**Intended Use:**
For In Vitro Diagnostic Use
Cytokeratin 14 (CK14) [LL002] is a mouse monoclonal antibody that is intended for laboratory use in the qualitative identification of cytokeratin 14 protein by immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human tissues. 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.

**Summary and Explanation:**
Cytokeratin 14 (CK14) is a type I (acidic) human intermediate filament protein of 50 kDa, which usually pairs with CK5, a type II (basic) cytokeratin. In neoplastic cells, CK14 is a useful marker in identification of basal cell epithelium in prostate and myoepithelium in breast, and has also been shown to be a marker of squamous cell carcinoma in lung and in other histological types of various cancers (1-8). The CK14 monoclonal antibody is usually cocktailed with CK5 and may be used in a panel of CK5/CK14 + p63 + AMACR (P504S) or CK7/18 to assess neoplasia in prostate biopsies and breast cancers (7, 9, 10).

**Principle of Procedure:**
Antigen detection in tissues and cells is a multi-step immunohistochemical process. The initial step binds the primary antibody to its specific epitope. After labeling the antigen with a primary antibody, a secondary antibody is added to bind to the primary antibody. An enzyme label is then added to bind to the secondary antibody; this detection of the bound antibody is evidenced by a colorimetric reaction.

**Source:** Mouse monoclonal
**Species Reactivity:** Human
**Clone:** LL002
**Isotype:** IgG3
**Total Protein Concentration:** ~10 mg/ml. Call for lot specific Ig concentration
**Epitope/Antigen:** CK14
**Cellular Localization:** Cytoplasmic
**Positive Tissue Control:** Prostate
**Known Applications:** Immunohistochemistry (formalin-fixed paraffin-embedded tissues)
**Supplied As:** Buffer with protein carrier and preservative

**Storage and Stability:**
Store at 2°C to 8°C. Do not use after expiration date printed on vial. If reagents are stored under conditions other than those specified in the package insert, they must be verified by the user. Diluted reagents should be used promptly; any remaining reagent should be stored at 2°C to 8°C.

**Protocol Recommendations:**
**Peroxide Block:** Block for 5 minutes with Biocare's Peroxidazed 1.
**Pretreatment Solution (recommended):** Diva

**Pretreatment Protocol:**
Heat Retrieval Method:
Retrieve sections under pressure using Biocare's Decloaking Chamber, followed by a wash in distilled water; alternatively, steam tissue sections for 45-60 minutes. Allow solution to cool for 10 minutes then wash in distilled water.
Protocol Recommendations Cont’d:

**Protein Block (Optional):** Incubate for 5-10 minutes at RT with Biocare’s Background Punisher.

**Primary Antibody:** Incubate for 30 minutes at RT.

**Probe:** Incubate for 10 minutes at RT with a secondary probe.

**Polymer:** Incubate for 10 minutes at RT with a tertiary polymer.

**Chromogen:** Incubate for 5 minutes at RT with Biocare’s DAB – OR – Incubate for 5-7 minutes at RT with Biocare’s Warp Red.

**Counterstain:** Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha’s Bluing Solution for 1 minute. Rinse with deionized water.

Technical Note:

This antibody has been standardized with Biocare’s MACH 4 detection system. It can also be used on an automated staining system and with other Biocare polymer detection kits.

Limitations:

The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to fixation, heat-retrieval method, incubation times, tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times and titers listed are not applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based on exclusive use of Biocare products. Ultimately, it is the responsibility of the investigator to determine optimal conditions. The clinical interpretation of any positive or negative staining should be evaluated within the context of clinical presentation, morphology and other histopathological criteria by a qualified pathologist. The clinical interpretation of any positive or negative staining should be complemented by morphological studies using proper positive and negative internal and external controls as well as other diagnostic tests.

Quality Control:


Precautions:

1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable hazardous materials according to U.S. 29 CFR 1910.1200, OSHA Hazard Communication and EC Directive 91/155/EC. Sodium azide (NaN₃) used as a preservative is toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up in plumbing. (Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976) (11)

2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come into contact with sensitive areas, wash with copious amounts of water. (12)

3. Microbial contamination of reagents may result in an increase in nonspecific staining.

4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.

