Intended Use:
Capture® Ready-Screen® (Pooled Cells) is intended for use in the detection of unexpected IgG antibodies to red blood cells by manual, semi-automated, or automated solid phase red blood cell adherence methods.

Summary of the Test:
Unexpected antibodies are found in the sera of 0.3 to 3% of donor and patient populations. Many antibodies are of clinical importance since they may cause decreased red blood cell survival as the result of hemolytic transfusion reactions, hemolytic disease of the newborn or autoimmune hemolytic anemia. In vitro antibody detection (screening) tests are employed to reveal the presence of these antibodies in patient and donor sera. Selected red blood cells, such as those provided as Capture® Ready-Screen, are incubated with test sera or plasma under conditions that facilitate antibody detection. Capture® Ready-Screen (Pooled Cells) is not recommended for pretransfusion tests done in lieu of a major crossmatch to detect unexpected antibodies in patient samples.

Principle of the Test:
Capture® Ready-Screen is a modulated solid phase antibody detection system based upon the procedures of Plage et al. (1973) and Li et al. (1985). Membranes of red blood cells have been bound to and dried on the surfaces of polystyrene microbeads. The membrane antigens are used to capture red blood cell-specific antibodies from patient or donor sera or plasmas. Following a brief incubation period, unbound residual immunoglobulins are washed from the wells and replaced with a suspension of anti-IgG-coated indicator red blood cells. Centrifugation brings the indicator red cells in contact with antibodies bound to the reagent red blood cell membranes. In the case of a positive test, the migration of the indicator red blood cells to the bottom of the wells is prevented against the anti-IgG-coated complexes formed on the surface of the immobilized reagent layer. As a consequence of antibody binding, the indicator red cells adhere to the screening cells on a second immobilized layer. In the absence of detectable antigen-antibody interactions (negative test), the indicator red blood cells will not be inhibited during their migration and will settle to the bottom of the wells as unagggregated red cell buttons.

Reagents:
1. Capture® Ready-Screen (Pooled Cells) consisting of 1 x 8 strips carrying the bound and dried red blood cell membranes prepared from a pool of two to five donors. Twelve 1 x 8 strips are packaged with a support frame and enclosed in a foil pouch to which a desiccant and moisture indicator have been added. Each strip is ready to be used as supplied. Strips can be used singly or in multiples. Store the strips at 2-20°C (under refrigeration or at room temperature) when not in use. If the anti-IgG antibody enclosed within a pouch shows the presence of moisture (by the presence of a white/gray indicator turning from blue to pink), the strip should not be used. Unsealed strips, desiccant and moisture indicator should be carefully resealed within the foil pouch to prevent exposure to moisture that can destroy the red blood cell membranes. Strips within resealed pouches should not be used if the humidity indicator shows the presence of moisture. Strips removed from pouches should be used within eight hours.
2. Master List: provided with each lot of Capture® Ready-Screen indicates the code and antigenic composition of each donor whose red blood cells are used to prepare the dried reagent monolayers.

Adjacent Reagents to Capture Test Wells:
1. Capture USG: a low ionic strength solution containing glycine, tromethamine, urea and the preservative sodium azide (0.1%). Store at 1-10°C.
2. Capture R Positive Control Serum (Weeks): contains antibodies to red blood cells. Sodium azide (0.1%) is added as a preservative. Store at 1-10°C.
3. Capture R Negative Control Serum: contains no antibodies to red blood cells. Sodium azide (0.1%) is added as a preservative. Store at 1-10°C.

NOTICE: This in-drum components (Capture® Ready-Screen wells, Capture® Ready Indicator Red Cells, Capture USG and Capture R Control Serum) are used to perform Capture® Ready-Screen assays and are used interchangeably with other component lots. Provided the components are within their dating periods. NOTE: Master Lists are lot specific.

Procedures:
1. For in vitro diagnostic use.
2. This reagent contains 0.1% sodium azide. Warning: H302 Harmful if swallowed.

