

EDX Borrelia Run Control Summary	
Catalog Number	BORRC
Analyte	<i>Borrelia burgdorferi</i>
Matrix	Synthetic Matrix
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	1.0mL
Number of Vials Per Kit	5 Vials
Number of Uses	Multiple Use
Shelf Life	18 Months from Date of Manufacture
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

INTENDED USE:

The EDX Borrelia Run Control is an external quality control, intended to be used with *Borrelia burgdorferi* assays to monitor the performance of that given assay. The control is used to monitor the presence of *Borrelia burgdorferi* DNA. Routine use of EDX Borrelia Run Control allows laboratories to evaluate the day-to-day and lot-to-lot variation of their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

The EDX Borrelia Run Control contains whole, intact organisms. The control is intended to test the entire process of a molecular assay including extraction, detection, and amplification.

The EDX Borrelia Run Control is value assigned using digital droplet PCR. EDX Borrelia Run Control is formulated in Synthetic Matrix, which contains preservatives.

PROCEDURE:

The EDX Borrelia Run Control requires an extraction step. The control must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction technique.

The EDX Borrelia Run Control is an unassayed control and does not have assigned values. The control is not a substitute for the manufacturer's kit controls provided with the assay. EDX Borrelia Run Control is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations. Expected results utilizing EDX Borrelia Run Control must be established by the end user for their specific assay.

STORAGE AND HANDLING:

The EDX Borrelia Run Control should be stored at -20°C or below.

Thaw EDX Borrelia Run Control at room temperature and vortex briefly prior to use.

Once thawed, EDX Borrelia Run Control 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 dilute.

Do not use EDX Borrelia Run Control beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX Borrelia Run Control should be considered biohazardous. Universal precautions and proper disposal should be practiced¹. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.

Discard product if packaging is damaged or leaking. Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution. Dispose of all materials and liquids used in the procedure as if they contain pathogenic agents.

REFERENCES:

¹ Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee, 2007 Guideline for Isolation Precautions: Preventing Transmission

SYMBOL REFERENCES:



Catalog Number



Lot Number



For In Vitro Diagnostic Use



Biological Risks



Expiration Date



Upper Limit of Temperature



Manufacturer



Caution



Consult Instructions for Use



Positive Control



European Mark of Conformity



Authorized Representative



Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands



Exact Diagnostics LLC
3400 Camp Bowie Blvd CBH-214
Fort Worth Texas 76107
United States