

Bond™ Ready-to-Use Primary Antibody Smooth Muscle Actin (alpha sm-1)

Catalog No: PA0943

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EN	FR	IT	DE	ES	PT
SV	EL	DA	NL	NO	TR

Instructions for Use

Please read before using this product.

Mode d'emploi

À lire avant d'utiliser ce produit.

Istruzioni per l'uso

Si prega di leggere, prima di usare il prodotto.

Gebrauchsanweisung

Bitte vor der Verwendung dieses Produkts lesen.

Instrucciones de uso

Por favor, leer antes de utilizar este producto.

Instruções de Utilização

Leia estas instruções antes de utilizar este produto.

Bruksanvisning

Var god läs innan ni använder produkten.

Οδηγίες Χρήσης

Παρακαλούμε διαβάστε τις οδηγίες πριν χρησιμοποιήσετε το προϊόν αυτό.

Brugsanvisning

Læs venligst før produktet tages i brug.

Gebruiksaanwijzing

Lezen vóór gebruik van dit product.

Bruksanvisning

Vennligst les denne før du bruker produktet.

Kullanım Talimatları

Lütfen bu ürünü kullanmadan önce okuyunuz.

Check the integrity of the packaging before use.

Vérifier que le conditionnement est en bon état avant l'emploi.

Prima dell'uso, controllare l'integrità della confezione.

Vor dem Gebrauch die Verpackung auf Unversehrtheit überprüfen.

Comprobar la integridad del envase, antes de usarlo.

Verifique a integridade da embalagem antes de utilizar o produto.

Kontrollera att paketet är obrutet innan användning.

Ελέγξτε την ακεραιότητα της συσκευασίας πριν από τη χρήση.

Kontroller, at pakken er ubeskadiget før brug.

Controleer de verpakking vóór gebruik.

Sjekk at pakningen er intakt før bruk.

Kullanmadan önce ambalajın bozulmamasını kontrol edin.

www.LeicaBiosystems.com

Bond™ Ready-To-Use Primary Antibody

Smooth Muscle Actin (alpha sm-1)

Catalog No: PA0943

Intended Use

This reagent is for *in vitro* diagnostic use.

Smooth Muscle Actin (alpha sm-1) monoclonal antibody is intended to be used for the qualitative identification by light microscopy of human alpha smooth muscle actin in formalin-fixed, paraffin-embedded tissue by immunohistochemical staining using the automated BOND system (includes Leica BOND-MAX system and Leica BOND-III system).

The clinical interpretation of any staining or its absence should be complemented by morphological studies and 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

Immunohistochemical techniques can be used to demonstrate the presence of antigens in tissue and cells (see "Using BOND Reagents" in your BOND user documentation). Smooth Muscle Actin (alpha sm-1) primary antibody is a ready to use product that has been specifically optimized for use with Bond Polymer Refine Detection. The demonstration of human alpha smooth muscle actin is achieved by first allowing the binding of Smooth Muscle Actin (alpha sm-1) to the section, and then visualizing this binding using the reagents provided in the detection system. The use of these products, in combination with the automated BOND system (includes Leica BOND-MAX system and Leica BOND-III system), reduces the possibility of human error and inherent variability resulting from individual reagent dilution, manual pipetting and reagent application.

Reagents Provided

Smooth Muscle Actin (alpha sm-1) is a mouse anti-human monoclonal antibody produced as a purified IgG fraction, and supplied in Tris buffered saline with carrier protein, containing 0.35% ProClin™ 950 as a preservative.

Total volume = 7 mL.

Clone

asm-1

Immunogen

Synthetic amino terminal decapeptide of alpha smooth muscle isoform of actin.

Specificity

Human alpha smooth muscle actin.

Ig Class

IgG2a

Total Protein Concentration

Approx 10 mg/mL.

Antibody Concentration

Greater than or equal to 0.2 mg/L as determined by ELISA.

Dilution and Mixing

Smooth Muscle Actin (alpha sm-1) primary antibody is optimally diluted for use on the BOND system (includes Leica BOND-MAX system and Leica BOND-III system). Reconstitution, mixing, dilution or titration of this reagent is not required.

Materials Required But Not Provided

Refer to "Using BOND Reagents" in your BOND user documentation for a complete list of materials required for specimen treatment and immunohistochemical staining using the BOND system (includes Leica BOND-MAX system and Leica BOND-III system).

Storage and Stability

Store at 2–8 °C. Do not use after the expiration date indicated on the container label.

The signs indicating contamination and/or instability of Smooth Muscle Actin (alpha sm-1) are: turbidity of the solution, odor development, and presence of precipitate.

Return to 2–8 °C immediately after use.

Storage conditions other than those specified above must be verified by the user¹.

Precautions

- This product is intended for *in vitro* diagnostic use.
- The concentration of ProClin™ 950 is 0.35 %. It contains the active ingredient 2-methyl-4-isothiazolin-3-one, and may cause irritation to the skin, eyes, mucous membranes and upper respiratory tract. Wear disposable gloves when handling reagents.
- To obtain a copy of the Material Safety Data Sheet contact your local distributor or regional office of Leica Biosystems, or alternatively, visit the Leica Biosystems' Web site, www.LeicaBiosystems.com

- 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 precautions². Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents or specimens. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water. Seek medical advice.
- Consult Federal, State or local regulations for disposal of any potentially toxic components.
- Minimize microbial contamination of reagents or an increase in non-specific staining may occur.
- Retrieval, incubation times or temperatures other than those specified may give erroneous results. Any such change must be validated by the user.

Instructions for Use

Smooth Muscle Actin (alpha sm-1) primary antibody was developed for use on the automated BOND system (includes Leica BOND-MAX system and Leica BOND-III system) in combination with Bond Polymer Refine Detection. The recommended staining protocol for Smooth Muscle Actin (alpha sm-1) primary antibody is IHC Protocol F. No pretreatment is recommended.

Results Expected

Normal Tissues

asm-1 detected alpha smooth muscle actin in the cytoplasm of smooth muscle cells. These cells can be found in vascular walls, intestinal muscularis mucosae and muscularis propria and in the stroma of various tissues. It also reacted with myoepithelium of various glands, notably salivary and mammary glands. (Total number of normal cases evaluated = 99).

Tumor Tissues

asm-1 detected the smooth muscle actin protein in 5/6 leiomyosarcomas, 4/4 leiomyomas, 2/2 cavernous hemangiomas, 1/7 fibrosarcomas, 1/3 fibrous histiocytomas, 1/1 angioleiomyoma, 1/1 hemangiopericytoma sarcoma and 1/1 mesenchymoma. No staining was observed in gastrointestinal stromal tumors (0/5), chondrosarcomas (0/4), pleomorphic rhabdomyosarcomas (0/2), alveolar rhabdomyosarcomas (0/2), synovial sarcomas (0/2), a fibrolipoma (0/1), a lipoma (0/1), a solitary fibrous tumor (0/1), an epithelioid sarcoma (0/1), a mesothelioma (0/1), a liposarcoma (0/1), a myxoliposarcoma (0/1), a dermatofibrosarcoma (0/1), a fibromatosis (0/1), a ganglioneuroma (0/1), tumors of the thyroid (0/3), lung tumors (0/4), liver tumors (0/4), ovarian tumors (0/4), brain tumors (0/2), tumors of the esophagus (0/1), breast tumors (0/2), stomach tumors (0/2), tumors of the tongue (0/2), metastatic tumors of unknown origin (0/2), kidney tumors (0/2), tumors of the cervix (0/2), testicular tumors (0/2), colon tumors (0/2), tumors of the rectum (0/2), skin tumors (0/2), a tumor of the larynx (0/1) or a tumor of the thymus (0/1). (Total number of abnormal cases evaluated = 90).

PA0943 is recommended for the identification of human alpha smooth muscle actin in normal and neoplastic tissues.

Product Specific Limitations

Smooth Muscle Actin (alpha sm-1) has been optimized at Leica Biosystems for use with Bond Polymer Refine Detection and BOND ancillary reagents. Users who deviate from recommended test procedures must accept responsibility for interpretation of patient results under these circumstances. The protocol times may vary, due to variation in tissue fixation and the effectiveness of antigen enhancement, and must be determined empirically. Negative reagent controls should be used when optimizing retrieval conditions and protocol times.

Troubleshooting

Refer to reference 3 for remedial action.

Contact your local distributor or the regional office of Leica Biosystems to report unusual staining.

Further Information

Further information on immunostaining with BOND reagents, under the headings Principle of the Procedure, Materials Required, Specimen Preparation, Quality Control, Assay Verification, Interpretation of Staining, Key to Symbols on Labels, and General Limitations can be found in "Using BOND Reagents" in your BOND user documentation.

Bibliography

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Date of Issue

16 June 2015

Anticorps Primaire Prêt À L'emploi Bond™ Smooth Muscle Actin (alpha sm-1)

Référence: PA0943

Utilisation Prévue

Ce réactif est destiné au diagnostic *in vitro*.

L'anticorps monoclonal Smooth Muscle Actin (alpha sm-1) est destiné à l'identification qualitative par microscopie optique de l'actine alpha du muscle lisse humain dans des tissus fixés au formol et enrobés de paraffine par coloration immunohistochimique à partir du système BOND automatisé (qui comprend les systèmes Leica BOND-MAX et Leica BOND-III).

L'interprétation clinique de tout marquage ou de son absence doit être complétée par des études morphologiques utilisant des contrôles appropriés et évaluée dans le contexte des antécédents cliniques du patient et des autres tests diagnostiques par un pathologiste qualifié.

Résumé et Explications

Les techniques immunohistochimiques peuvent être utilisées pour la mise en évidence d'antigènes sur tissus ou cellules (voir « Utilisation des réactifs BOND » dans votre manuel d'utilisation BOND). L'anticorps primaire Smooth Muscle Actin (alpha sm-1) est prêt à l'emploi et a été spécialement optimisé pour Bond Polymer Refine Detection. La preuve de l'actine alpha du muscle lisse humain s'obtient d'abord par l'établissement de la liaison entre Smooth Muscle Actin (alpha sm-1) et la section, puis la visualisation de cette liaison en utilisant les réactifs fournis dans le système de détection. L'utilisation de ces produits, en combinaison avec le système BOND automatisé (qui comprend les systèmes Leica BOND-MAX et Leica BOND-III), réduit le risque d'erreurs humaines et la variabilité inhérente résultant de la dilution des réactifs individuels, du pipetage manuel et de l'application des réactifs.

Réactifs Fournis

Smooth Muscle Actin (alpha sm-1) est un anticorps monoclonal anti-humain de souris, produit comme IgG purifiée et conditionnée dans du tampon salin Tris avec une protéine de transport, contenant 0,35% de ProClin™ 950 comme conservateur.

Volume total = 7 ml.

Clone

asm-1

Immunogène

Décapeptide synthétique à extrémité amino-terminale de l'isoforme alpha de l'actine du muscle lisse.

Spécificité

Actine alpha du muscle lisse humain.

Classe d'Ig

IgG2a

Concentration Totale en Protéine

Environ 10 mg/ml.

Concentration en Anticorps

Supérieure ou égale à 0,2 mg/l déterminée par ELISA.

Dilution et Mélange

L'anticorps primaire Smooth Muscle Actin (alpha sm-1) est dilué de manière optimale pour une utilisation sur le système BOND (qui comprend les systèmes Leica BOND-MAX et Leica BOND-III). Reconstitution, mélange, dilution et titration de ce réactif non nécessaires.

Matériel Nécessaire Mais Non Fournis

Veuillez vous référer à la section "Utilisation des réactifs BOND" dans votre mode d'emploi BOND pour obtenir une liste détaillée des matériaux requis pour le traitement des échantillons et la coloration immunohistochimique via le système BOND (qui comprend les systèmes Leica BOND-MAX et Leica BOND-III).

Conservation et Stabilité

Conserver entre 2 et 8 °C. Ne pas utiliser après la date de péremption indiquée sur l'étiquette du récipient.

Une turbidité de la solution, une présence d'odeurs ou de précipité sont des signes indicateurs d'une contamination et/ou d'une instabilité de Smooth Muscle Actin (alpha sm-1).

Remettre à 2–8 °C immédiatement après usage.

Des conditions de stockage différentes de celles ci-dessus doivent être contrôlées par l'utilisateur¹.

Précautions

- Ce produit est conçu pour le diagnostic *in vitro*.
- La concentration de ProClin™ 950 est de 0,35 %. Contient du 2-méthyl-4-isothiazoline-3-one (principe actif) et peut entraîner des irritations de la peau, des yeux, des muqueuses et des voies aériennes supérieures. Porter des gants jetables lors de la manipulation des réactifs.
- Pour obtenir une copie de la fiche technique des substances dangereuses, contactez votre distributeur local ou le bureau régional de Leica Biosystems, ou allez sur le site Web de Leica Biosystems, www.LeicaBiosystems.com

- Les échantillons, avant et après fixation, et tous les matériels ayant été en contact avec eux, devraient être manipulés comme s'ils étaient à risque infectieux et éliminés avec les précautions adéquates ². Ne jamais pipeter les réactifs à la bouche et éviter le contact de la peau et des muqueuses avec les réactifs ou les échantillons. Si des réactifs ou des échantillons entrent en contact avec des zones sensibles, rincer abondamment à l'eau. Consultez un médecin.
- Renseignez-vous sur les règlements fédéraux, nationaux et locaux pour l'élimination des composés potentiellement toxiques.
- Éviter une contamination microbienne des réactifs qui peut entraîner un marquage non spécifique.
- Des durées ou températures de démasquage ou d'incubation autres que celles spécifiées peuvent donner des résultats erronés. Tout changement doit être validé par l'utilisateur.

Mode d'emploi

L'anticorps primaire Smooth Muscle Actin (alpha sm-1) a été développé pour être utilisé sur le système BOND automatisé (qui comprend les systèmes Leica BOND-MAX et Leica BOND-III) en combinaison avec le Bond Polymer Refine Detection. Le protocole de marquage recommandé pour l'anticorps primaire Smooth Muscle Actin (alpha sm-1) est IHC Protocol F. Aucun pré-traitement n'est recommandé.

Résultats Attendus

Tissus sains

Le clone asm-1 a détecté l'actine alpha du muscle lisse dans le cytoplasme des cellules musculaires lisses. Ces cellules se trouvent dans les parois vasculaires, la muscularis mucosae et la muscularis propria intestinales et dans le stroma de divers tissus. Il a également réagi avec le myoépithélium de diverses glandes, notamment les glandes salivaires et mammaires. (Nombre total de cas normaux évalués = 99).

