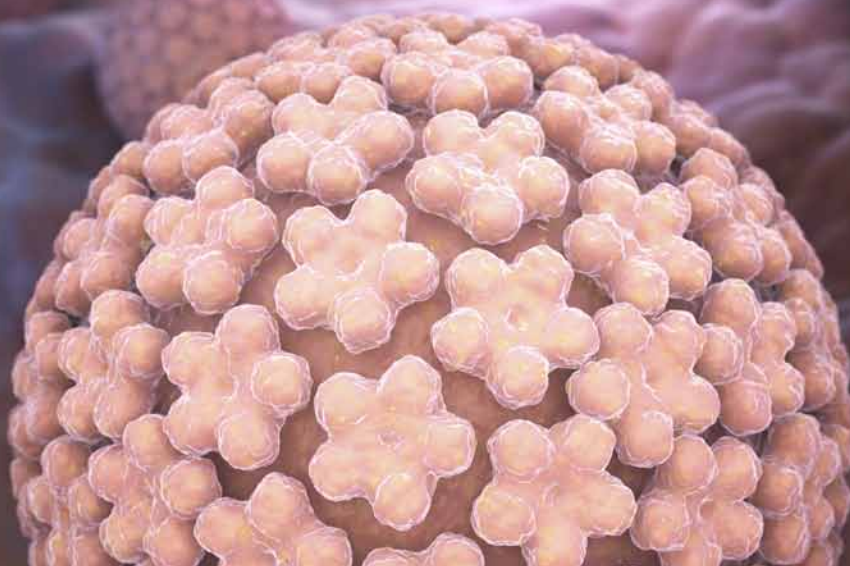


MOLECULAR DIAGNOSTICS FOR SEXUAL TRANSMITTED DISEASES



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HIBRIDIZATION ON STRIP PRODUCTS

PRODUCTOS BASADOS EN HIBRIDACIÓN EN TIRA

GENERAL PROCEDURE

Procedimiento General

- All the reagents are ready to use
Todos los reactivos están listos para usar
- The tests can be performed both manual and automatically
Los tests pueden realizarse tanto manual como automáticamente
- Kits include all the PCR reagents, even the Taq polymerase
Los kits incluyen todos los reactivos de PCR, incluso la Taq polimerasa
- Internal controls included
Controles internos incluidos

Step 1 Paso 1

DNA sample extraction
Extracción del ADN de la muestra

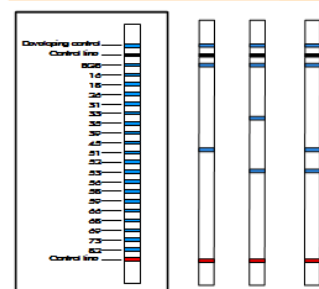
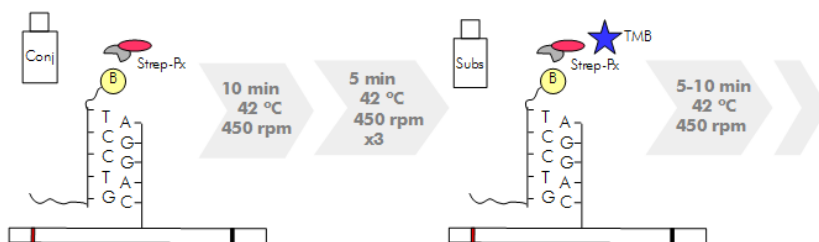
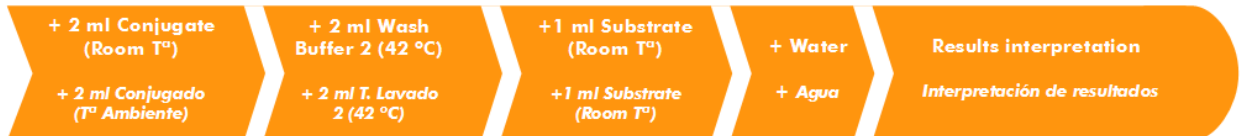
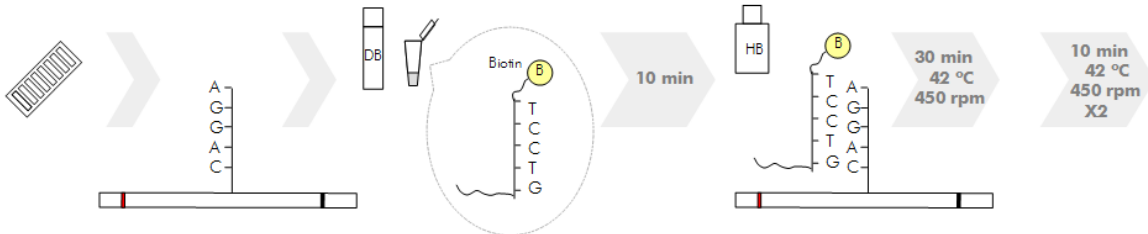
Step 2 Paso 2

