LORNE LABORATORIES

INSTRUCTIONS OF USE

Lorne Rea IQC Total Blood Kit internal control

Red Blood Cell Suspension: 25-30%

IVD CE

REF 940406R

1011

Principle of the method

These reagents are In Vitro Diagnostic Medical Devices (IVDMD) of human origin. They are completing the AB0-Rh1 blood grouping series (red blood cells tests and plasma tests) and Rh-K phenotyping series. The use of this internal control enables detection of deficiencies caused by the operator, but the test methods, by the reagents used, by the instruments used and by the environment. This allows preventive and corrective actions to be taken regularly to improve proficiency.

Intended purpose – Overview

The internal control test is based on blood samples with well known, determined phenotypes. This control is used in the same way as the normal patient blood samples. The results of testing these samples should match exactly the blood group phenotypes on the vial. The test is based on the principle of haemagglutination. The RBC with antigen agglutinates the antibody of the reagent or plasma.

Composition of the Kit

The Rea IQC Total Blood Kit contains four 6 ml vials as below.

Product	Blood group	Rh, Kell phenotype			Antibodies	
					Regular	Irregular
REA IQC 1	A	R_1R_1K+	D+C+E-c-e+ RH1,2,-3,-4,5	K+ KEL 1	Anti-B	
REA IQC 2	B	R_1R_2	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	R_2R_2	D+C-E+c+e- RH1,-2,3,4,-5	K- KEL-1	Anti-A, Anti-B	

Rea IQC Total Blood Kit contains RBC and plasma with determined, well known blood group and phenotype. The suspension HTC level is between 25% to 30%.

Precautions

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

The red blood cell concentrates and the plasma used for Rea IQC Total Blood Kit have been tested by the Hungarian Blood Transfusion Service in accordance with the operative decree 3/2005. (II. 10.) EU regarding blood preparations for transfusion. All human blood preparations, from which these test cells are produced, were found non-reactive for HIV1, 2, HbsAg and HCV by procedures recommended by the European Council. In addition, they have been found to be negative in a serologic test for syphilis.

However, none of the methods currently known can absolutely guarantee that the products do not contain any transmissible pathogen. It is advisable to wear gloves and safety spectacles.

Special protective measures, conditions for disposal and disinfection should be implemented in accordance with local operating regulations.
Do not use leaking or damaged reagent.

Storage and transporting conditions
The reagents must be stored between +2°C and +8°C. Their performance is guaranteed by the manufacturer in the method recommended from the first use to the expiry date on the label. It must not be used beyond that date. It is advisable to minimize time outside the refrigerator and to avoid leaving the vials at room temperature between uses. DO NOT FREEZE.

Test procedure
Centrifuge for 3 minutes with 1000 RCF before using Rea IQC Total Blood Kit. The internal controls have to be used in the same conditions as the patient samples are used with manual or automated technique, based on to the instruction for use of the used reagents.

Interpretation of the results
The result of the test should entirely match the information displayed on the vial with blood group and phenotype. The expected results given by the Rea IQC Total Blood Kit enables the validation of patient samples with the responsibility of the qualified personnel. The difference between the expected results and testing results shows malfunction or irregularity. Based on this, decisive corrective action should be taken.

Limitations of the method
The Rea IQC Total Blood Kit should only be used by professional personnel.
Do not use the Rea IQC Total Blood Kit if noticeable haemolysis is present.
Turbidity, change in colour, or haemolysis may point to bacterial or other contamination. A reagent with these characteristics must not be used.
Match the vials cap colour with the label colour to avoid contamination.
Use only clean, bacteria free instruments and equipment.
Pay attention to:
Storage conditions and reagent expiry date
Follow strictly the instructions for use of the reagents
Regular calibration and maintenance of instruments is recommended.

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 EU 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)

Packaging: 4 x 6 ml - REF 940406R

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