

CLARIFICATION OF “RARE” BLOOD GROUPS AND SUBGROUPS

Annex II List A includes reagents for determining blood groups of ‘ABO system, rhesus (C, c, D, E, e) and anti-Kell. Questions have arisen as to the scope of devices and reagents covered and in particular so called “rare” blood groups and subgroups. The following interpretation was agreed at the December 2003 meeting of the Medical Device Experts Group, MDEG.

List A refers to:

“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”¹.

The use of the word ‘system’ appears to have lead to some confusion. However, the table below defines reagents and devices that are included within Annex II List A. These reagents are used for the routine determination of ABO, RH and K types.

TABLE 1 – Reagents covered by Annex II, List A

Annex II List A Terminology	Reagents & Devices Included	Corresponding Antigen - ISBT Nomenclature
ABO System	Anti-A Anti-B Anti-AB Reagent red cells for reverse grouping	ABO1 ABO2 ABO1, ABO2 Not relevant
Rhesus (C, c, D, E, e)	Anti-D Anti-C Anti-E Anti-c Anti-e	RH1 RH2 RH3 RH4 RH5
Anti-Kell	Anti-K	K1

Other antigens, subgroups and variants of these systems are of minor importance in transfusion practice. Therefore, reagents for the characterization of these antigens are not included in Annex II. Blood grouping reagents/devices not listed in Annex II are regulated as general IVDs.

¹ Directive 98/7



医课汇
公众号
专业医疗器械资讯平台
WECHAT OF
HLONGMED



hlongmed.com
医疗器械咨询服务
MEDICAL DEVICE
CONSULTING
SERVICES



医课培训平台
医疗器械任职培训
WEB TRAINING
CENTER



医械宝
医疗器械知识平台
KNOWLEDG
ECENTEROF
MEDICAL DEVICE



MDCPP.COM
医械云专业平台
KNOWLEDG
ECENTEROF MEDICAL
DEVICE