Specificity: It is checked to ensure whether the reagent is specific for the purpose or not. For example, specificity of Anti-A Monoclonal Antibodies is checked with ‘B’ & ‘O’ cells.

Avidity, Intensity & titre of Anti-A, Anti-B & Anti AB Monoclonal Antibodies are as per I.P standards.

PROBLEMS IN ABO GROUPING:
The ABO Group of an individual can only be clearly determined if the results of forward & reverse typing match properly. Following factors are responsible for discrepancies in ABO Grouping:
1. Improper identification of specimen.
2. Improper techniques like,
   - Cell to reagent ratio.
   - Failure to identify haemolysis
   - Improper storage of Reagents.
3. Improper centrifuge calibration resulting in over/ under centrifugation.
4. Patients may fail to express ABO antigens on red cells due to diseases like Leukemia & lymphoma.
5. Acquired B antigen can occur due to infections; gram negative septicaemia, carcinoma colon, Blood Group chimera is an individual with two population of cells which may occur as a result of either Bone marrow transplantation or Transfusion of group ‘O’ blood to ‘A’ or ‘B’ patient.
6. Rouleaux formation; It occurs in patients with abnormal Albumin/ globulin concentration or in cord blood samples due to Whartons Jelly contamination.
7. Acquired antibodies ie
   - Anti- A1 in A2 persons
   - Anti- H in Bombay phenotype
   - Cold auto - antibodies
   - Unexpected allo-antibodies.

BIBLIOGRAPHY

LIMITED EXPRESSED WARRANTY DISCLAIMER
The manufacturer limits the warranty to the test kit, in as much as that the test kit will function as an in vitro diagnostic assay within the limitations and specifications as described in the product instruction manual, when used strictly in accordance with the instructions contained therein. The manufacturer’s liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to for claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

FOR IN VITRO USE ONLY

The Anti-A, Anti-B and Anti-AB Monoclonal Antibodies are in vitro culture supernatant of hybrids obtained by cellular fusion (Hybridoma Technology).

GROUPING PRINCIPLE:
The ABO Grouping is defined both by the presence of ‘A’ and/or ‘B’ Antigens on the surface of the red blood cells and by the simultaneous presence of anti-A and/or anti-B antibodies in the serum. An individual has in his serum the antibodies corresponding to the antigens which are not on his Red Blood Cells. It is thus necessary to identify the erythrocyte antigens by the known Anti- A, Anti-B and Anti-AB Monoclonal Antibodies (forward typing) and then confirm the results by verifying the presence of corresponding antibodies in the blood serum to be tested with control cells: ‘A’ and ‘B’. (Reverse Typing). Human Red blood cells, possessing ‘A’ and/or ‘B’ Antigen will agglutinate in the presence of antibody directed towards the antigen. For example agglutination of RBCs with Anti-A Monoclonal Antibodies indicates the presence of ‘A’ Antigen on the red blood cells.

STORAGE AND PACK SIZE:
The Anti-A, Anti-B and Anti-AB Monoclonal Antibodies are packed in 10 ml dropper vial. The antibodies are stable at 2-8°C until the expiry date mentioned on the reagent vial label. Sodium azide is added to the antibodies at 0.1% concentration as preservative.

SAMPLE COLLECTION:
Blood sample should be collected with a suitable anticoagulant in a sterile stoppered container & should be tested immediately.

If testing is delayed, blood should be stored at 2-8°C & must be examined not later than 48 hours. Haemolysed samples should not be used for testing and clotted blood should be used within 24 hours of collection.