5. Do not use reagent after the expiration date printed on the vial.

6. The MSDS is available upon request and is located at http://biocare.net/support/msds/.
References:


Troubleshooting:

Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.
**Citocheratina 14**

**IVD** Dispositivo medico-diagnostico in vitro

**Produttore:** Biocare Medical  
**Codice:** CM 185 B,C

**Descrizione:** 0,5, 1 ml concentrato  
**Diluizione:** 1:100-1:200

**Uso:**  
Per uso diagnostico in vitro

La citocheratina 14 (CK14) [LL002] è un anticorpo monoclonale murino destinato per uso di laboratorio nell'identificazione qualitativa della proteina citocheratina 14 mediante immunoistochemica (IHC) in tessuti umani fissati con paraffina fissati in formalina (FFPE). L'interpretazione clinica di qualsiasi colorazione o la sua assenza deve essere integrata da studi morfologici che utilizzano controlli adeguati e deve essere valutata nel contesto dell'anamnesi clinica del paziente e di altri test diagnostici da parte di un patologo qualificato.

**Descrizione:**  
La citocheratina 14 (CK14) è una proteina del filamento intermedio umana di tipo I (acido) di 50 kDa, che di solito si accoppia con CK5, una citocheratina di tipo II (base). Nelle cellule neoplastiche, CK14 è un utile marker nell'identificazione dell'epitelio delle celle basali nella prostata e nel mioepitelio nella mammella, e ha anche dimostrato di essere un marker del carcinoma a celle squamose nei polmoni e in altri tipi istologici di vari tumori [1-8]. L'anticorpo monoclonale CK14 viene solitamente preparato con CK5 e può essere usato in un pannello di CK5 / CK14 + p63 + AMACR (P504S) o CK7 / 18 per valutare la neoplasia nelle biopsie prostatiche e nei tumori della mammella [7, 9, 10].

**Origine:** monoclonale di topo  
**Reattività:** uomo, altri non testati  
**Clone:** LL002  
**Isoptipo:** IgG3  
**Concentrazione proteica totale:** ~ 10 mg/ml.  
**Epitopo/Antigene:** CK14  
**Localizzazione cellulare:** Citoplasmatica  
**Controllo positivo:** Prostata  
**Applicazioni nota:** immunoistochemica (tessuti fissati in formalina e inclusi in paraffina)  
**Fornito come:** buffer con carrier proteico e conservante
Conservazione e stabilità:
 Conservare a 2 °C e 8 °C. Non utilizzare dopo la data di scadenza stampata sulla vial. Se i reagenti sono stoccati in condizioni diverse da quelle specificate nel foglietto illustrativo, devono essere verificati dall'utente. I reagenti diluiti dovrebbero essere usati immediatamente; qualsiasi reagente residuo deve essere conservato a 2 °C e 8 °C.

Precauzioni:
1. Questo anticorpo contiene meno dello 0,1% di sodio azide. Concentrazioni inferiori a 0,1% non sono riportate come pericolose come da comunicazione U.S. 29 CFR 1910.1200, OSHA Hazard e direttiva CE 91/155/EC. La sodio azide (NaN₃) usata come conservante è tossico se ingerita. La sodio azide può reagire con le tubature di piombo e di rame e formare azidi metallici altamente esplosive. Durante lo smaltimento, lavare con grandi volumi di acqua per evitare l'accumulo di azide nelle tubature. (Center for Disease Control, 1976 National Institute of Occupational Safety and Health, 1976).
2. I campioni, prima e dopo la fissazione, e tutti i materiali esposti a loro dovrebbero essere trattati come se in grado di trasmettere infezioni e smaltiti con le dovute precauzioni. Non pipettare i reagenti con la bocca ed evitare il contatto delle membrane mucose e della pelle con reagenti e campioni. Se i reagenti o campioni entrano in contatto con aree sensibili lavare con abbondante acqua. (3)
3. Contaminazione microbica dei reagenti può comportare un aumento aspecifico della colorazione.
5. Non utilizzare il reagente dopo la data di scadenza stampata sul flacone.