Intended Use

For in vitro diagnostic use only
For use with the ID-Micro Typing System™ Buffered Gel Card
For Direct Agglutination Test

The Anti-Lea reagent (Anti-LE1) is for the qualitative in vitro detection of human Lea positive red blood cells by the direct agglutination test. The Anti-Leb reagent (Anti-LE2) is for the qualitative in vitro detection of human Leb positive red blood cells by the direct agglutination test.

Summary and Explanation

Monoclonal Anti-Lea and Anti-Leb (Anti-LE1 and Anti-LE2) blood grouping reagents enable red blood cells to be classified as one of four phenotypes: Le(a-b+), Le(a+b-), Le(a-b-), Le(a+b+). The latter phenotype, Le(a+b+), is extremely rare in Caucasians and African Americans. Agglutination of red blood cells with Anti-Lea or Anti-Leb indicates the presence of the corresponding antigen on the red blood cell surface. Lewis antigens are also present in serum and other body fluids. Cord cells do not express Lewis antigens in sufficient quantity to be agglutinated by these reagents and therefore will group as Le(a-b-). An infant's true Lewis status does not normally become apparent until the age of two years (approximately).

Principles of Procedure

When used by the recommended technique, the reagents will cause agglutination (clumping) of red blood cells carrying the Lea or Leb antigen. Lack of agglutination of the red blood cells demonstrates the absence of the Lea or Leb antigen.

Reagents

Anti-Lea (Murine Monoclonal) and Anti-Leb (Murine Monoclonal) are supplied as two separate reagents.

Anti-Lea (Murine Monoclonal) is supplied as one reagent.
• 1 vial containing 3 mL of murine monoclonal antibody of type IgM (cell line LEA1) containing 0.1% (w/v) sodium azide and bovine material (i.e., bovine serum albumin, fetal bovine serum).

Anti-Leb (Murine Monoclonal) is supplied as one reagent.
• 1 vial containing 3 mL of murine monoclonal antibody of type IgM (cell line LEB1) containing 0.1% (w/v) sodium azide and bovine material (i.e., bovine serum albumin, fetal bovine serum).

Any bovine material used in the manufacture of these products is sourced from USDA approved facilities.

No preparation of the reagent(s) is required. Use directly from the vial. Do not dilute.

Storage Requirements

Store at 2–8 °C.
Do not freeze.
Do not use beyond expiration date. The format of the expiration date is expressed as YYYY-MM-DD (year-month-day).
May be at 18–25 °C while in use.
Replace cap when not in use.
Specimen Collection

- No special preparation of the patient/donor is required prior to specimen collection.
- Specimens should be collected by aseptic technique with an anticoagulant.
- The specimen should be tested as soon as possible after collection. If testing is delayed, the specimen should be stored at 2–8 °C.
- Do not use collection tubes that contain plasma/cell separation media.
- Samples collected in EDTA should be tested within seven days from collection.
- Donor blood collected in ACD, CPD, CP2D, CP2D with AS-3 and CPDA-1 may be tested until the expiration date of the donation.
- Clotted, hemolyzed, grossly icteric, or contaminated blood specimens should not be used.
- Grossly lipemic samples containing particulates that clog the gel, as indicated by diffuse blotches of red blood cells in the microtube, may be clarified by centrifugation or filtration and retested.
- Specimens should not be exposed to extreme heat.

Precautions

Do not use if turbid.
Do not dilute.
Do not freeze.
Do not use beyond the expiration date.
The Anti-Lea reagent contains 0.1% (w/v) sodium azide.
The Anti-Leb reagent contains 0.1% (w/v) sodium azide.
Handle and dispose of reagents as potentially infectious, in accordance with local, state, and national laws.
This reagent is for in vitro diagnostic use only.

**CAUTION:**
Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive compounds. If discarded into sink, flush with a large volume of water to prevent azide buildup.

**CAUTION:**
Appropriate care should be taken in the use and disposal of this product. Source materials may include human components and antibody producing cells that are used in the manufacture of polyclonal and monoclonal products.

**CAUTION:**
Contains material of murine origin; therefore, handle appropriately as the absence of murine viruses has not been determined.