Tissus tumoraux

Le clone asm-1 a détecté la protéine actine du muscle lisse dans 5/6 léiomyosarcomes, 4/4 léiomyomes, 2/2 hémangiomes caverneux, 1/7 fibrosarcomes, 1/3 histiocytomes fibreux, 1/1 angioléiomyome, 1/1 hémangiopéricytome et 1/1 mésenchymome. Aucun marquage n'a été observé dans des tumeurs stromales gastro-intestinales (0/5), chondrosarcomes (0/4), rhabdomyosarcomes pléomorphes (0/2), rhabdomyosarcomes alvéolaires (0/2), sarcomes synoviaux (0/2), un fibrolipome (0/1), un lipome (0/1), une tumeur fibreuse solitaire (0/1), un sarcome épithélioïde (0/1), un mésothéliome (0/1), un liposarcome (0/1), un liposarcome myxoïde (0/1), un dermatofibrosarcome (0/1), une fibromatose (0/1), un ganglioneurome (0/1), des tumeurs de la thyroïde (0/3), tumeurs du poumon (0/4), tumeurs du foie (0/4), tumeurs de l'ovaire (0/4), tumeurs du cerveau (0/2), tumeurs de l'œsophage (0/1), tumeurs du sein (0/2), tumeurs de l'estomac (0/2), tumeurs de la langue (0/2), tumeurs métastatiques d'origine inconnue (0/2), tumeurs du rein (0/2), tumeurs du col de l'utérus (0/2), tumeurs de la testicule (0/2), tumeurs du côlon (0/2), tumeurs du rectum (0/2), tumeurs de la peau (0/2), une tumeur du larynx (0/1) ou une tumeur du thymus (0/1). (Nombre total de cas anormaux évalués = 90).

PA0943 est recommandé pour la détection de la actine alpha du muscle lisse humain dans les tissus normaux et néoplasiques.

Limites Spécifiques du Produit

Smooth Muscle Actin (alpha sm-1) a été optimisé chez Leica Biosystems pour une utilisation avec Bond Polymer Refine Detection et les réactifs auxiliaires BOND. Les utilisateurs qui ne respectent pas les procédures de test recommandées prennent la responsabilité de l'interprétation des résultats des patients dans ces conditions. Les durées du protocole doivent être déterminées empiriquement, à cause des variations de fixation des tissus et d'efficacité du renforcement antigénique. Des contrôles négatifs des réactifs devraient être réalisés lors de l'optimisation des conditions de démasquage et des durées du protocole.

Identification des Problèmes

Voir la référence 3 pour connaître les actions correctrices.

Prenez contact avec votre distributeur local ou avec le bureau régional de Leica Biosystems pour signaler tout marquage inattendu.

Informations Complémentaires

Des informations complémentaires sur l'immunomarquage avec les réactifs BOND, les principes de la méthode, le matériel nécessaire, la préparation des échantillons, le contrôle qualité, les vérifications d'analyse, l'interprétation du marquage, les légendes et symboles sur les étiquettes et les limites générales, peuvent être obtenues dans « Utilisation des réactifs BOND » dans votre manuel d'utilisation BOND.

Bibliographie

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14. Wagner K-U, Young WS, Liu X et al. Oxytocin and milk removal are required for post-partum mammary-gland development. *Genes and Function*. 1997; 1(4):233-244.
15. Skalli O, Ropraz P, Trzeciak A et al. A monoclonal antibody against α -smooth muscle actin: a new probe for smooth muscle differentiation. *The Journal of Cell Biology*. 1986; 103:2787-2796.

Date de Publication

16 juin 2015

Anticorpo Primario Pronto All'uso Bond™ Smooth Muscle Actin (alpha sm-1)

N. catalogo: PA0943

Uso Previsto

Reagente per uso diagnostico *in vitro*.

L'anticorpo monoclonale Smooth Muscle Actin (alpha sm-1) è destinato all'identificazione qualitativa in microscopia ottica dell'alfa-actina del muscolo liscio umano in tessuti fissati in formalina e inclusi in paraffina, tramite colorazione immunostochimica con il sistema automatizzato BOND (include il sistema Leica BOND-MAX e il sistema Leica BOND-III).

L'interpretazione clinica di un'eventuale colorazione, o della sua assenza, deve avvalersi di studi morfologici e di opportuni controlli ed essere effettuata da patologi qualificati, nel contesto dell'anamnesi clinica del paziente e di altri test diagnostici.

Sommario e Spiegazione

Grazie alle tecniche di immunostochimica è possibile dimostrare la presenza di antigeni nel tessuto e nelle cellule (vedere "Uso dei reagenti BOND" nella documentazione per l'utente BOND). L'anticorpo primario Smooth Muscle Actin (alpha sm-1) è un prodotto pronto per l'uso che è stato ottimizzato in modo specifico per l'impiego con il Bond Polymer Refine Detection. La dimostrazione dell'alfa-actina del muscolo liscio umano si ottiene in primo luogo consentendo il legame di Smooth Muscle Actin (alpha sm-1) con la sezione e quindi visualizzando il legame stesso per mezzo dei reagenti forniti nel sistema di rilevazione. L'uso di questi prodotti in combinazione con il sistema automatizzato BOND (include il sistema Leica BOND-MAX e il sistema Leica BOND-III), riduce la possibilità di errori umani e la variabilità inerente derivante dalla diluizione dei reagenti, dal pipettaggio manuale e dall'applicazione dei reagenti.

Reagenti Forniti

Il Smooth Muscle Actin (alpha sm-1) è un anticorpo monoclonale murino anti-umano prodotto come frazione IgG purificata e fornito in soluzione salina tamponata Tris con proteina carrier, contenente 0,35% di ProClin™ 950 come conservante.

Volume totale = 7 ml.

Clone

asm-1

Immunogeno

Decapeptide sintetico ammino-terminale dell'isoforma alfa-actina del muscolo liscio.

Specificità

Alfa-actina del muscolo liscio umano.

Classe Ig

IgG2a

Concentrazione Proteica Totale

Circa 10 mg/ml.

Concentrazione Dell'anticorpo

Uguale o superiore a 0,2 mg/l, determinata mediante ELISA.

Diluizione e Miscelazione

L'anticorpo primario Smooth Muscle Actin (alpha sm-1) è diluito in modo ottimale per essere usato con il sistema BOND (include il sistema Leica BOND-MAX e il sistema Leica BOND-III). Non è necessario ricostituire, miscelare, diluire o titolare il reagente.

Materiale Necessario Non Fornito

Per una lista completa dei materiali necessari al trattamento dei campioni e alla colorazione immunostochimica usando il sistema BOND (include il sistema Leica BOND-MAX e il sistema Leica BOND-III), consultare "L'uso dei reagenti BOND" nel proprio manuale utente BOND.

Conservazione e Stabilità

Conservare a 2–8 °C. Non utilizzare dopo la data di scadenza indicata sull'etichetta del contenitore.

I segni di contaminazione e/o instabilità del Smooth Muscle Actin (alpha sm-1) sono: torbidità della soluzione, formazione di odori e presenza di un precipitato.

Riportare a 2–8 °C immediatamente dopo l'uso.

L'utente deve verificare eventuali condizioni di conservazione diverse da quelle specificate¹.

Precauzioni

- Il prodotto è destinato all'uso diagnostico *in vitro*.
- La concentrazione del ProClin™ 950 è 0,35 %. Esso contiene il principio attivo 2-metil-4-isotiazolin-3-one e può causare irritazione alla cute, agli occhi, alle membrane mucose e alle alte vie respiratorie. Per la manipolazione dei reagenti usare guanti monouso.
- Una copia della Scheda di sicurezza può essere richiesta al distributore locale o all'ufficio di zona di Leica Biosystems o, in alternativa, visitando il sito di Leica Biosystems www.LeicaBiosystems.com

- I campioni, prima e dopo la fissazione, e tutti i materiali esposti ad essi devono essere manipolati come potenziali vettori di infezione e smaltiti con le opportune precauzioni². Non pipettare mai i reagenti con la bocca ed evitare il contatto dei reagenti o dei campioni con la pelle e le membrane mucose. Se un reagente o un campione viene a contatto con zone sensibili, lavare abbondantemente con acqua. Consultare un medico.
- Consultare la normativa nazionale, regionale o locale vigente per lo smaltimento dei componenti potenzialmente tossici.
- Ridurre al minimo la contaminazione microbica dei reagenti per evitare il rischio di una colorazione non specifica.
- Tempi o temperature di incubazione diversi da quelli specificati possono fornire risultati erronei. Ogni eventuale modifica deve essere validata dall'utente.

Istruzioni per l'uso

L'anticorpo primario Smooth Muscle Actin (alpha sm-1) è stato sviluppato per l'uso nei sistemi automatizzati BOND (include il sistema Leica BOND-MAX e il sistema Leica BOND-III) in combinazione con il Bond Polymer Refine Detection. Il protocollo di colorazione consigliato per l'anticorpo primario Smooth Muscle Actin (alpha sm-1) è l'IHC Protocol F. Non è consigliato alcun pre-trattamento.

Risultati Attesi

Tessuti normali

Il clone asm-1 ha rilevato la presenza di alfa-actina del muscolo liscio nel citoplasma delle cellule muscolari lisce. Queste cellule si possono trovare nelle pareti vascolari, nella muscolaris mucosae e nella muscolare propria dell'intestino, nonché nello stroma di diversi tessuti. Ha reagito anche al mioepitelio di svariate ghiandole, in particolare le ghiandole salivari e mammarie. (Numero complessivo di casi normali valutati = 99).

Tessuti neoplastici

Il clone asm-1 ha rilevato la presenza di proteina dell'actina muscolare liscia in 5/6 leiomiomasarcomi, 4/4 leiomiomi, 2/2 emangiomi cavernosi, 1/7 fibrosarcomi, 1/3 istiocitomi fibrosi, 1/1 angioleiomioma, 1/1 emangiopericitoma e 1/1 mesenchimoma. Non è stata osservata alcuna colorazione in tumori stromali del tratto gastrointestinale (0/5), condrosarcomi (0/4), rhabdomyosarcomi pleomorfi (0/2), rhabdomyosarcomi alveolari (0/2), sarcomi sinoviali (0/2), un fibrolipoma (0/1), un lipoma (0/1), un tumore solitario fibroso (0/1), un sarcoma epitelioide (0/1), un mesotelioma (0/1), un liposarcoma (0/1), un mixoliposarcoma (0/1), un dermatofibrosarcoma (0/1), una fibromatosi (0/1), un ganglioneuroma (0/1), tumori tiroidei (0/3), tumori polmonari (0/4), tumori epatici (0/4), tumori ovarici (0/4), tumori cerebrali (0/2), un tumore esofageo (0/1), tumori della mammella (0/2), tumori dello stomaco (0/2), tumori della lingua (0/2), tumori metastatici di origine ignota (0/2), tumori renali (0/2), tumori della cervice (0/2), tumori testicolari (0/2), tumori del colon (0/2), tumori del retto (0/2), tumori della pelle (0/2), un tumore della laringe (0/1) o un tumore timico (0/1). (Numero complessivo di casi anomali valutati = 90).

PA0943 è raccomandato per la rilevazione della alfa-actina del muscolo liscio umano nei tessuti normali e neoplastici.

Limitazioni Specifiche del Prodotto

Il Smooth Muscle Actin (alpha sm-1) è stato ottimizzato da Leica Biosystems per l'uso con il Bond Polymer Refine Detection e con i reagenti ausiliari BOND. Gli utenti che modificano le procedure raccomandate devono assumersi la responsabilità dell'interpretazione dei risultati relativi ai pazienti in tali circostanze. I tempi del protocollo possono variare in base alle variazioni nella fissazione del tessuto e nell'efficienza del potenziamento dell'antigene e devono essere definiti in modo empirico. Nell'ottimizzazione delle condizioni di riconoscimento e dei tempi del protocollo si devono impiegare dei controlli negativi del reagente.

Soluzione Problemi

Per le azioni di rimedio consultare il riferimento bibliografico n. 3.

Per riferire una colorazione inusuale rivolgersi al distributore locale o all'ufficio di zona di Leica Biosystems.

Ulteriori Informazioni

Altre informazioni sull'immunocolorazione con i reagenti BOND si trovano in "Uso dei reagenti BOND" nella documentazione per l'utente BOND, ai titoli Principio della procedura, Materiali necessari, Preparazione del campione, Controllo di qualità, Verifica del saggio, Interpretazione della colorazione, Leggenda dei simboli delle etichette e Limitazioni generali.

Bibliografia

1. Clinical Laboratory Improvement Amendments of 1988, Final Rule 57 FR 7163 February 28, 1992.
2. Villanova PA. National Committee for Clinical Laboratory Standards (NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. 1991; 7(9). Order code M29-P.
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Data di Pubblicazione

16 giugno 2015

Gebrauchsfertiger Bond™ -Primärantikörper Smooth Muscle Actin (alpha sm-1)

Bestellnr.: PA0943

Verwendungszweck

Dieses Reagenz ist für die *In-vitro*-Diagnostik bestimmt.

Smooth Muscle Actin (alpha sm-1) monoklonaler Antikörper ist für den qualitativen Nachweis von humanem glattmuskulärem Alpha-Aktin in formalinfixiertem, paraffineingebettetem Gewebe durch immunhistochemische Färbung mithilfe des automatisierten BOND-Systems (bestehend aus dem Leica BOND-MAX-System und dem Leica BOND-III-System) mittels Lichtmikroskopie vorgesehen.

Die klinische Auswertung der An- oder Abwesenheit einer Färbung sollte durch morphologische Untersuchungen und geeignete Kontrollen ergänzt werden und sollte im Zusammenhang mit der Krankengeschichte eines Patienten und anderen diagnostischen Tests von einem qualifizierten Pathologen vorgenommen werden.

Zusammenfassung und Erläuterung

Immunhistochemische Methoden können dazu verwendet werden, die Anwesenheit von Antigenen in Geweben und Zellen zu demonstrieren (sehen Sie dazu "Das Arbeiten mit BOND-Reagenzien" in Ihrem BOND-Benutzerhandbuch). Der Primärantikörper Smooth Muscle Actin (alpha sm-1) ist ein gebrauchsfertiges Produkt, das speziell für den Gebrauch mit dem Bond Polymer Refine Detection optimiert wurde. Der Nachweis von humanem glattmuskulärem Alpha-Aktin wird erzielt, indem zunächst die Bindung von Smooth Muscle Actin (alpha sm-1) mit dem Schnitt ermöglicht und dann diese Bindung mithilfe der im Nachweissystem enthaltenen Reagenzien optisch dargestellt wird. Die Verwendung dieser Produkte in Kombination mit dem automatisierten BOND-system (bestehend aus dem Leica BOND-MAX-System und dem Leica BOND-III-System) reduziert die Wahrscheinlichkeit von menschlichem Versagen sowie die inhärente Variabilität, die aus der Verdünnung der einzelnen Reagenzien, der manuellen Pipettierung und der Anwendung der Reagenzien resultieren.

Mitgelieferte Reagenzien

Smooth Muscle Actin (alpha sm-1) ist ein monoklonaler Maus-Anti-Human-Antikörper, der als gereinigte IgG-Fraktion präsentiert wird, in Tris-gepufferter Salzlösung mit einem Trägerprotein geliefert wird und 0,35% ProClin™ 950 als Konservierungsmittel enthält.

Gesamtvolumen = 7 ml.

Klon

asm-1

Immunogen

Synthetisches aminoterminales Dekapeptid von glattmuskulärer Alpha-Isoform von Aktin.

