

SBNEG Stabilized Blood Dilution Matrix

Instructions for Use

Product Overview	
Name	Stabilized Blood Dilution Matrix
Part Number	SBNEG
Fill Volume	20mL
Storage Temperature	-20°C or below
Regulatory Status	For In Vitro Diagnostic Use

Product Description

The Stabilized Blood Dilution Matrix is designed for use in molecular diagnostic workflows. Each lot is formulated in a proprietary matrix containing preservatives and does not contain any positive analytes. This matrix is suitable for diluting positive patient specimens or contrived samples for assay development, validation, and routine use. When aliquoted into appropriate vessels, the Stabilized Blood Dilution Matrix may also be used as a daily negative run control. The product is non-infectious and stable under recommended storage conditions. The product is tested and found negative for HBsAg, HCV, HIV-1, HIV-2, HIV-1Ag, or HIV-1 NAT, West Nile Virus NAT, Zika NAT, and Syphilis using FDA-approved materials.

Intended Use

The Stabilized Blood Dilution Matrix is intended for use as a negative matrix. It may be used to dilute positive samples or controls for assay development, validation, and verification, including precision, linearity, and limit of detection studies. Additionally, the Stabilized Blood Dilution Matrix may be aliquoted into appropriate vessels and used as a daily negative run control to monitor assay specificity and detect potential contamination events.

This product is not intended to replace manufacturer-provided negative controls and should not be used as an internal control within assay reagents.

Principles of the Procedure

The Stabilized Blood Dilution Matrix is a whole blood derived medium containing preservatives and is free of positive analytes. It is used to dilute positive patient samples or controls for use in molecular diagnostic workflows, including assay development, validation, and verification studies. When used as a negative control, the Stabilized Blood Dilution Matrix must be extracted and tested using the same procedures applied to clinical samples. When processed alongside clinical samples, it serves as a full-process control for verifying assay performance, monitoring reagent integrity, and assessing operator technique.

End users are responsible for validating the performance of the Stabilized Blood Dilution Matrix within their specific assay system. The Stabilized Blood Dilution Matrix is not intended to replace assay-specific internal or external controls provided by test kit manufacturers.

Storage and Handling

The Stabilized Blood Dilution Matrix should be stored at -20°C or below. Thaw at room temperature and vortex briefly prior to use. Once thawed, Stabilized Blood Dilution Matrix is stable for 24 hours when stored at 2-8°C. Product can be frozen and reused a maximum of four (4) times. After the fourth freeze/thaw, any remaining materials must be disposed of.

Do not use Stabilized Blood Dilution Matrix beyond the expiration date.

Limitations

For in vitro diagnostic use. Intended for professional use only. Each laboratory must establish its own standard operating procedures and instructions.

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Warnings and Precautions

The Stabilized Blood Dilution Matrix does not contain infectious agents. However, the product should be handled as potentially biohazardous. Always use universal precautions when handling the product and any associated materials. Do not pipette by mouth. Avoid smoking, eating, or drinking in areas where controls or clinical specimens are handled.

Wear appropriate personal protective equipment (PPE), including gloves, lab coats, and eye protection when handling this product. Avoid inhalation, ingestion, or direct contact with skin and eyes. In case of skin or eye contact, flush thoroughly with water.

In case of inadequate ventilation, use respiratory protection. Wash contaminated clothing before reuse. Clean spills immediately using a freshly prepared 0.5% sodium hypochlorite (bleach) solution or equivalent disinfectant.

Dispose of all waste materials, including used vials and consumables, as if they contain infectious agents, in accordance with local, regional, and national biohazard regulations. Do not use product if packaging is damaged, leaking, or past the expiration date.

Symbols



Catalog Number



Lot Number



Expiration Date



Upper Limit of Temperature



Caution



For In Vitro Diagnostic Use



Negative Control



Instructions For Use



Manufacturer