Procedure

Materials Provided

ORTHÔ™ Sera Anti-Lea
ORTHÔ™ Sera Anti-Leb

Materials Required but not Provided

- Isotonic saline
- ORTHÔ™ Sera Papain
- Reagent red blood cells suitable for the control of Anti-Lea
- Reagent red blood cells suitable for the control of Anti-Leb
- MTS™ Buffered Gel Card

**NOTE:**
Store cards upright at 2–25 °C.

**CAUTION:**
Inspect the condition of the card before use.
Do not use gel cards that have not been shipped in an upright position.
Do not use cards beyond expiration date.
Do not freeze or expose cards to excessive heat.
Use reagents as furnished.

- Micropipetters for delivery of 25 µL and 50 µL
- Pipet tips
- Marking pen
- ORTHÔ™ Workstation
  or ORTHÔ VISION® Analyzer
  or ORTHÔ VISION® Max Analyzer
  or ORTHÔ Optix™ Reader
Test Procedure

NOTE:
The reagents have been standardized for use by the technique described below.

The direct agglutination test procedure listed below is for manual testing only. When using instruments (see Materials Required but not Provided), follow the procedures that are contained in the operator’s manual provided by the device manufacturer.

Direct Agglutination Test
1. Prepare an approximate 0.8% red blood cell suspension from patient or donor cells, using isotonic saline.
2. Allow the card and the reagent(s) to come to 18–25 °C before use. A clear liquid layer should appear on top of the opaque gel in each microtube.
3. Visually inspect gel cards before use.
   CAUTION: Do not use gel cards if the gel matrix is absent or the liquid level in the microtube is at or below the top of the gel matrix.
   Do not use gel cards that show signs of drying, discoloration, bubbles, crystals, or other artifacts.
   Do not use cards if foil seals appear damaged or opened.
   NOTE: Refer to the ID-Micro Typing System™ Interpretation Guide for additional information related to the visual inspection of gel cards before use.
4. Label the card appropriately with a sample identifier.
5. Remove the foil seal from the MTS™ Buffered Gel Card or from the individual microtubes to be used for testing.
   CAUTION: Do not remove card foil seal until ready to use. Foil should be removed immediately before testing or within 1 hour of testing. Once opened, the gel may begin to dry out which could affect test results (refer to Limitations of the Procedure). After removing the foil, visually inspect all gel cards to ensure that residual film does not block the opening of any microtube.
6. Add 25 μL of the reagent to the appropriate reaction chamber(s) of the opened card.
   CAUTION: Do not touch the pipet to the side of the reaction chamber. If this occurs, change the pipet tip before proceeding to the next chamber.
7. Add 50 μL of 0.8% red blood cell suspension to the appropriate reaction chamber(s) of the card.
   CAUTION: Do not touch the pipet to the side of the reaction chamber. If this occurs, change the pipet tip before proceeding to the next chamber.
8. Add 50 μL of ORTHO™ Sera Papain to the appropriate reaction chamber(s) of the card.
   CAUTION: Do not touch the pipet to the side of the reaction chamber. If this occurs, change the pipet tip before proceeding to the next chamber.
9. Observe that the contents of the reaction chamber(s) are combined. If necessary tap gently.
   NOTE: Assure that the reagents remain in the reaction chamber. There should be no mixing of reactants with reagents in the column prior to centrifugation.
10. Incubate at 18–25 °C for 15 minutes.
11. Centrifuge the card at the preset conditions, as installed by the instrument manufacturer.
12. Read the front and back of the individual columns for macroscopic agglutination or hemolysis upon test completion.
13. Record the reaction strength.

Interpretation of Results

Negative Result = No agglutination and no hemolysis of the red blood cells is a negative test result. A complete sedimentation of all red blood cells is present in the bottom of the microtube.

Positive Result = Agglutination of the red blood cells is a positive test result. Red blood cells may remain suspended on the top of the gel or are dispersed throughout the gel in varying degrees. A few red blood cells may form a button in the bottom of the microtube in some positive reactions.
**Reaction Grading Guide (Use in conjunction with Diagram 1)**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 Negative</td>
<td>Unagglutinated red blood cells form a well-defined button at the bottom of the microtube.</td>
</tr>
<tr>
<td>1+ Reaction</td>
<td>Red blood cell agglutinates are observed predominantly in the lower half of the gel microtube. Unagglutinated red blood cells form a button in the bottom of the microtube.</td>
</tr>
<tr>
<td>2+ Reaction</td>
<td>Red blood cell agglutinates are dispersed throughout the length of the gel microtube. Few unagglutinated red blood cells may be observed in the bottom of the microtube.</td>
</tr>
<tr>
<td>3+ Reaction</td>
<td>The majority of red blood cell agglutinates are trapped in the upper half of the gel microtube.</td>
</tr>
<tr>
<td>4+ Reaction</td>
<td>Solid band of red blood cell agglutinates on top of the gel. A few agglutinates may filter into the gel but remain near the predominant band.</td>
</tr>
<tr>
<td>Mixed Field</td>
<td>Red blood cell agglutinates at the top of the gel or dispersed throughout the gel microtube accompanied by a button of negative red blood cells in the bottom of the microtube. See Note below.</td>
</tr>
</tbody>
</table>

**NOTE:** Caution must be taken in interpreting a reaction as mixed field. Additional patient history and testing will be necessary for resolution. However, not all mixed cell situations have a sufficient minor population to be detected.