Spezifität

Humanes glattmuskuläres Alpha-Aktin.

Ig-Klasse

IgG2a

Gesamtproteinkonzentration

Ca. 10 mg/ml.

Antikörperkonzentration

Größer oder gleich 0,2 mg/l, bestimmt mit ELISA.

Verdünnung und Mischung

Der primäre Antikörper Smooth Muscle Actin (alpha sm-1) weist eine optimale Verdünnung für die Verwendung mit dem BOND-system (bestehend aus dem Leica BOND-MAX-System und dem Leica BOND-III-System) auf. Rekonstitution, Mischen, Verdünnen oder Titrieren dieses Reagenzes ist nicht erforderlich.

Erforderliche, Aber Nicht Mitgelieferte Materialien

In Ihrer BOND-Benutzerdokumentation finden Sie unter "Verwendung von BOND-Reagenzien" eine vollständige Liste der Materialien, die für die Probenvorbereitung und die immunhistochemische Färbung mit dem BOND-system (bestehend aus dem Leica BOND-MAX-System und dem Leica BOND-III-System) benötigt werden.

Lagerung und Stabilität

Bei 2–8 °C lagern. Nach Ablauf des auf dem Behälterkett angegebenen Verfallsdatums nicht mehr verwenden.

Zeichen, die auf eine Kontamination und/oder Instabilität von Smooth Muscle Actin (alpha sm-1) hinweisen, sind eine Trübung der Lösung, Geruchsentwicklung, und das Vorhandensein von Präzipitat.

Unmittelbar nach Gebrauch wieder bei 2–8 °C aufbewahren.

Andere als die oben angegebenen Lagerungsbedingungen müssen vom Anwender selbst getestet werden¹.

Vorsichtsmaßnahmen

- Dieses Produkt ist für die *In-vitro*-Diagnostik bestimmt.

- Die Konzentration von ProClim™ 950 beträgt 0,35 %. Es enthält 2-Methyl-4-isothiazolin-3-on als aktiven Bestandteil und kann Reizungen der Haut, Augen, Schleimhäute und oberen Atemwege verursachen. Tragen Sie beim Umgang mit Reagenzien Einweghandschuhe.
- Ein Exemplar des Sicherheitsdatenblattes erhalten Sie von Ihrer örtlichen Vertriebsfirma, von der Regionalniederlassung von Leica Biosystems oder über die Webseite von Leica Biosystems unter www.LeicaBiosystems.com
- Behandeln Sie Präparate vor und nach der Fixierung sowie sämtliche damit in Berührung kommenden Materialien so, als ob sie Infektionen übertragen könnten und entsorgen Sie sie unter Beachtung der entsprechenden Vorsichtsmaßnahmen². Pipettieren Sie Reagenzien niemals mit dem Mund und vermeiden Sie den Kontakt von Haut oder Schleimhäuten mit Reagenzien oder Präparaten. Falls Reagenzien oder Präparate mit empfindlichen Bereichen in Kontakt kommen, spülen Sie diese mit reichlich Wasser. Holen Sie anschließend ärztlichen Rat ein.
- Beachten Sie bei der Entsorgung potentiell toxischer Bestandteile die behördlichen und örtlichen Vorschriften.
- Mikrobielle Kontaminationen sollten minimiert werden, da es sonst zu einer Zunahme unspezifischer Färbungen kommen kann.
- Die Verwendung anderer als die angegebenen Retrievals, Inkubationszeiten oder Temperaturen kann zu fehlerhaften Ergebnissen führen. Diesbezügliche Änderungen müssen vom Anwender selbst getestet werden.

Gebrauchsanleitung

Der primäre Antikörper Smooth Muscle Actin (alpha sm-1) wurde für die Verwendung in dem automatisierten BOND-System (bestehend aus dem Leica BOND-MAX-System und dem Leica BOND-III-System) in Kombination mit Bond Polymer Refine Detection entwickelt. Das empfohlene Färbeverfahren für den Primärintikörper Smooth Muscle Actin (alpha sm-1) ist das IHC Protocol F. Eine Vorbehandlung wird nicht empfohlen.

Erwartete Ergebnisse

Normale Gewebe

Klon asm-1 wies glattmuskuläres Alpha-Aktin im Zytoplasma von glattmuskulösen Zellen nach. Diese Zellen sind in Gefäßwänden, intestinalen Muscularis mucosae und Muscularis propria und im Stroma von verschiedenen Geweben zu finden. Außerdem reagierte es mit Myoepithelium verschiedener Drüsen, insbesondere Speicheldrüsen und Milchdrüsen. (Anzahl der insgesamt untersuchten Normalgewebeprobe(n) = 99).

Tumorgewebe

Klon asm-1 wies das glattmuskuläre Alpha-Aktin-Protein in 5/6 Leiomyosarkomen, 4/4 Leiomyomen, 2/2 kavernösen Hämangiomen, 1/7 Fibrosarkomen, 1/3 fibrösen Histiozytomen, 1/1 Angioleiomyom, 1/1 malignes Hämangioperizytom und 1/1 Mesenchymom. Bei gastrointestinalen Stromatumoren (0/5), Chondrosarkomen (0/4), pleomorphen Rhabdomyosarkomen (0/2), alveolären Rhabdomyosarkomen (0/2), synovialen Sarkomen (0/2), einem Fibrolipom (0/1), einem Lipom (0/1), einem einzelnen fibrösen Tumor (0/1), einem epithelioiden Sarkom (0/1), einem Mesotheliom (0/1), einem Liposarkom (0/1), einem Myxoliposarkom (0/1), einem Dermatofibrosarkom (0/1), einer Fibromatose (0/1), einem Ganglioneurom (0/1), Tumoren der Schilddrüse (0/3), Lungentumoren (0/4), Lebertumoren (0/4), Ovarialtumoren (0/4), Gehirntumoren (0/2), Tumoren der Speiseröhre (0/1), Brusttumoren (0/2), Magentumoren (0/2), Zungentumoren (0/2), metastasierenden Tumoren unbekanntes Ursprungs (0/2), Nierentumoren (0/2), Zervixtumoren (0/2), Hodentumoren (0/2), Kolontumoren (0/2), Rektumtumoren (0/2), Hauttumoren (0/2), einem Tumor des Larynx (0/1) oder einem Thymustumor (0/1) wurde keine Färbung nachgewiesen. (Anzahl der insgesamt untersuchten pathologischen Gewebeprobe(n) = 90).

PA0943 wird für den Nachweis von humanes glattmuskuläres Alpha-Aktin in normalem und neoplastischem Gewebe empfohlen.

Produktspezifische Einschränkungen

Smooth Muscle Actin (alpha sm-1) wurde von Leica Biosystems zur Verwendung mit dem Bond Polymer Refine Detection und BOND-Zusatzreagenzien optimiert. Anwender, die andere als die empfohlenen Testverfahren verwenden, müssen unter diesen Umständen die Verantwortung für die Auswertung der Patientenergebnisse übernehmen. Die Verfahrenszeiten können aufgrund von Unterschieden in der Gewebefixierung und der Wirksamkeit der Antigenverstärkung variieren und müssen empirisch bestimmt werden. Bei der Optimierung der Retrieval-Bedingungen und Verfahrenszeiten sollten negative Reagenzkontrollen verwendet werden.

Fehlersuche

Maßnahmen zur Abhilfe beim Auftreten von Fehlern finden Sie in Referenz 3.

Falls Sie ungewöhnliche Färbegergebnisse beobachten, wenden Sie sich an Ihre örtliche Vertriebsfirma oder an die Regionalniederlassung von Leica Biosystems.

Weitere Informationen

Weitere Informationen zur Immunfärbung mit BOND-Reagenzien finden Sie in den Abschnitten Grundlegende Vorgehensweise, Erforderliches Material, Probenvorbereitung, Qualitätskontrolle, Assay-Verifizierung, Deutung der Färbung, Schlüssel der Symbole auf den Etiketten und Allgemeine Einschränkungen in "Das Arbeiten mit BOND-Reagenzien" in Ihrem BOND-Benutzerhandbuch.

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Ausgabedatum

16 Juni 2015

Anticuerpo Primario Listo Para Usar Bond™ Smooth Muscle Actin (alpha sm-1)

Catálogo N°.: PA0943

Indicaciones de Uso

Este reactivo es para uso diagnóstico *in vitro*.

El anticuerpo monoclonal Smooth Muscle Actin (alpha sm-1) está pensado para su utilización en la identificación cualitativa mediante microscopía óptica de la alfa actina de músculo liso humana en tejido fijado en formol y embebido en parafina, mediante tinción inmunohistoquímica utilizando el sistema BOND automatizado (incluye el sistema Leica BOND-MAX y el sistema Leica BOND-III).

La interpretación clínica de cualquier tinción o de la ausencia de ésta debe complementarse con estudios morfológicos y controles adecuados, y debe evaluarla un patólogo cualificado junto con el historial clínico del paciente y con otras pruebas diagnósticas.

Resumen y Explicación

Las técnicas inmunohistoquímicas pueden ser utilizadas para detectar la presencia de antígenos en tejidos y células (véase "Uso de reactivos BOND" en la documentación de usuario suministrada por BOND). El anticuerpo primario Smooth Muscle Actin (alpha sm-1) es un producto listo para usar que se ha optimizado específicamente para su uso con Bond Polymer Refine Detection. La demostración de la alfa actina de músculo liso humana se puede llevar a cabo primero permitiendo la unión de Smooth Muscle Actin (alpha sm-1) a la sección y luego visualizando esta unión usando los reactivos proporcionados en el sistema de detección. La utilización de estos productos, en combinación con el sistema BOND automatizado (incluye el sistema Leica BOND-MAX y el sistema Leica BOND-III), reduce las posibilidades de que se produzca un error humano y la variabilidad inherente que resulta de la dilución de un reactivo individual, del pipeteo manual y de la aplicación de un reactivo.

Reactivos Suministrados

Smooth Muscle Actin (alpha sm-1) es un anticuerpo monoclonal antihumano de ratón que se produce como una fracción de IgG purificada, y se suministra en solución salina tamponada de Tris con proteína portadora, que contiene el 0,35% de ProClin™ 950 como conservante.

Volumen total = 7 mL.

Clon

asm-1

Inmunógeno

Decapéptido amino terminal sintético de la isoforma alfa de la actina de músculo liso.

Especificidad

Alfa actina de músculo liso humana.

Clase de Ig

IgG2a

Concentración Total de Proteína

Aprox. 10 mg/mL.

Concentración de Anticuerpos

Mayor o igual a 0,2 mg/L según lo determinado por ELISA.

Dilución y Mezcla

El anticuerpo primario Smooth Muscle Actin (alpha sm-1) se diluye óptimamente para usarse en el sistema BOND (incluye el sistema Leica BOND-MAX y el sistema Leica BOND-III). No es necesaria la reconstitución, mezcla, dilución o titulación de este reactivo.

Material Necesario Pero No Suministrado

Consulte el apartado "Utilización de reactivos BOND" de la documentación de usuario BOND para leer una lista completa de los materiales requeridos en el tratamiento de muestras y en la tinción inmunohistoquímica con el sistema BOND (incluye el sistema Leica BOND-MAX y el sistema Leica BOND-III).

Conservación y Estabilidad

Debe conservarse a 2–8 °C. No utilizar después de la fecha de caducidad que aparece en la etiqueta.

Los signos de contaminación y/o inestabilidad de Smooth Muscle Actin (alpha sm-1) son turbidez de la solución, aparición de olor y presencia de precipitado.

Volver a guardar a 2–8 °C inmediatamente después de su uso.

Si las condiciones de conservación son diferentes de las especificadas, el usuario debe realizar las comprobaciones necesarias¹.

Precauciones

- Este producto es para uso diagnóstico *in vitro*.
- La concentración de ProClin™ 950 es de 0,35 %. Contiene el principio activo 2-metil-4-isotiazolin-3-ona, que puede producir irritación en la piel, ojos, mucosas y tracto respiratorio superior. Lleve siempre guantes desechables cuando manipule los reactivos.

- Si desea obtener un ejemplar de la Hoja de datos de seguridad de los materiales, póngase en contacto con su distribuidor o con la oficina regional de Leica Biosystems, o visite la página Web de Leica Biosystems en www.LeicaBiosystems.com
- Las muestras, antes y después de ser fijadas, y cualquier material en contacto con ellas, deben ser tratados como sustancias capaces de transmitir infecciones y deben ser eliminadas con las precauciones correspondientes². No pipetee nunca los reactivos con la boca, y evite el contacto de la piel y las mucosas con reactivos o muestras. Si algún reactivo o alguna muestra entra en contacto con zonas sensibles, lávelas con agua abundante. Consulte a un médico.
- Consulte la normativa federal, nacional o local referente a la eliminación de sustancias potencialmente tóxicas.
- Minimice la contaminación microbiana de los reactivos, ya que puede producir un aumento de las tinciones inespecíficas.
- Los tiempos de exposición e incubación, y las temperaturas diferentes de las especificadas pueden dar resultados erróneos. Cualquier cambio que se produzca deberá ser validado por el usuario.

Instrucciones de Uso

El anticuerpo primario Smooth Muscle Actin (alpha sm-1) se ha desarrollado para usarse en el sistema BOND automatizado (incluye el sistema Leica BOND-MAX y el sistema Leica BOND-III) en combinación con la Bond Polymer Refine Detection. El protocolo de tinción recomendado para el anticuerpo primario Smooth Muscle Actin (alpha sm-1) es IHC Protocol F. No se recomienda tratamiento previo.

Resultados Esperados

Tejidos normales

El clon osm-1 detectó la alfa actina de músculo liso en el citoplasma de las células de músculo liso. Estas células pueden encontrarse en la pared vascular, la capa muscular de la mucosa intestinal y la muscular propia, y en el estroma de diversos tejidos. También reacciona con el mioepitelio de distintas glándulas, en particular las glándulas salivales y mamarias. (Cifra total de casos normales evaluados = 99).

Tejidos tumorales

El clon osm-1 detectó la proteína actina de músculo liso en 5/6 liomiosarcomas, 4/4 liomiosarcomas, 2/2 hemangiomas cavernosos, 1/7 fibrosarcomas, 1/3 histiocitomas fibrosos, 1/1 angioliomoma, 1/1 hemangiopericito sarcoma y 1/1 mesenquimoma. No se observó tinción en tumores del estroma gastrointestinal (0/5), condrosarcomas (0/4), rhabdomyosarcomas pleomórficos (0/2), rhabdomyosarcomas alveolares (0/2), sarcomas sinoviales (0/2), un fibrolipoma (0/1), un lipoma (0/1), un tumor fibroso solitario (0/1), un sarcoma epiteloide (0/1), un mesotelioma (0/1), un liposarcoma (0/1), un mixoliposarcoma (0/1), un dermatofibrosarcoma (0/1), una fibromatosis (0/1), un ganglioneuroma (0/1), tumores tiroideos (0/3), tumores pulmonares (0/4), tumores hepáticos (0/4), tumores ováricos (0/4), tumores cerebrales (0/2), tumores esofágicos (0/1), tumores mamarios (0/2), tumores gástricos (0/2), tumores de la lengua (0/2), tumores metastásicos de origen desconocido (0/2), tumores renales (0/2), tumores del cuello uterino (0/2), tumores testiculares (0/2), tumores de colon (0/2), tumores del recto (0/2), tumores de la piel (0/2), un tumor de la laringe (0/1) ni un tumor del timo (0/1). (Cifra total de casos anormales evaluados = 90).

