

EDX Negative Run Control Summary

Catalog Number	NEG000
Matrix	True EDTA Plasma
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	36 Months from Date of Manufacture
Precautions	Biological Risks
Regulatory Status	For In Vitro Diagnostic Use

INTENDED USE:

The EDX Negative Run Control is a run control for various molecular assays. The control is used to monitor the absence of Adenovirus, BKV, CMV, EBV, HBV, HCV, HHV-6, HIV-1/2, HSV-1/2, JC Virus, VZV, and Zika Virus in molecular assays. EDX Negative Run Control consists of True EDTA Plasma, allowing laboratories to evaluate their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

The EDX Negative Run Control is formulated in True EDTA Plasma that is non-reactive for Adenovirus DNA, BKV DNA, CMV DNA, EBV DNA, HBV DNA, HCV RNA, HHV-6 DNA, HIV-1/2 RNA, HSV-1/2 DNA, JC Virus DNA, VZV DNA, and Zika Virus RNA, HBsAg and antibodies for HIV-1/2, and HCV.

PROCEDURE:

The EDX Negative 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. EDX Negative Run Control is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations.

STORAGE AND HANDLING:

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

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

Once thawed, EDX Negative Run Control is stable for 5 days 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 after one use. Do not reuse. Do not dilute.

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

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:

The EDX Negative Run Control has been tested to be negative for Adenovirus DNA, BKV DNA, CMV DNA, EBV DNA, HBV DNA, HCV RNA, HHV-6 DNA, HIV-1/2 RNA, HSV-1/2 DNA, JC Virus DNA, VZV DNA, and Zika Virus RNA, HBsAg and antibodies for HIV-1/2 and HCV but 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



Expiration Date



Upper Limit of Temperature



Manufacturer



Caution



Consult Instructions for Use



Negative Control



European Mark of Conformity



Authorized Representative



Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands



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