GENETIC DISEASES

MOLECULAR DIAGNOSTICS

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immuno & molecular diagnostics

Rev. 2

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HYBRIDIZATION ON STRIP

GENERAL PROCEDURE

DNA sample extraction

Polymerase Chain Reaction (PCR)

MJ Mini Gradient Thermal Cycler (BioRad)
Mastercycler Personal (Eppendorf)
S1000 Thermal Cycler (BioRad)
2720 Thermal Cycler (Applied Biosystems)

Hybridization protocol

Manual Procedure

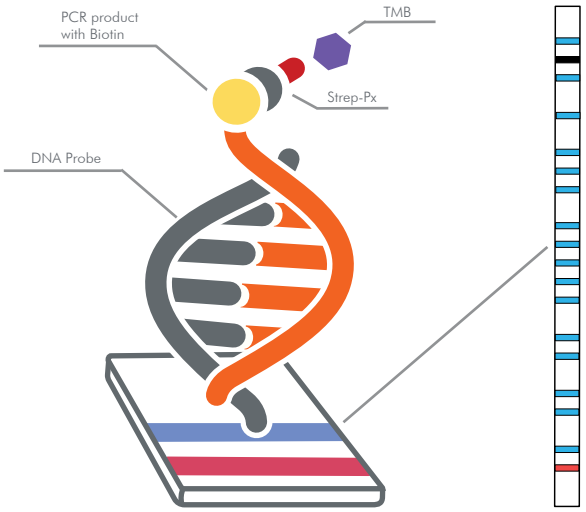
PST-60HL (Biosan)

Automatic Procedure

Profiblot T30 (Tecan)
Profiblot T48 (Tecan)
Autoblot 3000H (medTEC)
Tendigo (Fujirebio)
DynaHeat (Dynex)

Visual/Automatic reading

BioScitec R2 or S1 scanner



HIGHLIGHTS

- All the reagents are ready to use.
- Kits include all the PCR and hybridization reagents, even the Taq Polymerase.
- Internal controls of amplification and hybridization included.
- 2-8 °C transport and storage.
- Scanner reading available.
- The hybridization procedure can be performed both manual or automatically.
- 18 months of shelf-life.
- High sensitivity and specificity.
- Same hybridization protocol for all the products.
- CE IVD marked.
- Many different types of validated samples.
- Up to 24 lines in the same strip.

CELIACSTRIP

Test for the detection of HLA haplotypes associated to Celiac disease

Celiac disease is a chronic inflammatory condition of the intestine that is triggered by the consumption of gluten or associated proteins found in wheat, barley and rye. It is one of the most common conditions affecting the Caucasian population, with a prevalence of between 1:100 and 1:500 in Europe and North America.

Susceptibility to gluten sensitivity is to some extent genetically predetermined. In most of the human populations studied, 90-95% of patients were carriers of the heterodimer HLA-DQ2, encoded by alleles DQA1*05 and DQB1*02 in cis position (more common in Central and Northern Europe) or in trans position (more common in Mediterranean countries).

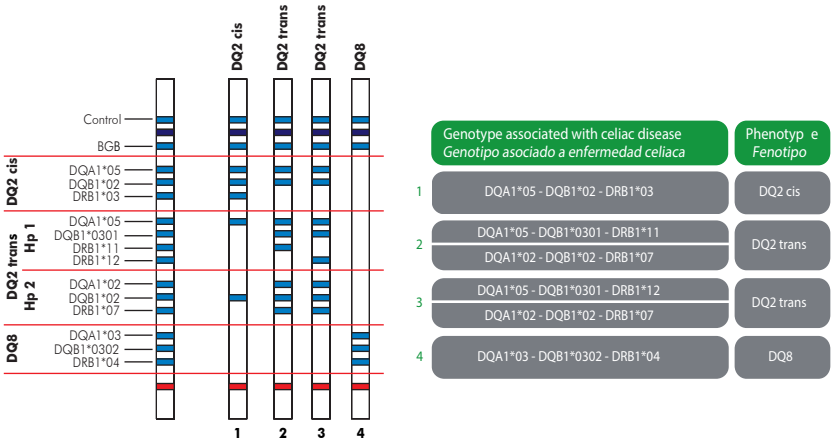
The remaining patients (5-10%) often have a second heterodimer, HLA-DQ8 (mainly in indigenous South American patients), encoded by alleles DQA1*03 and DQB1*0302. Patients who are non-carriers of DQ2 or DQ8 may show at least one separate DQ2 allele; very few cases have been described where both alleles are absent.

