

Tissue-Tek Genie®

User-Fillable Capsule Sealing System

REF 8610-K050

Instructions for use

For *in vitro* diagnostic use.

Intended purpose

Intended use: The Tissue-Tek Genie® User-Fillable Capsule Sealing System is designed to fill and seal Capsules with primary antibody or probe solutions by the laboratory. The sealed Capsules are used on the Tissue-Tek Genie® Advanced Staining System in a manner similar to the prefilled, Ready-to-Use primary antibody Capsules commercialized by Sakura Finetek.

This device is a non-automated accessory that assists a qualified user of the automated Tissue-Tek Genie® Advanced Staining System to qualitatively detect target proteins or nucleic acids in formalin-fixed, paraffin embedded (FFPE) specimen sections by immunohistochemistry (IHC) or chromogenic in situ hybridization (CISH) staining to aid the diagnosis of a pathological state.

Limitations

1. This product is only meant for use with the Tissue-Tek Genie Advanced Staining System.
2. Before using the user-fillable capsule sealing system read this instruction for use and the instructions provided in the operating manual of the Tissue-Tek Genie Advanced Staining System. Each capsule made with the Tissue-Tek Genie User-Fillable Capsule Sealing System can only be filled and used once. Sakura Finetek has not

validated the cleaning of these capsules and re-use with a second reagent.

3. This product has been optimized using Tissue-Tek Genie® Pro Antibody Diluent and Genemed® mRNA probes. The use of any other antibody diluent or probes should be validated by the laboratory.
4. Ensure that the rim of the Capsule is dry and free of any solution before placing the Capsule Seal on it as this may prevent the Capsule Seal from properly adhering to the Capsule.
5. Do not fill Capsule with more than 450 µL of antibody or probe solution as overfilling may prevent the Capsule Seal from properly adhering to the Capsule.
6. Sealed Capsules should be stored in Capsule Trays with the Seal-side up. Sealed Capsules in this configuration can be stored at 2-8°C for up to 1 week for immunohistochemistry (IHC) primary antibodies or in-situ hybridization (ISH) probes.
7. For optimal seal integrity, use sealing tool to seal capsules. Capsules sealed by hand are more likely to leak prior to use.
8. Improper attachment of the User-Fillable Capsule to the Reagent Dispense Area (RDA) -Tag may lead to disconnect, the loss of reagent identity, and the inability to be scanned by the Tissue-Tek Genie Advanced Staining System.

Summary and principle

The Tissue-Tek Genie User-Fillable Capsule Sealing System (REF 8610-K050) is a Kit consisting of:

- 1 Tissue-Tek Genie® User-Fillable Capsule Sealer
- 2 Tissue-Tek Genie® User-Fillable Capsule Trays
- 50 Tissue-Tek Genie® User-Fillable Capsules
- 50 Tissue-Tek Genie® User-Fillable Capsule Seals

This Kit enables laboratories to use unique antibodies or probes that are not commercialized by Sakura Finetek. Specifically, the Capsules and Seals were designed for laboratories to fill Capsules with antibody or probe solutions of their choice. The Capsules are sealed using the Tissue-Tek Genie User-Fillable Capsules and Seals along with the Tissue-Tek Genie® User-Fillable Capsule Sealing System (REF 8610-K050).

Chromogenic in-situ hybridization (CISH)

Chromogenic in situ hybridization (CISH) is an established *in vitro* diagnostic method to visualize the presence of particular DNA or RNA present within a sliced section of tissue. CISH is accomplished in two steps: 1) a labeled or hapten-tagged probe detects the target DNA or RNA for which it is developed to recognize, and 2) a chromogenic enzyme conjugates with the anti-hapten antibody to enable detection of the antibody-antigen interaction under a light microscope.