PCR*

* OpeGen kits include all the necessary reagents even Taq polymerase

Step 3 Paso 3

Hybridization protocol
Protocolo de hibridación



*25 µl Denaturing Solution + 25 µl PCR A+B in STD Panel Strip /
*25 µl Solución Desnaturalizante + 25 µl PCRA+B en STD Panel Strip

PRODUCTS

Productos

STD PANEL STRIP

Introduction

At present, sexually transmitted diseases (STDs) make up the most common group of infectious diseases that must be reported in the majority of the world's countries. Their incidence is elevated, and more than 20 pathogenic microorganisms are known to be transmitted by sexual contact, with *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* and *Mycoplasma (genitalium and hominis)* being the most common.

The current permanent trend of increasing sexually transmitted diseases, especially among young people under 25 years, makes their early and accurate diagnosis of great interest.

The STD Panel Strip test is a test based on the reverse blot technique that allows the detection of 10 pathogens associated to sexually transmitted diseases: *Chlamydia trachomatis* (discriminating variants L1, L2 and L3, that cause *lymphogranuloma venereum*), *Neisseria gonorrhoeae*, *Mycoplasma genitalium*, *Trichomonas vaginalis*, *Ureaplasma parvum*, *Ureaplasma urealyticum*, *Mycoplasma hominis*, *Herpes simplex 1*, *Herpes simplex 2*, and *Treponema pallidum*.

Introducción

En la actualidad, las enfermedades de transmisión sexual (ETS o STDs) conforman el grupo más frecuente de enfermedades infecciosas de declaración obligatoria en la mayoría de los países del mundo. Su incidencia es elevada y se conocen más de 20 microorganismos patógenos que se transmiten por contacto sexual, siendo los más frecuentes *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* y *Mycoplasma (genitalium y hominis)*.

La tendencia actual de incremento permanente de las enfermedades de transmisión sexual, sobre todo entre los jóvenes menores de 25 años, hace que su diagnóstico precoz y certero sea de gran interés.

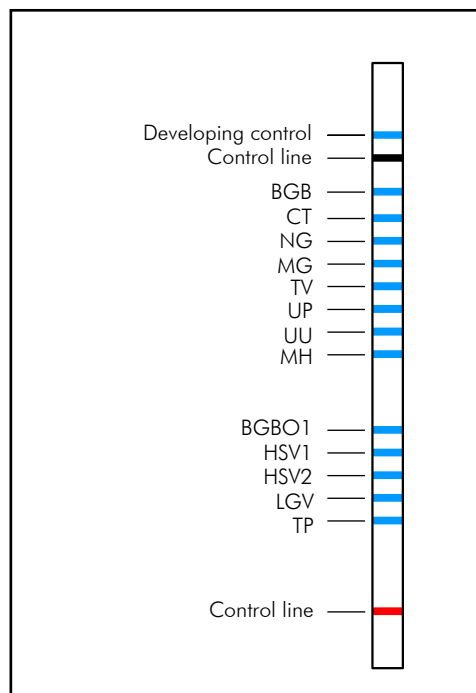
El test STD Panel Strip es un test basado en la técnica del blot reverso que permite la detección de 10 patógenos asociados a enfermedades de transmisión sexual: *Chlamydia trachomatis* (distinguiendo las variantes L1, L2 y L3 que provocan *linfogranuloma venereo*, LGV), *Neisseria gonorrhoeae*, *Mycoplasma genitalium*, *Trichomonas vaginalis*, *Ureaplasma parvum*, *Ureaplasma urealyticum*, *Mycoplasma hominis*, *Herpes simplex 1*, *Herpes simplex 2*, y *Treponema pallidum*.

RESULTS

Resultados

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Introduction

Human *Papillomavirus* (HPV) is responsible for a variety of skin and mucosa disorders. To date, over 100 different HPV genotypes have been described, of which more than 40 infect the anogenital tract. Of these, approximately 1/3 is associated with cervical cancer and anal neoplasm. The anogenital HPVs are generally divided into two categories: those with a low oncogenic potential risk (Low-Risk group) and those with a medium-high oncogenic potential risk (High-Risk group). The high-risk HPVs are generally associated with high-grade precancerous lesions and invasive cancer, while low-risk HPVs are frequently found in asymptomatic or benign conditions such as genital warts.

Intended use

High PapillomaStrip test allows qualitative detection of the DNA from 19 human *Papillomavirus* subtypes of medium-high risk: 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 69, 73 and 82.

On the other hand, Low PapillomaStrip test allows the genotyping of DNA samples from 18 human *Papillomavirus* subtypes of low risk: 6, 11, 40, 42, 43, 44, 54, 61, 62, 67, 70, 71, 72, 74, 81, 83, 84 y 91.