El PA0943 se recomienda para la detección de alfa actina de músculo liso humana en tejidos normales y neoplásicos.

Limitaciones Específicas del Producto

Smooth Muscle Actin (alpha sm-1) se ha optimizado en Leica Biosystems para su uso con Bond Polymer Refine Detection y reactivos auxiliares BOND. Los usuarios que se aparten de los procedimientos de análisis recomendados deben asumir la responsabilidad de interpretar los resultados del paciente tomando en cuenta estas circunstancias. Los tiempos de protocolo pueden diferir debido a la variación en la fijación de los tejidos y a la eficacia en la preservación del antígeno, y deben determinarse empíricamente. Se debe utilizar reactivos de control negativos a la hora de optimizar las condiciones de detección y los tiempos de protocolo.

Resolución de Problemas

Consulte la referencia 3 para ver las acciones correctoras.

Contacte con su distribuidor local o la oficina regional de Leica Biosystems para informar de cualquier tinción anómala.

Más Información

Para obtener más información sobre inmunotinciones con reactivos BOND, consulte los apartados Principio del procedimiento, Material necesario, Preparación de las muestras, Control de calidad, Verificación del análisis, Interpretación de la tinción, Clave de símbolos en las etiquetas y Limitaciones generales de la sección "Utilización de reactivos BOND" de la documentación de usuario suministrada por BOND.

Bibliografía

1. Clinical Laboratory Improvement Amendments of 1988, Final Rule 57 FR 7163 February 28, 1992.
2. Villanova PA. National Committee for Clinical Laboratory Standards (NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. 1991; 7(9). Order code M29-P.
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11. Oberpenning F, Meng J, Yoo JJ et al. De novo reconstitution of a functional mammalian urinary bladder by tissue engineering. *Nature Biotechnology*. 1999; 17:149-155.
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14. Wagner K-U, Young WS, Liu X et al. Oxytocin and milk removal are required for post-partum mammary-gland development. *Genes and Function*. 1997; 1(4):233-244.
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Fecha de Publicación

16 de junio de 2015

Anticorpo Primário Pronto a Usar Bond™ Smooth Muscle Actin (alpha sm-1)

Nº de catálogo: PA0943

Utilização Prevista

Este reagente destina-se a utilização diagnóstica *in vitro*.

O anticorpo Smooth Muscle Actin (alpha sm-1) destina-se a ser utilizado para a identificação qualitativa, por microscopia óptica, da alfa actina do músculo liso humano em tecidos fixados em formol e impregnados em parafina por coloração imuno-histoquímica utilizando o sistema BOND automatizado (inclui o sistema Leica BOND-MAX e o sistema Leica BOND-III).

A interpretação clínica de qualquer coloração ou da sua ausência deve ser complementada por estudos morfológicos utilizando controlos adequados, e deve ser avaliada no contexto da história clínica do doente e de outros testes complementares de diagnóstico por um anátomo-patologista qualificado.

Resumo e Explicação

As técnicas de imunohistoquímica podem ser usadas para demonstrar a presença de antígenos em tecidos e células (ver "Usar os Reagentes BOND" na sua documentação do utilizador BOND). O anticorpo primário Smooth Muscle Actin (alpha sm-1) consiste num produto pronto usar que foi especificamente otimizado para utilização com Bond Polymer Refine Detection. A demonstração da alfa actina do músculo liso humano é conseguida permitindo primeiro a ligação da actina do músculo liso (alpha sm-1) ao corte de tecido e visualizando depois esta ligação com os reagentes fornecidos no sistema de detecção. O uso destes produtos, combinado com o sistema BOND automatizado (inclui o sistema Leica BOND-MAX e o sistema Leica BOND-III), reduz a possibilidade de erro humano de variação inerente devido à diluição do reagente individual, pipetagem manual e aplicação do reagente.

Reagentes Fornecidos

Smooth Muscle Actin (alpha sm-1) é um anticorpo monoclonal anti-humano de rato produzido como uma fracção de IgG purificada, e fornecida em solução salina com tampão Tris com proteína transportadora, contendo 0,35% de ProClin™ 950 como conservante.

Volume total = 7 mL.

Clone

asm-1

Imunogénio

Decapéptido terminal amino sintético da isoforma alfa de actina do músculo liso.

Especificidade

Alfa actina do músculo liso humano.

Classe De Ig

IgG2a

Concentração de Proteínas Totais

Aproximadamente 10 mg/mL.

Concentração de Anticorpos

Maior ou igual a 0,2 mg/L conforme determinado por ELISA.

Diluição e Mistura

O anticorpo primário Smooth Muscle Actin (alpha sm-1) é devidamente diluído para uso no sistema BOND (inclui o sistema Leica BOND-MAX e o sistema Leica BOND-III). Não é necessária reconstituição, mistura, diluição ou titulação deste reagente.

Materiais Necessários Mas Não Fornecidos

Consulte "Uso de reagentes BOND" em sua documentação de usuário BOND para ter uma lista completa de materiais necessário para coloração imuni-histoquímica e tratamento da amostra usando o sistema BOND (inclui o sistema Leica BOND-MAX e o sistema Leica BOND-III).

Armazenamento e Estabilidade

Armazene a uma temperatura de 2 a 8 °C. Não utilize após o fim do prazo de validade referido no rótulo do recipiente.

Os sinais que indicam contaminação e/ou instabilidade de Smooth Muscle Actin (alpha sm-1) são: turvação da solução, desenvolvimento de odor e presença de precipitado.

Coloque entre 2 e 8 °C imediatamente depois de utilizar.

Condições de armazenamento diferentes das acima especificadas devem ser confirmadas pelo utilizador ¹.

Precauções

- Este produto destina-se a utilização diagnóstica *in vitro*.
- A concentração de ProClin™ 950 é de 0,35 %. Contém o ingrediente activo 2-metil-4-isotiazolina-3-a e pode provocar irritação da pele, olhos, membranas mucosas e vias aéreas superiores. Use luvas descartáveis quando manipular os reagentes. Use luvas descartáveis quando manipular os reagentes.

- Para obter uma cópia da Ficha de Dados de Segurança do Material, entre em contacto com o seu distribuidor local ou sucursal regional da Leica Biosystems ou, em alternativa, visite o site da Leica Biosystems na internet, www.LeicaBiosystems.com
- As amostras, antes e depois da fixação, e todo o material que a elas seja exposto, devem ser manipulados como se fossem capazes de transmitir infecção e eliminados usando as precauções adequadas². Nunca pipete reagentes com a boca e evite o contacto entre a pele e membranas mucosas com reagentes ou amostras. Se reagentes ou amostras entrarem em contacto com os olhos, lave-os com uma quantidade abundante de água. Consultar um médico.
- Consulte os regulamentos federais, estatais e locais relativamente à eliminação de quaisquer componentes potencialmente tóxicos.
- Minimizar a contaminação microbiana dos reagentes ou poderá ocorrer um aumento da coloração inespecífica.
- A utilização de tempos e temperaturas de recuperação e incubação diferentes dos especificados pode produzir resultados erróneos. Qualquer alteração deste tipo deve ser validada pelo utilizador.

Instruções de Utilização

O anticorpo primário Smooth Muscle Actin (alpha sm-1) foi desenvolvido para uso no sistema BOND automatizado (inclui o sistema Leica BOND-MAX e o sistema Leica BOND-III) em combinação com a Bond Polymer Refine Detection. O protocolo de coloração indicado para o anticorpo primário Smooth Muscle Actin (alpha sm-1) é o IHC Protocol F. Não é recomendado nenhum pré-tratamento.

Resultados Esperados

Tecidos normais

O Clone osm-1 detectou alfa actina do músculo liso no citoplasma de células do músculo liso. Estas células podem ser encontradas nas paredes vasculares, nas camadas muscularis mucosae e muscularis propria intestinais e no estroma de vários tecidos. Também reagiu com o mioepitélio de várias glândulas, em particular das glândulas salivares e mamárias (número total de casos normais avaliados = 99).

Tecidos tumorais

O Clone osm-1 detectou a proteína actina do músculo liso em 5/6 leiomiossarcomas, 4/4 leiomiomas, 2/2 hemangiomas cavernosos, 1/7 fibrossarcomas, 1/3 histiocitomas fibrosos, 1/1 angioleiomioma, 1/1 hemangiopericitossarcoma e 1/1 mesenquimoma. Não foi observada coloração em tumores estromais gastrointestinais (0/5), condrossarcomas (0/4), rabiomiossarcomas pleomórficos (0/2), rabiomiossarcomas alveolares (0/2), sarcomas sinoviais (0/2), fibrolipoma (0/1), lipoma (0/1), tumor fibroso solitário (0/1), sarcoma epitelióide (0/1), mesotelioma (0/1), lipossarcoma (0/1), mixolipossarcoma (0/1), dermatofibrossarcoma (0/1), fibromatose (0/1), ganglioneuroma (0/1), tumores da tireóide (0/3), tumores pulmonares (0/4), tumores hepáticos (0/4), tumores ovários (0/4), tumores cerebrais (0/2), tumores do esófago (0/1), tumores mamários (0/2), tumores gástricos (0/2), tumores da língua (0/2), metástases tumorais de origem desconhecida (0/2), tumores renais (0/2), tumores do colo do útero (0/2), tumores testiculares (0/2), tumores do cólon (0/2), tumores do recto (0/2), tumores da pele (0/2), tumor da laringe (0/1) ou tumor do timo (0/1) (número total de casos anormais avaliados = 90).

PA0943 é recomendado para a deteção da alfa actina do músculo liso humano em tecidos normais e neoplásicos.

Informações Específicas do Produto

Smooth Muscle Actin (alpha sm-1) foi otimizada na Leica Biosystems para utilização com a Bond Polymer Refine Detection e reagentes auxiliares BOND. Utilizadores que se desviem dos procedimentos de teste recomendados devem assumir a responsabilidade pela interpretação dos resultados dos doentes nestas circunstâncias. Os tempos de protocolo podem variar, devido a variações na fixação tecidual e na eficácia de valorização com antigénios, devendo ser determinados de forma empírica. Os controlos de reagente negativos devem ser usados quando se optimizam as condições de recuperação e os tempos do protocolo.

Resolução de Problemas

Consulte a referência 3 para acções de resolução.

Entre em contacto com o seu distribuidor local ou com a sucursal regional da Leica Biosystems para notificar qualquer coloração pouco habitual.

Informações Adicionais

Poderá encontrar informações adicionais sobre imunocoloração com reagentes BOND nas secções de Princípios do Procedimento, Material Necessário, Preparação da Amostra, Controlo de Qualidade, Verificação do Ensaio, Interpretação da Coloração, Significado dos Símbolos nos Rótulos e Limitações Gerais em "Utilizar os Reagentes BOND" na documentação do utilizador BOND.

Bibliografia

1. Clinical Laboratory Improvement Amendments of 1988, Final Rule 57 FR 7163 February 28, 1992.
2. Villanova PA. National Committee for Clinical Laboratory Standards (NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. 1991; 7(9). Order code M29-P.
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9. Varayoud J, Ramos JG, Joazeiro PP et al. Characterization of fibroblastic cell plasticity in the lamina propria of the rat uterine cervix at term. *Biology of Reproduction*. 2001; 65:375-383.

10. Lyall F, Barber A, Myatt L et al. Hemeoxygenase expression in human placenta and placental bed implies a role in regulation of trophoblast invasion and placental function. *The FASEB Journal*. 2000; 14:208-219.
11. Oberpenning F, Meng J, Yoo JJ et al. De novo reconstitution of a functional mammalian urinary bladder by tissue engineering. *Nature Biotechnology*. 1999; 17:149-155.
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14. Wagner K-U, Young WS, Liu X et al. Oxytocin and milk removal are required for post-partum mammary-gland development. *Genes and Function*. 1997; 1(4):233-244.
15. Skalli O, Ropraz P, Trzeciak A et al. A monoclonal antibody against α -smooth muscle actin: a new probe for smooth muscle differentiation. *The Journal of Cell Biology*. 1986; 103:2787-2796.

Data de Emissão

16 de Junho de 2015

Bond™ Primär Antikropp - Färdig Att Användas

Smooth Muscle Actin (alpha sm-1)

Artikelnummer: PA0943

Användningsområde

Reagenset är avsett för *in vitro*-diagnostik.

Smooth Muscle Actin (alpha sm-1) monoklonal antikropp är avsedd att användas för kvalitativ identifiering med ljusmikroskopi av humant alfa-aktin från glatt muskelvävnad i formalinfixerad, paraffinbäddad vävnad genom immunhistokemisk färgning med användning av det automatiska BOND-systemet (som innefattar systemen Leica BOND-MAX och Leica BOND-III).

Den kliniska tolkningen av varje infärgning, eller utebliven infärgning, måste alltid kompletteras med morfologiska studier och lämpliga kontroller. Utvärderingen bör göras av kvalificerad patolog och inkludera patientens anamnes och övriga diagnostiktester.

Förklaring och Sammanfattning

Immunhistokemiska tekniker kan användas för att påvisa antigener i vävnader och celler (se "Använda BOND-reagens" i Bondanvändardokumentationen). Smooth Muscle Actin (alpha sm-1) primär antikropp är en produkt, färdig att användas, som har optimerats specifikt för att användas med Bond Polymer Refine Detection. Påvisande av humant aktin från glatt muskelvävnad uppnås genom att först låta Smooth Muscle Actin (alpha sm-1) bindas till snittet och därefter visualisera denna bindning med de reagenser som medföljer i detektionssystemet. Om du använder dessa produkter i kombination med det automatiska BOND-systemet (som innefattar systemen Leica BOND-MAX och Leica BOND-III) minskar du risken för mänskliga misstag och de oundvikliga variationer som blir resultatet av individuell reagensutspädning och manuell pipettering och reagensanvändning.

Ingående Reagenser

Smooth Muscle Actin (alpha sm-1) är en anti-human monoklonal antikropp från mus, producerad som en renad IgG-fraktion, och levereras i trisbuffrad koksalltösning med bärarprotein. Lösningen innehåller 0,35% ProClin™ 950 som konserveringsmedel.

Total volym = 7 ml.

Klon

asm-1

Immunogen

Syntetisk aminoterminal dekaeptid från alfa-isoformen av aktin från glatt muskelvävnad.

Specifitet

Humant alfa-aktin från glatt muskelvävnad.

Ig-klass

IgG2a

Total Proteinkoncentration

Omkring 10 mg/ml.

Antikropps-koncentration

Större än eller lika med 0,2 mg/l enligt bestämning med ELISA.

