

# ORTHO® Confidence System

Qualitative Controls to Validate Blood Bank Procedures

**REF**

6902096

## 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 test results are reported.

Since commercial blood grouping reagents and reagent red blood cells must meet FDA specificity requirements, extensive daily specificity testing by blood bank laboratories would be redundant. Reagent reactivity should be confirmed by each laboratory. The antibody and red blood cell samples supplied in ORTHO Confidence System provide a means of confirming the reactivity of routinely used reagents and are to be tested on each day of use according to the Directions for Use accompanying each reagent. Observation of expected test results with ORTHO Confidence System will confirm the reactivity of anti-A, anti-B, anti-A, B, anti-D (anti-Rh<sub>0</sub>) and the anti-IgG component of anti-human globulin, 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 antibody directed against antigens on those red blood cells. No agglutination indicates the absence of the demonstrable antigen or antibody.

The antibody and red blood cell samples provided in ORTHO Confidence System will confirm the reactivity of the reagents used for ABO and Rh determinations, the anti-IgG component of anti-human globulin, as well as reverse grouping cells and reagent red blood cells used in antibody detection tests.

Component of ORTHO Confidence System	Methodology Used	Reagent Under Test
ORTHO Confidence Cell 1 A <sub>1</sub> B rr	forward grouping	anti-A anti-B anti-A, B†
ORTHO Confidence Cell 2 O R <sub>1</sub> r	Rh determination	anti-D Rh control†
ORTHO Confidence Antibody (dilute anti-A, -B, -D and -c̄)	reverse grouping	group A and B cells
	antibody detection	screening cells anti-human globulin (AHG)

†Optional reagents

## REAGENTS

ORTHO Confidence System consists of three reagents.

1. ORTHO Confidence Cell 1 — A<sub>1</sub>B rr (dce/dce) human red blood cells pooled into a 3% suspension
2. ORTHO Confidence Cell 2 — O R<sub>1</sub>r (DCe/dce) human red blood cells in a 3% suspension

In order to maintain the integrity of the cell membrane with its antigens, ORTHO Confidence Cell 1 and ORTHO Confidence Cell 2 are suspended in a phosphate-citrate buffered diluent to which a purine, a steroid and nucleosides have been added to maintain reactivity and/or retard hemolysis during the dating period. Chloramphenicol (1:3,000), neomycin sulfate (1:10,000) and gentamicin (1:20,000) have been added to retard bacterial contamination.

3. ORTHO Confidence Antibody — dilute murine monoclonal anti-A and anti-B blended with human IgG anti-D (anti-Rh<sub>0</sub>) and anti-c̄ (anti-hr') containing bovine albumin, sodium chloride, sodium phosphate, EDTA and sodium azide 0.1% as a preservative. The anti-A and anti-B are sufficiently diluted to demonstrate A and B antigen stability. The Rh-hr antibodies are diluted to give approximately a 2-3+ reaction at the antiglobulin phase, confirming the reactivity of screening cells and the anti-IgG component of anti-human globulin.

Store at 2 to 8°C. Replace cap when not in use.

For in vitro diagnostic use. No U.S. Standard of Potency.

These reagents are ready to use as furnished.

Extreme turbidity, precipitation or hemolysis of the red blood cells may indicate product alteration. Do not use reagents after the expiration date shown on vial labels.

# ORTHO

CAUTION: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested in accordance with current FDA required tests. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

WARNING: Contains sodium azide. Sodium azide may react with lead and copper plumbing to form highly explosive metal azide. On disposal, flush with a large volume of water to prevent azide buildup.

**PROCEDURE**

The procedures below are for manual testing only. When using automated instruments, follow the procedures that are contained in the operator’s manual provided by the device manufacturer. Laboratories must follow their approved validation procedures to demonstrate compatibility of this product with other test methods, either manual or automated.

**Materials Provided**

1. ORTHO Confidence Cell 1 (1 x 10 mL)
2. ORTHO Confidence Cell 2 (1 x 10 mL)
3. ORTHO Confidence Antibody (2 x 8 mL)

**Required Supplementary Materials**

1. Test tubes, 10 x 75 mm or 12 x 75 mm
2. Incubator, 37°C
3. Centrifuge
4. Isotonic saline
5. Antibody enhancement solution (such as ORTHO Bovine Albumin, ORTHO Polymerized Bovine Albumin or ORTHO® Antibody Enhancement Solution), if used
6. Anti-human globulin containing anti-IgG (such as ORTHO Anti-Human Globulin, Anti-IgG, -C3d; polyspecific or ORTHO Anti-IgG)
7. IgG sensitized cells (such as ORTHO® Coombs Control), if used

**Directions for Use**

The cells and antibody in ORTHO Confidence System are intended to simulate normal blood samples. The cells and antibody supplied with ORTHO Confidence System should be tested by following standard procedures in accordance with the Directions for Use accompanying each reagent used routinely. Mix reagent red cells well prior to use.

