REFERENCE GUIDE
positive control slides

product code: Q116C.0000
Q300C.0000
Q400C.0000
Q601C.0000

PRETREATMENT OF PARAFFIN SECTIONS
PROTEOLYTIC TREATMENT
HYBRIDIZATION PROCEDURE
DETECTION PROCEDURE & STAINING PROCEDURE

GUIDE RÉFÉRENCE
postive control slides

product code: Q116C.0000
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Q601C.0000

PRE-TRAITEMENT DES SECTIONS PARAFFINÉES
TRAITEMENT PROTEOLYTIQUE
PROTOCOLE D'HYBRIDATION
PROTOCOLE DE DÉTECTION & PROTOCOLE DE COLORATION

HANDLEIDING
positive control slides

product code: Q116C.0000
Q300C.0000
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SNIJDEN EN PLAKKEN VAN PARAFFINE COUPES
PROTEOLYTISCHE VOORBEHANDELING
HYBRIDISATIE PROCEDURE
DETECTIE PROCEDURE & TEGENKLEURINGS PROCEDURE

ANLEITUNG
positive control slides

product code: Q116C.0000
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HERSTELLUNG VON PARAFFINSCHNITTEN
PROTEOLYTISCHE BEHANDLUNG
HYBRIDISIERUNGSPROZEDUR
DETEKTIONSPROCEDUR & FÄRBEPROZEDUR

GUIA DE REFERENCIA
postive control slides

product code: Q116C.0000
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PRETRATAMIENTO DE LOS CORTES DE PARAFINA
TRATAMIENTO PROTEOLITICO
PROTOCOLO DE HIBRIDACION
PROTOCOLO DE DETECCION & PROTOCOLO DE TINCION

METODICA D'USO
positive control slides

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PRETRATTAMENTO DELLE SEZIONI IN PARAFFINA
TRATTAMENTO PROTEOLITICO
PROCEDIMENTO DI IBRIDAZIONE
PROCEDIMENTO DI DETEZIONE & PROCEDIMENTO DI COLORAZIONE

DATA SHEET-v4 POSITIVE CONTROL SLIDES

Pan Path

Product **HPV 16 Positive control slides**
EBV/EBER Positive control slides
HSV 1/2 Positive control slides
Kappa/Lambda Positive control slides

Code **Q116C.0000, Q300C.0000, Q400C.0000, Q601C.0000**

Technical specifications

Cat. No.	Description	Contents	Results
Q116C.0000	HPV 16 positive control slides (CONTROL + HPV 16)	Cytological specimen of cultured, formalin fixed CaSki cell line	> 90% of the cells are positive for HPV 16, each cell containing ± 350 copies of the viral genome
Q200C.0000	CMV positive control slides (Control + CMV)	Formalin fixed, paraffin embedded culture of infected cell line; 4-6 um section	> 50% of the cells are positive for CMV
Q300C.0000	EBV/EBER positive control slides (CONTROL + EBV/EBER)	Formalin fixed, paraffin embedded culture of P3HR-1 cell line, 4-6 um section	> 90% of the cells are positive for EBV in low copy numbers; approx. 5% are producer cells with high copy numbers
Q400C.0000	HSV 1/2 positive control slides (CONTROL + HSV 1/2)	Formalin fixed, paraffin embedded culture of HSV 1/2 infected lung fibroblast cell line, 4-6 um section	Approx. 50% of the cells are positive for HSV 1/2
Q601C.0000	Kappa/Lambda positive control slides (CONTROL + k/l)	Formalin fixed, paraffin embedded human tonsil, 4-6 um section	B-cells and plasma cells in human lymphoid tissue are positive for either kappa or lambda; unbalanced ratios are indicative for monoclonal proliferation

Application : positive control slides for respective probes for use in *in situ* hybridisation (ISH)
Format : 1 box containing 2 slides, double wells, teflon coated ; each well contains 1 specimen
Storage : room temperature, protected from light and humidity
Stability : until expiry date printed on label
Precautions : the fixation procedure has made the specimens, which may contain potential infectious material non-infectious; however it is advised to observe normal precautions for handling infectious agents

Related products
Please contact your local supplier for further information.

