



# ONGOING PERFORMANCE MONITORING FOR ROUTINE PATIENT TESTING

## HIGHLIGHTS

- + **WHOLE ORGANISM:** FULL PROCESS QC FOR MOLECULAR BABESIA ASSAYS
- + **PATIENT-LIKE MATRIX:** FORMULATED IN HUMAN WHOLE BLOOD WITH CRYOPROTECTANT
- + **LOW-POSITIVE CONTROLS:** TRULY CHALLENGE ASSAY PERFORMANCE AT CRITICAL DECISION POINTS
- + **LONG SHELF LIFE:** MINIMUM 2-YEAR STABILITY AT FROZEN TEMPERATURES
- + **LOT-TO-LOT CONSISTENCY:** MANUFACTURED UNDER cGMP AND ISO 13485 CONDITIONS

ACCURUN Babesia Positive Molecular Control Kit (2020-0155) is developed to meet the needs of growing usage of molecular PCR assays for Babesia detection. The product is designed as a ready-to-use quality control solution to measure day-to-day performance of Babesia molecular assays. Each kit contains whole organism positive materials, negative diluent and lysis buffer. The materials are formulated for use with in vitro diagnostic molecular test methods that detect *Babesia microti*.

Product Description	Target Strain	Material Number	Pack Size	Concentration Target
ACCURUN Babesia Positive Molecular Control Kit	<i>Babesia microti</i> full genome	2020-0155	<ul style="list-style-type: none"> <li>Positive control (2020-0157): 5 x 2.0mL vials</li> <li>Negative diluent (2020-0156): 5 x 4.0mL vials</li> <li>Lysis buffer (2020-0158): 5 x 2.0mL vials</li> </ul>	~250-300 organisms/mL (measured by ddPCR)

\*See Package Insert for instructions for use.

For In Vitro Diagnostic Use.

## LGC CDx QUALITY MEASUREMENT TOOLS FOR TICK-BORNE DISEASE

Type	LGC CDx Solution
Validation and Qualification Materials	<ul style="list-style-type: none"> <li>Babesia Antibody Positive Plasma</li> <li>AccuSet Babesia Performance Panel (serology)</li> <li>AccuSet Lyme Performance Panel</li> </ul>
Quality Control	<ul style="list-style-type: none"> <li>ACCURUN Babesia Positive Molecular Control Kit</li> <li>ACCURUN® 132 Lyme IgM Positive Control</li> <li>ACCURUN® 130 Lyme IgG Positive Control</li> <li>ACCURUN® 810 Multi-Marker Serology Negative Control</li> </ul>
Lyme Disease Antibody Positive Plasma	<ul style="list-style-type: none"> <li>Lyme Disease Total Antibody Positive Plasma</li> <li>Lyme Disease IgM Antibody Positive Plasma</li> <li>Lyme Disease IgG Antibody Positive Plasma</li> </ul>

## RELATED INFORMATION

LGC CDx - Quality Control Solutions for Blood-borne Markers [▶](#)

ACCURUN and AccuPlex Catalog [▶](#)

Disease State Materials and Panel Catalog [▶](#)

Custom Capabilities [▶](#)