CE IVD

# Mouse anti-Uroplakin II

## Cat. No.: MSK102-05 (0.5 ml Concentrate); MSG102 (6 ml Ready-to-use)

## Instructions for use

**Intended use**
This antibody is designed for the specific localisation of Uroplakin II in formalin-fixed, paraffin-embedded tissue sections.
Anti-Uroplakin II antibody is intended for in vitro diagnostic use.

**Specifications**

| | |
|---|---|
| **Specificity:** | Human Uroplakin II |
| **Synomym:** | MGC138598, UP2, UPII |
| **Clone:** | BC21 |
| **Isotype:** | Mouse IgG1 κ |
| **Species reactivity:** | Human +, others not tested |
| **Immunogen:** | Peptide corresponding to amino acids 36-50 of human Uroplakin II |

**Summary and Description**
The Uroplakins Ia, Ib, II and III are structural proteins of terminally differentiated urothelial cells. In non neoplastic urothelium cells Uroplakins are expressed in the luminal membrane of superficial (umbrella) cells.
The Uroplakin II antibody (clone BC21) stains positive in 78% of urothelial carcinomas including metastases in formalin-fixed, paraffin-embedded tissue sections (1). Uroplakin II is regarded as a specific marker for the identification of urothelial carcinomas in patients with metastases of unknown primary tumour. It seems to be significantly more sensitive than Uroplakin III (1).

**Reagent provided**
Mouse monoclonal antibody in buffer with carrier protein and preservative for stabilisation in the following formats:

| | | |
|---|---|---|
| **Concentrate:** | 0.5 ml | (Cat. No. MSK102-05) |
| **Ready-to-use:** | 6 ml | (Cat. No. MSG102) |

**Dilution of primary antibody**
Dilution of Zytomed Systems' concentrated antibody depends on the detection system used. The final working dilution must always be determined by the user. The elaboration of staining protocol should be done by an experienced specialist. For Zytomed Systems' recommendations see chapter 'Staining procedure'.

**Storage and handling**
The antibody should be stored at 2-8°C without further dilution.
Dilutions of the concentrated antibody should be done with a suitable antibody dilution buffer (e.g. ZUC025 from Zytomed Systems). The diluted antibody should be stored at 2-8°C after use. Stability of this working solution depends on various parameters and has to be confirmed by appropriate controls. The antibody provided is suitable for use until the expiry date indicated on the label, if stored at 2-8°C. Do not use product after the expiry date.
Positive and negative controls should be run simultaneously with all specimens. If unexpected staining is observed which cannot be explained by variations in laboratory procedures and a problem with the antibody is suspected, contact Zytomed Systems' technical support or your local distributor.

**Precautions**
Use through qualified personnel only.
Wear protective clothing to avoid contact of reagents and specimens with eye, skin and mucous membranes. If reagents or specimens come in contact with sensitive area, wash with large amounts of water.
Microbial contamination of the reagent must be avoided, since otherwise non-specific staining may occur. Sodium azide ($NaN_3$), used for stabilisation, is not considered hazardous material in the concentration used. Reaction of sodium azide with lead or copper in drainage pipes can result in the formation of highly explosive metallic azides. Sodium azide should be discarded in a large volume of running water to avoid formation of deposits.
Material safety data sheets (MSDS) are available upon request.

**Staining procedure**
Refer to the following table for conditions specifically recommended for this antibody. Also refer to detection system data sheets for guidance on specific staining protocols or other requirements.

| Parameters | Zytomed Systems recommendations |
|---|---|
| *Pre-treatment | Heat Induced Epitope Retrieval (for example in Citrate Buffer pH 6.0 ZUC028) |
| *Control tissue | Urothelial carcinomas or non-neoplastic urothelium |
| *Working dilution | 1:50-1:100 (for concentrates) |
| *Incubation time | 30 – 60 minutes |

**Quality control**
The recommended positive control tissues for this antibody are urothelial carcinomas or normal urothelium. We recommend carrying out a positive and a negative control with every staining run. Please refer to the instructions of the detection system for guidance on general quality control procedures.

**Troubleshooting**
If you observe unusual staining or other deviations from the expected results please read these instructions carefully, refer to the instructions of the detection system for relevant information or contact your local distributor.

**Expected results**
This antibody stains positive in the plasma membrane in formalin-fixed, paraffin-embedded tissue sections. In addition cytoplasmic staining of varying intensity can be detected. Further details about the expression pattern of Uroplakin II can be found in the chapter 'Summary and Description'. Interpretation of the staining results is solely the responsibility of the user. Any experimental result should be confirmed by a medically established diagnostic procedure.

**Limitations of the Procedure**
Immunohistochemistry is a complex technique involving both histological and immunological detection methods. Tissue processing and handling prior to immunostaining, for example variations in fixation and embedding or the inherent nature of the tissue can cause inconsistent results (Nadji and Morales, 1983). Endogenous peroxidase, alkaline phosphatase or biotin may cause non-specific staining depending on the detection system used. Tissues containing Hepatitis B Surface Antigen (HBsAg) may give false positive results with HRP (horse radish peroxidase) detection systems (Omata *et al*, 1980). Inadequate counterstaining and mounting can influence the interpretation of the results.
Zytomed Systems warrants that the product will meet all requirements described from its shipping date until the expiry date is reached, if the product is stored and utilised as recommended. No additional guarantees can be given. Under no circumstances shall Zytomed System be liable for any damages arising out of the use of the reagent provided.

**Performance characteristics**
Zytomed Systems has conducted studies to evaluate the performance of the antibody for use with a standard detection system. The product has been found to be sensitive and specific to the antigen of interest with minimal or no cross-reactivity.

**Bibliography**

1. Hoang L et al. Mod Pathol 26 Suppl 2-218A, 2013
2. Wu X et al. J Urol 174:2138-2142, 2005
3. Omata M et al. Am J Clin Pathol 73:626-632, 1980
4. Nadji M, Morales AR. Ann N Y Acad Sci 420:134-138, 1983



September 23, 2015 Rev: A0915 Doc: DBE_MSK102-05_MSG102


Explanations of the symbols on the product label:

| | | | | | |
|---|---|---|---|---|---|
| REF | Bestellnummer<br>Catalog Number<br>Reference du catalogue | | Verwendbar bis<br>Use By<br>Utiliser jusque | | Gebrauchsanweisung beachten<br>Consult Instructions for use<br>Consulter les instructions d'utilisation |
| LOT | Chargenbezeichnung<br>Batch Code<br>Code du lot | | Lagerungstemperatur<br>Temperature Limitation<br>Limites de température | RUO | Nur für Forschungszwecke<br>For Research Use Only<br>Pour la recherche uniquement |
| IVD | In vitro Diagnostikum<br>In Vitro Diagnostic Medical Device<br>Dispositif médical de diagnostic in vitro | | Achtung<br>Warning<br>Attention | | Hersteller / Manufacturer / Fabricant<br>Zytomed Systems GmbH • Anhaltinerstraße 16<br>14163 Berlin, Germany • Tel: (+49) 30-804 984 990<br>www.zytomed-systems.com |