

PRODUCT DESCRIPTION

Printer Paper for the PAP-4 Series Platelet Aggregation Profilers is a high-quality, thermal-sensitive paper roll designed for use with aggregometer models bearing serial numbers 71104 and above. This paper is specifically sized and formatted to ensure optimal compatibility with the integrated chart recorder system of the PAP-4 Series, enabling clear, accurate, and permanent recording of platelet aggregation tracings and test data.

Each roll provides consistent thermal imaging performance for documentation of real-time platelet aggregation results. The paper is non-adhesive, low-dust, and manufactured to preserve print fidelity throughout standard storage and handling conditions in clinical laboratory environments.

INTENDED PURPOSE

Printer Paper is intended for use with the integrated chart recording system of the PAP-4 Series Platelet Aggregation Profilers (Serial Numbers 71104 and above). It serves as a medium for generating permanent hardcopy tracings of platelet aggregation results, allowing laboratories to document and archive test outcomes for clinical review, quality control, and regulatory compliance.

DETECTION / MEASUREMENT

Printer Paper provides a permanent visual record of platelet aggregation responses by capturing thermal tracings that reflect changes in light transmission during testing. Used in conjunction with reagents, Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples and control materials, Printer Paper supports the assessment of platelet aggregation by documenting aggregation curves as generated by the PAP-4 Series Platelet Aggregation Profilers. This documentation ensures traceability, facilitates result interpretation, and supports quality assurance throughout the platelet aggregation testing workflow.

PRODUCT FUNCTION

Printer Paper functions as a thermal recording medium within the PAP-4 Series Platelet Aggregation Profilers. It captures real-time platelet aggregation tracings by printing changes in light transmission measured during testing. These printed tracings provide a permanent record of results when evaluating platelet function, investigating potential inherited or acquired platelet disorders, or monitoring the effectiveness of anti-platelet therapies. The use of Printer Paper ensures reliable documentation for result interpretation, regulatory compliance, and quality assurance in platelet aggregation studies.

SPECIFIC INFORMATION PROVIDED

Printer Paper is not intended for the detection of a specific disorder, condition, or risk factors.

Printer Paper serves as a critical accessory in the platelet aggregation testing process by providing a permanent thermal printout of aggregation tracings. These printouts reflect changes in light transmission measured by the PAP-4 Series Platelet Aggregation Profilers and are used to document platelet responses. When used in conjunction with Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples, reagents, and controls, Printer Paper supports the evaluation of platelet function by enabling the visual interpretation and archival of aggregation results.

AUTOMATION

Printer Paper is designed specifically for use with semi-automated Light Transmission Platelet Aggregometers. It is intended for use with the PAP-4 Series Platelet Aggregation Profilers equipped with an integrated thermal chart recorder, beginning with Serial Number 71104 and above.

QUALITY / QUANTITY

There are no established primary standards for Printer Paper. Each roll is manufactured to meet defined thermal sensitivity and physical specifications to ensure reliable and consistent recording of platelet aggregation tracings. Accurate and durable printouts contribute to the traceability, reproducibility, and reliability of test results.

Printer Paper is supplied as one roll per package. Each roll is designed for single-use within the integrated chart recorder of the PAP-4 Series Platelet Aggregation Profilers (Serial Numbers 71104 and above).

SPECIMEN TYPE

The test specimen is prepared from sodium citrate anticoagulated whole blood. In routine platelet aggregation testing, the test sample is Platelet Rich Plasma (PRP), and the test blank is Platelet Poor Plasma (PPP). In specialized assays such as the Ristocetin Cofactor Assay, the test sample may be Platelet Poor Plasma (PPP), with a blank consisting of Lyophilized Platelets reconstituted in TRIS Buffered Saline (TBS).

Printer Paper is intended for use in recording results generated during platelet aggregation testing performed on human or animal plasma samples. It serves to document aggregation tracings that reflect the concentration, extent, and rate of platelet aggregation compared to the blank.

TESTING POPULATION

Printer Paper is designed for use in recording platelet aggregation results from Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples derived from both human and animal sources. The prevalence and incidence of platelet function disorders or anti-platelet drug usage may influence aggregation results but do not affect the function or use of Printer Paper.

- Human: The prevalence and incidence of inherited platelet disorders, acquired platelet dysfunctions, and anti-platelet drug usage vary across human populations.
- Animal: The prevalence and incidence of platelet-related conditions vary by animal species.

IN VITRO DIAGNOSTIC

Printer Paper is intended for in vitro diagnostic use as a single-use accessory in platelet aggregation testing. It is for professional laboratory use only and is not intended for injection, ingestion, or direct contact with patients.

INTENDED USER

Printer Paper is intended for professional laboratory use by qualified personnel.