**CAUTION:** Clots, particulates or other artifacts may cause some red blood cells to be entrapped at the top of the gel that may cause an anomalous result in a negative test (refer to Limitations of the Procedure, item 5.)

**Diagram 1: Examples of Reaction Grades**

**NOTE:** Refer to ID-Micro Typing System™ Interpretation Guide® for additional information.

**Stability of Reaction**

For best results, it is recommended that reactions should be read immediately following centrifugation.

**Quality Control**

Quality Control (QC) of reagents is required. Quality Control should be performed on each lot of reagent on each day of use according to standard operating procedures.

Reagent red blood cells may be used direct from the vial as control cells in ORTHO Sera tests, including 0.8% Resolve® Panel A, 0.8% Resolve® Panel B, 0.8% Resolve® Panel C (Untreated Only), 0.8% Selectogen® and 0.8% Surgiscreen®.

**Limitations of the Procedure**

1. Strict adherence to the procedures and recommended equipment is essential.
2. Proper centrifuge calibration is particularly important to the performance of the MTS™ Buffered Gel Card. The MTS™ Centrifuge and ORTHO™ Workstation have been exclusively designed to provide the correct time, speed, and angle.
3. The expression of certain red blood cell antigens may diminish in strength during storage, particularly in EDTA samples. Better results will be obtained with fresh samples.
4. Suppressed or weak expression of blood group antigens may give rise to false-negative reactions.
5. Care should be taken when performing tests on cord blood samples as Lewis antigens are not fully expressed at birth.
6. Anomalous results may be caused by the following:
   - Fibrin or particulate matter
   - Red blood cell samples from cord blood samples when using ORTHO™ Sera Anti-Leb.
   - Red blood cells sticking to the sides of the reaction chamber
Intended for Use in the United States

BLOOD GROUPING REAGENT
Anti-Le<sup>a</sup> (Murine Monoclonal)
Anti-Le<sup>b</sup> (Murine Monoclonal)
ORTHO™ Sera

INSTRUCTIONS FOR USE

- Do not use cards that appear damaged (i.e., break in foil seal or break, crack or bubble in the column), exhibit drying (i.e., liquid level is at or below the top of the gel matrix) or exhibit discoloration (due to bacterial contamination, which can cause false reactions).
- Loss of fluid in the card column may cause (weak) false positive results.
- J reactions may occasionally be observed with high red blood cell concentrations. J reactions may also be observed if during centrifugation the card is not seated properly in the holder or not allowed to spin at a 90° angle.

**NOTE:**
A J reaction consists of cells forming a button at the bottom of the gel matrix or microtube when either end of the cell button goes up the side of the column.

- False positive or false negative test results can occur from bacterial or chemical contamination of test materials, inadequate incubation time or temperature, improper centrifugation, improper storage of materials, or omission of test samples.

7. Tests with these or other anomalous results should be repeated.
8. Erroneous results could occur if final reactions are not read upon completion of centrifugation.
9. Mixed cell populations may be encountered as a result of, for example, transfusion, fetal maternal hemorrhage, or transplantation. Consult patient history when results of this nature are encountered before assigning an antigen type.
10. Donor/Patient red blood cells must be diluted with isotonic saline, before adding the red blood cells to the microtube.