CISH demonstration for proper funneling of reagent is achieved through the sequential application of probe and kit components as follows:

- Tissue-Tek Genie® Dewax Solution (REF 8865-G001)
- Tissue-Tek Genie® Wash Buffer Solution (REF 8874-G004)
- Tissue-Tek Genie® Citrate Antigen Retrieval Solution (REF 8742-G001)
- Tissue-Tek Genie® Proteinase K (REF 9811-M100)
- Tissue-Tek Genie® CISH Probe (REF 9XXX-C010) or CISH probe, ready-to-use

- Tissue-Tek Genie® User-Fillable Capsule Sealing System (REF 8610-K050) to be filled with CISH probe
- Tissue-Tek Genie® CISH SSC Stringent Wash Buffer (REF 9810-G001)
- Tissue-Tek Genie® Protein Block (part of REF 8826-K250)
- Tissue-Tek Genie® CISH Amplifier (REF 9808-M100) (binds to the FITC labeled Tissue-Tek Genie® CISH Probe) or CISH Amplification Linker (binds to the labeled CISH probe)
- Tissue-Tek Genie® User-Fillable Cartridge (REF 9809-G006)
- Tissue-Tek Genie® Peroxidase Block (part of REF 8826-K250)
- Tissue-Tek Genie® Link (binds to the CISH Amplifier (part of REF 8826-K250)
- Tissue-Tek Genie® Poly HRP-Conjugate (binds to the Link) (part of REF 8826-K250)
- Tissue-Tek Genie® DAB (part of REF 8826-K250) (visualizes the detected protein)
- Tissue-Tek Genie® DAB Intensifier (REF 8826-K250)

Tissue-Tek Genie® Hematoxylin (REF 8830-M250) is then used to visualize the nuclei of cells. The CISH stained slide is coverslipped and the FFPE specimen section is reviewed using a light microscope.

Immunohistochemistry (IHC)

Immunohistochemistry (IHC) staining is an established *in vitro* diagnostic method to visualize the presence of particular proteins within a sliced section of tissue to study the microscopic structures of tissues, (i.e., histology). IHC staining is accomplished in two steps: 1) a primary antibody detects a particular target protein for which it is developed to recognize, and 2) a chromogenic or fluorescent enzyme conjugate with the primary antibody to enable detection of the antibody-antigen interaction. In chromogenic detection under a light microscope, an enzyme conjugated to the antibody cleaves a substrate to produce a colored precipitate at the location of the protein. In fluorescent detection, a fluorophore

conjugated to the antibody is visualized using fluorescence microscopy.

Immunohistochemistry (IHC) demonstration for proper funneling of reagent is achieved through the sequential application of antibody and kit components as follows:

- Tissue-Tek Genie® Dewax Solution (REF 8865-G001)
- Tissue-Tek Genie® Wash Buffer Solution (REF 8874-G004)
- Tissue-Tek Genie® Protein Block (part of REF 8826-K250)
- Tissue-Tek Genie® Primary Antibody (REF 8XXX-C010 or 8XXX-M250) or primary antibody, ready-to-use
- Tissue-Tek Genie® User-Fillable Capsule Sealing System (REF 8610-K050) to be filled with primary antibody or the Tissue-Tek Genie® User-Fillable Cartridge for Biomarker-Binding Reagent (REF 8622-G006) to be filled with primary antibody
- Tissue-Tek Genie® Peroxidase Block (part of REF 8826-K250)
- Tissue-Tek Genie® Link (part of REF 8826-K250)
- Tissue-Tek Genie® Poly HRP-Conjugate (part of REF 8826-K250) (binds to the Link)
- Tissue-Tek Genie® DAB (part of REF 8826-K250) (visualizes the detected protein)
- Tissue-Tek Genie® DAB Intensifier (part of REF 8826-K250)

Tissue-Tek Genie® Hematoxylin (REF 8830-M250) is then used to visualize the nuclei of cells. The slide is coverslipped and the FFPE specimen section is reviewed using a light microscope.

The Tissue-Tek Genie User-Fillable Cartridges for Biomarker-Binding Reagent (REF 8622-G006) are available for large volume antibody solutions.

Refer to the Operating Manual of the Tissue-Tek Genie Advanced Staining System for General Operating Procedures.

