INSTRUCTIONS FOR USE

Rea IQC Total Blood Kit internal control

Red Blood Cell Suspension: 15%

REF 44130, 44140

IVD CE 1011

Introduction:

The Rea IQC Total Blood Kit is an in vitro diagnostic medical device (IVDMD) of human origin. The kit is completing the AB0-Rh1 blood grouping series (red blood cells test and plasma tests) and Rh-K phenotyping series. Using the control kit enables the user to detect irregularities caused by the method, reagents, instrument or environment, thus allowing to take preventive and corrective actions.

Intended purpose – Overview

The internal control kit is assayed from blood samples with well known, determined phenotypes. The control should be handled and used exactly as a normal patient blood sample. Results of control testing must exactly match the blood groups, phenotype and antibodies printed on the vial label. Test principle is haemagglutination. The RBC with antigen agglutinates if the corresponding antibody is present in the reagent or plasma.

Composition of the Kit

REA IQC Total Blood Kit contains four constant Rh phenotypes listed below:

Product	Blood group	Rh, Kell phenotype			Antibodies	
					Regular	Irregular
REA IQC 1	A	R1R1K+	D+C+E-c-e+ RH1,2,-3,-4,5	K+ KEL 1	Anti-B	
REA IQC 2	B	R1R2	D+C+E+c+e+ RH1,2,3,4,5	K- KEL-1	Anti-A	Anti-K
REA IQC 3*	AB	rr	D-C-E-c+e+ RH-1,-2,-3,4,5	K- KEL-1		Anti-D
REA IQC 4*	0	R2R2	D+C-E+c+e- RH1,-2,3,4,-5	K- KEL-1	Anti-A, Anti-B	

HCT value of suspension is 15 %.

Precautions

All reagents of human origin and all substrates that have come into contact with the samples must be handled as potentially infectious materials.

Red Blood Cell concentrates, and the plasma used in Rea IQC Total Blood Kit has been tested by the Hungarian Blood Transfusion Service in accordance with the operative decree 3/2005. (II. 10.) EüM regarding blood products for transfusion. All human blood products used in production were found non-reactive for Lues, HIV1, 2, HbsAg and HCV by procedures recommended by the European Council, however, none of the methods currently known can absolutely guarantee that the products do not contain any transmissible pathogen.

It is recommended to wear gloves and safety goggles.

Special protective measures, conditions for waste disposal and disinfection should be implemented in accordance with local regulations.

Do not use leaking or damaged reagent.

Storage and transporting conditions

The reagents must be transported and stored between +2°C and +8°C.

Do not keep at room temperature longer than necessary. DO NOT FREEZE!

Performance is guaranteed by the manufacturer until expiry date only if the conditions regarding storage, transport and utilization are respected.

Do not use after the date of expiry!

Test procedure

Centrifuge the Rea IQC Total Blood Kit for 3 minutes at 1200 g RCF before use. After centrifugation the control should be handled exactly as a patient sample. It is compatible with both manual and automated techniques. Read and follow the IFU of reagents.

Interpretation of the results

Test results of each control vial must exactly match with the blood group, phenotype and antibodies printed on the vial label.
Matching results confirm that the workflow is correct and enables the operator to validate the patient samples.
In case of unmatching results, further investigation of the method, reagents, instrument and environment is strongly recommended.
Validation of patient samples should be suspended until correct control results are achieved.

Limitations of the method

The Rea IQC Total Blood Kit should be used by qualified personnel only.
Do not use the Rea IQC Total Blood Kit if noticeable haemolysis is present.
Double-check and match the colour codes (cap and label colour must match) in order to avoid contamination.
Use only clean, bacteria-free instruments.
Pay extra attention to the following:

- storage conditions and expiry date of reagents
- strictly follow the IFU of reagents
- calibration and maintenance of instrument(s)

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.) Decree 2/2005 (II. 10.) of EüM regulation of quality and safety for collecting, testing, processing, storing and distribution of human blood and blood components, and their individual technical requirements (localization of Directive 2002/98/EC and Directive 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 REAGENS Ltd. to info@reagenskft.hu email address and to your (local) national Competent Authority.

Packaging: 4 x 6 ml - REF 44130
4 x 4 ml - REF 44140

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