

EDX Bulk Negative Summary	
Catalog Number	NEG050
Matrix	True EDTA Plasma
Preservative	ProClin® 300
Storage	-20°C or Below
Fill Volume	50mL
Quantity	1 Bottle
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 Bulk Negative is a negative 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, HSV-1/2, JC Virus, VZV, and Zika Virus in molecular assays. EDX Bulk Negative consists of True EDTA Plasma, allowing laboratories to evaluate their molecular assay and test for operator proficiency.

PRODUCT DESCRIPTION:

The EDX Bulk Negative 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 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 Bulk Negative is True EDTA Plasma and is provided to customers as a bulk 50 mL container. The customer is responsible for aliquoting the material into individual vials (not provided by Exact Diagnostics) upon first use. Immediately freeze aliquots at -20°C or below. Once thawed, the material can be stored at 2-8°C for up to 5 days.

The EDX Bulk Negative requires an extraction step. The product must be treated in a similar manner to other tested samples. This allows the operator to assess their extraction technique. EDX Bulk Negative is to be tested according to the assay manufacturer's or testing laboratory's instructions and recommendations.

STORAGE AND HANDLING:

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

Thaw EDX Bulk Negative at room temperature prior to use.

Once thawed, EDX Bulk Negative 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.

Do not use EDX Bulk Negative beyond the expiration date.

LIMITATIONS:

For In Vitro Diagnostic Use.

WARNINGS AND PRECAUTIONS:












The EDX Bulk Negative has been tested to be negative Adenovirus DNA, BKV DNA, CMV DNA, EBV DNA, HBV DNA, HCV RNA, HHV-6 DNA, HIV-1 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.

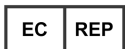
Discard product if packaging is damaged or leaking. Disinfect liquids, materials or spills with a 0.5% sodium hypochlorite solution. Dispose of all materials and liquids used in the procedure as if they contain pathogenic agents.

REFERENCES:

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

SYMBOL REFERENCES:

-  REF Catalog Number
-  LOT Lot Number
-  IVD For In Vitro Diagnostic Use
-  Expiration Date
-  Upper Limit of Temperature
-  Manufacturer
-  Caution
-  CONTROL - Negative Control
-  Consult Instructions for Use
-  European Mark of Conformity
-  EC REP Authorized Representative



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