

## DISCOVERY Yellow Kit

**REF**

760-239

07698445001



### INTENDED USE

For Research Use Only. Not for use in diagnostic procedures.

### SUMMARY AND EXPLANATION

DISCOVERY Yellow Kit is a detection kit used for demonstrating the presence of unique antigens in tissues and cells. The DISCOVERY Yellow Kit was designed for antigen localization in frozen sections and/or formalin-fixed, paraffin-embedded (FFPE) tissue sections, to be used in conjunction with the DISCOVERY series of instruments and Ventana Medical Systems' ancillary reagents for optimal performance.

### MATERIAL PROVIDED

Description	Components (Part #)	Test Size	Storage
DISCOVERY Yellow Kit	(1) 5 mL DISCOVERY Yellow (253-4946) (proprietary novel yellow chromogen)	50	2-8° C (Do not freeze)
	(1) 15 mL DISCOVERY Yellow Buffer (253-4947) (pH adjust to optimize enzymatic reaction)	50	2-8° C (Do not freeze)

One kit of DISCOVERY Yellow Kit contains enough reagent for 50 tests. Further dilution may result in loss of antigen staining. Differences in tissue processing and technical procedures in the laboratory may produce significant variability in results and require regular use of controls. (See Tissue Control section.)

### MATERIALS REQUIRED BUT NOT PROVIDED

An appropriate alkaline phosphatase (AP) conjugate and a DISCOVERY Yellow Kit are required to obtain IHC and ISH results. The components can be ordered together or individually. Below is a list of the related components that can be run with the DISCOVERY Yellow Kit to obtain IHC results.

Description	Components (Catalog #)	Test Size	Storage
UltraMap Alk Phos conjugates	UltraMap anti-Rb Alk Phos (760-4314, 05269709001)	125	2-8° C (Do not freeze)
	UltraMap anti-Ms Alk Phos (760-4312, 05269687001)	125	2-8° C (Do not freeze)
DISCOVERY NP-AP Detection	DISCOVERY anti-Rabbit NP (760-4817, 07425317001)	125	2-8° C (Do not freeze)
	DISCOVERY anti-Mouse NP (760-4816, 07425309001)	125	2-8° C (Do not freeze)
	DISCOVERY anti-NP-AP (760-4827, 07425325001)	125	2-8° C (Do not freeze)

Below is a list of the related components that can be run with the DISCOVERY Yellow Kit to obtain ISH results.

Components (Catalog #)	Test Size	Storage
DISCOVERY anti-DIG AP (760-4825, 07256302001)	50	2-8° C (Do not freeze)
DISCOVERY anti-DNP AP (760-4824, 07339739001)	50	2-8° C (Do not freeze)

Staining reagents, such as VENTANA detection kits and ancillary components, including negative and positive tissue control slides, are not provided.

**STORAGE AND STABILITY**

Upon receipt and when not in use, store at 2-8°C. Do not freeze.

To ensure proper reagent delivery and stability of the antibody, replace the dispenser cap after every use and immediately place the dispenser in the refrigerator in an upright position.

Every reagent is expiration dated. When properly stored, the reagent is stable to the date indicated on the label. Do not use reagent beyond the expiration date.

**SPECIMEN PREPARATION**

FFPE tissues are suitable for use with primary antibodies and/or probes when used with VENTANA detection kits and a DISCOVERY instrument. The recommended tissue fixative is 10% neutral buffered formalin.<sup>1</sup> Slides should be stained immediately, as antigenicity of cut tissue sections may diminish over time.


It is recommended that positive and negative controls should be run simultaneously with unknown specimens.

**WARNINGS AND PRECAUTIONS**

1. For Research Use Only (RUO).
2. For professional use only.
3. Do not use beyond the specified number of tests.
4. ProClin 300 solution is used as a preservative in this reagent. It is classified as an irritant and may cause sensitization through skin contact. Take reasonable precautions when handling. Avoid contact of reagents with eyes, skin, and mucous membranes. Use protective clothing and gloves.
5. Positively charged slides may be susceptible to environmental stresses resulting in inappropriate staining. Ask your Roche representative for more information on how to use these types of slides.
6. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions. In the event of exposure, the health directives of the responsible authorities should be followed.<sup>2,3</sup>
7. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
8. Avoid microbial contamination of reagents as it may cause incorrect results.
9. For further information on the use of this device, refer to the instrument User Guide, and instructions for use of all necessary components located at [navifyportal.roche.com](http://navifyportal.roche.com).
10. Consult local and/or state authorities with regard to the recommended method of disposal.
11. Product safety labeling primarily follows EU GHS guidance. Safety data sheet available for professional user on request.
12. To report suspected serious incidents related to this device, contact the local Roche representative and the competent authority of the Member State or Country in which the user is established.

