SUMMARY
Careful control of both manual and automated techniques for detecting antibodies is essential. Testing of a weak IgG Anti-D with group O Rh D red cells in parallel with routine antiglobulin or enzyme tests will confirm the efficacy of one of the chosen techniques.

PRINCIPLE
When used by the recommended techniques, the reagent will cause agglutination (clumping) of red cells carrying Rh D antigen. No agglutination when tested against Rh D positive red cells usually indicates a problem with the anti-human globulin or enzyme test (see Limitations).

REAGENT
Lorne Precise Weak Anti-D Control Reagent is prepared from pools of human serum containing low activity Anti-D. The pool is diluted in inert serum to give a final concentration of 0.10 IU/ml Anti-D. ABO antibodies are not absorbed. The reagent is supplied at the optimal dilution, for use with all the recommended techniques stated below without the need for further dilution or addition. For lot reference number and expiry date see Vial Label.

STORAGE
Reagent vials should be stored at 2 - 8°C on receipt. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity. This reagent has undergone transportation stability studies at 37°C and -25°C as described in document EN13640:2002.

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 7 days of collection. 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 or Isotonic saline 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 past 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 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.
8. Materials used to produce the reagent were tested at source and found to be negative for HIV 1+2 and HCV antibodies and HBsAg using approved microbiological tests.
9. No known tests can guarantee that products derived from human or animal sources are free from infectious agents. Care must be taken in the use and disposal of each vial and its contents.

DISPOSAL OF REAGENT AND DEALING WITH SPILLAGES
For information on disposal of the reagent and decontamination of a spillage site see Material Safety Data Sheets. available on request.

CONTROLS AND ADVICE
1. It is recommended that a positive control (ideally Rh R, cells) and a negative control (or cells only) be tested in parallel with each batch of tests.
2. In the Tube Technique one volume is approximately 50µl when using the vial dropper provided.
3. The use of the reagents 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 reagents are in use.
4. User must determine suitability of the reagents for use in other techniques.

REAGENTS AND MATERIALS REQUIRED
- Anti-human globulin i.e. Lorne Polyspecific AHG Elite (Cat # 435010) or anti-IgG i.e. Lorne Monospecific Anti-IgG (Cat # 401010).
- Coombs cell washer.
- Glass test tubes (10 x 75 mm or 12 x 75 mm).
- IgG sensitised red cells i.e. Lorne Coombs Control Cells (Cat # 970010).
- Enzyme reagent i.e. Lorne Papenzyme-Plus (Cat # 441010) or Lorne Bromellite (Cat # 443010).
- PBS solution (pH 6.8-7.2) or Isotonic saline solution (pH 6.5-7.5).
- Positive (ideally Rh) and negative (rn) control red cells.
- Test tube centrifuge.
- Volumetric pipettes.
- Water bath or dry heat incubator equilibrated to 37°C ± 2°C.

RECOMMENDED TECHNIQUE
Lorne Precise Anti-D should be tested in parallel with all indirect antiglobulin and enzyme techniques using the techniques stated in the Recommended Techniques for the reagent being controlled.

INTERPRETATION OF TEST RESULTS
1. Positive: Agglutination of the Rh R test red cells constitutes a positive test result and within the accepted limitations of the test procedure, indicates that there was no problem with the antiglobulin or enzyme test.
2. Negative: No agglutination of the Rh R test red cells constitutes a negative result and within the accepted limitations of the test procedure, indicates that there is a problem with the antiglobulin or enzyme test. This can be due to one or more of the following factors:
   - Inadequate serum: cells ratio
   - Inadequate incubation of tests
   - Inadequate washing
   - Deterioration or omission of AHG reagent
   - Improper centrifugation
   - Excessive agitation, at the reading stage
   - Inactivity of enzyme preparation
   - Inadequate technique e.g. standard one-stage enzyme techniques are less sensitive than two stage or phased one-stage techniques

STABILITY OF THE REACTIONS
1. Washing steps should be completed without interruption and tests centrifuged and read immediately after addition of the reagent. Delays may result in dissociation of antigen-antibody complexes, causing false negative or weak positive results.
2. Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.

LIMITATIONS
1. Lorne Precise Anti-D is for use with group O cells only due to the fact that ABO antibodies have not been absorbed.
2. This test may contain low levels of Anti-C or Anti-E.
3. The reagent must not be used for Rh D typing or for preparing sensitised cells for assuring Anti-IgG activity in negative Anti-Human Globulin tests.
4. False positive or false negative results may also occur due to:
   - Contamination of test materials
   - Improper cell concentration
   - Improper incubation time or temperature
   - Improper or excessive centrifugation
   - Introduction of human serum/gamma globulins into test
   - Improper storage of test materials or omission of reagent
   - Deviation from the recommended techniques

SPECIFIC PERFORMANCE CHARACTERISTICS
1. The reagent has been characterised by the procedures mentioned in the Recommended Techniques.
2. Prior to release, each batch of Lorne Precise Weak Anti-D is tested by the Recommended Techniques against a panel of antigen-positive red cells to ensure suitable reactivity.
3. The Quality Control of this reagent was performed using red cells that had been washed twice with PBS or Isotonic saline prior to use.
4. The specificity of the reagent is confirmed by screening with a panel of group O Rh D negative red cells which bear antigens with an incidence of 1% or greater in the random population.
5. Antibodies to Xg, D, Yh, Yt, Co, Wr, Bg and Vw may not be excluded in routine specificity testing and detection will depend upon availability of appropriate test cells. This can also be said for Yf, Mw and Vx and other low frequency antigens which may not be excluded in routine specificity testing and detection will depend upon availability of appropriate test cells.
6. The reagents comply with the recommendations contained in the latest issue of the Guidelines for the UK Blood Transfusion Services.

DISCLAIMER
1. The user is responsible for the performance of the reagent by any method other than those mentioned in the Recommended Techniques.
2. Any deviations from the Recommended Techniques should be validated prior to use.
BIBLIOGRAPHY


AVAILABLE REAGENT SIZES

<table>
<thead>
<tr>
<th>Vial Size</th>
<th>Catalogue Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 ml</td>
<td>209005</td>
</tr>
<tr>
<td>1000 ml</td>
<td>209000*</td>
</tr>
</tbody>
</table>

*This size is For Further Manufacturing Use (FFMU) only and is therefore not CE marked.

For the availability of other sizes, please contact:

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley, Reading,
Berkshire, RG6 4UT
United Kingdom
Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
E-mail: info@lornelabs.com

TABLE OF SYMBOLS

<table>
<thead>
<tr>
<th>LOT</th>
<th>Batch Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>REF</td>
<td>Catalogue Reference</td>
</tr>
<tr>
<td></td>
<td>Expiry Date</td>
</tr>
<tr>
<td></td>
<td>Read Pack Insert</td>
</tr>
<tr>
<td></td>
<td>Store At</td>
</tr>
<tr>
<td></td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>

in-vitro Diagnostic