Expected results

Cellular Staining Pattern: N/A

Positive Tissue Control: N/A

There is no expected result for use of this accessory. As a standalone device, this product cannot be tested for sensitivity and specificity. This accessory must be used in conjunction with a primary antibody or CISH probe as well as other reagents associated with Tissue-Tek Genie® Advanced Staining System. Refer to the Instruction for Use (IFU) or Package Insert (PI) of the primary antibody or CISH probe used with this accessory for the expected patient sample results.

It is recommended to include appropriate tissue controls onto each specimen slide to help in identifying any deviation that might occur during the staining process.

the clinical interpretation of the stained tissue must be made by a qualified pathologist.

Cautions and warnings

1. For professional use only. Take reasonable precautions when handling. Wear protective gloves, clothing, and eye/face protection when handling primary antibody solutions.
2. When handling probes, use sterile handling techniques to prevent contamination from environmental nucleases. Wipe down gloved hands, surfaces, and materials with 70% alcohol solution prior to handling probes. Always use filtered pipette tips when handling probes.
3. The Capsule Sealer and Capsule Tray may contain sharp edges. Use with caution.
4. After sealing, it is recommended to invert the sealed Capsules to check for any leaks. If leaking is observed, do not use the Capsule on the Tissue-Tek Genie Advanced Staining System.
5. Use caution when attaching the sealed capsule to the RDA tag. Excessive pressure applied to the sides of the capsule can cause the seal to detach from the capsule.
6. Minimize handling of capsules between filling and use to prevent leaks.

Specimen collection and preparation for analysis

For tissue specimens, routinely processed, formalin fixed, paraffin embedded tissues are suitable for use with this product when used with Tissue-Tek Genie

reagents and a Tissue-Tek Genie Advanced Staining System (see Materials required but not supplied section). The recommended tissue fixative is 10% (v/v) neutral buffered formalin for 24-72 hours. Variable results may occur because of prolonged fixation or special processes such as decalcification of bone marrow preparations. Each section should be sliced to 3-5 μm in thickness and placed on a positively charged glass slide. Slides containing the tissue section may be baked for at least 30 minutes to overnight in a $60^{\circ}\text{C} \pm 2^{\circ}\text{C}$ oven. Slides should be stained immediately, as quality of sliced tissue sections may diminish over time.

Storage conditions

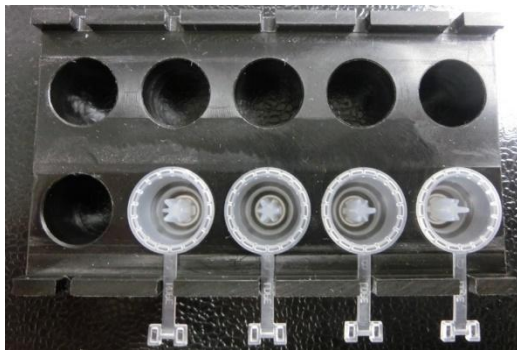
Store the Capsule Sealing System components at room temperature ($15\text{-}30^{\circ}\text{C}$) away from moisture. For date of expiration, refer to the label on the product.

Store sealed Capsules at $2\text{-}8^{\circ}\text{C}$ with the Seal-side up.

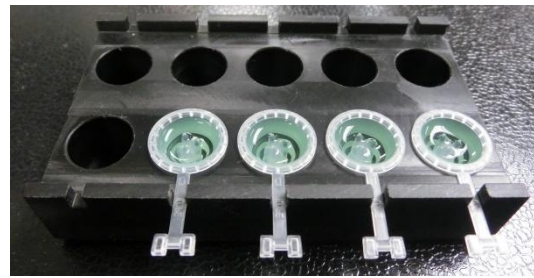
Instructions for use

Tissue-Tek Genie® User-Fillable Capsule Sealing System (8610-K050):

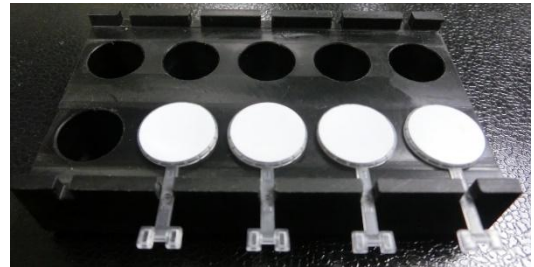
1. Print RDA-Tag Labels of the desired antibody or probe and affix to RDA-Tags.
2. Place empty Capsules into the Capsule Tray.



