BIO/DATA CORPORATION

AN ISO 13485 REGISTERED COMPANY

PROFILER PAPER

PAP-4 Series Platelet Aggregation Profiler
Serial Number 71103 and Below

INSTRUCTIONS FOR USE

REF 101375
IVD
-20°C 40°C
ENGLISH - EN

PRODUCT DESCRIPTION

Profiler 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 71103 and below. 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

Profiler Paper is intended for use with the integrated chart recording system of the PAP-4 Series Platelet Aggregation Profilers (Serial Numbers 71103 and below). 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

Profiler 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, Profiler 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

Profiler 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 Profiler Paper ensures reliable documentation for result interpretation, regulatory compliance, and quality assurance in platelet aggregation studies.

SPECIFIC INFORMATION PROVIDED

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

Profiler 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 latelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples, reagents, and controls, Profiler Paper supports the evaluation of platelet function by enabling the visual interpretation and archival of aggregation results.

AUTOMATION

Profiler 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 71103 and below.

QUALITY / QUANTITY

There are no established primary standards for Profiler 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.

Profiler 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 71103 and below).

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).

Profiler 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

Profiler 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 Profiler 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

Profiler 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

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

TEST PRINCIPLE

Profiler 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 Profiler 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

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

PRODUCT LIMITATIONS

Profiler 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 101375: 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

Profiler Paper does not require temperature protection during shipment.

Upon receipt, store Profiler Paper in its original packaging in a clean, dry area away from direct sunlight and sources of heat or humidity.

Do not expose Profiler Paper to extreme conditions that may degrade thermal sensitivity or print quality.

STERILITY

Profiler 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 Profiler Paper.

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

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

Handle Profiler 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 Profiler Paper in its original packaging until use to maintain cleanliness and imaging performance.

Dispose of used Profiler 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

Profiler 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 Profiler Paper must be disposed of in compliance with applicable regulations and laboratory policies.

SPECIAL FACILITIES

Profiler 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 Profiler 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 71103 and below), 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

Profiler 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 Profiler 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 Profiler Paper, and establish acceptable control ranges based on their patient population.

RESULTS

Profiler 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 Profiler Paper supports the interpretation and review of aggregation results by preserving the integrity of test output and minimizing recording variability. While Profiler 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

Profiler 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 Profiler 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 Profiler Paper is recommended.

EXPECTED VALUES

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

ANALYTICAL PERFORMANCE

Profiler 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 Profiler 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 Profiler 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
REF	**Catalog Number**
	Caution
CE	**CE Marked & Registered Product**
	Consult Instructions For Use
EU REP	**European Union Representative**
IVD	**In Vitro Diagnostic Device**
	Manufacturer
	Must Read
NON STERILE	**Non-Sterile**
2	**Single Use Only**
	Temperature Limitations
UK CA	**United Kingdom Marked & Registered Product**
UK REP	**United Kingdom Representative**

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REVISION HISTORY

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

For a complete product catalog, please visit our website at www.biodatacorp.com or contact our Customer Service Department.

THE BIO/DATA CORPORATION PRODUCT LINE INCLUDES GENERAL PURPOSE, PROFESSIONAL LABORATORY USE PRODUCTS INTENDED TO INDUCE AND REPORT PLATELET FUNCTION ACTIVITY AND RESPONSES. THIS PRODUCT IS WARRANTED TO PERFORM AS DESCRIBED IN ITS LABELING INCLUDING THE INSTRUCTIONS FOR USE. BIO/DATA CORPORATION MAKES NO CLAIM OR WARRANTY, EXPRESSED OR IMPLIED, OF THE CAPABILITY, FITNESS, OR MERCHANTABILITY FOR ANY OTHER PURPOSE. IN NO EVENT SHALL BIO/DATA CORPORATION BE LIABLE FOR ANY CONSEQUENTIAL DAMAGES ARISING OUT OF AFORESAID EXPRESSED WARRANTY.

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