CELERUS DIAGNOSTICS

Androgen Receptor

Monoclonal Mouse Anti-Androgen Receptor Clone AR-D12

REF **014-1095**

Ready-To-Use ▪ 100 Tests/50 Tests

Concentrate ▪ 1mL

INTENDED USE

IVD For in vitro diagnostic use.

Celerus monoclonal mouse anti-Androgen receptor, clone AR-D12, is intended for laboratory use in identifying androgen receptor in normal or neoplastic tissue using light microscopy. Abnormalities in the AR signaling pathway have been linked to a number of diseases, including prostate cancer and male infertility. This antibody 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

The androgen receptor is a type of nuclear receptor, which is activated by binding of either of the androgenic hormones testosterone or dihyrotestosterone. The main function of the androgen receptor is as a DNA binding transcription factor which regulates gene expression. However, the androgen receptor also has additional functions independent of DNA binding. The AR signaling pathway plays a key role in development and function of male reproductive organs, including the prostate and epididymis. AR also plays a role in non-reproductive organs, such as muscle, hair follicles, and brain.

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

AR-D12

Ig Class

IgG_1

Immunogen

Recombinant human androgen receptor.

Ready-To-Use in Primary Antibody Cartridge

Celerus anti-androgen receptor 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 1:25–1:50. This is a guide only and users should determine their own optimal working dilutions.

SPECIFICITY

This antibody reacts with androgen receptor. This antibody does not cross-react with estrogen receptor, progesterone receptor, or glucocorticoid receptors.

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

Androgen receptor 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

In the prostate, nuclear immunoreactivity has been observed in the secretory cells, basal cells, smooth muscle cells and fibroblasts. Moderate immunostaining has been found in spermatogonia, spermatocytes and Sertoli cells of the testes, with weaker staining seen in Leydig and peritubular myoid cells. Strong to moderate expression of androgen receptor has been demonstrated by IHC in uterine myometrial cells, cervical squamous cells, ovarian stromal cells, and syncytiotrophoblasts and cytotrophoblasts of the placenta. Endometrial glandular and stromal cells also express androgen receptor at all phases of the menstrual cycle. In the breast, the nuclei of acinar cells, myoepithelial cells and stromal cells were reported to stain positively. Androgen receptor was also demonstrated in cardiac muscle, striated muscle and in smooth muscle of arteries, bladder and GI tract. In skin, positive staining has been observed in cells of the hair follicles, sweat glands and squamous cells of the epidermis. Other cells which have been shown to give moderate to strong immunostaining include hepatocytes of the liver and cells of the anterior and posterior pituitary.

Abnormal Tissues

In adenocarcinomas of the prostate androgen receptor has been demonstrated by IHC to be present in the nuclei of most neoplastic cells with neuroendocrine differentiation. The majority of breast and ovarian carcinomas evaluated also express androgen receptor. The nuclei of glandular and stromal endometrial cells have been shown to stain positively in adenomyosis and external endometriosis. Malignant cells in both glandular and solid lesions of grade II endometrial adenocarcinomas were found to be immunoreactive. Androgen receptor expression has also been demonstrated in meningiomas.

REFERENCES

Jänne OA, et al. Androgen receptor and mechanism of androgen action. Ann Med 1993; 25:83.

Kimura N, et al. Immunocytochemical localization of androgen receptor with polyclonal antibody in paraffin-embedded human tissues. J Histochem Cytochem 1993; 41(5):671.

Horie K, et al. Immunohistochemical localization of androgen receptor in the human endometrium, decidua, placenta and pathological conditions of the endometrium. Hum Reproduct 1992; 7(10):1461.

Nakada SY, et al. The androgen receptor status of neuroendocrine cells in human benign and malignant prostatic tissue. Canc Res 1993; 53:1967.

Schulz TJ, et al. Immunocytochemical analysis of androgen receptor in breast cancer and correlation with estrogen and progesterone receptors. Lab Invest 1993; 68(1):19A(#92).

Bryan RM, et al. Androgen receptors in breast cancer. Canc 1984; 54(11):2436.

Chadha S, et al. An immunohistochemical evaluation of androgen and progesterone receptors in ovarian tumors. Hum Pathol 1993; 24(1):90.

Kühnel R, et al. Androgen receptor predominance in human ovarian carcinoma. J Steroid Biochem 1987; 26(3):393.

Carroll RS, et al. Androgen receptor expression in meningiomas. J Neurosurg 1995; 82:453.

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