TRANSFUSION MEDICINE

INSTRUCTIONS FOR USE

ORTHO CONFIDENCE™ WB
Simulated Whole Blood Quality Control Kit

REF 6842785

Intended Use

For *in vitro* diagnostic use only

The ORTHO CONFIDENCE™ WB Quality Control Kit is intended for use as qualitative controls to assure the reliability of basic blood bank serological reagents and automated/manual blood grouping systems using column agglutination techniques.

Summary and Explanation

The purpose of daily quality assurance in the blood bank is to confirm the reliability of the test system. The test system includes reagents, test procedures and equipment. Testing known samples is an accepted method of quality control. If expected test results are observed, procedures are being performed accurately and reagents and equipment are performing properly. If unexpected results are observed, the problem may be due to improper test performance, faulty equipment or contamination or deterioration of reagents. The source of the problem should be determined and resolved before patient/donor test results are reported.

The ORTHO CONFIDENCE™ WB Quality Control Kit provides a means of confirming the reactivity of routinely used reagents and is to be tested on each day of use. Observation of expected test results with the ORTHO CONFIDENCE™ WB Quality Control Kit will confirm the reactivity of ABO, Rh, and K antibodies, as well as reverse grouping cells and reagent red blood cells used for antibody detection.

Principle of Procedure

The procedures used with these reagents are based on the principle of agglutination. Normal human red blood cells will agglutinate in the presence of the appropriate antibody directed against antigens on those red blood cells. No agglutination indicates the absence of the demonstrable antigen or antibody.

Reagents

The ORTHO CONFIDENCE™ WB Quality Control Kit is prepared from red blood cells collected from blood donors. ABO antibodies are of monoclonal origin and anti-D, anti-c, and anti-Fy^a antibodies are of polyclonal origin. Polyclonal anti-D source material is prepared from an initial concentration of <10 IU/mL to a concentration of approximately 0.1 IU/mL.

The concentration of red blood cells in each of the samples is 15% ± 2%. The red cells are suspended in a preservative solution to retard haemolysis and bacterial contamination.

- Vial 1 - Group A_1B D+C+E+c+e+ (R_1R_2)
- Vial 2 - Group O D+C+E-c-e+ (R_1R_1) K+, anti-A, anti-B, anti-c
- Vial 3 - Group A D+C-E+c+e- (R_2R_2) Fy(a-), anti-B, anti-Fy^a
- Vial 4 - Group B D-C-E-c+e+ (rr) K-, anti-A, anti-D (concentration of approximately 0.1 IU/mL)

Storage Requirements

Store at 2–8 °C.

Precautions

- Do not transfer any of these reagent red cells to another container as this could result in spillage or contamination.
- Do not use beyond the product expiry date.
- Do not freeze.
- Do not use if marked haemolysis is observed. Slight discoloration in the supernatant is normal over the shelf life of the product. Extreme turbidity, precipitation or haemolysis of the red blood cells may indicate product alteration.
- Do not use if evidence of contamination is present.
- Replace vial caps when not in use.
- Allow the vials to warm to room temperature (18-25 °C) prior to use.
- Refer to the Material Safety Data Sheet (MSDS) available from Ortho Clinical Diagnostics, Inc. for more specific information.

Caution:	**Source material from which this product is derived was found non-reactive for HBsAg, Anti-HIV 1/2 and Anti-HCV. No known test methods can offer assurance that products derived from human blood will not transmit infectious disease. Appropriate care should be taken in the use and disposal of this product.**

Procedure

This reagent has been validated for use manually on the BioVue® System and for use on the AutoVue® Innova/Ultra automated blood grouping test system and therefore its suitability for use by other technologies cannot be guaranteed. Customers who choose to use commercial antisera and red cell reagents in an off-label manner must ensure the test method is appropriate by validating its intended use.

When using automated instruments, follow the procedures that are contained in the operator's manual provided by the device manufacturer.

The ORTHO CONFIDENCE™ WB Quality Control Kit is intended to simulate normal blood samples. The samples contained in the ORTHO CONFIDENCE™ WB Quality Control Kit must be used at room temperature (18-25 °C) and should be tested by following standard procedures in accordance with the applicable Instructions for Use for routine reagent use..

Vials are required to be centrifuged prior to first use. Centrifugation must be performed according to the user's standard laboratory practice for the centrifugation of patient samples. Subsequent upright, refrigerated storage eliminates the requirement for further centrifugation unless mixing has occurred.