Limitations of Procedure

Product Positive control slides

- The REMBRANDT® Positive control slides are solely applicable as a control for the respective probes applied in ISH.
- Appropriate medical decisions are only possible if the medical traceability is ensured. The product is intended for professional use as an aid in the diagnosis by *in situ* hybridisation.
- Either human tissue sections or human cytological preparations may be used. Samples must be fixed in buffered formalin or alcohol. Sections should be cut at 4 um thickness, glued to the glass slides with a bio-adhesive (e.g. organosilane), dried at room temperature, subsequently dried at 37 °C overnight, complete deparaffinisation in xylene and alcohol series and air dried. Cytological specimen should be prepared as required by the user, fixed with cytological fixation agent, rinsed in distilled water prior to the ISH procedure and air dried.
- Many factors can influence the performance of the ISH procedure. Failure in detection can be due to i.e. improper sampling, handling, the time lapse between tissue removal and fixation, the size of the tissue specimen in the fixation medium, the fixation time, processing fixed tissue, the thickness of the section, the bio-adhesive on the slide, deparaffinisation procedure, incubation times, incubation temperatures, all other reagents (i.e. deparaffinisation reagents, proteolytic treatment, probes etc.) used in the procedure and interpretation of results.
- The performance of the ISH procedure is also affected by the sensitivity of the method and the DNA or RNA target load; in case the limit of the sensitivity is reached or when the target DNA or RNA load is too low, a false negative reaction may be the result.
- The clinical interpretation of the results should not be established on the basis of a single test result. Moreover, diagnosis should also take the clinical history, symptoms, as well as morphological data into consideration. Negative results therefore do not rule out any possibility of a positive specimen.
- The REMBRANDT® test results are not to be relied on in case the sampling, sampling method, quality, sample preparation, other reagents used, controls and procedure followed is not optimal.
- Therapeutic considerations based on the result of this test alone should not been taken. Positive results should be verified by other traditional diagnostic methods such as but not limited to clinical history, symptoms, as well as morphological data.
- The medical profession should be aware of risks and factors influencing the intensity, the absence or presence of probe signals which can not be foreseen when applying this test.
- The user should carefully consider the risk and use of sample material for this test in case the sample material does not contain sufficient or representative test material.
- Laboratory personnel performing the test should be knowledgeable and be able to interpret the test results.

Interpretation of the results

First, check the negative and positive controls that have been incubated with the test slides simultaneously:
- The negative control should be really negative, i.e. not show any localised colour precipitations. If the negative control could be interpreted as being positive, discard the results since no conclusions can be drawn.
- The positive control should show colour precipitations in conformity with the localisation of the target DNA or RNA. The colour should show the proper shade and must be clearly visible in the preferential cell/ tissue type and correspond to the target localisation.

In the test slides, start under low power magnification and focus on localisation and colour to see whether:
- The positivity (colour precipitation) observed is localised in the cell type preferred by the target.
- The colour has the right shade (no endogenous or formalin pigment).

Use high power magnification to see whether:
- The positive staining texture (granular, etc), demarcation and localisation are conform the positive control staining pattern.

Product in combination with other devices

The REMBRANDT® Positive control slides are intended for stand-alone usage. The in vitro diagnostic is intended to be used in combination with standard formalin fixed, paraffin embedded tissue blocks, standard tissue freezing, tissue sectioning (microtome), standard cytological preparation methods, hot plate(s), stove(s), incubation device(s), water bath(s), temperature and incubation time control(s), other needed reagents (but not supplied with this reagent) for ISH and a microscope. The combination has been tested and validated. Since the standard formalin fixed, paraffin embedded tissue blocks, standard tissue freezing, tissue sectioning (microtome), standard cytological preparation methods, hot plate(s), stove(s), incubation device(s), water bath(s), temperature controls, incubation time control(s) and other needed reagents such as but not limited to proteolytic reagents, labelled probes, detection reagents and a microscope is not combined with the device as a product, conformity with the essential requirements is not applicable. Assay validation criteria are mentioned in *'Interpretation of the results'* and are also depending on the target; since the Positive control slides can be used for different ISH applications and are also depending on the target load, the validation criteria may vary.

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