

BABPOS Babesia Control 1E5 cp/mL Instructions for Use

| Product Overview | |
|---------------------|----------------------------------|
| Name | Babesia Control 1E5 cp/mL |
| Part Number | BABPOS |
| Matrix | Stabilized Blood Dilution Matrix |
| Analyte | <i>Babesia microti</i> |
| Fill Volume | 1.0mL |
| Number of vials | 15 |
| Storage Temperature | -20°C or below |
| Regulatory Status | For In Vitro Diagnostic Use |

Product Description

The Babesia Control 1E5 cp/mL contains whole, intact *Babesia microti*. This control is designed to evaluate the full molecular diagnostic workflow, including nucleic acid extraction, amplification, and detection. Each lot is formulated in a proprietary matrix containing preservatives and tested using digital PCR quantification, ensuring lot-to-lot consistency. The product is non-infectious, stable under recommended storage conditions, and suitable for use as a daily run control in a laboratory setting.

Intended Use

The Babesia Control 1E5 cp/mL is an external quality control intended for use with molecular diagnostic assays for the detection of *Babesia microti* DNA. This control is designed to evaluate assay performance, including test precision, lot-to-lot consistency, limit of detection, and operator technique. Routine use of the control allows laboratories to monitor the accuracy and reliability of their molecular workflow.

Principles of the Procedure

The Babesia Control 1E5 cp/mL contains whole *Babesia microti* organism formulated in a stabilized blood dilution matrix with preservatives. The organism is structurally intact, allowing the control to be processed in parallel with patient specimens to assess the entire molecular diagnostic workflow, including nucleic acid extraction, amplification, and detection. This control 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 establishing expected performance ranges for their specific assay system. The Babesia Control 1E5 cp/mL is not intended to replace assay-specific internal or external controls provided by test kit manufacturers.

The control can also be used in analytical validation studies, such as limit of detection, linearity, or precision assessments. It is suitable for dilution using the FWDX Stabilized Blood Dilution Matrix (SBNEG).

Storage and Handling

The Babesia Control 1E5 cp/mL should be stored at -20°C or below. Thaw Babesia Control 1E5 cp/mL at room temperature and vortex and centrifuge briefly prior to use. Once thawed, Babesia Control 1E5 cp/mL 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 Babesia Control 1E5 cp/mL 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.

BABPOS Babesia Control 1E5 cp/mL Instructions for Use

Warnings and Precautions

The Babesia Control 1E5 cp/mL contains the whole organism. The product should be handled as potentially biohazardous. Always use universal precautions when handling the control 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



Biological Risks



For In Vitro Diagnostic Use



Positive Control



Instructions For Use



Manufacturer