DISCOVERY ChromoMap RED Kit

REF 760-160

05266653001

Σ 125

INTENDED USE

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

SUMMARY AND EXPLANATION

The ChromoMap Red Kit was designed for biotin-free antigen localization in frozen sections or formalin-fixed, paraffin-embedded tissue sections, to be used in conjunction with the Discovery series of instruments and Ventana Medical Systems' ancillary reagents for optimal performance.

MATERIAL PROVIDED

DISCOVERY ChromoMap Red Kit contains sufficient reagent for 125 tests.

One 25 mL dispenser of DISCOVERY Fast Red CM contains Fast Red KL Salt ($C_8H_8N_3O_2$) and ProClin 300.

One 12.5 mL dispenser of DISCOVERY Activator R CM contains magnesium chloride ($MgCl_2$) and ProClin 300.

One 12.5 mL dispenser of DISCOVERY Naphthol CM contains Naphthol AS-TR Phosphate ($C_{18}H_{13}ClNO_5P$) and ProClin 300.

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.

MATERIALS REQUIRED BUT NOT PROVIDED

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

An appropriate conjugate is required in conjunction with DISCOVERY ChromoMap Red Kit, such as DISCOVERY UltraMap anti-Ms Alk Phos (P/N 760-4312) or DISCOVERY UltraMap anti-Rb Alk Phos (P/N 760-4314).

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

Formalin-fixed, paraffin-embedded (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.[1] 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. Consult local and/or state authorities for the recommended method of disposal. In the event of exposure, the health directives of the responsible authorities should be followed.[2,3]
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.
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
WARNING 	H317	May cause an allergic skin reaction.
	H412	Harmful to aquatic life with long lasting effects.
	P261	Avoid breathing mist or vapours.
	P273	Avoid release to the environment.
	P280	Wear protective gloves.
	P333 + P313	If skin irritation or rash occurs: Get medical advice / attention.
	P362 + P364	Take off contaminated clothing and wash it before reuse.
	P501	Dispose of contents / container to an approved waste disposal plant.

EUH208: Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.

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.

The Discovery series of instruments and both the UltraMap Alk Phos Conjugates and the ChromoMap Red 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.

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 symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see elabdoc.roche.com/symbols for more information).

GTIN Global Trade Item Number

REVISION HISTORY

Rev	Updates
F	Updates to the Warnings and Precautions section.

INTELLECTUAL PROPERTY

CONTACT INFORMATION

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