Exact Diagnostics Bulk CSF Negative

REF 12019432

IVD

Exact Diagnostics Bulk CSF Negative Summary	
Catalog Number	12019432
Non-Reactive Analytes	*Anaplasma phagocytophilum* *Babesia microti* *Bartonella quintana* *Borrelia burgdorferi* *Ehrlichia chaffeensis* Coxsackievirus A9 Enterovirus (EV) Herpes Simplex Virus-1 (HSV-1) Herpes Simplex Virus-2 (HSV-2) Varicella Zoster Virus (VZV)
Matrix	Synthetic CSF Matrix
Storage	-20°C or Below
Shelf Life	36 Months from Manufacture Date
Number of Freeze-Thaw Cycles	4
Open-Vial Stability	5 Days at 2-8°C
Quantity	1 Bottle
Fill Volume	50 mL
Regulatory Status	For In Vitro Diagnostic Use

INTENDED USE:

The Exact Diagnostics Bulk CSF Negative is an independent external quality run control intended to monitor the absence of *Anaplasma phagocytophilum*, *Babesia microti*, *Bartonella quintana*, *Borrelia burgdorferi*, *Ehrlichia chaffeensis*, Enterovirus (EV), Herpes Simplex Virus-1 (HSV-1), Herpes Simplex Virus-2 (HSV-2), and Varicella Zoster Virus (VZV) in various molecular assays.

This product can be used to detect errors in laboratory testing procedures, including potential contamination events.

This product also allows laboratories to evaluate their molecular assay and test for operator proficiency.

This product may be utilized to dilute cerebrospinal fluid (CSF) specimens or to spike-in specimens that are in matrices other than CSF.

SUMMARY AND PRINCIPLE:

The Exact Diagnostic Bulk CSF Negative 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 as well as analyte-containing materials for purposes such as validation and verification of molecular assays.

PRODUCT DESCRIPTION:

The Exact Diagnostic Bulk CSF Negative is a synthetically formulated CSF (cerebrospinal fluid) matrix intended to simulate negative patient specimens for the purpose of testing 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 RNA, Herpes Simplex Virus-1 DNA, Herpes Simplex Virus-2 DNA and Varicella Zoster Virus DNA.

PROCEDURE:

The Exact Diagnostics Bulk CSF Negative 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 competent authority, as required.

STORAGE AND STABILITY:

The Exact Diagnostics Bulk CSF Negative will be stable until the expiration date when stored at -20°C or below.

Completely thaw the product at room temperature, then mix by inversion before use.

If desired, this product may be aliquoted into individual vials (not provided by Exact Diagnostics) upon first use. Immediately freeze the aliquots at -20°C or below.

Once thawed, this product is stable for 5 days when stored at 2-8°C.

The product can also be frozen and reused a maximum of four (4) times. After the fourth freeze-thaw, any unused materials should be discarded immediately or after 5 days if stored at 2-8°C.

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 practiced[1]. 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

UNITED STATES Exact Diagnostics
100 South Jones Street, Suite 100,
Fort Worth, Texas 76104

Bio-Rad Laboratories, Inc.

Clinical Diagnostics Group

9500 Jeronimo Road
Irvine, California 92618
(800) 854-6737
FAX (949) 598-1550
bio-rad.com/qualitycontrol

Technical Service:
(800) 854-6737

United States Customer Service: *4000 Alfred Nobel Drive • Hercules, California 94547 • Phone (510) 724-7000 • FAX (510) 741-6373*
Also in: South Granville, Australia, *Phone +61 (2) 9914 2800 • Fax +61 (2) 9914 2888* ***Vienna, Austria,*** *Phone +43 (0) 1 877 89 01 9 • Fax +43 (0) 1 876 56 29* ***Temse, Belgium,*** *Phone +32 (0) 3 710 53 00 • Fax +32 (0) 3 710 53 01* ***São Paulo, Brazil,*** *Phone +55 11 3065-7550* ***Montréal, Canada,*** *Phone +1 514 334 4372 • Fax +1 514 334 0872* ***Shanghai, China,*** *Phone +86 21 6169 8500 • Fax +86 21 6169 8599* ***Prague, Czech Republic,*** *Phone +420 241 431 660* ***Symbion Science Park, Denmark,*** *Phone +45 44 52 10 00 • Fax +45 44 52 10 01* ***Helsinki, Finland,*** *Phone +358 9 804 22 00* ***Marnes-la-Coquette, France,*** *Phone +33 (0)1 47 95 60 00 • Fax +33 (0)1 47 41 91 33* ***Munich, Germany,*** *Phone +49 (0) 89 31884 393 • Fax +49 (0) 89 31884 136* ***Athens, Greece,*** *Phone +30 210 7774396 • Fax +30 210 7774376* ***Quarry Bay, Hong Kong,*** *Phone +85 2 2789 3300 • Fax +85 2 2789 1257* ***Budapest, Hungary,*** *Phone +36 1 459 6190 • Fax +36 1 459 6101* ***Haryana, India,*** *Phone +91 124 4029300 • Fax +91 124 2398115* ***Rishon Le Zion, Israel,*** *Phone +972 03 963 6025 • Fax +972 03 951 4129* ***Milan, Italy,*** *Phone +39 024 94 86 600 • Fax +39 02 21609399* ***Tokyo, Japan,*** *Phone +81 3 6361 7070 • Fax +81 3 5463 8481* ***Seoul, Korea,*** *Phone +82 080 007 7373 • Fax +82 (2) 3472 7003* ***Mexico D.F., Mexico,*** *Phone +52 (55) 5488 7670 • Fax +52 (55) 1107 7246* ***Veenendaal, The Netherlands,*** *Phone +31 (0) 318 540 666 • Fax +31 (0) 318 542 216* ***Auckland, New Zealand,*** *Phone +64 (9) 415 2280 • Fax +64 (9) 415 2284* ***Oslo, Norway,*** *Phone +47 23 38 41 30 • Fax +47 23 38 41 39* ***Warsaw, Poland,*** *Phone +48 22 331 99 99 • Fax +48 22 331 99 88* ***Amadora, Portugal,*** *Phone +351 21 47 27 700 • Fax +351 21 472 7777* ***Moscow, Russia,*** *Phone +7 (495) 721-14-04 • Fax +7 (495) 721-14-12* ***Singapore,*** *Phone +65 6415 3170 • Fax +65 6415 3189* ***Johannesburg, South Africa,*** *Phone +27 11 442 8508 • Fax +27 11 442 8525* ***Madrid, Spain,*** *Phone + 34 91 490 6580 • Fax +34 91 590 5211* ***Sundbyberg, Sweden,*** *Phone +46 844 98053 • Fax +46 8 55 51 27 80* ***Cressier, Switzerland,*** *Phone +41 (0) 61 717 9555 • Fax +41 (0) 61 717 9550* ***Taipei, Taiwan,*** *Phone +886 (2) 2578-7189 • Fax +886 (2) 2578-6890* ***Bangkok, Thailand,*** *Phone (662) 651 8311 • Fax (662) 651 8312* ***Hertfordshire, United Kingdom,*** *Phone +44 (0) 1923 471301 • Fax +44 (0) 1923 471340*

10/22