Spädning och Blandning

Smooth Muscle Actin (alpha sm-1) primär antikropp är optimalt utspädd för att användas på BOND-systemet (som innefattar systemen Leica BOND-MAX och Leica BOND-III). Denna reagens behöver inte rekonstitueras, blandas, spädas eller titreras.

Nödvändig Materiel Som Ej Medföljer

I avsnittet "Att använda Bondreagenser" i din användardokumentation för BOND hittar du en komplett lista över de material som krävs för preparatbehandling och immunohistokemisk infärgning i BOND-systemet (som innefattar systemen Leica BOND-MAX och Leica BOND-III).

Förvaring och Stabilitet

Förvara vid 2–8 °C. Använd ej efter det utgångsdatum som står på förpackningen.

Tecken på kontaminering och/eller instabilitet hos Smooth Muscle Actin (alpha sm-1) är grumling i lösningen, luktutveckling och förekomst av fällning.

Ställ tillbaka i 2–8 °C omedelbart efter användning.

Andra förvaringsbetingelser än de ovan angivna måste verifieras av användaren¹.

Säkerhetsföreskrifter

- Produkten är avsedd för *in vitro*-diagnostik.
- Koncentrationen av ProClin™ 950 är på 0,35 %. Det innehåller den aktiva beståndsdel 2-metyl-4-isotiazolin-3-on som kan verka irriterande på hud, ögon, slemhinnor och övre luftvägar. Använd engångshandskar när reagenserna hanteras.
- Du kan få tillgång till säkerhetsdatablad genom att kontakta en lokal distributör eller Leica Biosystems regionkontor. En annan möjlighet är Leica Biosystems webbplats på www.LeicaBiosystems.com

- Prover, både före och efter fixeringen, och allt material som använts tillsammans med dem ska hanteras som infektiöst avfall enligt gängse praxis². Pipettera aldrig reagenser med munnen och undvik att reagenser eller prover kommer i kontakt med hud och slemhinnor. Om reagenser eller prover kommer i kontakt med känsliga områden, skölj med stora mängder vatten. Sök läkarvård.
- Angående avfallshantering av potentiellt toxiska material hänvisar vi till gällande europeiska, nationella och lokala bestämmelser och förordningar.
- Minimera mikrobiologisk kontamination av reagens, annars kan en ökad icke-specifik infärgning bli resultatet.
- Återvinande och andra inkubationstider eller temperaturer än de angivna kan ge felaktiga resultat. Sådana förändringar ska valideras av användaren.

Instruktioner vid Användning

Smooth Muscle Actin (alpha sm-1) primär antikropp har utveckats för att användas på det automatiska BOND-systemet (som innefattar systemen Leica BOND-MAX och Leica BOND-III) i kombination med Bond Polymer Refine Detection. Rekommenderat färgningsprotokoll för Smooth Muscle Actin (alpha sm-1) primär antikropp är IHC Protocol F. Ingen förbehandling rekommenderas.

Förväntade Resultat

Normala vävnader

Klon *asm-1* detekterade alfa-aktin från glatt muskelvävnad i cytoplasma från glatta muskelceller. Dessa celler kan förekomma i kärlväggar, slemhinnan på intestinala muskler och muscularis propria samt i stroma på diverse vävnader. Den reagerade också med myoeptitel från diverse körtlar, främst saliv- och mjölkkörtlar. (Totalt antal utvärderade normalfall = 99).

Tumörvävnader

Klon *asm-1* detekterade aktinprotein från glatt muskelvävnad i 5/6 leiomyosarkom, 4/4 leiomyom, 2/2 ihåliga hemangiom, 1/7 fibrosarkom, 1/3 fibrösa histiocytom, 1/1 angioleiomyom, 1/1 hemangiopericytosarkom och 1/1 mesenkymom. Ingen färgning observerades i gastrointestinala stromacellstumörer (0/5), kondrosarkom (0/4), pleomorfa rabdomyosarkom (0/2), alveola rabdomyosarkom (0/2), synoviala sarkom (0/2), ett fibroliopoma (0/1), ett lipom (0/1), en ensam fibrös tumör (0/1), ett epitelialsarkom (0/1), ett mesoteliom (0/1), ett liposarkom (0/1), ett myxoliposarkom (0/1), ett dermatofibrosarkom (0/1), ett fibromat (0/1), ett ganglioneurom (0/1), tumörer i sköldkörtel (0/3), lungtumörer (0/4), levertumörer (0/4), äggstockstumörer (0/4), hjärntumörer (0/2), tumörer i matstrupe (0/1), brösttumörer (0/2), magsäckstumörer (0/2), tumörer i tunga (0/2), metastaserande tumörer av okänt ursprung (0/2), njurtumörer (0/2), livmoderhalstumörer (0/2), testikeltumörer (0/2), kolontumörer (0/2), tumörer i ändtarm (0/2), hudtumörer (0/2), en tumör i struphuvud (0/1) eller en tumör i bröst (0/1). (Totalt antal utvärderade onormala fall = 90).

PA0943 rekommenderas för detektering av humant alfa-aktin från glatt muskel i normal och neoplastisk vävnad.

Specifika Begränsningar För Produkten

Smooth Muscle Actin (alpha sm-1) har optimerats vid Leica Biosystems för att användas med Bond Polymer Refine Detection och BOND hjälpreagenser. Användare som avviker från rekommenderat testförfarande måste vid ändrade förhållanden ta ansvar för tolkningen av patientresultaten. Protokolliderna kan variera på grund av variationer i vävnadsfixering och hur effektivt antigenet intensifieras, och ska fastställas empiriskt. Negativa reagenskontroller ska användas då förhållanden för återvinande och protokolltider optimeras.

Felsökning

Se referens 3 för förslag till åtgärder.

Kontakta en lokal distributör eller Leica Biosystems regionkontor för att rapportera onormal infärgning.

Mer information

Mer information om immunfärgning med BOND-reagens finns under rubrikerna Bakgrund till metoden, Nödvändig materiel, Förbereda provet, Kvalitetskontroll, Verifiering av assayer, Tolka infärgningsresultat, Symbolförklaring för etiketter och Allmänna begränsningar i "Använda BOND-reagens" i Bonds användardokumentation.

Litteraturliste

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Utgivningsdatum

16 juni 2015

Έτοιμο Για Χρήση Πρωτογενές Αντίσωμα Bond™

Smooth Muscle Actin (alpha sm-1)

Αρ. καταλόγου: PA0943

Σκοπός Χρήσης

Αυτό το αντιδραστήριο προορίζεται για διαγνωστική χρήση *in vitro*.

Το μονοκλωνικό αντίσωμα Smooth Muscle Actin (alpha sm-1) προορίζεται για την ποιοτική ταυτοποίηση με μικροσκοπία φωτός της ανθρώπινης α-ακτίνης λείων μυών σε μονοποποιημένο σε φορμόλη και ενσωματωμένο σε παραφίνη ιστό με ανοσοϊστοχημική χρώση, με χρήση του αυτοματοποιημένου συστήματος BOND (περιλαμβάνει το σύστημα Leica BOND-2 και το σύστημα Leica BOND-III). Η κλινική ερμηνεία οποιασδήποτε χρώσης ή της απουσίας της θα πρέπει να συμπληρώνεται με μορφολογικές μελέτες και σωστούς μάρτυρες και θα πρέπει να αξιολογείται στα πλαίσια του κλινικού ιστορικού του ασθενούς και άλλων διαγνωστικών εξετάσεων από ειδικευμένο παθολογοανατόμο.

Περιληψη Και Επεξήγηση

Για την κατάδειξη της παρουσίας αντιγόνων στον ιστό και στα κύτταρα μπορούν να χρησιμοποιηθούν ανοσοϊστοχημικές τεχνικές (δείτε την ενότητα "Χρήση αντιδραστηρίων BOND" στο υλικό τεκμηρίωσης χρήσης της BOND). Το πρωτογενές αντίσωμα Smooth Muscle Actin (alpha sm-1) είναι ένα έτοιμο για χρήση προϊόν που έχει βελτιστοποιηθεί ειδικά για χρήση με το Bond Polymer Refine Detection. Η κατάδειξη της ανθρώπινης α-ακτίνης λείων μυών επιτυγχάνεται πρώτα, επιτρέποντας τη δέσμευση του Smooth Muscle Actin (alpha sm-1) στην τομή και, κατόπιν, απεικονίζοντας τη δέσμευση αυτή με χρήση των αντιδραστηρίων που παρέχονται στο σύστημα ανίχνευσης. Η χρήση αυτών των προϊόντων, σε συνδυασμό με το αυτοματοποιημένο σύστημα BOND (περιλαμβάνει το σύστημα Leica BOND-MAX και το σύστημα Leica BOND-III), μειώνει τις πιθανότητες ανθρώπινου λάθους και την εγγενή μεταβλητότητα που προκαλούνται από τις αραιώσεις των επιμέρους αντιδραστηρίων, τη χειροκίνητη διανομή με πιπέτα και την εφαρμογή των αντιδραστηρίων.

Αντιδραστήρια Που Παρέχονται

Το Smooth Muscle Actin (alpha sm-1) είναι ένα μονοκλωνικό αντι-ανθρώπινο αντίσωμα ποντικού που παράγεται ως κεκαθαρισμένο κλάσμα IgG και παρέχεται σε αλατούχο ρυθμιστικό διάλυμα Tris με πρωτεΐνη φορέα που περιέχει 0,35% ProCln™ 950 ως συντηρητικό. Συνολικός όγκος = 7 mL.

Κλώνος

asm-1

Ανοσογόνο

Συνθετικό αμινοτελικό δεκαεπταπίδιο της άλφα ισομορφής της ακτίνης λείων μυών.

Ειδικότητα

Ανθρώπινη α-ακτίνη λείων μυών.

Τάξη Ig

IgG2a

Συνολική Συγκέντρωση Πρωτεΐνης

Περίπου 10 mg/mL.

Συγκέντρωση Αντισώματος

Μεγαλύτερη ή ίση με 0,2 mg/L όπως προσδιορίζεται με ELISA.

Αραίωση Και Ανάμειξη

Το πρωτογενές αντίσωμα Smooth Muscle Actin (alpha sm-1) έχει αραιωθεί ιδανικά για χρήση στο σύστημα BOND (περιλαμβάνει το σύστημα Leica BOND-MAX και το σύστημα Leica BOND-III). Δεν απαιτείται ανασύσταση, ανάμειξη, αραίωση ή ηπλοδότηση του αντιδραστηρίου αυτού.

Υλικά Που Απαιτούνται Αλλά Δεν Παρέχονται

Ανατρέξτε στην ενότητα "Using BOND Reagents" (Χρήση αντιδραστηρίων BOND) στην τεκμηρίωση χρήσης του συστήματος BOND για τον πλήρη κατάλογο των υλικών που απαιτούνται για την επεξεργασία των δειγμάτων και την ανοσοϊστοχημική χρώση με χρήση του συστήματος BOND (περιλαμβάνει το σύστημα Leica BOND-MAX και το σύστημα Leica BOND-III).

Φύλαξη Και Σταθερότητα

Φυλάσσεται στους 2–8 °C. Μη χρησιμοποιείτε μετά την ημερομηνία λήξης που αναγράφεται στην ετικέτα του περιέκτη.

Οι ενδείξεις που υποδηλώνουν μόλυνση ή/και αστάθεια της Smooth Muscle Actin (alpha sm-1) είναι: θολρότητα του διαλύματος, ανάπτυξη οσμής και παρουσία ιζήματος.

Επαναφέρετε το προϊόν στους 2–8 °C αμέσως μετά τη χρήση.

Συνθήκες φύλαξης εκτός από αυτές που καθορίζονται παραπάνω πρέπει να επαληθεύονται από τον χρήστη¹.

Προφυλάξεις

- Το προϊόν αυτό προορίζεται για *in vitro* διαγνωστική χρήση.
- Η συγκέντρωση του ProCln™ 950 είναι 0,35 %. Περιέχει το δραστικό συστατικό 2-μεθυλ-4-ισοθαεζολιν-3-όνη και ενδέχεται να προκαλέσει ερεθισμό στο δέρμα, τους οφθαλμούς, τους βλεννογόνους και την άνω αναπνευστική οδό. Φοράτε αναλώσιμα γάντια κατά το χειρισμό των αντιδραστηρίων.

- Για να λάβετε ένα αντίτυπο του δελτίου δεδομένων ασφαλείας υλικού, επικοινωνήστε με τον τοπικό σας διανομέα ή τα περιφερειακά γραφεία της Leica Biosystems ή, εναλλακτικά, επισκεφθείτε τον ιστότοπο της Leica Biosystems, www.LeicaBiosystems.com
- Τα δείγματα, πριν και μετά τη μονιμοποίηση, καθώς και όλα τα υλικά που εκτίθενται σε αυτά, πρέπει να υποβάλλονται σε χειρισμό ως δυνητικά μεταδότης λοίμωξης και να απορρίπτονται με κατάλληλες προφυλάξεις. Μην αναρροφάτε ποτέ με πιπέτα τα αντιδραστήρια με το στόμα και αποφύγετε την επαφή του δέρματος και των βλεννογόνων με αντιδραστήρια ή δείγματα. Εάν τα αντιδραστήρια ή τα δείγματα έλθουν σε επαφή με ευαίσθητες περιοχές, πλύνετε με άφθονες ποσότητες νερού. Ζητήστε τη συμβουλή του γιατρού.
- Συμβουλευτείτε τους ομοσπονδιακούς, πολιτικούς ή τοπικούς κανονισμούς για απόρριψη τυχόν δυνητικών τοξικών συστατικών.
- Ελαχιστοποιήστε τη μικροβιακή μόλυνση των αντιδραστηρίων, διότι διαφορετικά ενδέχεται να αυξηθεί η μη ειδική χρώση.
- Ανάκτηση, χρόνοι ή θερμοκρασίες επώασης διαφορετικές από εκείνες που καθορίζονται ενδέχεται να δώσουν εσφαλμένα αποτελέσματα. Τυχόν τέτοια μεταβολή πρέπει να επικυρώνεται από το χρήστη.

Οδηγίες Χρήσης

Το πρωτογενές αντίσωμα Smooth Muscle Actin (alpha sm-1) αναπτύχθηκε για χρήση στο αυτοματοποιημένο σύστημα BOND (περιλαμβάνει το σύστημα Leica BOND-MAX και το σύστημα Leica BOND-III) σε συνδυασμό με το σύστημα ανίχνευσης Bond Polymer Refine Detection. Το συνιστώμενο πρωτόκολλο χρώσης για το πρωτογενές αντίσωμα Smooth Muscle Actin (alpha sm-1) είναι το IHC Protocol F. Δεν συνιστάται καμία προκαταρκτική επεξεργασία.