Specific primers for E6-E7 regions for each 37 HPVs detected with the kit are used to perform the multiplex PCR. Since the expression of the E6-E7 genes is directly associated with carcinogenesis, detection of these targets may provide significant biological and pathological information. Some studies showed that in cervical cancer samples that were positive for the E6 region, the L1 gene could not be detected in approximately 30% of cases, due to a gene deletion process that occurs when integrating DNA of high-risk HPV in epithelial cells.

Introducción

El virus del papiloma humano (HPV) es responsable de una variedad de afecciones de la piel y la mucosa. Hasta la fecha, se han descrito más de 100 genotipos de HPV diferentes, de los cuales más de 40 infectan el tracto anogenital. De ellos, aproximadamente 1/3 están asociados con cáncer cervical y neoplasia anal. Los HPVs anogenitales se dividen, generalmente, en dos categorías: aquéllos con un riesgo oncogénico potencial bajo (grupo de bajo riesgo) y aquéllos con un riesgo oncogénico potencial medio-alto (grupo de alto riesgo). Los HPVs de alto riesgo están asociados, generalmente, a lesiones precancerosas de alto grado y a cáncer invasivo, mientras que los HPVs de bajo riesgo se suelen encontrar en condiciones asintomáticas o benignas como las verrugas genitales.

Finalidad prevista

High PapillomaStrip permite la detección cualitativa en muestras de ADN de 19 subtipos de Papillomavirus de medio-alto riesgo: 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 69, 73 y 82.

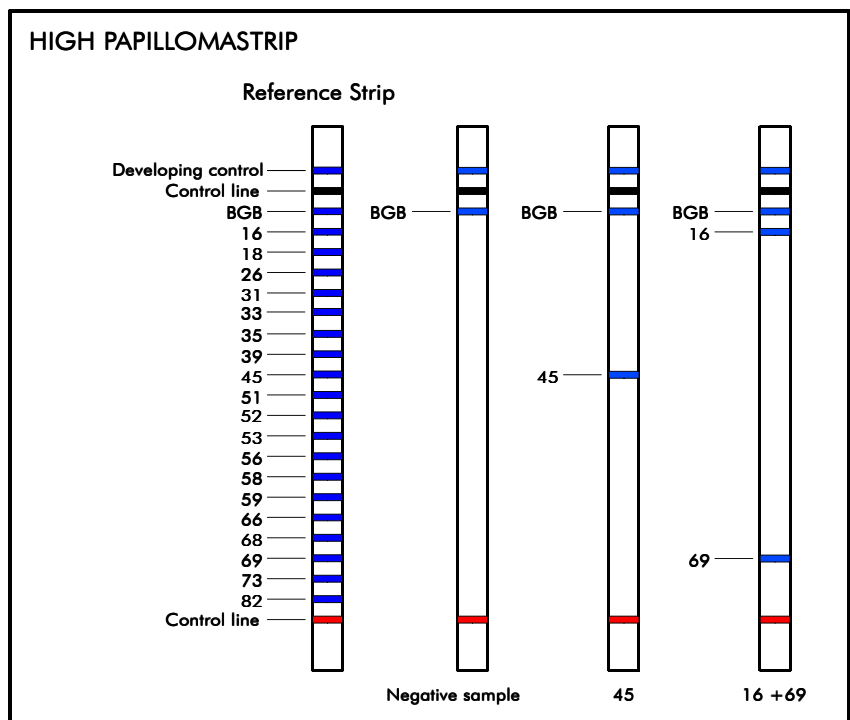
Por otra parte, Low PapillomaStrip test permite el genotipado de muestras de ADN de 18 subtipos de Papillomavirus de bajo riesgo: 6, 11, 40, 42, 43, 44, 54, 61, 62, 67, 70, 71, 72, 74, 81, 83, 84 y 91.

Para llevar a cabo la PCR multiplex, se utilizan primers específicos de las regiones E6-E7 de los 37 HPVs detectados con los kits. La expresión de los genes E6-E7 está directamente asociada con la carcinogénesis, por lo que la detección de estas dianas puede proporcionar información biológica y patológica importante. Hay estudios que demuestran que en muestras de cáncer cervical positivas para la región E6, el gen L1 puede no ser detectado en aproximadamente el 30% de los casos, debido a un proceso de delección génica, que ocurre cuando se integra ADN del HPV de alto riesgo en células epiteliales.