Performance Characteristics

Comparator Study Results
During comparator studies (data on file at Alba Bioscience Limited), blood samples were tested with ORTHO™ Sera Anti-Le<sup>a</sup> (Murine Monoclonal) and ORTHO™ Sera Anti-Le<sup>b</sup> (Murine Monoclonal) by ID-Micro Typing System™ Column Agglutination Technology (CAT) as follows:

**Including all samples:**

<table>
<thead>
<tr>
<th>Test</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>% Agreement</td>
</tr>
<tr>
<td>Anti-Le&lt;sup&gt;a&lt;/sup&gt;</td>
<td>240</td>
<td>97.5</td>
</tr>
<tr>
<td>Anti-Le&lt;sup&gt;b&lt;/sup&gt;</td>
<td>803</td>
<td>99.9</td>
</tr>
</tbody>
</table>

**Excluding DAT positive samples:**

<table>
<thead>
<tr>
<th>Test</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>% Agreement</td>
</tr>
<tr>
<td>Anti-Le&lt;sup&gt;a&lt;/sup&gt;</td>
<td>238</td>
<td>98.3</td>
</tr>
<tr>
<td>Anti-Le&lt;sup&gt;b&lt;/sup&gt;</td>
<td>803</td>
<td>99.9</td>
</tr>
</tbody>
</table>

LCL: lower confidence limit

* % Agreement between the ORTHO™ Sera Anti-Le<sup>a</sup> (Murine Monoclonal) or ORTHO™ Sera Anti-Le<sup>b</sup> (Murine Monoclonal) and comparator reagents only and does not indicate which reagents gave the correct results.

**Anti-Le<sup>a</sup>**

In performance evaluation studies, 1130 samples were tested with ORTHO™ Sera Anti-Le<sup>a</sup> (Murine Monoclonal) using the MTS™ Centrifuge. The one-sided exact 95% LCL of positive percent agreement (PPA) was 95.1% for agglutination tests based on a comparison of interpreted results. The PPA did not meet the acceptance criteria due to nine discrepant results (see sample classification and comments in the summary table below). The discordance between the trial and the comparator reagent could be attributed in four cases to the sample itself having a positive DAT result and in one case, where a change from the initial test outcome was noted, to a possible error with the initial test results. Four discrepant samples which confirmed the initial result on repeat testing have no rational explanation that can be attributed to the discrepant results. The one-sided exact 95% LCL of negative percent agreement was ≥99% for agglutination tests based on a comparison of interpreted results.

**Classification** | **Number of Discrepancies** | **Comment**
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>DAT Positive</td>
<td>4</td>
<td>DAT positive following investigation.</td>
</tr>
<tr>
<td>Possible test error</td>
<td>1</td>
<td>ORTHO™ Sera Anti-Le&lt;sup&gt;a&lt;/sup&gt; reagent and comparator reagent gave a concordant reaction on repeat testing.</td>
</tr>
<tr>
<td>Unresolved</td>
<td>4</td>
<td>ORTHO™ Sera Anti-Le&lt;sup&gt;a&lt;/sup&gt; reagent and comparator reagent continued to show different result following repeat testing.</td>
</tr>
</tbody>
</table>
In performance evaluation studies, 1124 samples were tested with ORTHO™ Sera Anti-Le\(^a\) (Murine Monoclonal) using the MTS™ Centrifuge. The one-sided exact 95% LCL of positive percent agreement was ≥99% for agglutination tests based on a comparison of interpreted results. The one-sided exact 95% LCL of negative percent agreement (NPA) was 96.3% for agglutination tests based on a comparison of interpreted results. The NPA did not meet the acceptance criteria due to seven discrepant results, one example being from cord blood (see sample classification and comments in the summary table below). The discordance between the trial and the comparator reagent could be attributed in one case to the sample itself having a DAT positive result and in two cases, where a change from the initial test outcome was noted, to a possible error with the initial test results. Three discrepant samples which confirmed the initial test results on investigation have no rational explanation that can be attributed to the discrepant results. One further discrepancy was not noted at the time by the trial site, therefore, no investigational testing was performed on this sample.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Number of Discrepancies</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAT Positive</td>
<td>1</td>
<td>DAT positive following investigation.</td>
</tr>
<tr>
<td>Possible test error</td>
<td>2</td>
<td>ORTHO™ Sera Anti-Le(^a) reagent and comparator reagent gave a concordant reaction on repeat testing.</td>
</tr>
<tr>
<td>Unresolved</td>
<td>4</td>
<td>ORTHO™ Sera Anti-Le(^b) reagent and comparator reagent continued to show different result following repeat testing or where no investigation was performed.</td>
</tr>
</tbody>
</table>

Results were evaluated against comparable FDA approved products using the appropriate methods for the comparators.

