

Ultra High Def™ Hematoxylin Instructions for Use

Catalog No.	ACR-027
Effective Date:	12/04/2017, IFU-154 Rev A
Intended Use	For In Vitro Diagnostic Use
Product Description	Hematoxylin is a histological staining reagent suitable for visualization of nuclei in tissue sections. Ultra High Def™ Hematoxylin, is designed for optimal performance when used together with automated IHC stainers
Summary and Explanation	Ultra High Def™ Hematoxylin is intended for use in the histologic demonstration of nuclear staining. This staining technique is used to make the critical distinction between a normal nucleus and an abnormal one.
Format	100 mL-Ready to use solution
Storage	Room Temperature. Do not use beyond the expiration date stated on the label.
Preparation of Reagent	Ultra High Def™ Hematoxylin is ready to use and does not require any preparation.
Protocol Recommendations	<ol style="list-style-type: none"> 1. After IHC procedure is completed, including chromogen- use Ultra High Def™ Hematoxylin for the counterstain by applying enough Hematoxylin to completely cover the tissue sections and incubate for 1-3 minutes depending on desired intensity. 2. Rinse with Tap or DI water for 30 seconds to 1 minute until water runs clear. 3. Incubate with bluing reagent for 30 seconds 4. Wash with Tap or DI water for 30 seconds to 1 minute 5. Follow suggested dehydration and mounting procedures based on chromogen used
Quality Control	Refer to CLSI Quality Standards for Design and Implementation of Immunohistochemistry Assay; Approved Guideline-Second edition (I/LA28-A2). CLSI Wayne, PA, USA (www.clsi.org) 2011
Troubleshooting	Contact StatLab Medical Products Technical Support at (800) 442-3573 or email ihctech@statlab.com
Warranty	There are no warranties, expressed or implied, which extend beyond this description. StatLab Medical Products is not liable for property damage, personal injury, or economic loss caused by the product.
Performance Characteristics	<p>The protocols for a specific application can vary. These include but are not limited to: Fixation, heat-retrieval method, incubation times, tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times and titers listed are not applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based on exclusive use of StatLab Medical Products. Ultimately, it is the sole responsibility of the investigator to determine optimal conditions. These products are tools that can be used for interpretation of morphological findings in conjunction with other diagnostic tests and pertinent clinical data by a qualified pathologist.</p>
Precautions:	<ol style="list-style-type: none"> 1. Wear disposable gloves when handling reagents 2. 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 in contact with sensitive areas, wash with copious amounts of water. 3. Microbial contamination of reagents may result in an increase in nonspecific staining. 4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change. 5. Do not use reagent after the expiration date printed on the label. 6. Safety Data Sheet is available upon request. 7. Consult OSHA, federal, state or local regulations for disposal of any toxic substances.

