Overview

Useful For
Detecting alloantibodies to epitopes on platelet glycoproteins IIb/IIIa, Ipb/Ix, Ia/IIa, IV and HLA Class I antigens to evaluate cases of immune mediated refractoriness to platelet transfusions, posttransfusion purpura, or neonatal alloimmune thrombocytopenia

Testing Algorithm
See Platelet Antibody Testing Algorithm in Special Instructions.

Special Instructions
- Platelet Antibody Testing Algorithm
- Platelet Antibody Screen, Serum Patient Information

Method Name
Solid Phase Enzyme-Linked Immunosorbent Assay (ELISA)

NY State Available
Yes

Specimen

Specimen Type
Serum Red

Advisory Information
For neonate testing, consider sending a maternal specimen instead of a neonate specimen as unbound platelet antibodies may not be detected in the neonate serum.

Necessary Information
If ordering electronically, answer all Prompt Questions for timely result reporting:

1. **Reason for request is required** for result interpretation.
   a. Use provided diagnosis options if appropriate. If specific diagnosis is unknown select the generic answer of Alloimmune Thrombocytopenia.
   b. Record only the diagnosis pertaining to this test.
   c. Record diagnosis description instead of code.

2. Indicate if patient has had intravenous immunoglobulin (IVIg) therapy in the last month: Yes or No

3. Indicate if the patient has received a platelet transfusion within 72 hours of collection (Transfused platelets will interfere with assay): Yes or No

4. Record the most recent platelet count, if available. If not available, enter "Not Available." Platelet count conversion: 93 x10(9)/L = 93 x10(6)/mL = 93 x 10(3)/microliter
Specimen Required

Patient Preparation: Do not collect within 72 hours of a platelet transfusion. Transfused platelets will interfere with this assay.

Container/Tube: Red top

Specimen Volume: 1.5 mL

Collection Instructions: Serum should be separated from red cells prior to shipping.

Forms
Platelet Antibody Screen, Serum Patient Information in Special Instructions

Specimen Minimum Volume
0.5 mL

Reject Due To

| Gross hemolysis | Reject |

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>Serum Red</td>
<td>Frozen (preferred)</td>
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<tr>
<td></td>
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Clinical and Interpretive

Clinical Information

Platelet antibodies may be allo- or autoantibodies and may be directed to a wide range of antigenic "targets" carried on platelet cytoplasmic membranes. Serum platelet antibody test is optimized to identify the presence of platelet allo-antibodies in the patient.

Platelet alloantibodies are involved in several clinical situations such as:

- Immune mediated refractoriness to platelet transfusions usually due to antibodies to HLA class I and sometimes to antibodies specific to platelet antigens.

- Neonatal alloimmune thrombocytopenia (NAIT)

- Posttransfusion purpura (PTP), which are usually associated with platelet-specific antibodies

This test is not recommended for the diagnosis of immune thrombocytopenia (ITP) or autoimmune thrombocytopenia. Tests that are optimized to detect antibodies bound to the platelets will be useful in these situations; cell-bound platelet antibody (Direct) test is strongly recommended instead (CBPAN / Cell Bound Platelet Auto-Antibody Screen, Blood).
Reference Values
Not applicable

Cautions
Erroneous results can occur from bacterial contamination of test materials, inadequate incubation periods, inadequate washing or decanting of test wells, exposure of substrate to stray light, omission of test reagents, exposure to higher or lower than prescribed temperature requirements, insufficient or excessive platelets, or omission of steps.

This assay is intended for use as a screening assay. The results of this assay should not be used as the sole basis for a clinical decision. The reaction patterns a test sample produces with this product should not be relied on solely to establish the identity of a platelet antibody. Therefore, positive or negative results obtained using this assay should be used in conjunction with clinical findings or other serological tests.

Some low-titer, low-avidity antibodies may not be detected using this assay.

The presence of other HPA polymorphic variants located on GPIlb/IIIa (HPA-6, 7, 8, 9, 10, 11, 14, 16, 17, 19, 20, 21), GPIa/IIa (HPA-13, 18), and GPIlb/IX (HPA-12) has not been determined for the antigens captured in this kit. Antibodies to these systems may be reactive in this assay.

Antibodies to low incidence HLA Class I antigens may not be detected using this product.

This test has not been evaluated for the detection of autoantibodies to platelet antigens. Instead, CBPAN / Cell-Bound Platelet Autoantibody Screen, Blood should be performed.

Clinical Reference

Performance
Method Description
Patient serum is added to microwells coated with platelet and HLA glycoproteins, allowing antibody, if present, to
bind. Unbound antibodies are then washed away. An alkaline phosphatase-labeled antihuman globulin reagent (anti-IgG/A/M) is added to the microwells and incubated. The unbound anti-IgG/A/M is washed away and the substrate p-nitrophenylphosphate (PNPP) is added to the wells and incubated. The reaction is stopped with stopping solution. The optical density of the color that develops is measured in a spectrophotometer and results are interpreted. (Package insert: PakPlus Waukesha, WI: Immucor GTI Diagnostics; 303469.IFUEN Rev E 2015-07-01)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday through Friday; 7:30 a.m.-5 p.m.

Saturday; 10 a.m.-6 p.m.

Analytic Time

2 days

Maximum Laboratory Time

4 days

Specimen Retention Time

7 days

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification

This test has been cleared, approved or is exempt by the U.S. Food and Drug Administration and is used per manufacturer’s instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

86022

LOINC® Information

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