Guidelines for the Blood Transfusion Services

11.3: Reference preparations

http://www.transfusionguidelines.org/red-book/chapter-11-reagent-manufacture/11-3-reference-preparations

11.3: Reference preparations

11.3.1: Introduction

One of the major regulatory requirements is a requirement for traceability to reference materials of higher order. In the case of blood grouping reagents there are several national and international reference preparations already available to manufacturers to ensure adequate potency of anti-A, anti-B and anti-D grouping reagents and the potency and/or performance of a number of other serology reagents or procedures.

As batch identifiers may change during the lifetime of these guidelines please refer to www.nibsc.org for guidance.

11.3.2: International Standards for minimum potency of anti-A and anti-B blood grouping reagents

These anti-A and anti-B preparations are the lyophilised residues of culture supernatants from murine monoclonal hybridomas BRIC 131 and ES4 respectively. The preparations, when reconstituted and diluted according to the supplied instructions, define the minimum acceptable potency of manufactured anti-A, anti-B, anti-A,B and anti-A+B blood grouping reagents, i.e. the titre of the grouping reagent should be at least equal to that of the appropriate minimum potency reference preparation.

11.3.3: International Standard for minimum potency of anti-D blood grouping reagents for use in direct tests

This preparation is the lyophilised residue of culture supernatant from a human-murine monoclonal heterohybridoma secreting an IgM anti-D (RUM-1). When reconstituted and diluted according to the supplied instructions, this material defines the minimum acceptable potency of anti-D grouping reagents in direct tube tests, i.e. the titre of the grouping reagent should be at least equal to that of the minimum potency reference preparation in tube tests using unmodified red cells and without additional agents.

11.3.4: International Council for Standardization in Hematology/International Society of Blood Transfusion (ICSH/ISBT) reference preparations for papain and anti-D

The intended use of these preparations is to ensure adequate sensitivity combined with freedom from false-positive reactions associated with some manufacturers' enzyme preparations and techniques. The recommended procedure is to test the papain reference material in conjunction with a suitable anti-D preparation of 2.5 to 3.5 IU/mL using a titration series for sensitivity, and a series of inert sera for false-positive reactions, according to the specified two-stage reference method in the product insert and to compare the titration scores with those obtained from testing the manufacturer's enzyme preparation in its recommended technique with the anti-D reference preparation and the inert sera.

11.3.5: UKBTS/NIBSC anti-D reference preparation for assuring operator and test performance

The current preparation (98/540) consists of lyophilised human plasma with a reconstituted anti-D potency of 1.8 IU/mL. At 1 in 20 dilution, it is intended to be used to assure the efficacy of red cell washing prior to the addition of an antiglobulin reagent. At 1 in 40 dilution, it is intended to be used in intra-laboratory monitoring to assess test operator variability in the detection of weak, macroscopic agglutination in the spin-tube antiglobulin test or equivalent reaction grades using automated methods.