DBS Montage™ Lung MultiPlex (Small Cell Lung Carcinoma vs. Lung Squamous Cell Carcinoma)

CATALOG NO: MPK-005

DESCRIPTION: 50 Tests

DILUTION: Ready-to-use

INTENDED USE

IVD: For In Vitro Diagnostic Use

This kit contains the following antibodies: CD56, Chromogranin A, Synaptophysin, Cytokeratin 5/6 and is intended for laboratory qualitative immunohistochemistry with normal and neoplastic formalin fixed, paraffin embedded tissue sections, to be viewed by light microscopy. This kit is intended as an adjunctive test to further classify neoplasms of the lung subsequent to the initial diagnosis, when assessing small cell lung carcinoma and lung squamous cell carcinoma. The CD56 antibody clone 123C3, Chromogranin A antibody clone LK2H10, and Synaptophysin antibody clone SYP02 are useful in identification of small cell lung carcinoma. The Cytokeratin 5/6 antibody clone D5/16 B4 is useful in the identification of lung squamous cell carcinoma. Clinical interpretation of staining results, both positive and negative, should be accompanied by histological studies with proper controls. Patients' clinical histories and other relevant diagnostic tests should be utilized by a qualified person when evaluating and interpreting results.

Clone	Immunogen	Isotype
123C3	CD56 (membrane preparation of a small cell carcinoma)	IgG1
LK2H10	Chromogranin A (human pheochromocytoma)	IgG1, kappa
SYP02	Synaptophysin (synthetic peptide encoding a region near the C-terminal end of the synaptophysin protein)	IgG1
D5/16 B4	CK5/6 (cytokeratin 5)	IgG1, kappa

SUMMARY AND EXPLANATION

CD56, also called neural cell adhesion molecule (N-CAM), is a cell surface glycoprotein with multiple isoforms. CD56 is expressed in the normal central nervous system, and can be found in peripheral nerves, most neuroendocrine cells, and skeletal muscle. CD56 is also expressed in some normal epithelia, ovarian stromal cells, uterine smooth muscle cells, chief and peptic cells of the stomach, osteoblasts, and NK and T cells. In abnormal tissue, CD56 is expressed in small cell lung carcinoma, acute and chronic myeloid leukemia, ovarian sex cord-stromal tumors, Wilms' tumor, neuroblastoma, and other neuroenocrine tumors. A low percent positivity of CD56 is found in ovarian carcinomas, endometrial carcinomas, and lung squamous cell carcinomas.

Chromogranin A is an acid calcium-binding glycoprotein found in secretory granules, neuroendocrine cells and neurons. Chromogranin A is a 439 amino acid protein that through post-translational processing generates biologically active peptides such as: vasostatins, chromostatin, chromacins, pancreastatin, WE-14, catestatin, parastatin, and GE-25. Chromogranin A is a marker of neuroendocrine tumors.

Synaptophysin is a 38 kD calcium-binding integral-membrane glycoprotein found in presynaptic vesicles in neurons and also in vesicles of various neuronal and epithelial neuroendocrine cells. Synaptophysin has been detected in neoplastic neuroendocrine cells of neural and epithelial type.

Cytokeratin 5 (CK5) is a 58 kD intermediate filament protein with normal expression in stratified squamous epithelia, including the basal, intermediate, and superficial cell layers, and also in transitional and complex epithelia, and mesothelial cells. Cytokeratin 6 (CK6) is a 56 kD intermediate filament protein normally found in proliferating squamous epithelium. Cytokeratins generate heterodimers used to form the cytoskeleton of a cell. In abnormal tissue, CK5/6 has been reported to be expressed in 82-100% lung squamous cell carcinomas, and in epithelioid mesothelioma and thymoma.

REAGENTS PROVIDED

MPK-005	
MPK-005A	
Montage™ DuoPlex Antibody (CD56 + Chromogranin A + Synaptophysin)	MPA 011-50
Montage™ DuoPlex Antibody (CK5/6)	MPA 010-50
Montage™ Tissue Primer	K 054-50MP
Montage™ Tris EDTA Antigen Retrieval Solution	K 043-50MP
MPD-002	
Montage™ Mouse HRP	M 011-50
Montage™ Mouse AP	M 013-50
Montage™ Background Blocker	K 023-50MP
Montage™ Hematoxylin	K 056-50MP
Montage™ High Contrast DAB Substrate Buffer	K 055-B-50MP
Montage™ High Contrast DAB Substrate Chromogen	K 055-C-50MP
Montage™ Perma Red Auto Plus Buffer	K 057-B-50MP
Montage™ Perma Red Auto Plus Chromogen	K 057-C-50MP
Not Applicable	EF4661
Montage™ Negative Control	K 053-MP

