Rea QC

for internal quality control in blood group serology

REF 44200

Introduction:

Rea QC is a human in vitro diagnostic (IVDMD) in vitro diagnostic (IVDMD) product of internal quality control for professional use. The ABO-RhD blood typing kits (red cell and plasma tests), Rh-K phenotyping kits and irregular antibodies are complementary. Its use allows the detection of various abnormalities (caused by treatment, reagents, equipment and environment) and the implementation of corrective measures.
Rea QC is a control for blood group, Rh phenotype and the presence of antibodies.

Target end-user: Laboratory assistant with blood group serology laboratory testing experience, good laboratory practice (GLP) experience

Intended purpose - Principle:

The internal quality control is based on blood samples of known blood group, phenotype and antibody content. These samples should be used under the same conditions as the test material samples. The results obtained shall be in accordance with the expected results for blood group, phenotype and antibody as indicated on the vial.
The procedure is based on the principle of hemagglutination, where red blood cells carrying the antigen agglutinate in the presence of a reagent or plasma containing the corresponding antibody.

Composition:

Product	**Main blood group**	**Rh, Kell phenotypes**			**Antibodies**	
					Regular	**Irregular**
REA QC 1	The	rr, K+	D-C-E-c+e+ RH-1,-2,-3,4,5	K+ KEL 1	Anti-B	Anti-D
REA QC 2	B	R1R2, K-	D+C+E+c+e+ RH1,2,3,4,5	K-KEL-1	Anti-A	Anti-Fya

The REA QC is prepared from red blood cells of human origin with known properties (always in the composition shown in the table above). The reagents contain group-matched plasma and irregular antibodies. haematocrit of the suspensions: 15 %.

Precautions:

1. All blood reagents and material in direct contact with samples should be considered potentially contaminated. Human blood products from which the Rea QC was drawn by the National Blood Service have been tested for HBsAg, anti-HIV 1-2, anti-HCV and anti-TP using CE-marked (Decree 3/2005 (II.10.) of the SRM; Decree 8/2003 (III.13.) of the ESzCsM) screening tests and the result is NOT REACTIVE, but this does not exclude the possibility of transmission of any infection.
2. It is advisable to wear protective gloves and glasses. Disposal of residues must be in accordance with current hygiene regulations. As with all substances of human origin, appropriate care should be taken. Any material that comes into contact with specimens is considered potentially infectious. Special precautions and regulations for the disposal and disinfection of such materials should be carried out in accordance with local regulations!
3. Do not use a damaged or leaking glass tube reagent!

Storage and transport:

The in vitro diagnostic medicinal product should be stored between +2 and +8 °C. When used, keep at room temperature only for the minimum time necessary for the test. Do not freeze!

Performance is guaranteed from first use until the expiry date on the label. The reagent cannot be used after the expiry date!

Test procedure:

The control should be used under the same conditions as the test material samples, following the instructions for use of the reagents used. Suitable for both manual and automated column agglutination techniques.
The Rea QC should be centrifuged at 1200g for 3 minutes before starting the tests.

Evaluation of the results:

The results obtained with REA QC should match the expected values on the vial for blood group, phenotypes and antibodies.

Adequate, confirmed results obtained with REA QC allow diagnostic validation of the test sample results by the investigator.

Different results indicate anomalies in the treatment, reagents, equipment and environment and require corrective action.

Limitations of the method:

-Reagents should only be used by qualified personnel.
-Do not use the REA QC control if you experience a noticeable haemolysis!
- Avoid mixing the samples of the kit! (the colour of the cap of the vial and the colour of the label are the same) when using REA QC
-Work only with clean tools and materials free from contamination!
-Points to pay particular attention to:

- storage conditions and expiry date
- the procedures described in the instructions for use must be followed
- calibration and maintenance of equipment and instruments used for tests
- anti-D is less than 0.1 lU/ml, agglutination may not occur

Packaging: 2 x 5 ml (REF 44200)

Bibliography:

1.) Transzfúziós szabályzat – Az OVSz módszertani levele 2. kiadás, OVSz, Bp. 2008. (Transfusion Guideline – 2nd Edition of Methodology Letters HNBTS, Hungary)

2) AABB Technical Manual, 17th edition, AABB, Bethesda, Maryland, USA

3.) Guidelines of Transfusion Services in the United Kingdom 7th Edition 2005

4) Regulation (EC) No 3/2005 (10.II.) on quality and safety standards and certain technical requirements for the collection, testing, processing, storage and distribution of human blood and blood components (Directives 2002/98/EC and 2004/33/EC)

Incident reporting:

For end-user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/746/EU on In vitro Diagnostic Medical Devices); if during the use of this device or as a result of this use, a serious incident occurs, please report it to REAGENTNS Ltd. to info@reagenskft.hu email address and to your (local) national Competent Authority.

Symbols used:

REF	Catalogue reference		Expiry date (YYYY.MM.DD)
LOT	Batch Number		Storage temperature
IVD	In vitro diagnostic		Legal manufacturer
	Consult instruction for use		

The Summary of Safety and Performance (SSP) will be available on https://ec.europa.eu/tools/eudamed as soon as EUDAMED is operational.
This document is available in several languages. In case of doubts or discrepancies, the wording of the master document in Hungarian takes precedence.
Changes to the previous version are highlighted in grey.

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