Αναμενόμενα Αποτελέσματα

Φυσιολογικοί ιστοί

Ο κλώνος asm-1 εντόπισε την α-ακτίνη λείων μυών στο κυτταρόπλασμα των λείων μυϊκών ινών. Τα κύτταρα αυτά είναι δυνατό να βρεθούν σε αγγειακά τοιχώματα, εντερικό μυϊκό βλεννογόνο και μυϊκή βλεννογόνια στοιβάδα, καθώς και στο στρώμα διαφόρων ιστών. Αντέδρασε επίσης με το μυστιόηλο διαφόρων αδένων, κυρίως σιελογόνων και μαστικών αδένων. (Συνολικός αριθμός φυσιολογικών περιστατικών που αξιολογήθηκαν = 99).

Νεοπλασματικοί ιστοί

Ο κλώνος asm-1 ανίχνευσε την πρωτεΐνη α-ακτίνη λείων μυών σε 5/6 λειομυοσάρκωματα, 4/4 λειομύμματα, 2/2 σπραγγιδή αιμαγγειώματα, 1/7 ινοσάρκωματα, 1/3 ινώδη ιστοκυττώματα, 1/1 αγγειολιόμωμα, 1/1 αιμαγγειοπερικυτταρικό σάρκωμα και 1/1 νεοεσχάρωμα. Δεν παρατηρήθηκε χρώση σε στρωματικούς όγκους του γαστρεντερικού (0/5), χονδροσάρκωματα (0/4), πλειομορφικά ραβδομυοσάρκωματα (0/2), κυψελιδικά ραβδομυοσάρκωματα (0/2), σαρκώματα του αρθρικού υμένα (0/2), ένα νολιπύωμα (0/1), ένα λιπύωμα (0/1), ένα μονήρη ινώδη όγκο (0/1), ένα επιθηλιοειδές σάρκωμα (0/1), ένα μεσοθηλίωμα (0/1), ένα λιπώσαρκωμα (0/1), ένα μυοειδές λιπώσαρκωμα (0/1), ένα δερματοϊνοσάρκωμα (0/1), μια ινωμάτωση (0/1), ένα γαγγλιονέυρωμα (0/1), όγκους του θυρεοειδούς (0/3), όγκους των πνευμόνων (0/4), όγκους του ήπατος (0/4), όγκους των ωοθηκών (0/4), όγκους εγκεφάλου (0/2), όγκους του οισοφάγου (0/1), όγκους μαστού (0/2), όγκους του στομάχου (0/2), μεταστατικούς όγκους άγνωστης προέλευσης (0/2), όγκους των νεφρών (0/2), όγκους του τραχήλου της μήτρας (0/2), όγκους των όρχεων (0/2), όγκους στο κόλον (0/2), όγκους του ορθού (0/2), όγκους του δέρματος (0/2), έναν όγκο του λάρυγγα (0/1) ή έναν όγκο του θύμου αδένα (0/1). (Συνολικός αριθμός μη φυσιολογικών περιστατικών που αξιολογήθηκαν = 90).

Το PA0943 συνιστάται για την ανίχνευση της ανθρώπινης α-ακτίνης λείων μυών σε φυσιολογικούς και νεοπλασματικούς ιστούς.

Ειδικοί Περιορισμοί Του Προϊόντος

Smooth Muscle Actin (alpha sm-1) έχει βελτιστοποιηθεί στην Leica Biosystems για χρήση με το Bond Polymer Refine Detection και τα βοηθητικά αντιδραστήρια BOND. Χρήστες που αποκλίνουν από τις συνιστώμενες διαδικασίες εξέτασης πρέπει να αποδεχονται την ευθύνη για ερμηνεία των αποτελεσμάτων ασθενών υπό τις συνθήκες αυτές. Οι χρόνοι του πρωτοκόλλου ενδέχεται να διαφέρουν, λόγω της μεταβλητότητας της μονιμοποίησης του ιστού και της αποτελεσματικότητας ενίσχυσης των ανιγόνων και πρέπει να προσδιορίζονται εμπειρικά. Κατά τη βελτιστοποίηση των συνθηκών ανάκτησης και των χρόνων πρωτοκόλλου, πρέπει να χρησιμοποιούνται αρνητικοί μάρτυρες αντιδραστηρίων.

Αντιμετώπιση Προβλημάτων

Σχετικά με τις διορθωτικές ενέργειες, ανατρέξτε στην παραπομπή 3.

Για να αναφέρετε περιπτώσεις ασυνήθιστης χρώσης, επικοινωνήστε με τον τοπικό σας διανομέα ή τα περιφερειακά γραφεία της Leica Biosystems.

Πρόσθετες Πληροφορίες

Μπορείτε να βρείτε περισσότερες πληροφορίες σχετικά με την ανοσοχρώση με αντιδραστήρια BOND, υπό τους τίτλους Αρχή της διαδικασίας, Απαιτούμενα υλικά, Προετοιμασία δείγματος, Ποιοτικός έλεγχος, "Επαλήθευση προσδιορισμού, Ερμηνεία της χρώσης, Υπόμνημα για τα σύμβολα στις ετικέτες και Γενικοί περιορισμοί στην ενότητα "Χρήση αντιδραστηρίων BOND" στο υλικό τεκμηρίωσης χρήσης της BOND.

Βιβλιογραφία

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2. Villanova PA. National Committee for Clinical Laboratory Standards (NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. 1991; 7(9). Order code M29-P.
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9. Varayoud J, Ramos JG, Joazeiro PP et al. Characterization of fibroblastic cell plasticity in the lamina propria of the rat uterine cervix at term. *Biology of Reproduction*. 2001; 65:375-383.
10. Lyall F, Barber A, Myatt L et al. Hemeoxygenase expression in human placenta and placental bed implies a role in regulation of trophoblast invasion and placental function. *The FASEB Journal*. 2000; 14:208-219.
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13. Bourgeois C, Robert B, Rebourcet R et al. Endothelin-1 and ETA receptor expression in vascular smooth muscle cells from human placenta: a new ETA receptor messenger ribonucleic acid is generated by alternative splicing of exon 3. *The Journal of Clinical Endocrinology & Metabolism*. 1997; 82(9):3116-3123.
14. Wagner K-U, Young WS, Liu X et al. Oxytocin and milk removal are required for post-partum mammary-gland development. *Genes and Function*. 1997; 1(4):233-244.
15. Skalli O, Ropraz P, Trzeciak A et al. A monoclonal antibody against α -smooth muscle actin: a new probe for smooth muscle differentiation. *The Journal of Cell Biology*. 1986; 103:2787-2796.

Ημερομηνία Έκδοσης

16 Ιουλίου 2015

Bond™ Brugsklart Primaert Antistof Smooth Muscle Actin (alpha sm-1)

Katalognummer.: PA0943

Tilsigtet Anvendelse

Dette reagens er beregnet til brug i *in vitro*-diagnostik.

Smooth Muscle Actin (alpha sm-1) monoklonalt antistof er beregnet til brug til kvalitativ identifikation med lysmikroskopi af humant alfa-aktin fra glatte muskler i formalin-fikseret, paraffin-indstøbt væv med immunhistokemisk farvning ved brug af det automatiske BOND system (bestående af Leica BOND-MAX-systemet og Leica BOND-III-systemet).

Den kliniske fortolkning af enhver farvning eller fravær af samme skal ledsages af morfologiske undersøgelser og egnede kontroller og skal evalueres af en uddannet patolog i konteksten af patientens anamnese samt andre diagnostiske prøver.

Resumé og Forklaring

Immunhistokemiske teknikker kan anvendes til at påvise tilstedeværelse af antigener i væv og celler (se "Anvendelse af BOND-reagenser" i BOND-brugerdokumentationen). Smooth Muscle Actin (alpha sm-1) primært antistof er et brugsklart produkt, som er blevet optimeret specielt til brug sammen med Bond Polymer Refine Detection. Påvisningen af humant alfa-aktin fra glatte muskler opnås ved først at muliggøre binding af Smooth Muscle Actin (alpha sm-1) til sektionen og derpå visualisere denne binding vha. de vedlagte reagenser. Brugen af disse produkter sammen med det automatiske BOND-system (bestående af Leica BOND-MAX-systemet og Leica BOND-III-systemet) reducerer risikoen for menneskelige fejl og de indbyggede variationer, som opstår ved individuel reagensfortynding, manual pipettering og reagensapplicering.

Leverede Reagenser

Smooth Muscle Actin (alpha sm-1) er et murint, anti-humant monoklonalt antistof fremstillet som en oprenset IgG-fraktion leveret i en Tris-bufferjusteret saltvandsopløsning med bærerprotein, indeholder 0,35% ProClin™ 950 som konserveringsmiddel.

Totalt volumen = 7 ml.

Klon

asm-1

Immunogen

Syntetisk amino-terminal decapeptid af isoform alfa-aktin fra glatte muskler.

Specifitet

Humant alfa-aktin fra glatte muskler.

Ig-klasse

IgG2a

Total Proteinkoncentration

Ca. 10 mg/ml.

Antistofkoncentration

Større end eller lig med 0,2 mg/l som bestemt med ELISA.

Fortynding og Blanding

Smooth Muscle Actin (alpha sm-1) primært antistof er fortyndet optimalt med henblik på brug i BOND-systemet (bestående af Leica BOND-MAX-systemet og Leica BOND-III-systemet). Rekonstitution, blanding, fortynding eller titrering af dette reagens er ikke påkrævet.

Nødvendige Materialer, der ikke Medfølger

Se under "Brug af BOND-reagenser" i BOND-brugsanvisningen for at se en komplet liste over de materialer, der skal bruges i forbindelse med behandling og immunhistokemisk staining af prøver ved hjælp af BOND-systemet (bestående af Leica BOND-MAX-systemet og Leica BOND-III-systemet).

Opbevaring og Stabilitet

Opbevares ved 2–8 °C. Må ikke anvendes efter udløbsdatoen, der er angivet på beholderens etiket.

De tegn, der indikerer, at Smooth Muscle Actin (alpha sm-1) er kontamineret og/eller ustabil, omfatter turbiditet af opløsningen, lugtudvikling og tilstedeværelse af præcipitat.

Sættes tilbage til opbevaring ved 2–8 °C umiddelbart efter brug.

Opbevaringsbetingelser, der adskiller sig fra de oven for specificerede, skal verificeres af brugeren¹.

Forholdsregler

- Dette produkt er beregnet til brug i *in vitro*-diagnostik.
- Koncentrationen af ProClin™ 950 er 0,35 %. Det indeholder det aktive indholdsstof 2-methyl-4-isothiazolin-3-one og kan forårsage irritation af hud, øjne, slimhinder og øvre luftveje. Der skal anvendes handsker ved håndtering af reagenser.
- En kopi af sikkerhedsdatabladet (MSDS) kan fås ved henvendelse til den lokale distributør eller til Leica Biosystems' regionale kontor. Det kan tillige hentes på Leica Biosystems' hjemmeside www.LeicaBiosystems.com

- Præparater, både før og efter fiksering, samt alle øvrige materialer, der eksponeres for disse, skal håndteres som værende i stand til at overføre infektion og skal bortskaffes under iagttagelse af passende forholdsregler². Afipettr ikke reagenser med munden, og undgå at reagenser og præparater kommer i kontakt med hud og slimhinder. Hvis reagenser eller præparater kommer i kontakt med følsomme områder, skal disse vaskes med rigelige mængder vand. Søg læge.
- Bortskaffelse af potentielt toksiske komponenter skal ske i overensstemmelse med gældende statslig eller lokal lovgivning.
- Mikrobiel kontamination af reagenser skal minimeres for at undgå en øget ikke-specifik farvning.
- Genfindning, inkubationstider eller -temperaturer ud over de specificerede kan give fejlagtige resultater. Enhver ændring af denne art skal valideres af brugeren.

Brugsanvisning

Smooth Muscle Actin (alpha sm-1) primært antistof er udviklet med henblik på brug i det automatiske BOND-system (bestående af Leica BOND-MAX-systemet og Leica BOND-III-systemet) kombineret med Bond Polymer Refine Detection. Den anbefalede farvningsprotokol for Smooth Muscle Actin (alpha sm-1) primært antistof er IHC Protocol F. Ingen forbehandling er anbefalet.

Forventede Resultater

Normala væv

Klon osm-1 påviste alfa-aktin fra glatte muskler i cytoplasmaet i glatte muskelceller. Disse celler findes i karvæggene, i intestinale muscularis mucosae og muscularis propria og i stroma i forskellige typer væv. Det reagerede endvidere med myoepitelet i forskellige kirtler, især i spyt- og brystkirtler. (Samlet antal normale tilfælde, der blev evalueret = 99).

Tumorvæv

Klon osm-1 påviste aktin-proteinet fra glatte muskler i 5/6 leiomyosarkomer, 4/4 leiomyomer, 2/2 kavernøse hæmangiomer, 1/7 fibrosarkomer, 1/3 fibrøse histiocytomer, 1/1 angioleiomyomer, 1/1 hemangiopericyto-sarkom og 1/1 mesenchymom. Der blev ikke observeret farvning i gastrointestinale stromatumorer (0/5), kondrosarkomer (0/4), pleomorfe rhabdomyosarkomer (0/2), alveolære rhabdomyosarkomer (0/2), synoviale sarkomer (0/2), fibrøst lipom (0/1), lipom (0/1), isoleret fibrøs tumor (0/1), epitel-sarkom (0/1), mesotheliom (0/1), liposarkom (0/1), myxoliposarkom (0/1), dermatofibrosarkom (0/1), fibromatose (0/1), ganglioneurom (0/1), tumorer i thyroidea (0/3), lungetumorer (0/4), levertumorer (0/4), ovarietumorer (0/4), hjernetumorer (0/2), tumorer i øsøfagus (0/1), tumorer i brystet (0/2), tumorer i maven (0/2), tumorer på tungen (0/2), metastatiske tumorer af ukendt oprindelse (0/2), nyretumorer (0/2), cervikale tumorer (0/2), tumorer i testis (0/2), tumorer i colon (0/2), tumorer i rektum (0/2), hudtumorer (0/2), tumor i larynx (0/1) eller tumor i thymus (0/1). (Samlet antal unormale tilfælde, der blev evalueret = 90).

PA0943 anbefales til detektion af humant alfa-aktin fra glatte muskler i normale og neoplastiske væv.

Produktspecifikke Begrænsninger

Smooth Muscle Actin (alpha sm-1) er blevet optimeret hos Leica Biosystems til brug sammen med Bond Polymer Refine Detection og BOND-hjælperagenser. Brugere, som afviger fra anbefalede test procedurer, må selv tage ansvaret for tolkningen af patientresultater under disse betingelser. Protokolliderne kan variere på grund af variationer i vævsfiksering og effektiviteten af antigenforbedring og skal bestemmes empirisk. Der skal anvendes negative reagenskontroller ved optimering af genfindingsbetingelser og protokollider.

Fejlfinding

Der henvises til reference 3 for afhjælpende foranstaltninger.

Kontakt den lokale distributør eller Leica Biosystems' regionale kontor for at rapportere usædvanlig farvning.

