BIO/DATA CORPORATION

AN ISO 13485 REGISTERED COMPANY

MAGNETUBE™

Micro Stir Bars and Micro Test Tubes In One

REF 107146

IVD

-20°C 40°C

INSTRUCTIONS FOR USE

ENGLISH - EN

PRODUCT DESCRIPTION

MagneTube™ combines the functionality of a plastic-coated magnetic Micro Stir Bar with a flat-bottom, silicone-coated Micro Test Tube designed to contain Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples for platelet aggregation testing. Engineered for use with the PAP-8E Platelet Aggregometer or with micro-volume adapters in the PAP-4 Series Platelet Aggregation Profilers, MagneTube ensures secure sample containment, consistent sample stirring, and precise optical alignment throughout incubation and testing procedures.

INTENDED PURPOSE

MagneTube™ is a single-use, silicone-coated Micro Test Tube with an integrated plastic-coated magnetic Micro Stir Bar, intended for containing and stirring Platelet Rich Plasma (PRP) or Platelet Poor Plasma (PPP) samples during platelet aggregation testing. It eliminates the need for a separate stir bar, streamlining the test setup and improving ease of use. MagneTube is designed for use with the PAP-8E Platelet Aggregometer or, when equipped with micro-volume adapters, the PAP-4 Series Platelet Aggregation Profilers.

DETECTION / MEASUREMENT

MagneTube™ ensures consistent sample stirring and secure containment of Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples during platelet aggregation studies, which is essential for accurately measuring changes in light transmission. Used in conjunction with reagents, diluents, and control samples, MagneTube supports the assessment of platelet aggregation by maintaining proper sample stirring, containment, and optical alignment within the aggregometer throughout incubation and testing.

PRODUCT FUNCTION

MagneTube™ provides a stable and secure environment for Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples by integrating consistent stirring within a flat-bottom test tube during platelet aggregation testing. Proper sample containment, alignment, and stirring within the platelet aggregometer are critical to obtaining reliable results when evaluating platelet function, investigating potential inherited or acquired platelet disorders, or monitoring the effectiveness of anti-platelet therapies.

SPECIFIC INFORMATION PROVIDED

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

MagneTube serves as a critical accessory in the platelet aggregation testing process by securely containing and stirring Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples. Proper stirring, sample containment, and positioning within the platelet aggregometer support the generation of accurate and reproducible aggregation curves, which are used in conjunction with reagents and controls to evaluate platelet function.

AUTOMATION

MagneTube™ is designed specifically for use with semi-automated and automated Light Transmission Platelet Aggregometers. It is intended for use with the PAP-8E Platelet Aggregometer, or with micro-volume adapters in the PAP-4 Series Platelet Aggregation Profilers.

QUALITY / QUANTITY

There are no established primary standards for MagneTube™. Each unit is manufactured for single use to deliver consistent containment and stirring of Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples. Proper sample containment, positioning, and stirring contribute to the reproducibility and reliability of test results.

MagneTube is packaged in one box containing 50 single-use units. Each unit consists of a siliconized, flat-bottom Micro Test Tube (7.25 x 55 mm) preloaded with a plastic-coated magnetic Micro Stir Bar.

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). For Ristocetin Cofactor Assays, the test sample is Platelet Poor Plasma (PPP), while the test blank consists of Lyophilized Platelets reconstituted in TRIS Buffered Saline (TBS).

MagneTube™ is intended for use with human or animal plasma in platelet aggregation testing. Results are evaluated based on the concentration, extent, and rate of aggregation compared to the blank.

TESTING POPULATION

MagneTube™ is designed for use with 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 the results of platelet aggregation testing but do not affect the use of MagneTube.

- 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

MagneTube™ 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

MagneTube™ is intended for professional laboratory use by qualified personnel.

TEST PRINCIPLE

MagneTube™ provides stable containment of Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples at 37°C during platelet aggregation testing. Proper positioning and stirring within the aggregometer ensure accurate optical alignment and consistent sample presentation, which are essential for reliable measurement of changes in light transmission as platelets aggregate. MagneTube supports optimal conditions for accurately capturing the platelet activation and aggregation process using the platelet aggregometer.

CALIBRATORS AND CONTROLS

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

PRODUCT LIMITATIONS

MagneTube™ 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 handling or reuse may affect test consistency and reliability.

CONTENTS PROVIDED

REF 107046: 1 Box of 50 MagneTube (7.25 x 55mm each)

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-8E Platelet Aggregometer or PAP-4 Series Platelet Aggregation Profiler *(Follow the Manufacturer's Instructions for Use)*
- Centrifuge
- Electronic Pipette
- Pipette Tips ②
- Plastic Sample Tubes and Caps *(for Dilutions)* ②

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

STORAGE AND STABILITY

MagneTube does not require temperature protection during shipment.