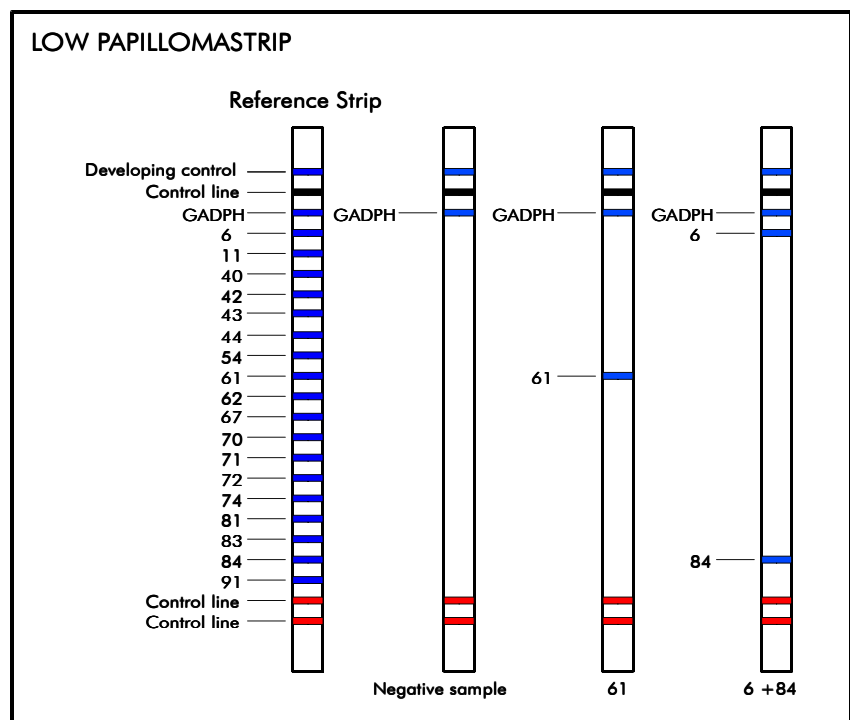
RESULTS

Resultados

High risk / Alto riesgo



Low risk / Bajo riesgo



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PRODUCTS BASED ON OLIGOIMMUNOCHROMATOGRAPHY

PRODUCTOS BASADOS EN OLIGOINMUNOCROMATOGRAFÍA

GENERAL PROCEDURE

Procedimiento General

- All the reagents are ready to use
Todos los reactivos están listos para usar
- Minimum necessary equipment
Mínimo equipamiento necesario
- Previous hybridization to the strip detection: it increases specificity and reproducibility of the process.
Hibridación previa a la detección de tira: aumenta la especificidad del proceso.
- Kits include all the PCR reagents, even the Taq polymerase
Los kits incluyen todos los reactivos de PCR, incluso la Taq polimerasa
- Internal controls included
Controles internos incluidos

Step 1 Paso 1

DNA sample extraction
Extracción del ADN de la muestra

Step 2 Paso 2

PCR*

* OpeGen kits include all the necessary reagents even Taq polymerase

Step 3 Paso 3

PCR Denaturation
Desnaturalización de la PCR

Colloid + 100 µl Hybridization B.
Coloide + 100 µl T. Hibridación

50 µl PCR + 50 µl Denaturing Sol.
+ 50 µl Sol. Desnaturalizante

Resuspended colloid
+ 10 µl denatured PCR

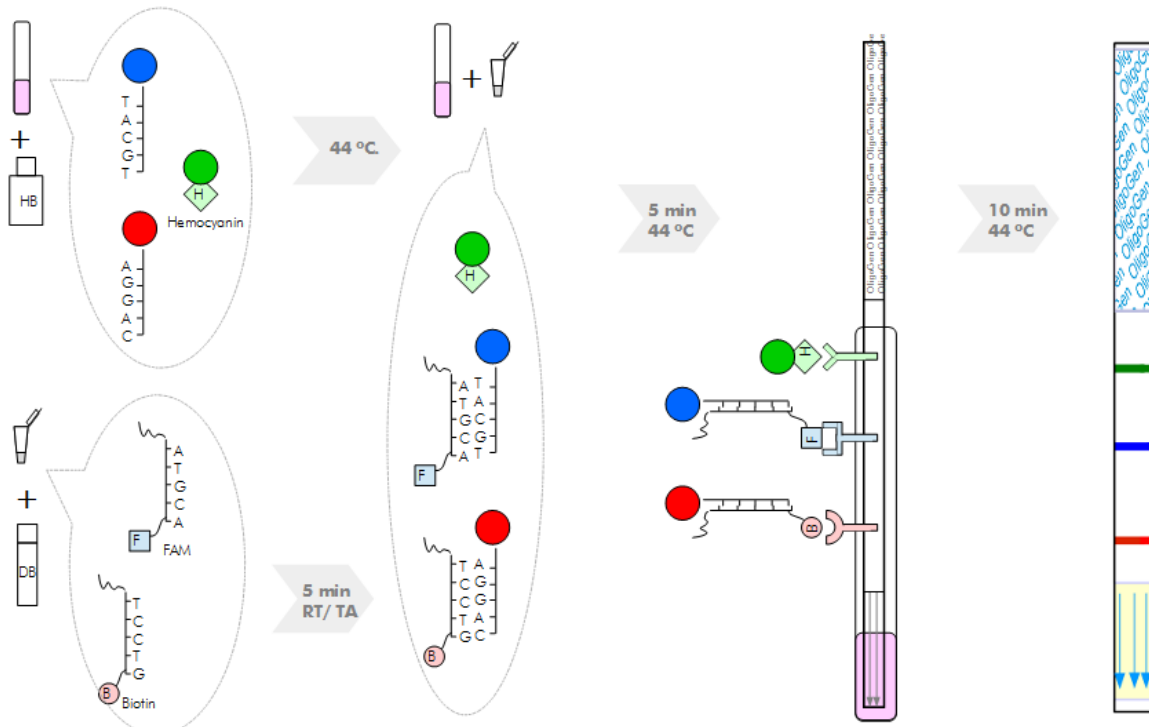
Coloide resuspendido
+ 10 µl PCR desnaturalizada