Yderligere Oplysninger

Yderligere oplysninger om immunfarvning med BOND-reagenser kan findes i "Anvendelse af BOND-reagenser" i BOND-brugerdokumentationen under overskrifterne Proceduremæssige principper, Nødvendige materialer, Præparatklargøring, Kvalitetskontrol, Analyseverifikation, Fortolkning af farvning, Nøgle til symboler på etiketter og Generelle begrænsninger.

Bibliografi

1. Clinical Laboratory Improvement Amendments of 1988, Final Rule 57 FR 7163 February 28, 1992.
2. Villanova PA. National Committee for Clinical Laboratory Standards (NCCLS). Protection of laboratory workers from infectious diseases transmitted by blood and tissue; proposed guideline. 1991; 7(9). Order code M29-P.
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Udgivelsesdato

16 juni 2015

Bond™ Klaar Voor Primaire Antilichaam te Gebruiken

Smooth Muscle Actin (alpha sm-1)

Catalogusnummer.: PA0943

Beoogd Gebruik

Deze reagens wordt gebruikt voor *in-vitro* -diagnostiek.

Smooth Muscle Actin (alpha sm-1) monoklonaal antilichaam is bedoeld om te worden gebruikt voor de kwalitatieve identificatie met behulp van lichtmicroscopie van humaan alfa-gladdespier-actine in formaline gefixeerd en in paraffine ingebed weefsel door middel van immunohistochemische kleuringen met het geautomatiseerde BOND-systeem (waaronder het Leica BOND-MAX-systeem en het Leica BOND-III-systeem).

De klinische interpretatie van iedere kleuring of de afwezigheid ervan moet worden aangevuld met morfologisch onderzoek en goede controles. De interpretatie moet worden geëvalueerd door een vakkundige patholoog binnen de context van de klinische geschiedenis van de patiënt en eventueel ander diagnostisch onderzoek.

Samenvatting en Uitleg

Immunohistochemische technieken kunnen gebruikt worden om de aanwezigheid van antilichamen in weefsel en cellen aan te tonen (zie "BOND-reagentie gebruiken" in de gebruikersdocumentatie van BOND). Smooth Muscle Actin (alpha sm-1) primaire antilichaam is een klaar voor gebruik product dat speciaal geoptimaliseerd is voor het gebruik met Bond Polymer Refine Detection. De demonstratie van humaan alfa-gladdespier-actine wordt gerealiseerd door eerst de binding van Smooth Muscle Actin (alpha sm-1) toe te staan aan de coupe en dan deze binding te visualiseren met behulp van de meegeleverde reagentia in het detectiesysteem. Door deze producten te gebruiken in combinatie met het geautomatiseerde BOND-systeem (waaronder het Leica BOND-MAX-systeem en het Leica BOND-III-systeem) neemt de kans op menselijke fouten af en zijn er ook minder afwijkingen voortvloeiende uit de individuele reagensverdunding, het handmatig pipetteren en de reagenstoepassing.

Meegeleverde Reagentia

Smooth Muscle Actin (alpha sm-1) is een anti-monoklonaal muisantilichaam geproduceerd als een gezuiverde IgG-fractie, en wordt geleverd in Tris gebufferde saline met draagproteïne, en bevat 0,35 % ProClin™ 950 als conserveringsmiddel.

Totale volume = 7 mL.

Kloon

asm-1

Immunogeen

Synthetisch decapeptide met eindstandig amine van de isovorm van alfa-gladdespier-actine.

Specificiteit

Humaan alfa-gladdespier-actine.

Ig-klasse

IgG2a

Totale Proteïneconcentratie

Ca. 10 mg/ml.

Antilichaamconcentratie

Groter of gelijk aan 0,2 mg/L zoals bepaald door ELISA.

Verdunding en Menging

Smooth Muscle Actin (alpha sm-1) primair antilichaam is optimaal verdund voor gebruik op het BOND-systeem (waaronder het Leica BOND-MAX-systeem en het Leica BOND-III-systeem). Reconstitutie, menging, verdunding of titratie van deze reagens is niet vereist.

Niet Meegeleverde Vereiste Materialen

Zie "BOND-reagentia gebruiken" in uw BOND-gebruikershandleiding voor een compleet overzicht van materialen die nodig zijn voor het verwerken van monsters en het uitvoeren van immunohistochemische kleuringen met het BOND-systeem (waaronder het Leica BOND-MAX-systeem en het Leica BOND-III-systeem).

Opslag en Stabiliteit

Opslaan bij temperaturen van 2–8 °C. Niet gebruiken na de expiratiedatum die op het etiket van de container staat.

Tekenen die contaminatie en/of instabiliteit van Smooth Muscle Actin (alpha sm-1) aangeven zijn: vertroebeling van de oplossing, geurontwikkeling en de aanwezigheid van neerslag.

Laat het systeem direct na gebruik terugkeren naar een temperatuur van 2–8 °C.

Opslagcondities andere dan degene die hierboven gespecificeerd zijn, dienen door de gebruiker geverifieerd te worden¹.

Voorzorgsmaatregelen

- Dit product is bedoeld voor *in-vitro* -diagnostiek.

- De concentratie van ProClin™ 950 is 0,35 %. Het bevat het actieve ingrediënt 2-methyl-4-isothiazoline-3-one, en kan irritatie veroorzaken aan de huid, ogen, slijmvlies en het bovenste deel van de luchtwegen. Draag wegwerphandschoenen bij het werken met reagentia.
- Om een kopie van het materiaalveiligheidsblad te verkrijgen, dient u contact op te nemen met uw lokale distributeur of het regionale kantoor van Leica Biosystems, of de website van Leica Biosystems te bezoeken: www.LeicaBiosystems.com
- Monsters moeten voor en na fixatie worden behandeld als potentiële overdragers van infecties en volgens de juiste voorzorgsmaatregelen worden afgedankt. Dit geldt tevens voor alle materialen die aan de monsters zijn blootgesteld². Reagentia mogen nooit met de mond worden gepipetteerd. Daarnaast moet contact tussen de huid/het slijmvlies en reagentia en monsters worden vermeden. Als reagentia of monsters in contact komen met gevoelige gebieden, moet u deze gebieden wassen met een ruime hoeveelheid water. Neem contact op met een arts.
- Raadpleeg de richtlijnen van de lokale of nationale overheid voor het afdanken van potentieel giftige componenten.
- Minimaliseer de kans van microbacteriële contaminatie van reagentia. Als u dit niet doet, kan er een toename van niet-specifieke kleuring optreden.
- Terugwinning, incubatietijden of temperaturen die afwijken van degenen die gespecificeerd zijn, kunnen tot onjuiste resultaten leiden. Iedere dergelijke verandering moet door de gebruiker gevalideerd worden.

Instructies Voor Gebruik

Smooth Muscle Actin (alpha sm-1) primair antilichaam is ontwikkeld voor gebruik op het geautomatiseerde BOND-systeem (waaronder het Leica BOND-MAX-systeem en het Leica BOND-III-systeem) in combinatie met Bond Polymer Refine Detection. Het aanbevolen kleuringprotocol voor Smooth Muscle Actin (alpha sm-1) primaire antilichaam is IHC Protocol F. Er wordt geen voorbehandeling aanbevolen.

Verwachte Resultaten

Normale weefsels

Kloon osm-1 detecteerde alfa-gladdespier-actine in het cytoplasma van gladdespiercellen. Deze cellen kunnen gevonden worden in vaatwanden, de intestinale muscularis mucosae en muscularis propria en in het stroma van diverse weefsels. De kloon reageerde ook met het myo-epithelium van diverse klieren, in het bijzonder de speeksel- en melkklieren. (Totaal aantal normale gevallen dat werd geëvalueerd = 99).

Tumorweefsels

Kloon osm-1 detecteerde het gladdespier-actine-eiwit in 5/6 leiomyosarcomen, 4/4 leiomyomen, 2/2 caverneuze hemangiomen, 1/7 fibrosarcomen, 1/3 fibreuze histiocytomen, 1/1 angioleiomyoom, 1/1 hemangiopericytosaaroom en 1/1 mesenchymoom. Er werd geen kleuring waargenomen in gastro-intestinale stromale tumoren (0/5), chondrosarcomen (0/4), pleomorfe rhabdomyosarcomen (0/2), alveolaire rhabdomyosarcomen (0/2), synoviale sarcomen (0/2), een fibrolipoom (0/1), een lipoom (0/1), een solitaire fibreuze tumor (0/1), een epitheloïde saroom (0/1), een mesothelioom (0/1), een liposaroom (0/1), een myxoliposaroom (0/1), een dermatofibrosaroom (0/1), een fibromatose (0/1), een ganglioneuroom (0/1), schildkliertumoren (0/3), longtumoren (0/4), levertumoren (0/4), eierstoktumoren (0/4), hersentumoren (0/2), een slokdarmtumor (0/1), borsttumoren (0/2), maagtumoren (0/2), tongtumoren (0/2), gemetastaseerde tumoren van onbekende oorsprong (0/2), niertumoren (0/2), baarmoederhalstumoren (0/2), testistumoren (0/2), colontumoren (0/2), rectumtumoren (0/2), huidtumoren (0/2), een larynx tumor (0/1) of een thymustumor (0/1). (Totaal aantal afwijkende gevallen dat werd geëvalueerd = 90).

PA0943 wordt aanbevolen voor het detecteren van humaan alfa-gladdespier-actine in normale en neoplastische weefsels.

Productspecifieke Beperkingen

Smooth Muscle Actin (alpha sm-1) is geoptimaliseerd door Leica Biosystems voor het gebruik met Bond Polymer Refine Detection en BOND-hulpreagentia. Gebruikers die afwijken van de aanbevolen testprocedures moeten de verantwoordelijkheid accepteren voor de interpretatie van de patiëntresultaten onder deze omstandigheden. De protocoltijden kunnen variëren door de variatie in weefselfixatie en de effectiviteit van antigeenversterking, en moet empirisch worden bepaald. Negatieve reagenscontroles dienen gebruikt te worden voor het optimaliseren van terugwinningscondities en protocoltijden.

Probleemoplossing

Raadpleeg referentie 3 voor herstelactie.

Neem contact op met uw lokale distributeur of het regionale kantoor van Leica Biosystems om een ongebruikelijke kleuring te melden.

Overige Informatie

Meer informatie over immunokleuring met BOND-reagentie, onder de titels Uitgangspunten, Vereiste materialen, Voorbereiding monsters, Kwaliteitscontrole, Verificatie van de analyse, Interpretatie van de kleuring, Legenda van symbolen op etiketten, en Algemene beperkingen kunt u vinden in "BOND-reagentia gebruiken" in de gebruikersdocumentatie van BOND.

Literatuurlijst

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Publicatiedatum

16 juni 2015

Bond™ Primært Antistoff Klart til Bruk

Smooth Muscle Actin (alpha sm-1)

Katalognummer: PA0943

Tiltent Bruk

Denne reagensen er til *in vitro* -diagnostisk bruk.

Smooth Muscle Actin (alpha sm-1) monoklonalt antistoff skal brukes til kvalitativ identifisering med lysmikroskopi av humant glattmuskelcelle-alfa-aktin i formalinfiksert, parafinnnøstøpt vev med immunhistokjemisk farging ved bruk av det automatiserte BOND-systemet (herunder Leica BOND-MAX-systemet og Leica BOND-III-systemet).

Den kliniske tolkningen av farging eller manglende farging skal være i tillegg til morfologiske undersøkelser og egnede kontroller, og skal evalueres av en kvalifisert patolog i lys av pasientens kliniske historie og eventuelle andre diagnostiske tester.

Oppsummering og Forklaring

Immunhistokjemiske teknikker kan brukes til å vise tilstedeværelse av antigener i vev og celler (se "Bruk av BOND-reagenser" i brukerdokumentasjonen for BOND-systemet). Det primære antistoffet Smooth Muscle Actin (alpha sm-1) er et produkt som er klart for bruk og spesielt optimalisert for bruk sammen med Bond Polymer Refine Detection. Påvisning av humant glattmuskelcelle-alfa-aktin oppnås ved først å la Smooth Muscle Actin (alpha sm-1) binde seg til snittet, og deretter visualisere denne bindingen ved å bruke reagensene som følger med deteksjonssystemet. Ved bruk av disse produktene kombinert med det automatiserte BOND-systemet (herunder Leica BOND-MAX-systemet og Leica BOND-III-systemet) reduseres risikoen for menneskelige feil og den iboende variasjon som skyldes individuell reagensfortynning, manuell pipettering og reagensapplikasjon.

Reagenser Som Følger Med

Smooth Muscle Actin (alpha sm-1) er et anti-humant, monoklonalt antistoff fra mus laget som en rensed IgG-fraksjon, og den leveres i en Triisubufret saltløsning med bærerprotein, og inneholder 0,35 % ProClin™ 950 som konserveringsmiddel.

Totalt volum = 7 ml.

Klon

asm-1

Immunogen

Syntetisk aminoterminalt decapeptid av isoform glattmuskelcelle-alfa-aktin.

Spesifisitet

Humant glattmuskelcelle-alfa-aktin.

Ig-klasse

IgG2a

Totalproteinkonsentrasjon

Cirka 10 mg/mL.

Antistoffkonsentrasjon

Større enn eller tilsvarende 0,2 mg/l i henhold til ELISA.

Fortynning og Blanding

Det primære antistoffet Smooth Muscle Actin (alpha sm-1) er optimalt fortynnet for bruk med BOND-systemet (herunder Leica BOND-MAX-systemet og Leica BOND-III-systemet). Rekonstituering, blanding, fortynning eller titrering av denne reagensen er ikke nødvendig.

Materiell Som Krevs, Men Som Ikke Medfølger

Under avsnittet "Bruk av BOND-reagenser" i brukerveiledningen for BOND finner du en komplett liste over de materialer som trengs til prøvebehandling og immunhistokjemisk farging med BOND-systemet (herunder Leica BOND-MAX-systemet og Leica BOND-III-systemet).

Oppbevaring og Stabilitet

Oppbevares ved 2–8 °C. Må ikke brukes etter utløpsdatoen angitt på produktetiketten.

Tegn på kontaminering og/eller ustabilitet for Smooth Muscle Actin (alpha sm-1) er: blakket løsning, endret lukt og bunnfall.

Returneres til 2–8 °C umiddelbart etter bruk.

Andre oppbevaringsbetingelser må valideres av brukeren¹.

Forholdsregler

- Dette produktet skal brukes til *in vitro*-diagnostikk.
- Konsentrasjonen av ProClin™ 950 er 0,35 %. Den inneholder virkestoffet 2-metyl-4-isotiasolin-3-on, og kan skape irritasjoner på hud, øyne, slimhinner og øvre luftveier. Bruk engangshansker ved håndtering av reagenser.
- Dataark om materialsikkerhet (MSDS) er tilgjengelig hos den lokale forhandleren eller regionkontoret til Leica Biosystems. Det kan også lastes ned fra nettsidene til Leica Biosystems: www.LeicaBiosystems.com

- Preparater (før og etter fiksering) og alt materiale som eksponeres for dem, skal behandles som potensielt smittefarlig og kasseres i samsvar med gjeldende forholdsregler². Hold aldri pipetter med reagens i munnen, og unngå at hud og slimhinner kommer i kontakt med reagenser og prøver. Hvis reagenser eller prøver kommer i kontakt med følsomme områder, skal de skylles med rikelig vann. Kontakt lege.
- Følg nasjonale og lokale forskrifter for kassering av komponenter som kan være giftige.
- Reduser mikrobiell kontaminering av reagensene til et minimum, ellers kan det forekomme økt uspesifisert farging.
- Gjennfinning, inkubasjonstider eller temperaturer som er annerledes enn det som er angitt, kan gi unøyaktige resultater. Slike endringer må valideres av brukeren.

