I.E.D. Unit (Ion-Exchange Decal Unit)

Ancillary Reagent
901-IED1203/2104-062123

BIOCARE MEDICAL

Available Product Formats	
Catalog Number	**Volume**
IED1203	140 mL
IED1204	500 mL

Intended Use:
For *in vitro* Diagnostic Use
The I.E.D. Unit (Ion-Exchange Decal Unit) is intended for laboratory professional use as a decalcification system that removes calcium from bone quickly while leaving superior cellular detail. The clinical interpretation of any staining or its absence should be complemented by morphological studies and proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

Summary and Explanation:
The I.E.D. Unit incorporates a strong cation ion-exchange resin in a weak acid solution to remove calcium ions from bone, while replacing them with hydrogen ions. The ion-exchange process does not require strong concentrated acid solutions as in traditional decalcification methods; so delicate cellular structures remain intact. This can be very important for performing staining procedures such as immunohistochemistry (IHC), especially for bone marrow. Over decalcification can destroy morphology that may affect the final staining quality and intensity.

Materials and Methods:
Reagents Provided:

Kit Catalog No.	Component Description	Quantity x Volume
IED1203	I.E.D. Unit (Ion-Exchange Decal Unit)	1 x 140 mL
IED1204	I.E.D. Unit (Ion-Exchange Decal Unit)	1 x 500 mL

* Refer to the Biocare Medical website located at http://biocare.net for information regarding catalog numbers and ordering.

BRR1203 is packaged in a 250mL container.
BRR1204 is packaged in a 1000mL container.

The number of uses for this product will depend on specimen size and I.E.D. Unit size.

Reconstitution, Mixing, Dilution, Titration:
The I.E.D. Unit is ready to use. No reconstitution, mixing, dilution, or titration is required.

Supplied As:
Acidic solution and beads. See Safety Data Sheet for additional details.

Storage and Stability:
Store at room temperature (20-25°C). The product is stable to the expiration date printed on the vial label when stored under these conditions. Do not use after expiration date. Storage under any condition other than those specified must be verified.

Specimen Preparation:
Tissues fixed in formalin are suitable for use prior to paraffin embedding. Osseous tissues should be decalcified prior to tissue processing to facilitate tissue cutting and prevent damage to microtome blades.[1,2]

Properly fixed and embedded tissues expressing the specified antigen target should be stored in a cool place. The Clinical Laboratory Improvement Act (CLIA) of 1988 requires in 42 CFR §493.1259(b) that "The laboratory must retain stained slides at least ten years from the date of examination and retain specimen blocks at least two years from the date of examination."[3]

Warning and Precautions:
1. Do not heat this solution beyond 37°C.
2. Handle materials of human or animal origin as potentially biohazardous and dispose of such materials with proper precautions. In the event of exposure, follow the health directives of the responsible authorities where used.[4,5]
3. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come into contact with sensitive areas, wash with copious amounts of water.[6]
4. Microbial contamination of reagents may interfere with subsequent specimen analysis.
5. Do not use reagent after the expiration date printed on the vial.
6. Follow local and/or state authority requirements for method of disposal.
7. The SDS is available upon request and is located at http://biocare.net.

This I.E.D. Unit contains components classified as indicated in the table below in accordance with Regulation (EC) No. 1272/2008.

Hazard	Code	Hazard Statement
	H314 H318	Causes severe skin burns and eye damage. Causes serious eye damage.
	H335 H302	May cause respiratory irritation. Harmful if swallowed.
N/A	H227	Combustible liquid.

Instructions for Use:
1. Bone marrow cores must be fixed approximately 4 to 24 hours, and then washed 5 minutes in running water.
2. Place bone marrow core biopsy in the I.E.D. unit solution for 2-3 hours. If possible, gentle agitation or low heat (37°C) on an orbital shaker will speed up the process. When decalcification is complete, wash tissue for 5 minutes in running tap water.
3. Process in the usual manner.

Technical Note:
1. All cation exchange resins will have color changes, and the end stage is usually reddish brown. This is a normal color variation. The cosmetic color of resins is not indicative of the resin's quality or activity. It has to do with the chemical process and how the natural chromophores in the resin line up. Thus, the color can vary from light tan to reddish brown, or even grey to black.

Quality Control:
Refer to CLSI Quality Standards for Design and Implementation of Immunohistochemistry Assays; Approved Guideline-Second edition (I/LA28-A2) CLSI Wayne, PA USA (www.clsi.org). 2011

Troubleshooting:
Follow the antibody specific protocol recommendations according to the data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.

Limitations:
General Limitations:
1. For *in vitro* diagnostic (IVD) Use
2. This product is for professional use only.
3. For use by physician prescription only. (Rx Only)

Product Specific Limitations:
Do not heat this solution beyond 37°C.

Biocare Medical
60 Berry Drive
Pacheco, CA 94553
USA

IVD

References:

1. Kiernan JA. Histological and Histochemical Methods: Theory and Practice. New York: Pergamon Press 1981.
2. Sheehan DC and Hrapchak BB. Theory and Practice of Histotechnology. St. Louis: C.V. Mosby Co. 1980.
3. Clinical Laboratory Improvement Amendments of 1988: Final Rule, 57 FR 7163, February 28, 1992.
4. Occupational Safety and Health Standards: Occupational exposure to hazardous chemicals in laboratories. (29 CFR Part 1910.1450). Fed. Register.
5. Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.
6. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.

Biocare Medical
60 Berry Drive
Pacheco, CA 94553
USA

IVD

Tel: 800-799-9499 | www.biocare.net | Fax: 925-603-8080