Sodium azide may react with lead and copper plumbing to form explosive compounds. If discarded into the sewer, flush with a large volume of water to prevent storage build-up.
3. All Capture® Ready-Screen reagents must be brought to 18-30°C before testing.
4. Capture® Ready Indicator Red Cells must be suspended before use by gently inverting each vial several times. It is normal for Capture® Ready Indicator Red Cells to aggregate slightly during 1-10°C storage. Capture® Ready Indicator Red Cells should not be used if the red blood cells darken from red to brown. If there is hemolysis, or if the cells fail to form properly in positive and negative control tests, slight hemolysis may occur with age.
5. Turbidity of Capture USG and Capture Control Reagents may be an indication of microbial contamination. Reagents that are contaminated should not be used.
6. Do not use reagents beyond their expiration dates. Labeling codes should not be used.
7. The format for the expiration code is CCYY-MM-DD (year-month-day).
8. Handle and dispose of reagents as if potentially infectious.

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

THE PACKAGING OF THIS PRODUCT [CROPPER [BUBS]] CONTAINS DRY NATURAL RUBBER.

Specimen Collection and Preparation:
Plasma or serum: Draw a blood specimen using an acceptable photochrom technique. Fresh serum or plasma (EDTA, ACD, CPD, CPD-A, CPD-S) may be used in this assay. All testing should be performed as soon as possible following collection to minimize the chances of false-positive or false-negative reactions due to improper storage or contamination of the specimen. Specimens that cannot be tested within 24 hours should be stored at 1-10°C as soon as possible. Alternatively, specimens can be separated from red blood cells and stored frozen. Weakly reactive antibodies may be eliminated and become undetectable in specimens stored at room temperature for several days before testing.

Key:
- Underline = Addition or significant change.
- ▲ = Deletion of text.
**Procedure:**

1. **Materials Provided:**
   - Capture-R Ready-Set-Go (Pooled Cells) Microtubulin inosinase low toluequins
   - Additional Capturis Materials Required:
     - Capture-R Clean-Up Step 1 & 2 kit
     - Capture-R Positive Control Sample in dropper vials
     - Capture-R Negative Control Sample in dropper vials
   - Additional reagents materials required:
     - Detergent or proteinase or plasma
     - Markers
     - Tris buffer or other preservatives
     - Wash buffer, pH 6.9-7.2
     - Washing devices or wash units designed for manual dispensing
     - Dispersing materials or pipette designs for micropipettes
     - Blank strips for absorbance
     - Micropore reader (optional)

2. **Instructions:**
   - Bring all Capturis reagents and specimens to 10-20°C before testing.
   - Remove one Capuris Ready-Set-Go from the pouch, inspect the humidity indicator enclosed in the pouch. If the humidity indicator shows the presence of moisture, some of the strips in the pouch should be used. In the absence of signs of moisture, name, return unused strips, detect and humidity indicator to the pouch and carefully reseal the pouch.
   - Check the bottom of the strips. Do not use the strip if it is not unsealed to avoid any test identification.
   - The arrangement of Reagent Red Blood Cells is shown in Fig. 1.

3. **Testing Procedure:**
   - Place the strip in a frame holder. Note: the strip will only fit into the holder in the correct direction.
   - Add 1 drop (100 ± 10 μL) of Capture-R LESS to each test and control well.
   - Add Controls and patient or other specimen to Capture-R Ready-Set-Go (Pooled Cells) Microtubulin inosinase low toluequins.
     - Add 1 drop (50 ± 5 μL) of Capture-R Positive Control Sample (Smash) to one well.
     - Add 1 drop (50 ± 5 μL) of Capture-R Negative Control Sample to another well.
     - Add 1 drop (50 ± 5 μL) of the test sample to a separate well.

4. **Reading the Test:**
   - **Capturis-R Ready-Set-Go (Pooled Cells) Slide**

5. **Interpretation of Results:**
   - **Negative test:** Both Capture-R Ready-Set-Go indicator at the bottom of the test well with no areas of debris.
   - **Positive test:** Adherence of Capture-R Ready-Set-Go indicator to all or part of the reaction surface.

6. **Conclusion:**
   - Antibodies that are detected using Capture-R Ready-Set-Go can be identified using either Capture-R Ready-Set-Go, Capture-R Ready-Set-Go (Exten.) 1 and 2 or Capture-R Select, which provides a positive test that can be used with reagent red blood cells at all concentrations.

**Limitations:**

1. **Errorless test results** can occur from bacterial or chemical contamination of test materials, inappropriate incubation periods, incorrect centrifugation, inadequate washing of test wells, or omission of test-negative or -positive controls.

2. **Contamination of Capture-R Ready-Set-Go Red Cells IQC containing serum or plasma proteins will invalidate the results of this test.**

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**Bibliography:**