INSTRUCTIONS FOR USE

Rea QC - for internal quality control in blood group serology

IVD CE

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.

Principle:

The 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 fenotypes**			**Antibodies**	
					Regular	**Irregular**
REA QC 1	A	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. hematocrit 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 ECM; Decree 8/2003 (III.13.) of the ECM) 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!

Testing:

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 analytical 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 hemolysis!
- Avoid mixing the samples of the kit! (the color of the cap of the vial and the color 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)

Literature:

1.) Transfusion Regulation - Methodological Letter of the OCR 2nd edition, OCR, Bp. 2008.

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:

Any serious incident/unexpected event occurred during use of the product, must be reported to the manufacturer: REAGENS Kft, 1155 Budapest Wysocki utca 1, fax: +361-350 8354 or by email at info@reagenskft.hu and to: OGYÉI National Institue of Pharmacy and Nutrition Medical Device Directorate, using incident report forms available on website: https://ogyei.gov.hu/varatlan_esemeny_jelentes

Manufacturer:

REAGENS Kft. 1155 Budapest,

Wysocki u. 1. Magyarország

Version: 1.3v

Date of release: 2018.11.07.