

The Newly Formed Blood Cell Counting and Typing Team

Scope of Activity: The JCTLM Blood Cell Counting and Typing Team reviews nominations of certified reference materials that are intended for use in cell counting in bodily fluids, red blood serology, tissue typing and antibody quantification, and reference methods/procedures for cell counting in bodily fluids. One particular focus area is the products and applications listed in Annex II Lists A and B of the *In Vitro* Medical Devices Directive 98/79/EC (IVDD).

Team Members:

Confirmed:

Dr John Allan [Quotient]

Dr Johannes J. Hoffmann [Abbott Diagnostics Division]

Dr Mingting Peng [National Center for Clinical Laboratories, China]

Not Yet Confirmed:

Dr Yohko Kawai [International University of Health and Welfare]

Dr Jörg Neukammer [Physikalisch-Technische Bundesanstalt, PTB]

Dr Alexander von Ruecker [University of Bonn]

Dr Giuseppe d'Onofrio [Catholic University of Rome]

Four Questions Posted for the Blood Cell Counting and Typing Team

1. What is the current status of entries in the JCTLM Database with respect to the existing standardized measurands in the field of your team's scope of activity. What are the missing materials, and methods and calibration services providers for standardized measurands?

- red blood cell, white blood cell, and thrombocyte (see the next slide)
- there are missing reference materials in the database for CD4+ cell counting and CD34+ stem cell counting
- See measurands in the List A and List B of the *In Vitro* Medical Devices Directive 98/79/EC (IVDD)

2. Are there any key measurands for which Reference Measurement System Components exist that are not yet covered by JCTLM in your Review Team area?

- CD34+ stem cell counting and PNH (Paroxysmal nocturnal hemoglobinuria)

3. What are the new standardization projects underway in your field that could lead to JCTLM Database entries in the future?

- There is a pressing need for standardization of blood cell subtype counting and expression analysis for cancer immunotherapy/oncology field.
- antibody qualification issue.

4. Can you provide a contact list for reference material producers, developers of measurement procedures, providers of reference measurement services to be targeted/contacted by JCTLM with regard to the missing, and new nominations?

- NIBSC
- US Pharmacopeia
- ICSH
- Blood Banks
- Reagents/Assay Manufacturers, e.g. Quotient

Current Activity Status of the Blood Cell Counting and Typing Team

- **PTB's flow cytometry method for thrombocyte in whole blood at two levels of thrombocyte concentration (C3RMM34 and C3RMM35) is included in JCTLM database**
- **PTB's cytometry method for erythrocyte in whole blood (C3RMM31), and this nomination remains deferred to after the submission of the English version of DIN 58932-3 which was requested by the review team**
- **The team disapproved inclusion of C3RMM32 & C3RMM33 (blood leukocyte) because of a major revision requirement. PTB has not submitted the revisions.**
- **NIBSC's HLA specific allo-antibodies in human serum, and anti-C and anti-D antibodies in human defibrinated plasma are included in JCTLM database**

Focus Area of the Blood Cell Typing

List A

- Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: ABO system, rhesus (C, c, D, E, e) anti-Kell,
- reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D.

List B

- Reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: anti-Duffy and anti-Kidd,
- reagents and reagent products, including related calibrators and control materials, for determining irregular anti-erythrocytic antibodies,
- reagents and reagent products, including related calibrators and control materials, for the detection and quantification in human samples of the following congenital infections: rubella, toxoplasmosis,
- reagents and reagent products, including related calibrators and control materials, for diagnosing the following hereditary disease: phenylketonuria,
- reagents and reagent products, including related calibrators and control materials, for determining the following human infections: cytomegalovirus, chlamydia,
- reagents and reagent products, including related calibrators and control materials, for determining the following HLA tissue groups: DR, A, B,
- reagents and reagent products, including related calibrators and control materials, for determining the following tumoral marker: PSA,
- reagents and reagent products, including related calibrators, control materials and software, designed specifically for evaluating the risk of trisomy 21,
- the following device for self-diagnosis, including its related calibrators and control materials: device for the measurement of blood sugar.