CELERUS DIAGNOSTICS

Renal Cell Carcinoma

Monoclonal Mouse Anti-Renal Cell Carcinoma, Clone PN-15

REF **014-1114**

Ready-To-Use ▪ 100 Tests/50 Tests

Concentrate ▪ 1mL

INTENDED USE

IVD For in vitro diagnostic use.

Celerus monoclonal mouse anti-Renal Cell Carcinoma, clone PN-15, is intended for laboratory use in identifying a renal cell carcinoma marker in normal or neoplastic tissue using light microscopy. Renal Cell Carcinoma antibody recognizes a glycoprotein localized in the brush border of the proximal renal tubule. This antibody immunoreacts with approximately 90% of primary renal cell carcinomas and approximately 85% of metastatic renal cell carcinomas. It may be used with frozen or formalin-fixed paraffin-embedded tissue.

Positive results aid in the classification of normal and abnormal cells/tissues and serve as an adjunct to conventional histopathology. The clinical interpretation of any positive staining or its absence should be complemented by morphological and histological studies with proper controls. Evaluations should be made by a qualified individual in conjunction with the patient's clinical history and other diagnostic test results.

Refer to the Wave Instrument Operator's Manual for additional information concerning Materials Required but Not Provided; Storage; Staining Procedure; Troubleshooting; Interpretation of Staining; and General Limitations.

SUMMARY AND EXPLANATION

Renal Cell Carcinoma marker is a surface membrane glycoprotein localized to the brush border of the pars convoluta and pars recta segments of the proximal renal tubule and focally on the luminal surface of the Bowman's capsule adjoining the outgoing proximal tubule. Antibodies to Renal Cell Carcinoma marker are useful in identifying malignant cells from primary and metastatic renal cell carcinomas.

PRINCIPLE OF PROCEDURE

Immunohistochemistry is a multi-step process to identify specific cell markers within tissue biopsies or tumor specimens. The sequential steps include antigen retrieval (optional), antibody application, and antibody visualization followed by optional counterstaining. Specimens are then coverslipped and observed under light microscopy by trained personnel. Normally, multiple antibodies are tested to determine lineage and cell cycle markers. The Celerus Wave is an automated instrument that performs immunohistochemistry stains. For further information on the staining procedure, refer to the Celerus Wave Operator's Manual.

MATERIALS AND METHODS

Reagent Provided

Clone
PN-15

Ig Class
IgG_1, kappa

Immunogen
Microsomal fraction of human renal cortical tissue homogenate.

Ready-To-Use in Primary Antibody Cartridge

Celerus anti-renal cell carcinoma is provided with ProClin 300 as a preservative, in a Primary Antibody Cartridge (PAC), a self-contained dispenser of reagents. Each PAC contains sufficient reagent to complete 50 or 100 stained slides. PACs must remain upright to avoid spilling. PAC must be primed before first use. See Celerus Wave Operator's Manual for details.

Concentrated Antibody

Liquid
Liquid concentrated antibody is provided containing 15 mM sodium azide as a preservative and 1% bovine serum albumin as a carrier protein.

Lyophilized
Lyophilized antibody is provided containing 15mM sodium azide as a preservative. Reconstitute vial with 1.0 ml distilled water.

Dilution
The suggested dilution is 1:10–1:20. This is a guide only and users should determine their own optimal working dilutions.

SPECIFICITY

Reacts with a carbohydrate domain of the 200 kDa Renal Cell Carcinoma glycoprotein.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Wave instrument
2. Wave slide rack
3. Positively-charged microscope slides, appropriately labeled
4. Timer
5. Celerus Riptide for antigen retrieval (or equivalent)
6. Celerus Target Retrieval Solution (or equivalent)
7. Slide drying chamber
8. Xylene or xylene substitute
9. Reagent alcohol or ethyl alcohol
10. Distilled or deionized water
11. TBS wash buffer, pH 7.6
12. Positive and negative tissue controls
13. Celerus Negative Control Reagent (or equivalent)
14. Mounting Medium
15. Cover slips

STORAGE AND HANDLING

Ready-to-Use PAC, Liquid Concentrated and Lyophilized Antibody

Store reagent at 2-8 °C. Do not freeze. The reagent is stable until the expiration date on the container. Do not use reagent after the expiration date, as the activity cannot be ensured.