SPECIES REACTIVITY

Human, others not tested

PROTOCOL RECOMMENDATIONS

Tissue Primer: Block for 5 minutes with Montage™ Tissue Primer

Protein Block: Block for 5 minutes with protein block

Antibody Stain 1: Incubate with Montage™ DuoPlex Antibody CD 56 + Chromogranin A + Synaptophysin at RT for 30 minutes

Detection System 1: Incubate for 20 minutes using Montage™ Mouse HRP

Chromogen 1: Incubate for 5 minutes with Montage™ High Contrast DAB

Antibody Stain 2: Incubate with Montage™ DuoPlex Antibody CK5/6 at RT for 30 minutes

Detection System 2: Incubate for 20 minutes using Montage™ Mouse AP

Chromogen 2: Incubate in Montage™ Perma Red Auto Plus Buffer for a minute and then in Montage™ Perma Red Auto Plus Chromogen for 15 minutes

Counterstain: Incubate for 2 minutes using Montage™ Hematoxylin

PRECAUTIONS

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) 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 in contact with sensitive areas, wash with copious amounts of water. Microbial contamination of reagents may result in an increase in nonspecific staining. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change. The MSDS is available upon request.

LIMITATIONS AND WARRANTIES

There are no warranties, expressed or implied, which extend beyond this description. Diagnostic BioSystems is not liable for property damage, personal injury, or economic loss caused by this product.

STORAGE AND STABILITY

Store at 2ºC to 8ºC. 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 2ºC to 8ºC.

PERFORMANCE CHARACTERISTICS IN THE LUNG

CD56 staining will result in a **brown** color in the membrane and/or cytoplasm.

CD56 staining pattern in the lung:

Frequently Reacts	**Normal:** peripheral nerves, neuroendocrine cells, NK and T cells, pulmonary veins of the lung; **Abnormal:** small cell lung carcinoma cells, acute and chronic myeloid leukemia cells, ovarian sex cord-stromal tumors cells, Wilms' tumor cells, neuroblastoma cells, phaeochromocytoma cells, astrocytoma cells, schwannoma cells, synovial sarcoma cells, osteosarcoma cells, rhabdomyosarcoma cells, leiomyomatous tumors cells (but not vascular types), desmoplastic small cell tumor cells, natural killer (NK) and NK/T-cell lymphoma cells, multiple myeloma cells, mesothelioma cells, well differentiated neuroendocrine tumor and neuroendocrine carcinoma cells, thyroid adenoma/carcinoma cells (but not papillary carcinoma), adrenal cortical adenoma/carcinoma cells
Occasionally Reacts	**Normal:** smooth muscle in bronchial and bronchiolar system; **Abnormal:** Ewing's sarcoma cells, renal cell carcinoma cells
Does Not React or Rarely Reacts	**Abnormal:** lung squamous cell carcinoma cells, Neurofibroma cells, granular cell tumor cells, solitary fibrous tumor cells, vascular leiomyoma cells, ovarian carcinoma cells, endometrial carcinoma cells, angiosarcoma cells, and adenocarcinoma cells of the breast, stomach, colon, pancreas, and prostate

Chromogranin A staining will result in a **brown** color in the cytoplasm.

Chromogranin A staining pattern in the lung:

Frequently Reacts	**Normal:** neuroendocrine cells and neurons; **Abnormal:** small cell lung carcinoma cells and neuroendocrine and neuronal tumor cells
Does Not React or Rarely Reacts	**Abnormal:** glial tumor cells (with the exception of some oliogodendrogliomas), meningioma cells, choroid plexus tumor cells, schwannoma cells, malignant melanoma cells, adrenocortical tumor cells, mesothelioma cells, and sarcomas

Synaptophysin staining will result in a **brown** color in the cytoplasm.

Synaptophysin staining pattern in the lung:

Frequently Reacts	**Normal:** neuroendocrine cells and neurons; **Abnormal:** small cell lung carcinoma cells, neuroendocrine and neuronal tumor cells, and adrenal cortical tumor cells

Does Not React or Rarely Reacts	**Abnormal:** most non-neuroendocrine or neuronal neoplasm

CK5/6 staining will result in a **red** color in the cytoplasm.

CK5/6 staining pattern in the lung:

Frequently Reacts	**Normal:** epithelial cells and myoepithelial cells**; Abnormal:** lung squamous cell carcinoma cells, epithelioid mesothelioma cells, skin basal cell carcinoma cells, and thymoma cells
Occasionally Reacts	**Abnormal:** pancreas adenocarcinoma cells, breast adenocarcinoma cells, ovary adenocarcinoma cells
Does Not React or Rarely Reacts	**Normal:** non-epithelial cells; **Abnormal:** lung adenocarcinoma cells, lung small cell carcinoma cells, colon adenocarcinoma cells, prostate adenocarcinoma cells, hepatocellular carcinoma cells, cortical tumor cells, thyroid tumor cells, and neuroenocrine carcinoma cells

TROUBLESHOOTING

Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Diagnostic BioSystems Technical Support at 888-896-3350.

REFERENCES

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