Alba**Q-C**hek®

Simulated Whole Blood Controls

For use as controls of blood grouping reagents in column agglutination techniques

REF **Z498**

- **FOR *IN VITRO* DIAGNOSTIC USE**
- **No U.S. standard of potency**
- **Do not freeze**
- **Do not use if obviously discolored or hemolyzed**
- **Preservatives:**
  - o **chloramphenicol (0.349 g/L)**
  - o **neomycin sulfate (0.103 g/L)**

CAUTION: THE ABSENCE OF ALL VIRUSES HAS NOT BEEN DETERMINED.

INTERPRETATION OF LABELING SYMBOLS

LOT	Batch code
	Use by (YYYY-MM-DD)
REF	Product code
8°C 2°C	Storage temperature limitation (2-8 °C)
IVD	*In vitro* diagnostic medical device
	Consult instructions for use
	Manufacturer

INTENDED USE

Alba**Q-C**hek® is intended for use as ABO, RhD and antibody screening controls for automated/semi- automated 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 test results are reported.

Alba**Q-C**hek® provides a means of confirming the reactivity of routinely used reagents. Observation of expected test results with Alba**Q-C**hek®will confirm the reactivity of anti-A, anti-B, anti-A,B and anti-D (anti-Rho), as well as reverse grouping cells and reagent red blood cells used for antibody detection.

PRINCIPLE OF THE TEST

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 simulated whole blood samples provided in Alba**Q-C**hek® confirm the reactivity of the reagents used for ABO and Rh determinations, as well as reverse grouping cells and reagent red blood cells used in antibody detection tests.

REAGENT DESCRIPTION

Alba**Q-C**hek® is prepared from red blood cells collected from blood donors. Each individual donation contains the appropriate ABO and RhD blood group antigens and also the appropriate ABO blood group antibodies. ABO and anti-D antibodies are of monoclonal origin and anti-c is of polyclonal origin.

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

Vial 1 - Group A RhD Negative (rr) containing anti-B, anti-D
Vial 2 - Group O RhD Positive (R_1R_1) containing anti-A, anti-B, anti-c
Vial 3 - Group B RhD Positive (R_1r) containing anti-A
Vial 4 - Group A_2B RhD positive

The preservative solution has been specially formulated to preserve red cell integrity and antigenicity and contains the following components - trisodium citrate, citric acid, dextrose, inosine, neomycin sulfate (0.103 g/L) and chloramphenicol (0.349 g/L).

STORAGE CONDITIONS

Store at 2-8 °C.

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only
Do not freeze
Do not transfer any of the vial contents to another container as this could result in spillage or contamination
Do not use if evidence of contamination is present
Product should be used by qualified personnel
Do not use beyond the expiration date
Once opened, vials can be used for seven days
Slight discoloration in the supernatant is normal over the shelf-life of the product. In cases of extreme turbidity, precipitation or hemolysis of the red blood cells, the product should not be used
Replace vial caps when not in use
The format of the expiration date is expressed as YYYY-MM-DD (Year-Month-Day)

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 METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS. APPROPRIATE CARE SHOULD BE TAKEN IN THE USE AND DISPOSAL OF THIS PRODUCT.

As this reagent is of animal origin care must be taken during use and disposal as there is a potential infection risk.

MATERIALS

Material provided
Alba**Q-C**hek® Simulated Whole Blood Controls

Materials required but not provided

For automated testing:
- Ortho ProVue®/ORTHO VISION® Analyzer
- ID-MTS™ Gel Cards for Blood Grouping and Antibody Screening/Antibody Identification
- ID-MTS™ Diluent 2 *PLUS*
- Centrifuge (see 'Product Preparation' section for further instruction)

For semi-automated testing:
- MTS™ Work Table/ID-MTS™ Centrifuge and ID-MTS™ Incubator
- ID-MTS™ Gel Cards for Blood Grouping and Antibody Screening/Antibody Identification
- ID-MTS™ Diluent 2 *PLUS*
- Manual or electronic pipets: 10 µL, 25 µL and 50 µL
- Pipet tips
- Glass test tubes (12 x 75 mm or 10 x 75 mm)
- Dispenser pipet capable of delivering 0.5 mL and 1.0 mL
- Centrifuge (see 'Product Preparation' section for further instruction)

PROCEDURES

1. When using automated/semi-automated instruments, follow the procedures that are contained in the operator's manual provided by the instrument manufacturer.
2. Alba**Q-C**hek® is intended to simulate normal blood samples. The samples contained in Alba**Q-C**hek® must be used at room temperature (18-25 °C) and should be tested by following standard procedures in accordance with the Instructions for Use accompanying each reagent or consumable used routinely.

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

QUALITY CONTROL

Quality control testing must be performed according to the local, state, federal and accreditation requirements.

INTERPRETATION OF RESULTS

The following table illustrates the expected results in tests with Alba**Q-C**hek® and routine blood bank reagents.

Component of Alba**Q-C**hek®	Reagent Under Test	Expected Test Results*
Vial 1	Anti-A	+
	Anti-B	0
	Anti-A,B	+
	Anti-D	0
	A_1 cells	0
	B cells	+
Dependent on panel	Screening cell 1	+
	Screening cell 2	+
	Screening cell 3	0
Vial 2	Anti-A	0
	Anti-B	0
	Anti-A,B	0
	Anti-D	+
	A_1 cells	+
	B cells	+
Dependent on panel	Screening cell 1	0
	Screening cell 2	+
	Screening cell 3	+
Vial 3	Anti-A	0
	Anti-B	+
	Anti-A,B	+
	Anti-D	+
	A_1 cells	+
	B cells	0
	Screening cell 1	0
	Screening cell 2	0
	Screening cell 3	0
Vial 4	Anti-A	+
	Anti-B	+
	Anti-A,B	+
	Anti-D	+
	A_1 cells	0
	B cells	0
	Screening cell 1	0
	Screening cell 2	0
	Screening cell 3	0

***Discrepant results must be investigated further.**

STABILITY OF REACTION

For best results, it is recommended that reactions should be read immediately following centrifugation. Users should consult the Instructions for Use accompanying ID-MTS™ Gel Cards for Blood Grouping and Antibody Screening/Antibody Identification for additional information related to stability of the reaction prior to use.

LIMITATIONS

Improper techniques may invalidate the results obtained with this product.

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.

Individual laboratory procedures may affect the final reaction strength observed in tests performed with Alba**Q-C**hek®.

SPECIFIC 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 Procedures 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.

This reagent has been validated for use on the ORTHO VISION® Analyzer and ORTHO ProVue® Analyzer automated blood grouping test systems, and for the MTS™ Work Table. Its suitability for use by other technologies has not been validated.

BIBLIOGRAPHY

1. Roback, JD, Grossman BJ, Harris T, et al. AABB Technical Manual, 18th ed. AABB, 2014.
2. AABB Standards Program Committee. Standards for Blood Banks and Transfusion Services. 29th ed. AABB 2014.
3. ORTHO ProVue® Analyzer User's Guide (J21744).
4. ORTHO VISION™ Analyzer, ID-MTS™ Gel Cards, Reference Guide (J40050).
5. ID-Micro Typing System™ Interpretation Guide (6902201).
6. Instructions for Use for MTS™ A/B/D Monoclonal and Reverse Grouping Card (J32851).

DATE OF ISSUE

YYYY-MM-DD

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