Monoclonal Mouse Anti-Human Cytokeratin 10/13
Clone DE-K13

Code M7003

Intended use
For in vitro diagnostic use.
Monoclonal Mouse Anti-Human Cytokeratin 10/13, Clone DE-K13, is intended for use in immunohistochemistry (IHC). In formalin-fixed, paraffin-embedded tissue the antibody labels suprabasal cell layers of non-cornifying stratified epithelia, corresponding to cytokeratin 13 (1), while in frozen sections, the antibody labels suprabasal cell layers of both cornifying and non-cornifying stratified epithelia, corresponding to cytokeratin 10 and 13 (2). Differential classification of tumors is aided by the results from a panel of antibodies. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist. This antibody is intended to be used after the primary diagnosis of tumor has been made by conventional histopathology using nonimmunologic histochemical stains.

Summary and explanation
Cytokeratins are alpha-type fibrous polypeptides with a diameter of 7-11 nm. They are important components of the cytoskeleton in almost all epithelial cells as well as in some non-epithelial cell types. Cytokeratins are, generally, held to be the most ubiquitous markers of epithelial differentiation, and, so far, 20 distinct types numbered by Mol (3, 4) have been revealed. In contrast to other intermediate filaments, cytokeratins are made up of a highly complex multigene family of 40 to 68 kDa polypeptides. They can be divided into an acidic (type I) and a neutral-basic (type II) subfamily (3, 4). Cytokeratin 10 is an intermediate sized, acidic type I cytokeratin, with a molecular mass of 56.5 kDa, expressed only in epidermis of most body locations (3). Cytokeratin 10 expression is absent in basal cells but abundantly expressed in all suprabasal cells simultaneously with cytokeratin 1. Together they represent one of the first markers of epidermal differentiation (4, 5). Cytokeratin 13 is also an intermediate sized, acidic type I cytokeratin, although with a molecular mass of 54 kDa. It is a major component of several non-cornified stratified epithelia, including tongue mucosa, oesophagus, anal canal epithelium, tracheal epithelium, ureter cervix and urothelium (1, 3).

Reagent provided
Monoclonal mouse antibody provided in liquid form as cell culture supernatant dialysed against 0.05 mol/L Tris-HCl, pH 7.2, and containing 15 mmol/L NaN3.
Mouse IgG concentration: See label on vial.
The protein concentration between lots may vary without influencing the optimal dilution. The titer of each individual lot is compared and adjusted to a reference lot to ensure a consistent immunohistochemical staining performance from lot-to-lot.

Immunogen
Cytoskeletal preparation extracted from human ectocervical epithelium (3).

Specificity
In two-dimensional immunoblotting of A431 cells, a human vulvar squamous carcinoma cell line, the antibody labels dots corresponding to cytokeratin 13. The antibody also labels cytokeratin 10 in immunoblotting of cytokeratin-enriched cytoskeletal proteins isolated from human tissue (3).

Precautions
1. For in vitro diagnostic use.
2. For professional users.
3. This product contains sodium azide (NaN3), a chemical highly toxic in pure form. At product concentrations, though not classified as hazardous, sodium azide may react with lead and copper plumbing to form highly explosive build-ups of metal azides. Upon disposal, flush with large volumes of water to prevent metal azide build-up in plumbing.
4. As with any product derived from biological sources, proper handling procedures should be used.
5. Wear appropriate Personal Protective Equipment to avoid contact with eyes and skin.
6. Unused solution should be disposed of according to local, State and Federal regulations.

Storage
Store at 2-8 C. Do not use after expiration date stamped on vial. If reagents are stored under any condition other than those specified, the conditions must be verified by the user. There are no obvious signs to indicate instability of this product. Therefore, positive and negative controls should be run simultaneously with patient specimens. If unexpected staining is observed which cannot be explained by variations in laboratory procedures and a problem with the antibody is suspected, contact Dako Technical Support.

Specimen preparation
Paraffin sections: The antibody can be used for labelling paraffin-embedded tissue sections fixed in formalin. Pretreatment of deparaffinized tissues with heat-induced epitope retrieval is required. For heat-induced epitope retrieval, 10 mmol/L Tris buffer, 1 mmol/L EDTA, pH 9.0, was found efficient, whereas 10 mmol/L citrate buffer, pH 6.0; Dako Target Retrieval Solution, Code S1700 was found less efficient. Pre-treatment of tissues with heat-induced epitope retrieval is required.
proteinase K should be omitted. The tissue sections should not dry out during the treatment or during the following immunohistochemical staining procedure.

**Staining procedure**

These are guidelines only. Optimal conditions may vary depending on specimen type and preparation method, and should be validated individually by each laboratory. The performance of this antibody should be established by the user when utilized with other manual staining systems or automated platforms.

**Dilution:** Monoclonal Mouse Anti-Human Cytokeratin 10/13, Code M7003, may be used at a dilution range of 1:100-1:200 when applied on formalin-fixed, paraffin-embedded sections of human tonsil and using 15 minutes heat-induced epitope retrieval in 10 mmol/L Tris buffer, 1 mmol/L EDTA, pH 9.0, and 30 minutes incubation at room temperature with the primary antibody. The recommended negative control is Dako Mouse IgG2a, Code X0943, diluted to the same mouse IgG concentration as the primary antibody.

**Visualization:** Dako EnVision+ /HRP kits, e.g. Code K4005, are recommended. Follow the procedure enclosed with the selected visualization kit.

**Quality control:** Positive and negative control tissues as well as negative control reagent should be run simultaneously using the same protocol as the patient specimens.

**Staining interpretation**

Cells labeled by the antibody show a cytoplasmic staining pattern (1).

**Performance characteristics**

**Normal tissues:** On cryostat sections the antibody labels suprabasal cells and stratum corneum in the epidermis, suprabasal cells in esophagus and ectocervix, urothelium and thymic Hassal's bodies. The antibody displays heterogeneous staining of hair follicles. The basal cells of both epidermis, esophagus and ectocervix, as well as sebaceous gland, endocervix, mammary gland, hepatocytes, bile ducts, lung and stomach mucosa are not stained by the antibody (2). In formalin-fixed, paraffin-embedded tissue the antibody labels the entire thickness of the epithelium except the basal cells in normal esophageal epithelium (2). Normal squamous esophagus biopsies were labeled by the antibody (6).

**Abnormal tissues:** No labeling was seen in 80 cases of Barrett’s esophagus (6).

**References**


**Explanation of symbols**

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<tr>
<th>REF</th>
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<tbody>
<tr>
<td>IVD</td>
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