SAMPLE COLLECTION AND PREPARATION
Blood samples drawn with or without anticoagulant may be used for antigen typing. If testing is delayed then store specimens at 2-8°C. EDTA and citrate samples should be typed within 48 hours. Samples collected into ACD, CPD or CPDA-1 may be tested up to 35 days from the date of withdrawal. All blood samples should be washed at least twice with PBS before being tested.

PRECAUTIONS
1. The reagent is intended for in vitro diagnostic use only.
2. If a reagent vial is cracked or leaking, discard the contents immediately.
3. Do not use the reagent after the expiration date (see Vial Label).
4. Do not use the reagent if a precipitate is present.
5. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
6. The reagent has been filtered through a 0.2 µm capsule to reduce the bio- burden. Once a vial has been opened the contents should remain viable up until the expiry date as long as there is no marked turbidity, which can indicate reagent deterioration or contamination.
7. The reagent contains 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal flush away with large volumes of water.

CONTROLS AND ADVICE
1. It is recommended a positive control (ideally P1 weak cells) and a negative control be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. In the Tube Technique one volume is approximately 50µl; when using the vial dropper provided.
3. The use of the reagent and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagent is in use.

PROCEDURES
1. Prepare a 2-3% suspension of washed test red cells in PBS.
2. Place in a labelled test tube: 1 volume of Atlas Anti P1, reagent and 1 volume of test red cell suspension
3. Mix thoroughly and incubate at 2-8°C for 15 minutes.
4. Centrifuge all tubes for 20 seconds at 1000 rcf or for a suitable alternative time and force.
5. Gently resuspend red cell button and read macroscopically for agglutination

INTERPRETATION OF TEST RESULTS
1. Positive: Agglutination of the test red cells constitutes a positive test result and within accepted limitations of test procedure, indicates the presence of the P1 antigen on the test red cells.
2. Negative: No agglutination of the test red cells constitutes a negative result and within the accepted limitations of the test procedure, indicates the absence of the P1 antigen on the test red cells.

STABILITY OF THE REACTIONS
1. Tests should be read immediately after centrifugation
2. Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.

LIMITATIONS
1. The P1 antigen is poorly expressed on the cells of newborns.
2. There is a wide variation in the amount of P1 antigen present on different P1 positive cells. The strength of agglutination observed with such cells is likely to vary accordingly.
3. Stored blood may give weaker reactions than fresh blood.
4. False positive or false negative results may also occur due to:
   - Contamination of test materials
   - Improper storage, cell concentration, incubation time or temperature.
   - Improper or excessive centrifugation.
   - Deviation from the recommended techniques.

SPECIFIC PERFORMANCE CHARACTERISTICS
1. The reagent has been characterized by all the procedures mentioned in the Recommended Techniques.
2. Prior to release, each lot of Atlas Monoclonal Anti-P1 is tested by the Recommended Techniques against a panel of antigen-positive red cells to ensure suitable reactivity.

3. Specificity of source monoclonal antibody is demonstrated using a panel of antigen-negative cells.

4. The Quality Control of the reagent was performed using red cells that had been washed twice with PBS prior to use.

**ANALYTICAL PERFORMANCE**

The performance of the reagent has been validated by the test procedure defined in the instructions for use. Any deviations from this technique is the responsibility of the user.

**BIBLIOGRAPHY**