This product contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Table 1. Hazard information.

Hazard	Code	Statement
	H314	Causes severe skin burns and eye damage.
	P280	Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.
	P301 + P330 + P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
	P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
	P304 + P340 + P310	IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.

Hazard	Code	Statement
	P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
	P501	Dispose of contents/ container to an approved waste disposal plant.

**PROCEDURE**

VENTANA DISCOVERY reagents are for use on DISCOVERY instruments.

The parameters for the automated procedures can be displayed, printed and edited according to the procedure in the instrument User Guide.

**STAINING PROCEDURE / INSTRUCTIONS FOR USE**

Register the kit on your DISCOVERY series instrument. Open the package and take out the dispensers. Remove the cap from the nozzle of each dispenser and place it on the nozzle cap holder on the rear of the dispenser. While holding the dispenser upright, remove the yellow shipping key by pulling the key tab to disengage it from each end. Do not cover the nozzle tip or depress the dispenser while removing key. Place the dispensers on the reagent tray, along with the appropriate accessory reagents.

The DISCOVERY series of instruments and both the NP-AP (or UltraMap Alk Phos) Conjugates and the DISCOVERY Yellow Kit form an integrated system. ALL KIT COMPONENTS MUST BE USED TOGETHER in order to obtain high-quality and consistent results. Omitting or changing any of the solutions may compromise the final outcome.

Bulk reagents should be prepared using quality reagent-grade water, not tap water. Carboys for storing bulk reagents should be rinsed thoroughly between fillings.

**TISSUE CONTROL**

Staining results can be affected by endogenous phosphatase activity. Therefore, it is important to include a negative control on every tissue tested to identify areas of endogenous phosphatase activity and/or nonspecific binding of antibody. When this is done, the specificity of the staining reaction can be documented by comparing the negative control staining to the primary antibody staining. In addition, a known positive tissue should be run with every assay. The staining of the positive control serves as a baseline for evaluating run-to-run and/or day-to-day consistency.

**TROUBLESHOOTING**

1. If the positive control exhibits weaker staining than expected, other positive controls run during the same instrument run should be checked to determine if it is because of the primary antibody or one of the common secondary reagents.
2. If the positive control is negative, it should be checked to ensure that the slide has the proper bar code label. If the slide is labeled properly, other positive controls run on the same instrument run should be checked to determine if it is because of the primary antibody or one of the common secondary reagents. Tissues may have been improperly collected, fixed, or deparaffinized. The proper procedure should be followed for collection, storage and fixation.
3. If excessive background staining occurs, high levels of endogenous biotin may be present. Include a biotin blocking step in the staining protocol.
4. If all of the paraffin has not been removed, there may be no staining. Repeat the deparaffinization procedure.
5. If specific antibody staining is too intense, repeat the staining run and shorten the incubation time by 4 minute intervals until the desired stain intensity is achieved.
6. If tissue sections wash off the slide, slides should be checked to ensure that they are positively charged.
7. For corrective action, refer to the Instructions for Use section, the instrument User Guide or contact your local support representative.
8. If a reagent dispenser does not dispense fluid, check the priming chamber or meniscus for foreign materials or particulates, such as fibers or precipitates. If the dispenser is blocked, do not use the dispenser and contact your local support representative. Otherwise, re-prime the dispenser by aiming the dispenser over a waste container, removing the nozzle cap, and pressing down on the top of the dispenser.

## REFERENCES

1. Carson FL, Cappellano C. Histotechnology; A Self-Instructional Text, 5th edition. American Society for Clinical Pathology Press; 2020, 2022.
2. Occupational Safety and Health Standards: Occupational exposure to hazardous chemicals in laboratories. (29 CFR Part 1910.1450). Fed. Register.
3. Directive 2000/54/EC of the European Parliament and Council of 24 June 2020 on the protection of workers from risks related to exposure to biological agents at work.

## Symbols

Ventana uses the following symbol in addition to those listed in the ISO 15223-1 standard (for USA: see [elabdoc.roche.com/symbols](http://elabdoc.roche.com/symbols) for more information).



Global Trade Item Number

## REVISION HISTORY

Rev	Updates
C	Updates to Warnings and Precautions section. Updated to current template.

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