1. Perform ABO red cell grouping using ORTHO Confidence Cell 1. Perform D typing using ORTHO Confidence Cell 2. Record results on the laboratory daily work sheet or ORTHO Confidence System Blood Bank Quality Control Record sheet.
2. Perform reverse grouping and an antibody screening test using ORTHO Confidence Antibody and record results on the laboratory daily work sheet or ORTHO Confidence System Blood Bank Quality Control Record sheet.

**INTERPRETATION OF RESULTS**

The following chart illustrates the expected results in tests with ORTHO Confidence System and routine blood bank reagents.

Component of ORTHO Confidence System	Reagent Under Test	Expected Test Results*
ORTHO Confidence Cell 1 A <sub>1</sub> B rr	anti-A	+
	anti-B	+
	anti-A, B	+
ORTHO Confidence Cell 2 O R <sub>1</sub> r	anti-D (anti-Rh <sub>0</sub> )	+
	Rh control†	0
ORTHO Confidence Antibody	A <sub>1</sub> cells	+
	A <sub>2</sub> cells	+
	B cells	+
	screening cell 1 and AHG	+
	screening cell 2 and AHG	+
	screening cell 3 and AHG	+

**OPTIONAL TESTING**

Specificity testing of reagents, i.e., testing reagents against cells lacking the corresponding antigen, if desired, can be accomplished in the following manner.

Component of ORTHO Confidence System	Reagent Under Test	Expected Test Results*
ORTHO Confidence Cell 2 O R <sub>1</sub> r	anti-A	0
	anti-B	0
	anti-A, B	0
ORTHO Confidence Cell 1 A <sub>1</sub> B rr	anti-D (anti-Rh <sub>0</sub> )	0
	Rh control	0

NOTE: The use of IgG sensitized red cells is recommended if the test for weak D is performed.

\*Discrepant results must be investigated further.

**LIMITATIONS OF PROCEDURE**

1. ORTHO Confidence Cell 1 and ORTHO Confidence Cell 2 are designed to be tested with ABO and D(Rh<sub>0</sub>) reagents that have not been diluted.
2. ORTHO Confidence Cell 1 and ORTHO Confidence Cell 2 are not to be considered auto control cells for ORTHO Confidence Antibody.
3. ORTHO Confidence Antibody is designed to be used only with reagent red blood cells and is not suitable for blood grouping or typing.
4. ORTHO Confidence Antibody is a pooled reagent and is not suitable for specificity testing of reagent red blood cells.
5. Contaminated supplementary materials used in the procedures described may interfere with the test results.
6. Improper technique may invalidate the results obtained with these reagents.
7. Individual laboratory procedures may affect the final reaction strength observed in tests performed with ORTHO Confidence System.
8. 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.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

When properly stored and used according to the procedures described under Directions for Use, ORTHO Confidence System will confirm the reactivity of ABO reagents, anti-D (anti-Rh<sub>0</sub>) and the anti-IgG component of anti-human globulin as well as reagent red blood cells possessing A, B, D(Rh<sub>0</sub>) and/or c(hr') antigens.

Technical questions concerning these reagents should be directed to Customer Technical Support at 1-800-421-3311.

<b>SUMMARY OF REVISIONS</b>	
<b>Section</b>	<b>Revision</b>
<b>SUMMARY AND EXPLANATION</b>	Revised text for clarity and accuracy
<b>PRINCIPLE OF PROCEDURE</b>	Added "red blood" to description of cells
<b>REAGENTS</b>	Removed vial size from the description of the reagents Added "Replace cap when not in use" Removed "Do not dilute them" Added WARNING
<b>PROCEDURE</b>	Added statement regarding specifying for manual testing
<b>Materials Provided</b>	Added vial size of materials
<b>Directions for Use</b>	Revised text for clarity and accuracy
<b>INTERPRETATION OF RESULTS</b>	Removed footnote indicating optional reagents and tests Added footnote "Discrepant results must be investigated further"
<b>LIMITATIONS OF PROCEDURE</b>	#1: Revised text for clarity and accuracy Added Limitation #8
<b>SPECIFIC PERFORMANCE CHARACTERISTICS</b>	Updated Technical Support phone number
<b>BIBLIOGRAPHY</b>	Updated References

**BIBLIOGRAPHY**

Technical manual. 14th ed. Bethesda, MD: American Association of Blood Banks, 2002.

Standards for blood banks and transfusion services. 22nd ed. Washington, DC: American Association of Blood Banks, 2003.



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