Reconstituted Antibody

For reconstituted antibody, the reagent is stable for at least two months when stored at 4 °C. For long-term storage it is recommended that aliquots of the antibody be stored at -20 °C. Repeated freezing and thawing of the antibody should be avoided.

There are no signs to indicate instability of this reagent. To ensure a valid staining assay, the use of positive and negative tissue controls is recommended. Contact your Celerus representative if there are stability concerns prior to the expiration date.

PRECAUTIONS

1. For professional users.
2. Minimize microbial contamination of reagents or an increase in nonspecific staining may occur.
3. As with any product derived from biological sources, proper handling procedures should be used.
4. A Material Safety Data Sheet is available for professional users on request.
5. ProClin 300 is classified per applicable European Community (EC) Directives as: Irritant (Xi). The following are the appropriate Risk (R) and Safety (S) phrases.

R36 Irritating to eyes
R43 May cause sensitization by skin contact
S24 Avoid contact with skin
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S35 This material and its container must be disposed of in a safe way
S37/39 Wear suitable gloves and eye/face protection
S46 If swallowed, seek medical advice immediately and show this container or label.

WASTE DISPOSAL

Adhere to all local laws when disposing of the PAC.

PACKAGING DAMAGE

DO NOT USE a PAC if it is leaking, has leaked, has spilled, cannot be primed, or has visually apparent physical damage.

SPECIMEN COLLECTION AND HANDLING

Formalin-fixed paraffin embedded (FFPE) tissues, frozen tissues, or smears are suitable for use. Wave detection kits have been optimized for tissues fixed with 10% formalin. Ideally, each 4-6µ tissue section should be placed on charged slides on the lower 2/3 of the slide. Very large sections should be placed 1/4 inch below the lower end of the slide label.

Slides should be baked overnight at 37 °C, or at 60 °C for one hour.

Use standard histochemical techniques to deparaffinize processed slides. For uniformity of staining results, it is recommended that target retrieval be performed using the Celerus Riptide and Celerus Target Retrieval Solution (or equivalent) at 112 °C for 5 minutes. Avoid drying of the tissue specimen during this process. After all slides to be stained have been inserted and reagents mounted on the instrument, start the staining run.

When the slides have completed the staining run, remove them from the instrument, coverslip, and view under light microscopy.

PRODUCT-SPECIFIC LIMITATIONS

Renal Cell Carcinoma antibody, when used on the Wave instrument, detects antigens that survive routine formalin fixation, tissue processing, and sectioning. Users who deviate from recommended test procedures are responsible for interpretation and validation of patient results.

RESULTS EXPECTED/ PERFORMANCE CHARACTERISTICS

Normal Tissues
This antibody stains proximal renal tubule and focally on the luminal surface of the Bowman's capsule adjoining the outgoing proximal tubule, luminal surface of breast lobules and ducts, epididymal tubular epithelium, parathyroid parenchyma, and thyroid colloid.

Abnormal Tissues
This antibody is useful in identifying malignant cells from primary and metastatic renal cell carcinomas. Immunohistochemical detection of Renal Cell Carcinoma marker may also be utilized for subclassifying renal neoplasms. The majority of clear cell and papillary type renal cell carcinomas are positive.

REFERENCES

McGregor DK, Khurana KK, Cao C, Tsao CC, Ayala G, Krishnan B, Ro JY, Lechago J, Truong LD. Diagnosing primary and metastatic renal cell carcinoma. Am J Surg Pathol 2001;25(12):1485-92.

Avery AK, Beckstead J, Renshaw AA, Corless CL. Use of antibodies to RCC and CD10 in the differential diagnosis of renal neoplasms. Am J Surg Pathol 2000;24(2):203-10.

Pan C-C, Chen PC-H, Ho, D M-T. The diagnostic utility of MOC31, BerEP4, RCC marker and CD10 in the classification of renal cell carcinoma and renal oncocytoma: an immunohistochemical analysis of 328 cases. Histopathol 2004;45:452-9.

Ordonez NG. The diagnostic utility of immunohistochemistry in distinguishing between mesothelioma and renal cell carcinoma: a comparative study. Human Pathol 2004;35(6):697-710.

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