Materials Provided

- Vial 1 Simulated Whole Blood Control - Group A_1B D+C+E+c+e+ (R_1R_2)
- Vial 2 Simulated Whole Blood Control - Group O D+C+E-c-e+ (R_1R_1) K+, anti-A, anti-B, anti-c
- Vial 3 Simulated Whole Blood Control - Group A D+C-E+c+e- (R_2R_2) Fy(a-), anti-B, anti-Fya
- Vial 4 Simulated Whole Blood Control - Group B D-C-E-c+e+ (rr) K-, anti-A, anti-D (concentration of approximately 0.1 IU/mL)

Additional Materials Required but not Provided

For Automated Testing*:*

- BioVue® Cassettes
- Reagent Red Blood Cells
- Ortho AutoVue® Innova/Ultra

For Manual Testing:

- BioVue® Cassettes
- Reagent Red Blood Cells
- Manual or Electronic Pipettes
- Pipette Tips
- Timer
- Test Tubes
- BioVue® Centrifuge
- BioVue® Incubator

Interpretation of Results

The following table illustrates the expected results in tests with ORTHO CONFIDENCE™ WB Quality Control Kit and routine blood bank reagents.

Component of ORTHO CONFIDENCE™ WB Quality Control Kit	Reagent Under Test	Expected Test Results*
Vial 1	Anti-A	+
	Anti-B	+
	Anti-A,B	+
	Anti-D	+
	A_1 cells	0
	B cells	0
	Screening cell 1 (R_1R_1)	0
	Screening cell 2 (R_2R_2)	0
	Screening cell 3 (rr)	0
	Anti-C	+
	Anti-E	+
	Anti-c	+
	Anti-e	+
Vial 2	Anti-A	0
	Anti-B	0
	Anti-A,B	0
	Anti-D	+
	A_1 cells	+
	B cells	+
	Screening cell 1 (R_1R_1)	0
	Screening cell 2 (R_2R_2)	+
	Screening cell 3 (rr)	+
	Anti-C	+
	Anti-E	0
	Anti-c	0
	Anti-e	+
	Anti-K	+
Vial 3	Anti-A	+
	Anti-B	0
	Anti-A,B	+
	Anti-D	+
	A_1 cells	0
	B cells	+
	Screening cell 1 (R_1R_1)	**
	Screening cell 2 (R_2R_2)	**
	Screening cell 3 (rr)	**
	Anti-C	0
	Anti-E	+
	Anti-c	+
	Anti-e	0
Vial 4	Anti-A	0
	Anti-B	+
	Anti-A,B	+
	Anti-D	0
	A_1 cells	+
	B cells	0
	Screening cell 1 (R_1R_1)	+
	Screening cell 2 (R_2R_2)	+
	Screening cell 3 (rr)	0
	Anti-C	0
	Anti-E	0
	Anti-c	+
	Anti-e	+
	Anti-K	0

* Discrepant results must be investigated further.

** Results depend upon antigen configuration.

Quality Control

This product is a quality control reagent and its satisfactory performance when used by the recommended techniques represents an adequate level of control.

Limitations of the Procedure

1. ORTHO CONFIDENCE™ WB Quality Control Kit is designed to be tested with reagents that have not been diluted.
2. Improper techniques may invalidate the results obtained with this product.
3. False positive or false negative results can occur due to contamination of test materials, improper reaction temperature, improper storage of materials, and omission of test reagents.
4. Individual laboratory procedures may affect the final reaction strength observed in tests performed with ORTHO CONFIDENCE™ WB Quality Control Kit.
5. Under certain circumstances, the anti-c specificity present in Vial 2 may react at room temperature.

Performance Characteristics

- Each cell sample is shown to have a negative direct antiglobulin test.
- When properly stored and used according to standard procedures, these reagents will demonstrate the appropriate antigens / antibodies specified in the reagent description.
- The Procedure and Interpretation of Results must be followed closely to ensure the accuracy of the test results. Each laboratory should have a program that will train personnel on the proper use and handling of the product.
- Technical questions concerning this reagent should be directed to your local Customer Technical Support Center.

Glossary of Symbols

The following symbols may have been used in the labeling of this product.

Use by or Expiration Date (Year-Month-Day)	Manufacturer	Temperature Limitation
LOT Lot Number	IVD *In vitro* Diagnostic Medical Device	Consult Instructions for Use
REF Catalog Number or Product Code		

Summary of Revisions

Date of Revision	Version	Section	Description of Technical Changes*
2010-06-21	1.0		Initial version of Instructions for Use

* The change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.

CE

Alba Bioscience Limited
Ellen's Glen Road, Edinburgh EH17 7QT, UK

Distributed by
Ortho Clinical Diagnostics
a Johnson & Johnson company
1001 US Highway 202, Raritan, NJ 08869 USA