PRINCIPLE OF THE TEST
Antigens on reagent red blood cells will react with the corresponding antibodies present in patient's serum or plasma. This will cause agglutination (clumping of red blood cells), either directly or after the addition of Anti-Human Globulin (AHG) reagents.

REAGENT DESCRIPTION
These reagent red blood cells were prepared from blood donated by two Group O donors and are stored at 2-8°C suspensions of washed red blood cells in a preservative solution.

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 and the preservative, neomycin sulfate and chloramphenicol. The preservative RH-glycine of these reagent red blood cells are R, R, R. The full antigenic profile of the individual donors is shown on the enclosed antigen profile. One or more of these red blood cells may have been held in frozen storage until required.

The volume delivered by these dropper bottles is approximately 40 µL. Bearing this in mind, care should be taken to ensure that appropriate serum cell ratios are maintained in all test systems.

PRECAUTIONS
Store at 2-8 °C. Do not freeze. Do not use if obviously discolored or hemolyzed. Do not use beyond the notified expiry date.

CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH CURRENT COMMERCIAL TESTS. NO KNOWN METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.

This product has components (dropper bulbs) containing dry natural rubber. This reagent is for in vitro diagnostic use only.

SPECIMEN COLLECTION AND PREPARATION
Samples should be collected by a standard collection technique with or without anticoagulant. The specimen should be stored at refrigerated temperatures. Blood specimens exhibiting contamination should not be used. Collected samples or those collected in EDTA should be tested within fourteen days from collection. Donor blood may be tested up to the expiry date of the donation.

In vitro diagnostic medical device

STABILITY OF REAGENTS
Reactivity of reagents may decrease during the dating period and, therefore, should not be used after the expiration date. The rate at which the antigen reactivity (e.g. agglutinability) is lost is partially dependent upon individual donor characteristics that are neither controlled nor predicted by the manufacturer.

CRITICAL LIMITS
Due to dosage effects, weak antibodies may not be detected by reagent red blood cells showing heterologous expression of specific antigens.

Antigens specific for low incidence antigens not present on the test cells will not be detected.

In very rare cases potent antigens on the reagent red blood cells may cause unwanted positive reactions.

False positive or false negative results can occur due to contamination of test materials, improper reagent preparation, improper storage of materials, omission of test reagents and certain disease states.

SPECIFIC PERFORMANCE CHARACTERISTICS
The reagent red blood cells have been shown to have a negative direct antiglobulin test, indicating that no human IgG or C3 complement components are present on the surface of the reagent red blood cells. Prior to release, each lot of ALBAcyte Antibody Screen (2-Cell) is tested by FDA recommended methods to confirm the presence or absence of the appropriate antigens. No effect on local standards of potency.

BIBLIOGRAPHY

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