

PRODUCT DESCRIPTION:

The Mixed Titer Bacteria Panel for Platelets contains 12 x 0.1 mL microbial samples. This panel is designed for testing the performance of laboratory personnel using a post-storage bacterial detection test for platelets. Some panel members are negative and should not produce a positive signal. Positive samples should yield a wide range of signal strengths.

Sample Number	Sample ID	Expected Result using the Platelet PGDprime® Test
1	<i>Bacillus thuringiensis</i>	GP Detected
2	<i>Escherichia coli</i>	GN Detected
3	Negative	Not Detected
4	<i>Staphylococcus aureus</i>	GP Detected
5	<i>Klebsiella aerogenes</i> *	GN Detected
6	<i>Pseudomonas aeruginosa</i>	GN Detected
7	<i>Staphylococcus aureus</i>	GP Detected
8	<i>Streptococcus dysgalactiae</i>	GP Detected
9	<i>Klebsiella quasipneumoniae</i> **	GN Detected
10	<i>Staphylococcus epidermidis</i>	GP Detected
11	Negative	Not Detected
12	<i>Escherichia coli</i>	GN Detected

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*Formerly *Enterobacter aerogenes*

**Formerly *Klebsiella pneumoniae*

BIO SAFETY:

This panel contains live Biosafety Level 2 microorganisms and must be used within Biological Safety Level 2 facility or cabinet. Please consult your institution's regulations regarding the use of this panel. For a detailed discussion on biological safety see the 5th edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL), published by the CDC at <http://www.cdc.gov/biosafety/publications/bmb15/index.htm>.

PRECAUTIONS:

- Use Universal Precautions, this panel contains live bacteria.
- To avoid cross-contamination, use separate pipette tips for all reagents.

RECOMMENDED STORAGE AND HANDLING:

Mixed Titer Bacteria Panels for Platelets should be stored ≤-65°C to maximize the shelf-life. The panels can be stored at -20°C for one month with minimal loss of activity. Do not use a frost-free freezer. Do not thaw and refreeze the samples. Samples should be run within 30 minutes of thawing.

INSTRUCTIONS FOR THE PLATELETS:

- Platelets used for testing and reconstitution should be transfusion quality, 2-8 days post-collection and stored properly (22°C, rocking). The platelets should show no signs of deterioration or coagulation. The pH should be above 6.2.
- Following the manufacturer's instructions test the platelet sample to **ensure that it is non-reactive prior to using the platelets to reconstitute the panel members.**








INSTRUCTIONS FOR USE:

1. Samples to be tested should be thawed at room temperature for 15 minutes prior to use.
2. Ensure that the sample is in the bottom of the tube before adding the platelets.
3. Reconstitute the samples with 1 ml of platelets. Mix by gentle inversion. **Do Not Vortex.**
4. Perform the bacterial detection test per the instructions of the manufacturer, including the volume of sample to use and the number of samples to test in a single session.

DO NOT USE IN HUMANS. FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.

These products are intended for research, product development or manufacturing use only. These products are NOT intended for use in the manufacture or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans.

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	Catalog Number		Temperature Limitation
	Batch Code		Expiration Date
	For Research Use Only		Biological Risk
	Manufacturer		

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This product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.

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