

**Monoclonal Mouse
Anti-Human
Follicle Stimulating Hormone (FSH)
Clone C10**

Code M3504

Intended use

For in vitro diagnostic use.

Monoclonal Mouse Anti-Human Follicle Stimulating Hormone, Clone C10, is intended for use in immunohistochemistry (IHC). This antibody labels follicle stimulating hormone (FSH) in normal and neoplastic tissue. Results aid in the classification of pituitary adenomas (1). Differential classification 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

By immunohistochemistry (IHC), the antibody labels gonadotropic cells of the pituitary.

Refer to *Dako General Instructions for Immunohistochemical Staining* or the detection system instructions of IHC procedures for: Principle of Procedure, Materials Required, Not Supplied, Storage, Specimen Preparation, Staining Procedure, Quality Control, Troubleshooting, Interpretation of Staining, General Limitations.

Reagent provided

Monoclonal mouse antibody provided in liquid form as cell culture supernatant (containing fetal bovine serum) dialyzed against 0.05 mol/L Tris-HCl, pH 7.2, and containing 0.015 mol/L sodium azide. This product contains stabilizing protein.

Clone: C10 Isotype: IgG1, kappa.

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

Purified human FSH

Specificity

The antibody reacts with the β subunit of follicle stimulating hormone. By double monoclonal EIA, no detectable cross-reactivity was found against luteinizing hormone (LH), thyroid stimulating hormone (TSH), β human chorionic gonadotropin (β hCG), prolactin, human growth hormone (hGH), and human chorionic gonadotropin (hCG).

Precautions

1. For in vitro diagnostic use.
2. For professional users.
3. This product contains sodium azide (NaN_3), 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 conditions 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 labeling paraffin-embedded tissue sections fixed in formalin. Pre-treatment of deparaffinized tissue is not required.

Staining procedure

These are guidelines only. Optimal antibody concentration 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 Follicle Stimulating Hormone, Code M3504, may be used at a dilution of 1:50 when applied on formalin-fixed, paraffin-embedded sections using a 10 minute incubation at room temperature. It is recommended that the antibody is diluted in Dako Antibody Diluent (Code S0809). The recommended negative control reagent is Dako Negative Control, Mouse IgG1 (Code X0931), diluted to the same mouse IgG concentration as the primary antibody. Unless the stability of the diluted antibody and negative control has been established in the actual staining procedure, it is recommended to dilute these reagents immediately prior to use.

Visualization: Dako LSAB2 System/HRP, Dual Link Rabbit/Mouse (Codes K0675), is recommended. Follow the procedure enclosed with the selected visualization system(s).

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

The cellular staining pattern is cytoplasmic and heterogeneous.

Performance characteristics

Normal tissues:

Tissue Type (# tested)²	Labeled Tissue Elements
Adrenal (3)	0/3
Bone Marrow (3)	3/3 macrophages
Breast (3)	0/3
Brain/Cerebellum (3)	0/3
Brain/Cerebrum (3)	0/3
Cervix (3)	0/3
Colon (3)	0/3
Esophagus (3)	0/3
Heart (3)	0/3
Kidney (3)	0/3
Liver (3)	0/3
Lung (3)	0/3
Mesothelial Cells (3)	0/3
Nerve, Peripheral (3)	0/3
Ovary (3)	0/3
Pancreas (3)	0/3
Parathyroid (3)	0/3
Pituitary (3)	3/3 pituicytes
Prostate (3)	0/3
Salivary gland (3)	0/3
Skeletal muscle (3)	0/3
Skin (3)	0/3
Small intestine (3)	0/3
Spleen (3)	0/3
Stomach (3)	0/3
Testis (3)	0/3
Thymus (3)	0/3
Thyroid (3)	0/3
Tonsil (3)	0/3
Uterus (3)	0/3










Abnormal tissues:

In 94 cases of pituitary adenomas, the antibody labeled 7.7% of the cases and 5% of cases in a group of 86 cases (1).

References/ Bibliographie/ Literaturangaben

1. Cimpean AM, Melnic E, Băliușteanu B, Corlan A, Coculescu M, Rusu S, et al. Geographic-Related Differences of Pituitary Adenomas Hormone Profile: Analysis of Two Groups Coming from Southeastern and Eastern Europe. Int J Endocrinol. 2015;2015:192094. Epub 2015 May 11.
2. IHC003 Report On File

Explanation of symbols

 REF	Catalogue number		Temperature limitation	 IVD	In vitro diagnostic medical device
	Manufacturer	 LOT	Batch code		Contains sufficient for <n> tests
	Use by		Consult instructions for use	 EC REP	Authorized representative in the European Community



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TX02438/01

Revision 2020.07