DISORDERS

## 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 use one of the following:

- 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 Instructions 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** | SJ1D1 (IgG1 mouse) | | | | | | | ■ | | | | | | | | ■ | | ■ | | | | | | |
| | Immu103.44 (IgG1 mouse) | * | | | | | | | ■ | ■ | ■ | | | | | ■ | | ■ | | | | | | |
| **CD14** | RMO52 (IgG2a mouse) | | | | | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | ■ | ■ | | | | | | | | |
| **CD15** | 80H5 (IgM mouse) | | ■ | | | | ■ | | | ■ | | | | | | ■ | | ■ | | ■ | ■ | | | |
| **CD16** | 3G8 (IgG1 mouse) | | ■ | | | | ■ | ■ | ■ | ■ | | | | ■ | ■ | ■ | | ■ | ■ | | | | | |
| **CD19** | J3-119 (IgG1 mouse) | * | ■ | | | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | | | ■ | | | |
| **CD20** | B9E9 (IgG2a mouse) | * | ■ | | * | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | ■ | ■ | | ■ | | | | | | |
| **CD22** | SJ10.1H11 (IgG1 mouse) | * | | | | * | | ■ | | | ■ | | ■ | ■ | | ■ | | ■ | | | | | | |
| **CD23** | 9P25 (IgG1 mouse) | * | | | * | | ■ | ■ | | | | | ■ | | | ■ | | ■ | | | | ■ | | |
| **CD24** | ALB9 (IgG1 mouse) | | | | | | | ■ | | | | | | | | ■ | ■ | | | ■ | ■ | | | |
| **CD25** | B1.49.9 (IgG2a mouse) | * | | | * | | | ■ | | ■ | ■ | ■ | | ■ | | ■ | | ■ | | ■ | | | | |
| **CD27** | 1A4CD27 (IgG1 mouse) | * | | | | | | ■ | | | | ■ | | | | ■ | | | | | | | | |
| **CD33** | D3HL60.251 (IgG1 mouse) | * | | | | | | ■ | | ■ | ■ | ■ | ■ | | ■ | ■ | | | | | | | | |
| **CD34** | 581 (IgG1 mouse) | * | | | | | ■ | ■ | ■ | ■ | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | | ■ | | | |
| **CD36** | FA6.152 (IgG1 mouse) | | | | | * | ■ | | | | | | | | | ■ | ■ | | | | | | | |
| **CD38** | LS198-4-3 (IgG1 mouse) | * | ■ | | * | | | ■ | ■ | ■ | ■ | ■ | | | ■ | ■ | | ■ | ■ | | | | | |
| | T16 (IgG1 mouse) | | | | | | ■ | | | | | | | | | ■ | | ■ | ■ | | | | | |
| **CD41** | P2 (IgG1 mouse) | | | | * | | | ■ | | | | | | | | ■ | | | | | | | ■ | |
| **CD43** | DFT1 (IgG1 mouse) | | | | | | | | | | | | | ■ | | ■ | ■ | | | | | | | |
| **CD45** | J33 (IgG1 mouse) | | ■ | ■ | | | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | | ■ | | | | | | |
| **CD45RA** | ALB11 (IgG1 mouse) | | | | | | ■ | | | | | | | | | ■ | | | | | | | | |
| | 2H4LDH11LDB9 (IgG1 mouse) | | | | | | | | ■ | | | | | | ■ | ■ | | | | | | | | |
| **CD45RO** | 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** | YDJ1.2.2 (IgG1 mouse) | * | | | * | | ■ | | | | | | | | | ■ | | | | | | | | |
| **CD79a** | HM47 (IgG1 mouse) | | | | | | | ■ | | | | | ■ | | | ■ | | | | | | | | |
| **CD79b** | CB3-1 (IgG1 mouse) | | | | | | | ■ | | | | | ■ | | | ■ | | | | | | | | |
| **CD103** | 2G5 (IgG2a mouse) | | | | | * | ■ | | | | | | | | | ■ | | | | | | | | |
| **CD105** | TEA3/17.1.1 (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) | | | | | | | ■ | | | | | | | | ■ | | | | | | | | |
| **Myeloperoxydase** | CLB-MPO-1 (IgG2a mouse) | | | | | | ■ | ■ | | | | | | | | ■ | | | ■ | | | | | |
| **NG2** | 7.1 (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** | UCHT1-FITC/13B8.2-PE (IgG1 mouse) | | | | | | ■ | ■ | | | | | | | | ■ | | | ■ | ■ | ■ | | | |
| **CD3/CD8** | UCHT1-FITC/B9.11-PE (IgG1 mouse) | | | | | | ■ | ■ | | | | | | | | ■ | | | ■ | ■ | ■ | | | |
| **CD3/CD16+CD56** | UCHT1-FITC/3G8+N901-PE (IgG1 mouse) | | | | | | ■ | ■ | | | | | | | | ■ | | ■ | ■ | | ■ | | | |
| **CD3/CD19** | UCHT1-FITC/J3-119-PE (IgG1 mouse) | | | | | | ■ | ■ | | | | | | | | ■ | | ■ | ■ | ■ | ■ | | | |
| **CD3/HLA-DR** | UCHT1-FITC/Immu-357-PE (IgG1 mouse) | | | | | | ■ | ■ | | | | | | | | ■ | | ■ | | | ■ | | | |
| **CD45/CD14** | Immu19.2-FITC/RMO52-PE (IgG1 / IgG2a mouse) | | | | | | ■ | ■ | | | | | | | | ■ | | ■ | | | | | | |

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

* In development, pending achievement of CE compliance; not yet available for in vitro diagnostic use.

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