

Exact Diagnostics Synthetic Negative Run Control Summary	
Catalog Number	NEGSYN
Matrix	Synthetic Matrix
Storage	-20°C or Below until Expiration Date 5 Days at 2-8°C
Shelf Life	24 Months from Manufacture Date
Number of Freeze Thaw Cycles	4
Number of Vials Per Kit	5 Vials
Fill Volume	1.0 mL per Vial
Regulatory Status	In Vitro Diagnostic Use

INTENDED USE:

The EDX Synthetic Negative Run Control is a negative run control for various molecular assays. It is used to monitor the absence of *Anaplasma phagocytophilum*, *Babesia microti*, *Bartonella quintana*, *Borrelia burgdorferi*, *Ehrlichia chaffeensis*, Enterovirus (EV) Coxsackievirus A9, Herpes Simplex Virus-1 (HSV-1), Herpes Simplex Virus-2 (HSV-2), and Varicella Zoster Virus (VZV) in molecular assays. Routine use of the EDX Synthetic Negative Run Control allows laboratories to evaluate their molecular assay and test for operator proficiency.

This product may also be utilized for dilution or spike-in purposes.

SUMMARY AND PRINCIPLE:

The EDX Synthetic Negative Run Control is an external quality control to be used with molecular assays to monitor their intra- and inter-run performance. Routine use of external quality controls allows laboratories to capture run-to-run, day-to-day, instrument-to-instrument, operator-to-operator and lot-to-lot variations of their molecular assays. External quality controls can also be used to train laboratory operators and evaluate proficiency.

This product may also be used to dilute or spike-in positive specimens or analyte-containing materials for purposes such as assay validation and verification.

PRODUCT DESCRIPTION:

The EDX Synthetic Negative Run Control is a formulated synthetic matrix intended to test the entire process of a molecular assay, including extraction, amplification and detection.

This product is non-reactive for *Anaplasma phagocytophilum* DNA, *Babesia microti* DNA, *Bartonella quintana* DNA, *Borrelia burgdorferi* DNA, *Ehrlichia chaffeensis* DNA, Enterovirus (EV) Coxsackievirus A9 RNA, Herpes Simplex Virus-1 (HSV-1) DNA, Herpes Simplex Virus-2 (HSV-2) DNA, and Varicella Zoster Virus (VZV) DNA.

PROCEDURE:

The EDX Synthetic Negative Run Control should be treated in the same manner as patient specimens and tested according to the assay manufacturer's or testing laboratory's instructions and recommendations. Also follow the manufacturer's or testing laboratory's extraction recommendations.

If during the use of this device or as a result of its use, a serious incident occurs, please report it to Bio-Rad Laboratories and to your national health authority, as required.

STORAGE AND STABILITY:

The EDX Synthetic Negative Run Control will be stable until the expiration date when stored at -20°C or below.

Completely thaw the control at room temperature, then vortex briefly before use.

Once thawed, this product is stable for 5 days when stored at 2-8°C. The product can be frozen and reused a maximum of four (4) times. After the fourth freeze-thaw, any remaining materials should be discarded.

LIMITATIONS:

1. Do not use this product beyond the expiration date.
2. This product is for Laboratory/Professional use only.
3. This product is an unassayed control and does not have assigned values.
4. It is the responsibility of each laboratory to implement its own quality assurance program to determine the suitability of this product for its particular use and to establish its own target ranges and guidelines for interpretation of results obtained with this product.

SAFETY PRECAUTIONS:

1. Do not pipette by mouth. Do not smoke, eat, or drink in areas where specimens are handled.
2. Handle and dispose of all specimens, controls and materials used in testing as though they contain infectious agents.
3. Discard product if packaging is damaged or leaking. Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution.
4. Dispose of any discarded materials in accordance with the requirements of the local waste management authorities. In the event of damage to packaging, contact the local Bio-Rad Laboratories Sales Office or Bio-Rad Laboratories Technical Service.



WARNINGS AND PRECAUTIONS:

Universal precautions and proper disposal should be practiced¹. It is recommended that this product be handled in accordance with Biosafety Level 2 practices as described in the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH)², Biosafety in Microbiological and Biomedical Laboratories, or other equivalent guidelines.^{3,4}

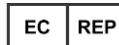
A Safety Data Sheet (SDS) is available for professional users on www.bio-rad.com.

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
2. U.S. Department of Health and Human Services Public Health Service Centers for Disease Control and Prevention and National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories- Sixth Edition HHS Publication (CDC) 300859: June 2020.
3. Clinical and Laboratory Standards Institute (CLSI). Protection of laboratory workers from Occupational Acquired infections; Approved Guideline – Third Edition. CLSI document M29-A3 (ISBN 1-56238-567-4), Clinical and Laboratory Standards Institute Wayne, Pennsylvania 19087-1898, USA 2005.
4. Clinical and Laboratory Standards Institute (CLSI) Clinical Laboratory Waste Management; Approved Guideline – Third Edition. CLSI document GP05-A3 (ISBN 1-56238-744-8), CLSI Wayne, Pennsylvania 19087, USA 2011



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