3. Pipette 420 – 450 μL of primary antibody or probe solution into the Capsule.



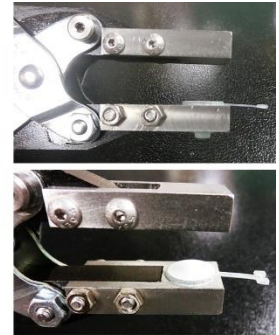
4. Place one Seal onto each Capsule.



5. Place Capsule into Sealer.



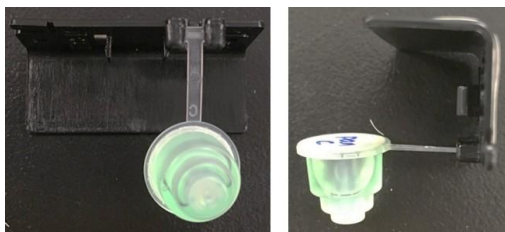
Place Capsule here
with Seal side up



6. Press Sealer arms together and hold for 5 seconds. Remove sealed Capsule from the Sealer.



7. Attach sealed Capsule to the RDA-Tag that was labeled in Step 1.



8. Mount the RDA-Tag onto the RDA.



9. On demand, place the RDA onto the Tissue-Tek Genie Advanced Staining System and initiate an IHC or ISH run according to the instructions in the Operating Manual.

Material required but not supplied

- Primary antibody or CISH probe, ready-to-use
- Tissue-Tek Genie® Reagent Dispense Area Tag (RDA-Tag) (REF 8618-G090)
- Tissue-Tek Genie® Reagent Dispense Area (RDA) (REF 8616-G090)
- Tissue-Tek Genie® RDA-Tag Label Kit (REF 8637-K001)
- Tissue-Tek Genie® Pro Antibody Diluent (REF 8866-G004)

Further information can be found on the Sakura Finetek USA website at www.sakuraus.com/Genie

Refer to the Tissue-Tek Genie Advanced Staining System operating manual for:

Operating instructions, including procedural operations, working with protocols, reagents and supplies

Troubleshooting

Testing run should include proper reagent and tissue controls.

- If the positive control exhibits negative, or weaker, or stronger staining, or more background staining than expected, other positive controls on the same instrument run should be examined to determine if this is due to the RDA, capsule, other reagents, software, instrumentation, or the processing and fixation of tissue specimen(s).
- If the paraffin has not been removed completely, the deparaffinization procedure should be verified.
- If tissue sections have washed off, slides should be examined to ensure that they are positively charged, and the specimen should be examined for possible inadequate processing or fixation.
- Refer to the Tissue-Tek Genie Advanced Staining System operating manual or contact your Sakura Finetek Technical support representative for information or assistance.

Order information / product provided

Product code, product name and quantity

(REF 8610-K050 Tissue-Tek Genie® User-Fillable Capsule Sealing System, 1 Kit

NOTE: The Safety Data Sheet (SDS) is available online on the Sakura Finetek USA website at www.sakuraus.com/SDS.html

Contact

If located within the United States, contact Sakura Finetek USA, Inc. by calling toll free **1-800-725-8723** or contact your Sakura Finetek representative or authorized distributor.

In countries, other than the United States, contact the nearest authorized Sakura Finetek instrument distributor or representative. Contact details may be found at www.sakura.com

Any incident should be reported to the manufacturer. In the European Union, any serious incident can also be reported to a competent authority of the appropriate Member State.

Symbols

- REF

 Catalog number
- LOT

 Batch code
- IVD

in vitro diagnostic medical device
- Temperature limitation
- Use by
- Manufacturer
- Consult instructions for use
- CE

 European Conformity
- EC

REP

 Authorized representative in the European Community

LOT

Please see product label for lot and expiration date information and if available the date of manufacture

Storage: 15°C 30°C

IVD

CE

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