BIO/DATA CORPORATION

AN ISO 13485 REGISTERED COMPANY

STIR BARS, MICRO

Magnetic, Plastic Coated

REF 105990

IVD

-20°C 40°C

INSTRUCTIONS FOR USE

ENGLISH - EN

PRODUCT DESCRIPTION
Micro Stir Bars are single-use, plastic-coated magnetic stir bars designed to deliver consistent and efficient stirring of Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples. Optimized for use with Micro Test Tubes in the PAP-8E Platelet Aggregometer, or with micro-volume adapters in the PAP-4 Series Platelet Aggregation Profilers, Micro Stir Bars promote uniform sample stirring throughout incubation and testing procedures.

INTENDED PURPOSE
Micro Stir Bars are single-use, plastic-coated stir bars intended for stirring Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples during incubation and testing. They are designed for use with Micro Test Tubes in the PAP-8E Platelet Aggregometer or with micro-volume adapters in the PAP-4 Series Platelet Aggregation Profilers.

DETECTION / MEASUREMENT
Micro Stir Bars facilitate uniform stirring of Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples during testing, which is essential for accurately measuring changes in light transmission. Used in conjunction with reagents, diluents, and control samples, they support the assessment of platelet aggregation by ensuring consistent sample stirring.

PRODUCT FUNCTION
Micro Stir Bars ensure proper and consistent stirring of Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples during platelet aggregation testing. This stirring is 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
Micro Stir Bars are not intended for the detection of a specific disorder, condition, or risk factors.

Micro Stir Bars serve as a critical component in the platelet aggregation testing process by ensuring consistent sample stirring. Proper stirring of Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) during testing supports the generation of accurate and reproducible aggregation curves, which are used in conjunction with reagents and controls to evaluate platelet function.

AUTOMATION
Micro Stir Bars are designed specifically for use with semi-automated and automated Light Transmission Platelet Aggregometers and are optimized 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 Micro Stir Bars. Each Micro Stir Bar is manufactured for single use and designed to provide consistent stirring performance when used with Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples in platelet aggregation testing. Proper stirring contributes to the reproducibility and reliability of test results.

Micro Stir Bars are packaged in two plastic tubes, each containing 25 stir bars, for a total of 50 stir bars per set..

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).

Micro Stir Bars are 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
Macro Stir Bars are 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 Macro Stir Bars.

- 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
Micro Stir Bars are intended for in vitro diagnostic use as a single-use accessory in platelet aggregation testing. They are for professional laboratory use only and are not intended for injection, ingestion, or direct contact with patients.

INTENDED USER
Micro Stir Bars are intended for Professional Laboratory Use by qualified personnel.

TEST PRINCIPLE
Micro Stir Bars provide consistent stirring of Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples at 37°C during platelet aggregation testing. Proper stirring ensures uniform distribution of reagents and maintains sample homogeneity, which is essential for accurate measurement of changes in light transmission as platelets aggregate. Micro Stir Bars facilitate optimal conditions for the platelet activation and aggregation process to be captured reliably by the platelet aggregometer.

CALIBRATORS AND CONTROLS
Micro Stir Bars do not require calibrators or controls. Proper function is ensured by consistent manufacturing quality and performance verification.

REAGENT LIMITATIONS
Micro Stir Bars will perform as specified when used according to the Instructions for Use. They are single-use devices 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 105990: 2 Tubes of 25 Micro Stir Bars Each (50 Total)

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)*
- Test Tubes, Micro *(Siliconized)* 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
Micro Stir Bars do not require temperature protection during shipment.

Upon receipt, store Micro Stir Bars between -20°C and 40°C in their original packaging.

STERILITY
Micro Stir Bars are not a sterile product. Handle with clean gloves and use aseptic technique to avoid contamination.

WARNINGS AND PRECAUTIONS
Wear PPE in accordance with laboratory policies and practices when handling Micro Stir Bars.

Follow standard precautions when preparing test specimens and samples.

Use Micro Stir Bars as single-use product; do not reuse to avoid cross-contamination.

Handle Micro Stir Bars carefully to prevent damage to the plastic coating, which may affect performance.

Store Micro Stir Bars in their original packaging until use to maintain cleanliness and integrity.

Dispose of used Micro Stir Bars 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

Micro Stir Bars do not contain any infectious materials. However, test specimens and samples used with the Micro Stir Bars must be considered potentially infectious and handled according to standard biosafety precautions. After testing, all specimens, samples, and used Micro Stir Bars must be disposed of in compliance with applicable regulations and laboratory policies.

SPECIAL FACILITIES

Micro Stir Bars do not require the use of special facilities within a laboratory environment.

PREPARATION FOR USE

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

- Remove a single Micro Stir Bar from the sealed packaging using clean gloves or sterile forceps.
- Place the Micro Stir Bar into the appropriate Micro Test Tube containing either the Platelet Rich Plasma (PRP) or Platelet Poor Plasma (PPP) sample, as required by the specific test protocol.
- Ensure the Micro Stir Bar is fully submerged in the sample before starting the platelet aggregation test.
- Use the Micro Stir Bar only once and discard after the test to avoid contamination.

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 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

Micro Stir Bars are single-use devices designed to provide consistent stirring 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 Micro Stir Bars relies on proper handling and use according to the Instructions for Use. Each laboratory should verify the performance of the entire test system, including reagents, instruments, and accessories like Micro Stir Bars, and establish acceptable control ranges based on their patient population.

RESULTS

Micro Stir Bars provide consistent stirring of Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples during incubation and testing, ensuring uniform stirring of reagents and samples. Proper use of Micro Stir Bars supports accurate measurement of platelet aggregation by maintaining sample homogeneity. While Micro Stir Bars do not directly affect aggregation patterns, their consistent performance is critical to achieving reliable and reproducible results when used with the PAP-8E Platelet Aggregometer or micro-volume adapters in the PAP-4 Series Platelet Aggregation Profilers.

LIMITATIONS

Micro Stir Bars are designed to provide consistent stirring during platelet aggregation testing but do not influence the biological reaction itself. Improper use, such as reusing Micro Stir Bars or damage to the plastic coating, may affect stirring efficiency 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 Micro Stir Bars are used as single-use items and handle samples according to established protocols. If test results are inconsistent, verification with a new sample and proper Micro Stir Bar use is recommended.

EXPECTED VALUES

Laboratories should ensure that Micro Stir Bars are used according to the Instructions for Use to maintain test integrity.

ANALYTICAL PERFORMANCE

Micro Stir Bars are designed to provide consistent and reliable stirring of Platelet Rich Plasma (PRP) and Platelet Poor Plasma (PPP) samples during platelet aggregation testing. Their performance contributes to the homogeneity of the sample and reagent mixture, which is critical for accurate light transmission measurements. While Micro Stir Bars do not directly influence platelet aggregation kinetics, improper stirring can affect test reproducibility and result accuracy. Consistent use of single-use, undamaged Micro Stir Bars ensures minimal variability due to sample 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**
	Single Use Only
	Temperature Limitations
UK CA	**United Kingdom Marked & Registered Product**
UK REP	**United Kingdom Representative**

REFERENCES

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

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