

PRODUCT INFORMATION

Product SKU	BORRC
Product Name	Borrelia Run Control
Kit Lot Number	20061602
Source Material	<i>Borrelia burgdorferi</i>
Date of Expiration	2021-12-31
Base Matrix	Synthetic Matrix
Preservative	ProClin® 300
Fill Volume	1.0 mL
Storage Temperature	-20°C or Below
Regulatory Status	CE-IVD
Testing Platform	In-House Borrelia Assay

This is an unassayed control and does not have assigned analyte values. The end user is responsible for determining the value of the control. This quality control material should be used in accordance with local, state, and/or federal regulations or accreditation requirements.

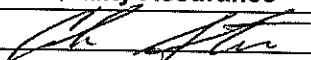
As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols.

TESTING DATA

Lot Number	Product Description	Target Concentration	Testing Results (Comparison of Target Value Against Reference Standard)	Quantity
20061602	Borrelia Run Control	20,000 cp/mL	Pass	5 Vials

Bioburden Testing Results	
Acceptance Criteria: Less than 10 CFU/mL	Pass

APPROVAL

Quality Assurance	Date
	13 Nov 20

Manufactured By: Exact Diagnostics, 3400 Camp Bowie Blvd. CBH-214, Fort Worth, Texas 76107
For assistance and reordering, contact Exact Diagnostics at 817.989.9262