Migration studies have been performed using the ORTHO™ Workstation and results were as follows:

<table>
<thead>
<tr>
<th>Reagent</th>
<th>Number of samples tested</th>
<th>Concordance*</th>
<th>Positive Samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-Le(^a)</td>
<td>100</td>
<td>100%</td>
<td>N 18, Frequency (%)</td>
</tr>
<tr>
<td>Anti-Le(^b)</td>
<td>100</td>
<td>100%</td>
<td>N 73, Frequency (%)</td>
</tr>
</tbody>
</table>

*Concordance indicates agreement between the ORTHO™ Workstation and the MTS™ Centrifuge only and does not indicate which systems gave the correct results.

Further migration studies have been performed for the ORTHO VISION\(^®\) and ORTHO VISION\(^®\) Max Analyzer. Comparator studies were performed using random samples and a screening test method was used to identify additional random samples of low antigen frequency. The performance of total samples is reported in the following paragraphs, as the unscreened and screened random sample totals show similar performance.

The results of the migration studies performed using the ORTHO VISION\(^®\) Analyzer were as follows:

<table>
<thead>
<tr>
<th>Test</th>
<th>N</th>
<th>% Agreement*</th>
<th>One-Sided Exact 95% LCL (%)</th>
<th>N</th>
<th>% Agreement*</th>
<th>One-Sided Exact 95% LCL (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-Le(^a)</td>
<td>611</td>
<td>99.8</td>
<td>99.2 95% LCL (%)</td>
<td>664</td>
<td>99.7</td>
<td>99.1 95% LCL (%)</td>
</tr>
<tr>
<td>Anti-Le(^b)</td>
<td>632</td>
<td>100.0</td>
<td>99.5 95% LCL (%)</td>
<td>600</td>
<td>99.3</td>
<td>98.5 95% LCL (%)</td>
</tr>
</tbody>
</table>

LCL: lower confidence limit

* Concordance indicates agreement between the ORTHO™ Workstation and the ORTHO VISION\(^®\) Analyzer only and does not indicate which system gave the correct results.

**Anti-Le\(^a\)**

In these migration studies, 1275 samples were tested with ORTHO™ Sera Anti-Le\(^a\) (Murine Monoclonal) using the ORTHO™ Workstation and the ORTHO VISION\(^®\) Analyzer. The one-sided exact 95% LCL of positive percent agreement was 99.2% for agglutination tests based on a comparison of interpreted results. The one-sided exact 95% LCL of negative percent agreement (NPA) was 99.1% for agglutination tests based on a comparison of interpreted results.

**Anti-Le\(^b\)**

In these migration studies, 1232 samples were tested with ORTHO™ Sera Anti-Le\(^b\) (Murine Monoclonal) using the ORTHO™ Workstation and the ORTHO VISION\(^®\) Analyzer. The one-sided exact 95% LCL of positive percent agreement was 99.5% for agglutination tests based on a comparison of interpreted results. The one-sided exact 95% LCL of negative percent agreement (NPA) was 98.5% for agglutination tests based on a comparison of interpreted results.
The NPA did not meet the acceptance criteria due to four discrepant results for which a root cause could not be determined. All four results are included in the percentage concordance analysis.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Number of Discrepancies</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unresolved</td>
<td>4</td>
<td>ORTHO™ Workstation and ORTHO VISION® Analyzer continued to show different results following repeat testing.</td>
</tr>
</tbody>
</table>

The results of the migration studies performed using the ORTHO VISION® Max Analyzer were as follows:

<table>
<thead>
<tr>
<th>Test</th>
<th>Positive</th>
<th>Negative</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>% Agreement</td>
<td>One-Sided Exact 95% LCL (%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anti-Lea</td>
<td>602</td>
<td>100.0</td>
<td>99.6</td>
</tr>
<tr>
<td>Anti-Leb</td>
<td>713</td>
<td>100.0</td>
<td>99.6</td>
</tr>
</tbody>
</table>

LCL: lower confidence limit

* Concordance indicates agreement between the ORTHO VISION® Analyzer and the ORTHO VISION® Max Analyzer only and does not indicate which system gave the correct results.

**Anti-Lea**

In these migration studies, 1261 samples were tested with ORTHO™ Sera Anti-Lea (Murine Monoclonal) using the ORTHO VISION® Analyzer and the ORTHO VISION® Max Analyzer. The one-sided exact 95% LCL of positive percent agreement was 99.5% for agglutination tests based on a comparison of interpreted results. The one-sided exact 95% LCL of negative percent agreement (NPA) was 99.1% for agglutination tests based on a comparison of interpreted results.