Colloid / denatured PCR
+ Strip

Coloide / PCR desnaturalizada
+ Tira

Results
Interpretation

Interpretación
de resultados



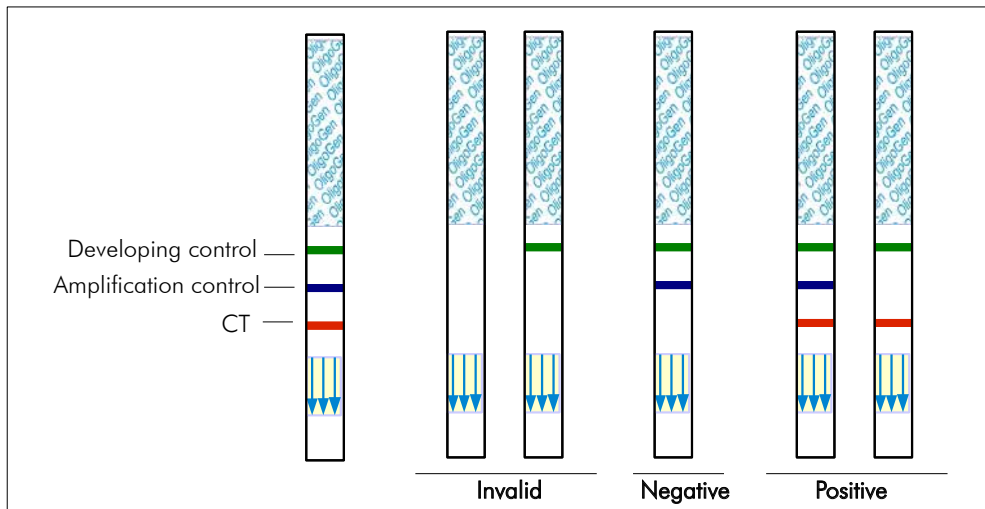
PRODUCTS

Productos

CT OligoGen

CT OligoGen is a test designed for the detection of *Chlamydia trachomatis* by simultaneous amplification of two independent targets of its DNA: one in the cryptic plasmid and another in its own genome and subsequent identification by immunochromatography. This test can detect infections caused by wild-type CT, the Swedish variant or those that do not carry the cryptic plasmid.

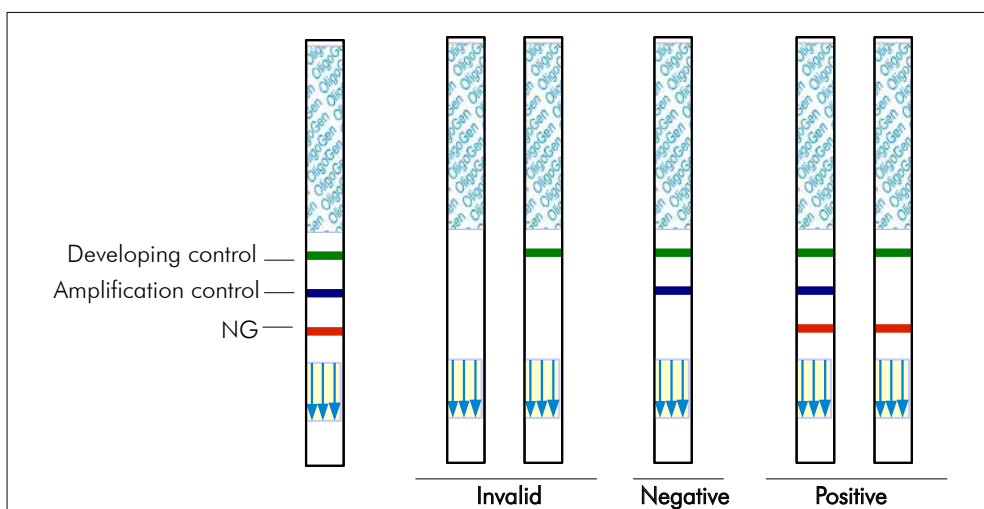
CT OligoGen es un test diseñado para la detección de *Chlamydia trachomatis* mediante la amplificación simultánea de dos dianas independientes de su ADN: una en el plásmido críptico y otra en el propio genoma y su posterior identificación mediante inmunocromatografía. Este test puede detectar las infecciones causadas por el tipo salvaje de CT, la variante Sueca o aquellas que no porten el plásmido críptico.