TEST PRINCIPLE

Printer Paper captures thermal printouts of platelet aggregation tracings generated by the PAP-4 Series Platelet Aggregation Profiler during testing at 37°C. As Platelet Rich Plasma (PRP) samples respond to various agonists, changes in light transmission are measured and recorded in real time. Proper installation of the Printer Paper ensures accurate documentation of these tracings, supporting the visual evaluation and archiving of platelet activation and aggregation responses under standardized testing conditions.

CALIBRATORS AND CONTROLS

Printer Paper does not require calibrators or controls. Proper function is ensured through consistent manufacturing quality and verified performance.

PRODUCT LIMITATIONS

Printer Paper will perform as specified when used according to the Instructions for Use. It is a single-use item and must be used prior to the expiration date printed on the packaging. Improper installation, handling, or use of incompatible paper may affect print quality, documentation accuracy, and overall test reliability.

CONTENTS PROVIDED

REF 105598: 1 Roll

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED

- Platelet Aggregation Reagents
- Purified Water (Distilled, Deionized, Reagent Grade), pH 5.3 – 7.2 for reconstitution
- TRIS Buffered Saline (TBS) or 0.85% physiological saline for dilutions



NOTE: USING BLOOD BANK SALINE WILL CAUSE ERRONEOUS RESULTS.

MATERIALS AND ACCESSORIES

- PAP-4 Series Platelet Aggregation Profiler
(Follow the Manufacturer's Instructions for Use)
- Macro Test Tubes (or Micro Test Tubes using micro-volume adapters) ②
- Macro Stir Bars (or Micro Stir Bars using micro-volume adapters) ②
- Centrifuge
- Electronic Pipette
- Pipette Tips ②
- Plastic Sample Tubes and Caps (for Dilutions) ②



NOTE: DISPOSABLE ITEMS SUCH AS TEST TUBES, STIR BARS, SAMPLE TUBES, AND CAPS ARE FOR ONE TIME USE ONLY

STORAGE AND STABILITY

- Printer Paper does not require temperature protection during shipment.
- Upon receipt, store Printer Paper in its original packaging in a clean, dry area away from direct sunlight and sources of heat or humidity.
- Do not expose Printer Paper to extreme conditions that may degrade thermal sensitivity or print quality.

STERILITY



Printer Paper is not a sterile product. Handle using clean gloves and avoid contact with surfaces that may introduce contamination into the testing environment.

WARNINGS AND PRECAUTIONS



Wear PPE in accordance with laboratory policies and practices when handling Printer Paper.



Follow standard precautions when preparing test specimens and operating the aggregometer.



Use Printer Paper as a single-use product; do not reuse to avoid data integrity issues.



Handle Printer Paper with clean gloves to prevent smudging or contamination that may affect print quality.



Avoid bending, creasing, or exposing the paper to moisture or extreme conditions, which may interfere with proper function.



Store Printer Paper in its original packaging until use to maintain cleanliness and imaging performance.



Dispose of used Printer Paper in accordance with applicable regulations and laboratory policies.



NOTE TO USER: ANY SERIOUS INCIDENT THAT OCCURS IN RELATION TO THIS PRODUCT SHALL BE REPORTED TO THE MANUFACTURER AND THE COMPETENT AUTHORITY OF THE MEMBER STATE IN WHICH THE USER AND / OR PATIENT ARE ESTABLISHED.

INFECTIOUS MATERIAL STATUS

Printer Paper does not contain any infectious materials. However, test specimens and samples used during platelet aggregation testing must be considered potentially infectious and handled according to standard biosafety precautions. After testing, all specimens, samples, and used Printer Paper must be disposed of in compliance with applicable regulations and laboratory policies.

SPECIAL FACILITIES

Printer Paper does not require the use of special facilities within a laboratory environment.

PREPARATION FOR USE



NOTE: REFER TO THE PAP-4 SERIES PLATELET AGGREGATION PROFILER OPERATOR MANUAL (IFU) FOR DETAILED INSTRUCTIONS.

- Remove Printer Paper from its packaging using clean gloves.
- Ensure the thermal side of the paper is properly oriented according to the aggregometer manufacturer's instructions.
- Load the roll into the integrated chart recorder of the PAP-4 Series Platelet Aggregometer (Serial Numbers 71104 and above), following the device-specific loading procedure.
- Advance the paper slightly to verify correct installation and print alignment before initiating testing.
- Use only one roll at a time. Do not reuse or reload partially used rolls.

PATIENT PREPARATION

Patients should refrain from taking aspirin or using aspirin-containing medications and products, as well as other medications, supplements, or energy drinks known to affect platelet function for 7 – 10 days prior to specimen collection. Ingestion of fatty foods, dairy products, and smoking should be avoided for 12 hours before specimen collection.



NOTE: CONSULTATION WITH A PHYSICIAN IS REQUIRED PRIOR TO MAKING ANY MEDICATION CHANGES.