Upon receipt, store MagneTube between -20°C and 40°C in its original packaging.

STERILITY

NON STERILE

MagneTube™ is not a sterile product. Handle using clean gloves and aseptic technique to avoid contamination.

WARNINGS AND PRECAUTIONS

Wear PPE in accordance with laboratory policies and practices when handling MagneTube™.

Follow standard precautions when preparing test specimens and samples.

Use MagneTube as a single-use product; do not reuse to avoid cross-contamination.

Handle MagneTube with gloves to prevent fingerprints that may interfere with the light path and compromise test accuracy.

Handle MagneTube carefully to avoid damaging the silicone coating, which could affect performance.

Store MagneTube in its original packaging until use to maintain cleanliness and integrity.

Dispose of used MagneTube 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

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

SPECIAL FACILITIES

MagneTube™ does not require the use of special facilities within a laboratory environment.

PREPARATION FOR USE

NOTE: REFER TO THE PAP-8E PLATELET AGGREGOMETER OR THE PAP-4 SERIES PLATELET AGGREGATION PROFILER OPERATOR MANUAL (IFU) FOR DETAILED INSTRUCTIONS.

NOTE: MAGNETUBE™ MUST BE HANDLED WITH GLOVES AND PLACED INTO THE PLATELET AGGREGOMETER CAREFULLY TO PREVENT FINGERPRINTS OR SMUDGES, WHICH CAN INTERFERE WITH THE LIGHT TRANSMISSION PATH AND COMPROMISE TEST RESULTS.

- Remove a single MagneTube™ from the packaging using clean gloves or sterile forceps.
- Label the MagneTube in accordance with the applicable test protocol.
- Place the labeled MagneTube into the aggregometer or instrument-specific test position as directed by the test protocol.
- Pipette the required volume of Platelet Rich Plasma (PRP) or Platelet Poor Plasma (PPP) into the MagneTube as specified in the test instructions.
- Use each MagneTube only once. Discard immediately after testing to prevent contamination or compromised results.

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-8E PLATELET AGGREGOMETER OR THE PAP-4 SERIES PLATELET AGGREGATION PROFILER OPERATOR MANUAL (IFU) FOR DETAILED INSTRUCTIONS.

NOTE: MAGNETUBE™ MUST BE HANDLED WITH GLOVES AND PLACED INTO THE PLATELET AGGREGOMETER CAREFULLY TO PREVENT FINGERPRINTS OR SMUDGES, WHICH CAN INTERFERE WITH THE LIGHT TRANSMISSION PATH AND COMPROMISE TEST RESULTS.

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

MagneTube™ is a single-use item designed to securely contain and stir Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples during platelet aggregation 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 MagneTube relies on proper handling 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 MagneTube - and establish acceptable control ranges based on their patient population.

RESULTS

MagneTube™ provides stable containment and stirring of Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples during incubation and testing, ensuring proper sample positioning within the aggregometer. Proper use of MagneTube supports accurate measurement of platelet aggregation by maintaining consistent sample alignment and minimizing handling variability. While MagneTube does not directly influence aggregation patterns, its role is critical to achieving reliable and reproducible test results with the PAP-8E Platelet Aggregometer or with micro-volume adapters in the PAP-4 Series Platelet Aggregation Profilers.

LIMITATIONS

MagneTube™ is designed to provide stable and consistent sample containment and stirring during platelet aggregation testing but does not influence the biological reaction itself. Improper use, such as reusing tubes or incorrect handling, may compromise sample integrity and lead to inconsistent or unreliable test results. The quality of platelet aggregation results depends on multiple factors, including sample quality, reagent performance, and instrument calibration. Laboratories should ensure that MagneTube is used as a single-use item and that samples are handled according to established protocols. If test results are inconsistent, verification with a new sample and proper use of MagneTube is recommended.

EXPECTED VALUES

Laboratories should ensure that MagneTube™ is used according to the Instructions for Use to maintain test integrity.

ANALYTICAL PERFORMANCE

MagneTube™ is designed to provide consistent and reliable containment and stirring of Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples during platelet aggregation testing. Proper use ensures accurate sample positioning within the aggregometer, which is essential for precise light transmission measurements. While MagneTube does not directly influence platelet aggregation kinetics, improper handling or reuse can affect test reproducibility and result accuracy. Consistent use of single-use, undamaged MagneTube minimizes variability related to sample containment and stirring. Laboratories should monitor overall test system performance, recognizing that variability in platelet aggregation results may arise from multiple factors, including reagent quality, instrument calibration, and sample handling.

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**

REFERENCES

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- Bio/Data Corporation. PAP-4 Series Platelet Aggregation Profiler Operator Manual. Horsham, PA.
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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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