NG OligoGen

NG OligoGen is a test designed for the detection of *Neisseria gonorrhoeae* by simultaneous amplification of two independent targets of its DNA and subsequent identification in immunochromatographic strips.

NG OligoGen es un test diseñado para la detección de *Neisseria gonorrhoeae* mediante la amplificación simultánea de dos dianas independientes de su ADN y su posterior identificación en tira inmunocromatográfica.



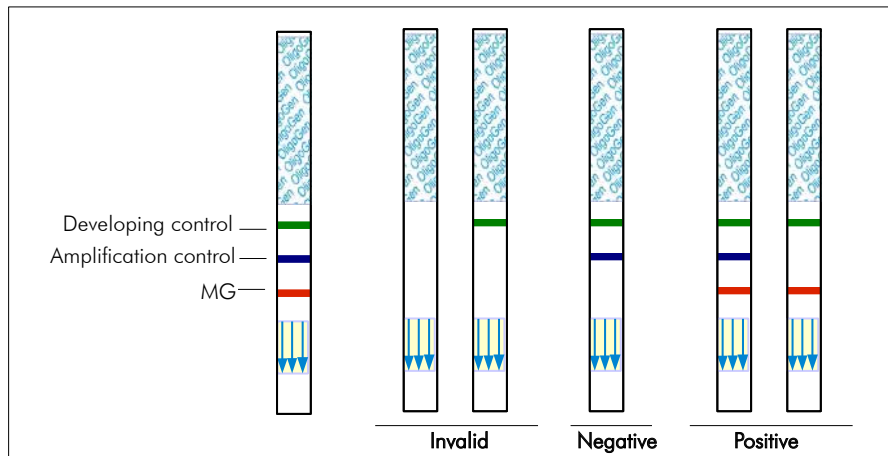
PRODUCTS

Productos

MG OligoGen

MG OligoGen test is a test designed for the qualitative detection of *Mycoplasma genitalium* (MG) through the amplification of a specific genomic region of adhesin protein (MgPa) gene and its subsequent identification by immunochromatography. This test allows the simple, economical and reliable detection of all infections caused by MG.

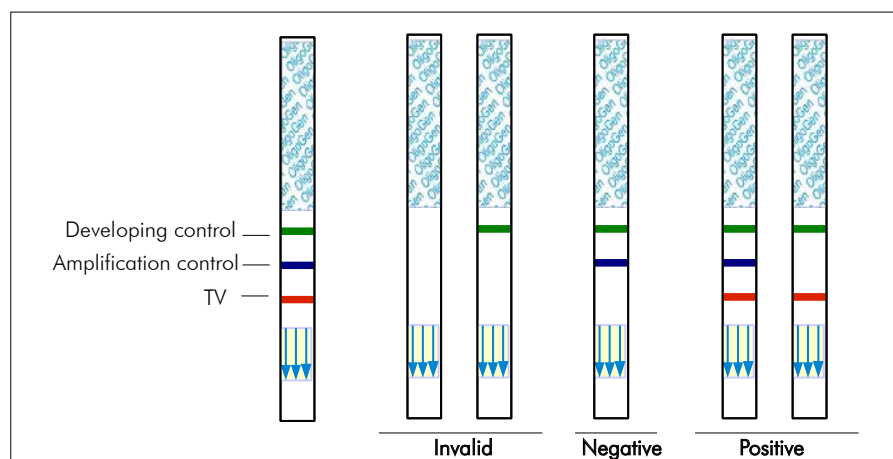
El test MG OligoGen es un test diseñado para la detección de Mycoplasma genitalium (MG) mediante la amplificación de una región genómica específica del gen de la adhesina MgPa y su posterior identificación mediante oligo-inmunocromatografía. Este test permite detectar de una manera sencilla, económica y fiable todas las infecciones causadas por MG.



TV OligoGen

TV OligoGen is a test designed for the qualitative detection of *Trichomonas vaginalis* (TV) through the amplification of a genomic region of TV (X83109), and its subsequent identification by immunochromatography. The test allows the simple, economical and reliable detection of all infections caused by the protozoan.

TV OligoGen es un test diseñado para la detección cualitativa de Trichomonas vaginalis (TV) mediante la amplificación de una región genómica de TV (X83109), y su posterior identificación mediante inmunocromatografía. El test permite detectar de una manera sencilla, económica y fiable todas las infecciones causadas por el protozoo.