SPECIMEN COLLECTION / SAMPLE PREPARATION / ASSAY PROCEDURE



NOTE: REFER TO THE PAP-4 SERIES PLATELET AGGREGATION PROFILER OPERATOR MANUAL (IFU) FOR DETAILED INSTRUCTIONS.



PRACTICE STANDARD PRECAUTIONS THROUGHOUT THE SPECIMEN COLLECTION, SAMPLE PREPARATION, AND ANALYTICAL PROCESSES. DISPOSE OF SHARPS AND BIOHAZARDOUS WASTE IN ACCORDANCE WITH APPLICABLE REGULATIONS AND LABORATORY POLICIES.

QUALITY CONTROL

Printer Paper is a single-use item designed to provide a clear and permanent thermal printout of platelet aggregation tracings during testing. To ensure overall test system performance and consistency, a known donor sample should be tested following the laboratory's standard platelet aggregation protocol. Quality control of Printer Paper relies on proper handling, installation, and use in accordance with the Instructions for Use. Each laboratory should verify the performance of the entire test system, including reagents, instruments, and accessories like Printer Paper, and establish acceptable control ranges based on their patient population.

RESULTS

Printer Paper provides a permanent, high-contrast thermal record of platelet aggregation tracings generated during testing, ensuring accurate documentation of light transmission changes. Proper use of Printer Paper supports the interpretation and review of aggregation results by preserving the integrity of test output and minimizing recording variability. While Printer Paper does not directly influence aggregation patterns, its role is essential for achieving reliable and traceable results with the PAP-4 Series Platelet Aggregation Profilers.

LIMITATIONS

Printer Paper is designed to provide accurate and consistent documentation of platelet aggregation test results but does not influence the biological reaction itself. Improper use, such as incorrect loading, using incompatible paper, or reusing partially used rolls, may result in poor-quality printouts and compromise result interpretation. The quality of platelet aggregation results depends on multiple factors, including sample quality, reagent performance, and instrument calibration. Laboratories should ensure that Printer Paper is used as a single-use item and that it is handled and installed according to established protocols. If test documentation is unclear or incomplete, reprinting with properly installed Printer Paper is recommended.

EXPECTED VALUES

Laboratories should ensure that Printer Paper is used according to the Instructions for Use to maintain the integrity of test documentation and support accurate result interpretation.

ANALYTICAL PERFORMANCE

Printer Paper is designed to provide consistent and reliable documentation of platelet aggregation tracings generated during testing. Proper use ensures accurate thermal recording of light transmission changes, which is critical for interpreting platelet function. While Printer Paper does not directly affect platelet aggregation kinetics, improper loading, handling, or use of incompatible paper may impact the quality and readability of test results. Consistent use of single-use, properly installed Printer Paper minimizes variability related to result documentation. Laboratories should monitor overall test system performance, recognizing that variability in platelet aggregation results may arise from multiple factors, including reagent quality, instrument calibration, sample handling, and data recording accuracy.

SYMBOLS



Bio-Hazardous



Catalog Number



Caution



CE Marked & Registered Product



Consult Instructions For Use



European Union Representative



In Vitro Diagnostic Device



Manufacturer



Must Read



Non-Sterile



Single Use Only



Temperature Limitations



United Kingdom Marked & Registered Product



United Kingdom Representative

REFERENCES

- Bio/Data Corporation. PAP-4 Series Platelet Aggregation Profiler Operator Manual. Horsham, PA.
- Born GV, Cross MJ. The Aggregation of Blood Platelets. J Physiol. 1963 Aug;168(1):178–95.
- Cattaneo M, Cerletti C, Harrison P, et al. Recommendations for the Standardization of Light Transmission Aggregometry: A Consensus of the Working Party from the Platelet Physiology Subcommittee of SSC/ISTH. J Thromb Haemost. 2013;11(4):1183–1189.
- Clinical and Laboratory Standards Institute (CLSI). Platelet Function Testing by Aggregometry; Approved Guideline – Fourth Edition. CLSI document H58-A. Wayne, PA: CLSI; 2008.
- Day HJ, Holmsen H. Laboratory tests of platelet function. Ann Clin Lab Sci. 1972 Jan-Feb;2(1):63–74.

- Eichelberger JW. Kinetic (Slope) Measurement of Platelet Aggregation. Bio/Data Corporation, Horsham, PA; 1984.
- Owen CA Jr, Bowie EJW, Thompson JH Jr. The Diagnosis of Bleeding Disorders. 2nd ed. Little, Brown, and Company; 1975.
- Siegel JD, Rhinehart E, Jackson M, Chiarello L; Health Care Infection Control Practices Advisory Committee. Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Health Care Settings. Am J Infect Control. 2007;35(10 Suppl 2):S65–164.

REVISION HISTORY

Document No: 107630 Revision: AA, June 2025

- Implemented IVDR Regulatory Requirements
- Reformatted and Reconfigured to Enhance Operator Use

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PRINTER PAPER INSTRUCTIONS FOR USE # 107630 REV AA