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Instructions for Use

ENVIRENE™

A Xylene Substitute	
Cat. no. CE016	16 ounce
Cat. no. CE128	1 gallon

INTENDED USE

Hardy Diagnostics Envirene™ is a safe alternative to xylene for use in tissue processing and staining procedures where xylene or carbol xylene is required.

SUMMARY

Envirene™ provides a greaseless and virtually odorless alternative to xylene. Envirene™ has an evaporation rate similar to xylene, thus mounting media may dry readily.

Toxicological studies with humans indicate that Envirene™ neither irritates nor sensitizes normal skin. Most plastics are not attacked by it, and internal parts of automatic tissue processors and stainers are safe from its selective solvent power.

REAGENT FORMULA

Envirene™ is a 100% blend of aliphatic hydrocarbons.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual Universal Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

Warning! Staining solutions are hazardous in nature. Wear appropriate safety apparel when working with staining solutions. It is recommended that staining procedures be performed under a hood with adequate ventilation.

Warning! Product is non-flammable but combustible. Keep away from heat and open flame. Avoid prolonged and repeated contact with skin. Avoid contact with eyes, skin and mucous membranes. If contact occurs, flush immediately with large amounts of water.

Storage: Upon receipt store at 15-30ºC. Products should not be used if there are any signs of contamination, deterioration, or if the expiration date has passed. Do not expose to excessive heat or moisture. Keep container closed when not in use.

PROCEDURE

Specimen Collection: Consult listed references for information on specimen collection.[1-3,5]

Reagent Preparation: Envirene™ is provided ready to use; no further processing is required.

Tissue Processing: For most tissue processing applications, Envirene™ may be used as xylene is used. All common dehydrants may be used, except for methanol. Denatured alcohol containing methanol may be used. If a tissue sample contains much fat, or brain tissue is to be processed, three stations of Envirene™ are recommended. When purging fluid transfer processors, xylene is recommended, but Envirene™ may be used as long as the purge cycle is run twice.

The use of anhydrous alcohol is necessary for the final clearing of slides. To adequately expose slides to anhydrous alcohol requires the traditional procedure for dehydration of three changes of anhydrous alcohol at one minute each change. Avoid "dipping", as this method will not remove water from the slide sufficiently. If Envirene™ becomes cloudy after the addition of the slides from 100% alcohol, return the slides to 100% alcohol and replace the Envirene™ with fresh stock. Hazy images indicate dehydration was inadequate. Protect alcohol from absorbing moisture from the air, especially in humid areas. After dehydration, slides should be exposed to three changes of Envirene™ of one minute each to remove all traces of alcohol from the tissue or cells. Inadequate clearing may occur if the slides are not exposed to the Envirene™ changes for a sufficient time, or if the clearant contains alcohol, seen especially in the last station. To keep the last station pure, the stations must be rotated frequently.

If deparaffinization is performed, at least three changes of Envirene™ at three minutes each with agitation are required. If blotchy or unusually pale staining occurs, it indicates deparaffinization was not adequate.

Parasitology Staining: When performing a trichrome or iron hematoxylin stain, use Envirene™ as a substitute for xylene and carbol xylene. It is recommended that at least three stations of 100% ethyl alcohol be used (Cat. no. ET107) at 3-5 minutes each followed by two stations of Envirene™ at 3-5 minutes each. If any cloudiness is observed in any station, replace immediately with fresh reagents.

Coverslipping: Because of the unique solvent action of Envirene™, the choice of mounting media is limited to toluene based products such as Cytoseal™ (Stephens Scientific, our Cat. no. 83114), Shandon's New Mounting Medium, Refrax Mounting Medium (Anatech, Ltd.), Coverbond (American S/P), Permount (Fisher Scientific), and Richard-Allan Mounting Medium.

For best results when coverslipping, spread a small amount of mounting medium along one edge of the coverslip, drain the slide for a few seconds, and invert the slide over the coverslip. Toluene or xylene may be used to remove coverslips that have set up.

LIMITATIONS

Note: Because of the unique action of the solvent in Envirene™, the choice of mounting media is limited. Organic or toluene based mounting media are required for use with this product. Water based mounting media should not be used. See previous section.

Chemically, Envirene™ is an aliphatic hydrocarbon (carbon atoms in a chain structure). As a chemical group, aliphatic

hydrocarbons are totally immiscible with water, even in trace amounts. Thus, clearing problems can occur if slides are not adequately exposed to anhydrous alcohol before exposing the slide to Envirene™ xylene replacement.

All staining dishes should be covered to prevent evaporation of reagents (screw cap Coplin jars or glass lids).

All solutions need to be changed periodically to prevent carry-over and/or watering down of the solutions. Carry-over of the solutions may cause lack of contrast and/or cloudiness on the slide.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as glass slides, microscopes, coverslips, Coplin jars, anhydrous alcohol, pipets, and mounting fluids, etc., are not provided.

QUALITY CONTROL

User Quality Control: It is recommended that each new lot of reagent be tested with known positive and negative controls and retested each week of use thereafter.[1,4,5]

It is recommended that positive controls be run in parallel with patient specimens and that results from any staining procedure be reported only if positive control smears are acceptable.

The microscope should be calibrated (within the last 12 months), and the objectives and oculars used for the calibration procedure should be in place on the microscope when objects are measured.[4]

REFERENCES

1. Anderson, N.L., et al. *Cumitech 3B; Quality Systems in the Clinical Microbiology Laboratory*, Coordinating ed., A.S. Weissfeld. American Society for Microbiology, Washington, D.C.

2. Jorgensen., et al. *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, D.C.

3. Tille, P., et al. *Bailey and Scott's Diagnostic Microbiology*, C.V. Mosby Company, St. Louis, MO.

4. Garcia, L.S. and D.A. Bruckner. 1993. *Diagnostic Medical Parasitology*, 2nd ed. American Society for Microbiology, Washington, D.C.

5. Isenberg, H.D. *Clinical Microbiology Procedures Handbook*, Vol. I, II & III. American Society for Microbiology, Washington, D.C.

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The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

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