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PRODUCTS

Productos

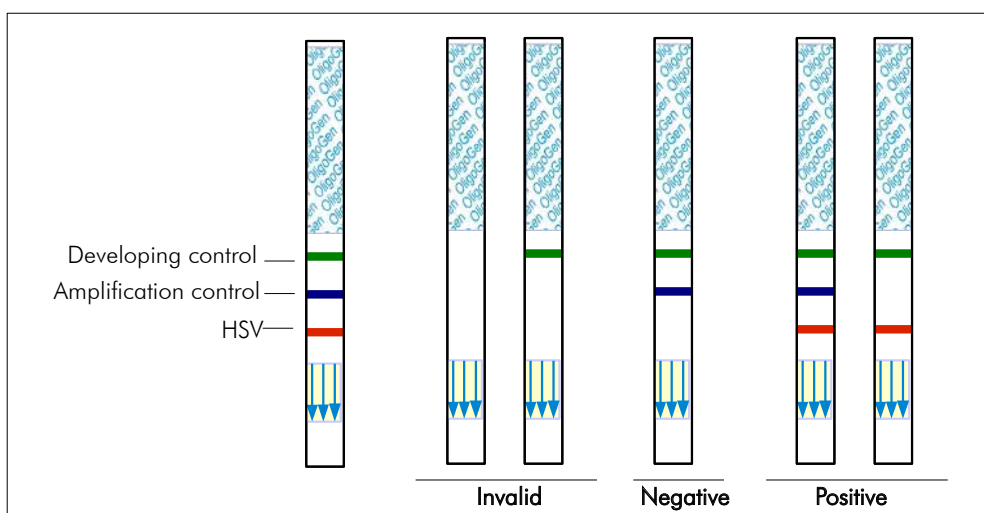
HSV 1/2

HSV OligoGen is a test designed for the qualitative detection and differentiation of *Herpes simplex virus* 1 and 2 through the simultaneous amplification of a common genomic region of DNA polymerase gene, and its subsequent identification by immunochromatography. The test allows for the simple, economical and reliable detection of all infections caused by the both types of virus.

Herpes simplex is an infectious viral disease, which is characterized by inflammation and the appearance of cutaneous lesions consisting of clusters of small vesicles surrounded by a red ring. These infections can affect the area around the mouth (oral herpes, also known as cold sores) or the area around the genitals (genital herpes). Until recently it was thought that oral herpes was caused by the *herpes simplex* type 1 virus and genital herpes by the *Herpes simplex* type 2 virus. Now we know that both viruses can cause lesions or sores in both parts of the body.

HSV OligoGen es un test diseñado para la detección cualitativa y diferenciación de Herpes simplex virus tipo 1 y 2, mediante una amplificación común para ambos tipos de virus de un región del gen de la DNA polimerasa y una posterior identificación específica mediante inmunocromatografía. El test permite detectar de una manera sencilla, económica y fiable las infecciones causadas por ambos tipos de HSV.

El Herpes simplex es una enfermedad infecciosa inflamatoria de tipo vírico que se caracteriza por la aparición de lesiones cutáneas formadas por pequeñas vesículas agrupadas en racimo y rodeadas de un aro rojo. Estas infecciones pueden afectar el área alrededor de la boca (herpes oral, también conocido como llagas herpéticas) o el área alrededor de los genitales (herpes genital). Hasta no hace mucho tiempo atrás se creía que el herpes oral era causado por el virus Herpes simplex tipo 1, mientras que el herpes genital era causado por el virus herpes simplex tipo 2. Ahora se sabe que ambos virus pueden causar lesiones o llagas en ambas áreas.



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PRODUCTS

Productos

CT + LGV OligoGen

CT/LGV OligoGen is a test designed for the qualitative detection of *Chlamydia trachomatis* (CT) and their serotypes L1, L2 and L3, causing agents of Lymphogranuloma venereum (LGV), through the simultaneous amplification of two genomic regions, one in the cryptic plasmid and another in the genome of CT (omp gene), and the *pmpH* gen for LGV, and its subsequent identification by immunochromatography. The test allows for the simple, economical and reliable detection of all infections caused by the bacteria, whether or not (Swedish variant) it contains the cryptic plasmid.

Infections by *C. trachomatis* affect humans exclusively. Despite being the pathogen of the greatest prevalence in sexually transmitted infections (STIs) in the Western world, it is one of the least-diagnosed aetiologic agents, due to the high percentage of cases of asymptomatic infection.