**Anti-Leb**

In these migration studies, 1316 samples were tested with ORTHO™ Sera Anti-Leb (Murine Monoclonal) using the ORTHO VISION® Analyzer and the ORTHO VISION® Max Analyzer. The one-sided exact 95% LCL of positive percent agreement was 99.6% for agglutination tests based on a comparison of interpreted results. The one-sided exact 95% LCL of negative percent agreement (NPA) was 98.3% for agglutination tests based on a comparison of interpreted results.

<table>
<thead>
<tr>
<th>Classification</th>
<th>Number of Discrepancies</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unresolved</td>
<td>5</td>
<td>No root cause could be established for the discordant results, however, for three samples the cell button appeared to be disrupted and not representative of a typical positive agglutination reaction.</td>
</tr>
</tbody>
</table>

A further migration study where a matrix approach test strategy was utilized was performed using the ORTHO Optix™ Reader. Four representative ORTHO™ Sera assays were selected for testing to migrate all 13 ORTHO™ Sera with the focus on comparable intended use and design characteristics (card types (buffered gel card and Anti-IgG gel card), special reagents (Papain) and test types (DAT and IAT)).

The results of the migration study using the ORTHO Optix™ Reader were as follows:

<table>
<thead>
<tr>
<th>Card Type</th>
<th>Test</th>
<th>Positive</th>
<th>Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>% Agreement</td>
<td>One-Sided Exact 95% LCL (%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buffered Gel</td>
<td>838</td>
<td>100.0</td>
<td>99.6</td>
</tr>
<tr>
<td>Anti-IgG</td>
<td>647</td>
<td>100.0</td>
<td>99.4</td>
</tr>
</tbody>
</table>

LCL: lower confidence limit

* Concordance indicates agreement between the ORTHO VISION® Analyzer and the ORTHO Optix™ Reader only and does not indicate which system gave the correct results.

In these migration studies, a total of 2293 test results were generated from 861 samples using the ORTHO Optix™ Reader and the ORTHO VISION® Analyzer. These comparator studies demonstrated greater than 95% negative percent agreement (NPA) and greater than 95% positive percent agreement (PPA) at the one-sided exact 95% LCL between the ORTHO Optix™ Reader and the ORTHO VISION® Analyzer.
Precision Study Results
As part of the performance evaluation, precision and lot to lot studies were performed using multiple operators, days and runs to confirm repeatability and reproducibility of test results in the same run, day and with the same operator and between runs, days and operators. The study took account of variables such as days of the week, times of day and supplementary reagents used in the testing. There were no discordant results; all expected positive test outcomes generated unequivocal positive reactions and all expected negative test outcomes generated unequivocal negative reactions.

Specific Performance Characteristics
Prior to release, each lot of ORTHO™ Sera Anti-Lea (Murine Monoclonal) and ORTHO™ Sera Anti-Leb (Murine Monoclonal) are tested in alignment with FDA recommendations against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity.

ORTHO™ Sera Anti-Lea (Murine Monoclonal) and ORTHO™ Sera Anti-Leb (Murine Monoclonal) Blood Grouping Reagents have been tested using the ID-Micro Typing System™ and when stored and used according to the recommended instructions for use, found to specifically agglutinate human red blood cells with the corresponding antigen.

The ORTHO™ Sera Anti-Lea (Murine Monoclonal) reagent reacts with cells expressing the Lea antigen and meets FDA potency requirements.
The ORTHO™ Sera Anti-Leb (Murine Monoclonal) reagent reacts with cells expressing the Leb antigen and meets FDA potency requirements.

For additional information or technical support, contact Ortho Care™ Technical Solutions Center at 1-800-421-3311.

Bibliography

Glossary of Symbols
The following symbols may have been used in the labeling of this product.

![Symbol Diagram]
## Summary of Revisions

<table>
<thead>
<tr>
<th>Date of Revision</th>
<th>Version</th>
<th>Section</th>
<th>Description of Technical Changes*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021-03-12</td>
<td>5.0</td>
<td>Materials Required but not Provided</td>
<td>Addition of ORTHO Optix™ Reader and removal of MTS™ Centrifuge.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Performance Characteristics Comparator Study Results</td>
<td>Addition of Performance Characteristics for ORTHO Optix™ Reader.</td>
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<tr>
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<td>Limitations of the Procedure</td>
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<td>Specific Performance Characteristics</td>
<td>Changed OCD Customer Technical Support to Ortho Care™ Technical Solutions Center.</td>
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<td>Removed 'J' from Interpretation Guide publication number.</td>
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<td>Glossary of Symbols</td>
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* The change bars indicate the position of a technical amendment to the text with respect to the previous version of the document.