Bruksanvisning

Det primære antistoffet Smooth Muscle Actin (alpha sm-1) er blitt utviklet for bruk med det automatiserte BOND-systemet (herunder Leica BOND-MAX-systemet og Leica BOND-III-systemet) i kombinasjon med Bond Polymer Refine Detection. Anbefalt fargeprotokoll for Smooth Muscle Actin (alpha sm-1) primært antistoff er IHC Protocol F. Ingen forbehandling anbefales.

Forventede resultater

Normalt vev

Klon asm-1 detekterte glattmuskelcelle-alfa-aktin i cytoplasma i celler fra glatt muskelvev. Slike celler kan finnes i karveggene, i intestinal muscularis mucosae, i muscularis propria og i stroma i ulike typer vev. Det reagerte også med myoepitelet i ulike typer kjertler, hovedsakelig spyttkjertler og brystkjertler. (Totalt antall normale tilfeller evaluert = 99).

Tumorvev

Klon asm-1 detekterte glatt muskelcelle-aktinprotein i 5/6 leiomyosarkomer, 4/4 leiomyomer, 2/2 kavernøse hemangiomer, 1/7 fibrosarkomer, 1/3 fibrøse histiocytomer, 1/1 angioleiomyom, 1/1 hemangiopericytosisarkom og 1/1 mesenkymom. Ingen farging ble observert i gastrointestinale stromale tumorer (0/5), kondrosarkomer (0/4), pleomorfe rhabdomyosarkomer (0/2), alveolære rhabdomyosarkomer (0/2), synoviale sarkomer (0/2), et fibrolipom (0/1), et lipom (0/1), en solitær fibrøs tumor (0/1), et epiteloidsarkom (0/1), et mesoteliom (0/1), et liposarkom (0/1), et myxoliposarkom (0/1), et dermatofibrosarkom (0/1), en fibromatose (0/1), et ganglioneurom (0/1), skjoldbruskkjerteltumorer (0/3), lungetumorer (0/4), levertumorer (0/4), ovarietumorer (0/4), hjernetumorer (0/2), øsofagustumorer (0/1), brysttumorer (0/2), magetumorer (0/2), tungetumorer (0/2), metastatiske tumorer av ukjent opprinnelse (0/2), nyretumorer (0/2), livmorhalsstumorer (0/2), testikkelstumorer (0/2), tykktarmtumorer (0/2), tumorer i rektum (0/2), hudtumorer (0/2), en tumor i strupen (0/1) eller en tumor i thymus (0/1). (Totalt antall unormale tilfeller evaluert = 90).

PA0943 anbefales til deteksjon av humant glattmuskelcelle-alfa-aktin i normale og neoplastiske vev.

Produktspesifikke Begrensninger

Smooth Muscle Actin (alpha sm-1) er optimalisert av Leica Biosystems til bruk sammen med Bond Polymer Refine Detection og BOND tilleggsreagenser. Brukere som avviker fra de anbefalte testprosedyrene, må selv ta ansvar for tolkningen av pasientresultater i slike situasjoner. Protokolltidene kan variere grunnet variasjon i vevsfiksering og effektiviteten til antigenforsterkningen, og må dermed bestemmes empirisk. Negative reagenskontroller bør brukes ved optimalisering av gjenvinningsforhold og protokolltidene.

Feilsøking

Se referanse nr. 3 for opprettingstiltak.

Ta kontakt med den lokale forhandleren eller regionkontoret til Leica Biosystems for å rapportere om unormal farging.

Ytterligere opplysninger

Du finner mer informasjon om immunfarging med BOND-reagenser i "Bruk av BOND-reagenser" i brukerdokumentasjonen for BOND-systemet under overskriftene Testprinsipper, Materiell som kreves, Preparering av prøver, Kvalitetskontroll, Analysekontroll, Tolkning av farging, Oversikt over symboler og Generelle begrensninger.

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Utgivelsesdato

16 juni 2015

Bond™ Kullanıma Hazır Primer Antikor Smooth Muscle Actin (alpha sm-1)

Katalog No: PA0943

Kullanım Amacı

Bu reagent, *in vitro* diagnostik kullanımı içindir.

Smooth Muscle Actin (alpha sm-1) monoklon antikor, formalinle fikse edilmiş, parafin bloklarda saklanmış dokuda insan alfa düz kas aktininin otomatik BOND sistemi (Leica BOND-MAX sistemini ve Leica BOND-III sistemini içerir) kullanılarak immunohistokimyasal boyama yoluyla, ışık mikroskopisinde nitel belirlenmesi amacıyla kullanılmak için amaçlanmıştır.

Herhangi bir boyamanın mevcut olması veya olmaması ile ilgili klinik yorumlama, morfolojik çalışmalarla ve uygun kontrollerle tamamlanmalıdır ve hastanın klinik geçmişi ve diğer diagnostik testler kapsamında kalifiye bir patolojist tarafından değerlendirilmelidir.

Özet ve Açıklama

İmmünohistokimyasal teknikler, doku ve hücrelerde antijen olduğunu göstermek amacıyla kullanılabilir (BOND kullanıcı dokümantasyonunuzdaki "BOND Reagent'lerinin Kullanılması" bölümüne bakınız). Smooth Muscle Actin (alpha sm-1) primer antikor, özellikle Bond Polymer Refine Detection ile kullanılmak üzere optimize edilmiş kullanıma hazır bir üründür. İnsan alfa düz kas aktininin gösterebilir, öncelikle Smooth Muscle Actin'in (alpha sm-1) seksiyona bağlanmasının beklenmesi, ardından teşhis sisteminde sağlanan reaktifler yardımıyla bu bağlanmanın görüldüğüyle elde edilir. Bu ürünlerin kullanımı, otomatikleştirilmiş BOND Sistemi ile kombinasyonlu olarak (Leica BOND-MAX sistemi ve Leica BOND-III sistemi de dahildir), insan hatalarının veya bireysel reagent seyreltmenin, elle pipetlemenin ve reaktif uygulamaların sonucu olarak ortaya çıkan doğal değişkenliklerin olasılığını azaltır.

Sağlanan Reagent'lar

Smooth Muscle Actin (alpha sm-1), bir saflaştırılmış IgG fraksiyonudur olarak oluşturulan bir fare anti-insan monoklonal antikorudur ve prezervatif olarak % 0,35 ProClin™ 950 içeren taşıyıcı proteine sahip Tris buffer salin içerisinde verilir.

Toplam hacim = 7 mL.

Clone

asm-1

İmmünojen

Alfa düz kas aktin izoformunun sentetik amino uç dekaeptidi.

Spesifite

İnsan alfa düz kas aktini.

Ig Sınıfı

IgG2a

Toplam Protein Konsantrasyonu

Yaklaşık 10 mg/mL.

Antikor Konsantrasyonu

ELISA tarafından belirlendiği gibi 0,2 mg/L'ye eşit veya bu değerden yüksek.

Dilüsyon ve Karışım

Smooth Muscle Actin (alpha sm-1) birincil antikor BOND Sistemi'nde (Leica BOND-MAX sistemini ve Leica BOND-III sistemini de içermektedir) kullanılmak üzere en uygun biçimde seyreltilmiştir. Bu reagent için sulandırma, karıştırma, dilüsyon veya titraj işlemlerinin yapılması gerekli değildir.

Sağlanmayan Ancak Gerekli Olan Materyaller

BOND Sistemi'ni (Leica BOND-MAX sistemini ve Leica BOND-III sistemini de içermektedir) kullanılarak örnek tedavi ve immünohistokimyasal boyamada gerekli materyallerin toplu bir listesini görebilmek için BOND kullanıcı belgelerinizdeki "BOND reagent'lerini Kullanma" bölümüne bakın.

Saklama ve Dayanıklılık

2–8 °C'de saklayın. Konteyner etiketinin üzerinde belirtilen son kullanım tarihinden sonra kullanmayın.

Smooth Muscle Actin (alpha sm-1) kontaminasyonunu ve/veya instabilitesini belirten işaretler: solüsyonun türbidesi, koku gelişimi ve presipitatin mevcut olması.

Kullanımdan hemen sonra 2–8 °C'ye dönün.

Yukarıda belirtilenlerin dışındaki saklama koşullarının, kullanıcı' tarafından kontrol edilmesi gerekir.

Önlemler

- Bu ürün, *in vitro* diagnostik kullanımı içindir.
- ProClin™ 950 konsantrasyonu % 0,35'dir. 2-metil-4-izotiazolin-3-tek etken maddesini içerir ve ciltte, gözlerde, muköz membranlarda ve üst solunum yolunda irritasyona neden olabilir. Reagent'larla işlem yaparken tek kullanımlık eldiven takın.
- Bir Material Safety Data Sheet (Malzeme Güvenlik Veri Sayfası) kopyası elde etmek için yerel distribütörünüze veya bölgesel Leica Biosystems ofisine başvurun veya alternatif olarak www.LeicaBiosystems.com Leica Biosystems internet sitesini ziyaret edin

- Fikse etme işleminden önce ve sonra numuneler ve bunlara maruz kalan tüm materyaller, enfeksiyon yayabilecek gibi ele alınmalı ve doğru önlemler alınarak atığa çıkartılmalıdır.² Reagent'lar asla ağızla pipetlenmemeli ve cildin ve muköz membranların reagent ve numunelerle temasından kaçınılmalıdır. Reagent veya numunelerin hassas alanlarla temas etmesi durumunda bu alanları bol su ile yıkayın. Doktora başvurun.
- Potansiyel tüm toksik komponentlerin imhası için federal, ulusal veya lokal düzenlemelere başvurun.
- Reagent'ların mikrobiyal kontaminasyonunu minimize edin, aksi durumda nonspesifik boyamada bir artış ortaya çıkabilir.
- Belirtilenler dışında retrieval, inkübasyon süreleri veya sıcaklıkları, hatalı sonuçlara neden olabilir. Tüm değişiklikler, kullanıcı tarafından doğrulanmalıdır.

Kullanım Talimatları

Smooth Muscle Actin (alpha sm-1) birincil antikor, otomatikleştirilmiş BOND Sistemi'nde (Leica BOND-MAX sistemini ve Leica BOND-III sistemini de içermektedir) Bond Polymer Refine Detection (BOND Polimer Arındırma Algılama) ile kombinasyonlu olarak kullanılmak üzere geliştirilmiştir. Smooth Muscle Actin (alpha sm-1) primer antikor için önerilen boyama protokolü IHC Protocol F'dir. Ön tedavi önerilmez.

Öngörülen Sonuçlar

Normal Dokular

Clone csm-1, düz kas hücrelerinin sitoplazmasında alfa düz kas aktini tespit etti. Bu hücreler, vasküler duvarlarda, intestinal muskularis mukozasında ve muskularis propriyada ve çeşitli doku stromalarında bulunabilir. Çeşitli bezlerin, özellikle tükürük ve meme bezlerinin miyoepitelyumuyla da tepki verdi. (Değerlendirilen toplam normal olgu sayısı = 99).

Tümörlü Dokular

Clone csm-1, leyomyosarkomlarda 5/6, leyomyomlarda 4/4, kavernöz hemanjiyomlarda 2/2, fibrosarkomlarda 1/7, fibröz histiyositomalarda 1/3, anjiyoleyomyomda 1/1, hemanjiyoperisito sarkomda 1/1 ve mezenkiyomada 1/1, düz kas aktin proteinini tespit etti. Gastrointestinal stromal tümörlerde (0/5), kondrosarkomlarda (0/4), pleomorfik rabdomyosarkomlarda (0/2), alveolar rabdomyosarkomlarda (0/2), sinovial sarkomlarda (0/2), bir fibrolipomada (0/1), bir lipomada (0/1), bir soliter fibröz tümörde (0/1), bir epiteloid sarkomda (0/1), bir mezoteliyomda (0/1), bir liposarkomda (0/1), bir miksiliposarkomda (0/1), bir dermatofibrosarkomda (0/1), bir fibromatozda (0/1), bir ganliyonömomda (0/1), tiroid tümörlerinde (0/3), akciğer tümörlerinde (0/4), karaciğer tümörlerinde (0/4), yumurtalık tümörlerinde (0/4), beyin tümörlerinde (0/2), yemek borusu tümörlerinde (0/1), meme tümörlerinde (0/2), mide tümörlerinde (0/2), dil tümörlerinde (0/2), bilinmeyen orijinli metastatik tümörlerde (0/2), böbrek tümörlerinde (0/2), serviks tümörlerinde (0/2), testis tümörlerinde (0/2), bağırsak tümörlerinde (0/2), rektum tümörlerinde (0/2), cilt tümörlerinde (0/2), larinks tümöründe (0/1) veya timus tümöründe (0/1) boyanma gözlenmedi. (Değerlendirilen toplam abnormal olgu sayısı = 90).

PA0943. normal ve neoplastik dokularda insan alfa düz kas aktini saptanması için tavsiye edilir.

Ürüne Özel Sınırlamalar

Smooth Muscle Actin (alpha sm-1), Leica Biosystems'da Bond Polymer Refine Detection ve BOND yardımcı reagent'ları ile birlikte kullanılmak üzere optimize edilmiştir. Önerilen test prosedürlerinin dışına çıkan kullanıcılar, bu şartlar altında hasta sonuçlarının yorumlanması için sorumluluğu kabul etmelidirler. Protokol süreleri, doku fiksasyonu ve antijen değerlendirme etkinliği nedeniyle değişiklik gösterebilir; bunlar ampirik olarak belirlenmelidir. Negatif reagent kontrolleri, retrieval koşulları ve protokol süreleri optimize edilirken kullanılmalıdır.

Arıza Giderme

Düzeltilici işlem için 3 no'lu referansa başvurun.

Olağandışı boyamayı rapor etmek için yerel distribütörünüze veya bölgesel Leica Biosystems ofisine başvurun.

Daha Fazla Bilgi

Prosedür Prensipleri, Gerekli Materyaller, Numune Hazırlığı, Kalite Kontrol, Test Doğrulaması, Boyamanın Yorumlanması, Etiketlerdeki Tuşlar ve Semboller ve Genel Sınırlamalar başlıkları altındaki BOND reagent'lar ile immünohistokimyasal boyama ile ilgili daha fazla bilgi, BOND kullanıcı dokümantasyonunuzun "BOND Reagent'larının Kullanılması" altında bulunabilir.

Kaynakça

1. Clinical Laboratory Improvement Amendments of 1988, Final Rule 57 FR 7163 February 28, 1992.
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