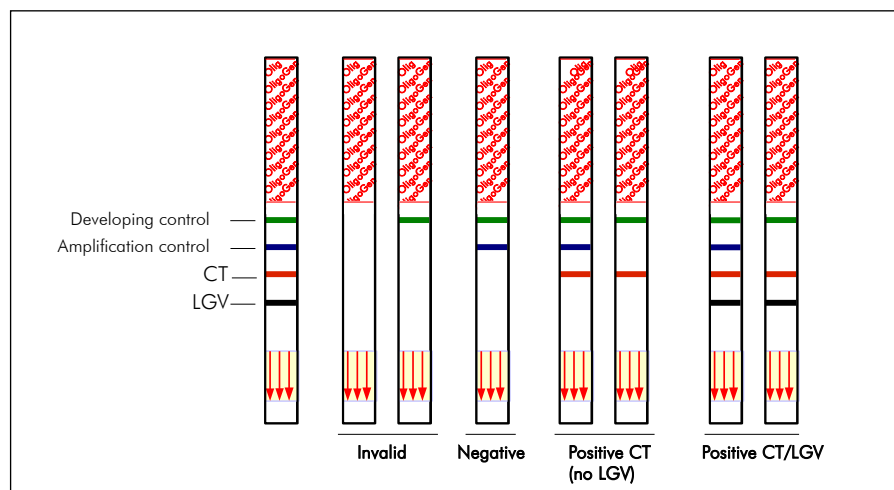
There are 18 known serotypes distributed in three biovars or pathotypes, each responsible for a different infectious process. One of these three biovars is the Lymphogranuloma venereum (LGV): systemic disease that involves the invasion of the lymph nodes produced by serotypes L1, L2 and L3.

The treatment of Lymphogranuloma venereum (LGV) is longer than for other infections caused by *C. trachomatis* and consequently it is important to make a differentiation of this pathotype in order to make a proper treatment.

CT/LGV OligoGen es un test diseñado para la detección de Chlamydia trachomatis (CT) y sus serotipos L1, L2 y L3, causantes de Linfogranuloma venéreo (LGV), mediante la amplificación de una región genómica específica de los genes plásmido críptico y Omp para CT y el gen pmpH para LGV, y su posterior identificación mediante oligo-inmunocromatografía. El test permite detectar de una manera sencilla, económica y fiable todas las infecciones causadas por CT/LGV, sean portadoras o no (variante sueca) del plásmido críptico. Las infecciones causadas por C. trachomatis afectan exclusivamente a humanos. A pesar de ser el patógeno de mayor prevalencia en las enfermedades de transmisión sexual (ETS) en el mundo occidental, es uno de los agentes etiológicos que menos se diagnostica, debido al alto porcentaje de casos de infección asintomática.

Se conocen 18 serovariantes distribuidos en tres biovariantes o patotipos, responsables cada uno de un cuadro infeccioso diferente. Una de estas tres biovariantes es el Linfogranuloma venereo (LGV) que es una enfermedad sistémica que implica invasión de los nodulos linfoides producida por los serotipos L1, L2 y L3.

El tratamiento del Linfogranuloma venéreo (LGV) es más largo que para otras infecciones causadas por C. trachomatis, por lo que es importante realizar la diferenciación de este patotipo para realizar el tratamiento adecuado.



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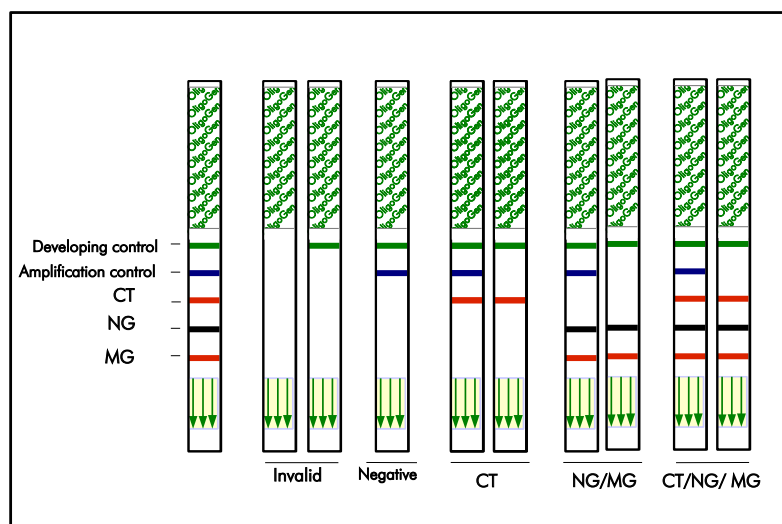
PRODUCTS

Productos

CT + NG + MG OligoGen

CT/NG/MG OligoGen es un test diseñado para la detección de *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Mycoplasma genitalium* (MG), mediante la amplificación de diferentes regiones genómicas específicas de cada patógeno y su posterior identificación mediante oligo-inmunoquimografía. El test permite detectar de una manera sencilla, económica y fiable todas las infecciones causadas por CT, NG y MG.

CT/NG/MG OligoGen kit is a test designed for the detection of Chlamydia trachomatis (CT) Neisseria gonorrhoeae (NG) and Mycoplasma genitalium (MG), through the amplification of different genomic regions, specific for each pathogen, and its subsequent identification by immunochromatography. The test allows the simple, economical and reliable detection of all infections caused by CT, NG and MG.



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OPERON S. A.
Camino del Plano, 19
50410 Cuarte de Huerva (Zaragoza) • Spain
Tel: +34 976 503 597 • Fax: +34 976 503 531

e-mail address: sales@operon.es

www.operon.es