CeliacStrip is a test based on the reverse hybridization technique designed for the detection of the presence or absence of complete haplotypes that encode HLA-DQ2 cis (DQB1*02, DQA1*05, DRB1*03), HLA-DQ2 trans (DQB1*0301, DQA1*05, DRB1*11/12 + DQB1*02, DQA1*02, DRB1*07) and HLA-DQ8 (DQB1*0302, DQA1*03, DRB1*04).

Highligths

- Very complete product, detects all alleles and haplotypes related to CD in a single test.
- Alleles are grouped by haplotype for ease of interpretation.
- Automatic interpretation is possible with reader.

Results



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HLA B5701 STRIP

Test for the detection of HLA B5701 alleles

Abacavir is used in the treatment of HIV-1 infection since 1999. The WHO recommends abacavir as a second-line treatment, owing to the of hypersensitivity associated with its use, which affects 5-8% of Caucasian patients.

Several studies have demonstrated the existence of a strong predictive correlation between hypersensitivity to abacavir and the presence of the HLA-B5701 allele. This correlation is strong to enable us to predict the risk of hypersensitivity to abacavir and classify individuals as low (<1%) or high (>70%) risk, based on the absence or presence of the HLA B5701 allele.

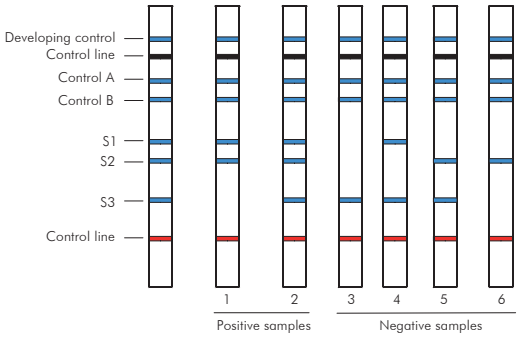
Several polymorphisms has been identified. One of them, located in the HCP5 gene (HLA complex P5), shows a perfect linkage disequilibrium with HLA B5701 (r2 = 1).

HLA B5701 Srip is a test based on the determination of the HLA B5701 alleles and the SNP of the HCP5 gene.

Highlights

- Reliable, sensitive and specific.
- No cross-reactions.
- Includes HCP5 which gives higher specificity.
- Easy interpretation.

Results



HLA B27 STRIP

Tests for the detection of HLA B27 alleles

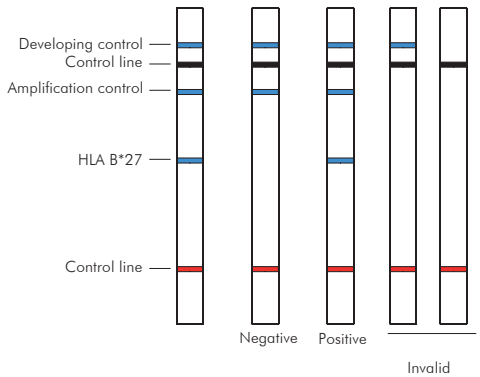
HLA B7 alleles have been associated with a wide range of pathologies such as ankylosing spondylitis (88-95% of patients), acute anterior uveitis (50-60% of patients).

HLA B27 Strip is a test based on the reverse hybridization technique designed for the detection of HLA B27 alleles associated with genetic predisposition to different diseases.

Highlights

- Reliable, sensitive and specific.
- No cross-reactions.
- Easy interpretation.

Results



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HEMOCHROMASTRIP

Test for the genotyping of point mutations associated with Thrombosis risk

Hereditary Hemochromatosis is an autosomal recessive genetic disease characterized by excessive iron absorption due to an altered iron metabolism, causing a progressive iron accumulation in different organs, leading to the development of diverse pathologies (cirrhosis, cardiopathy, diabetes mellitus, and other irreversible damages).

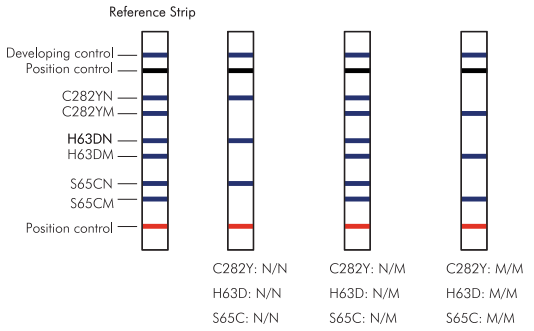
The disease has been associated with several HFE gene mutations (6p21.3). 60-100% of patients are homozygous for mutation C282Y, while 4 to 8% of patients carry the H63D mutation. Other mutations in the HFE gene have been identified with much lower carrier frequencies, as S65C mutation.

HemochromaStrip is a test based on the reverse hybridization technique designed for the detection of three point mutations of HFE gene associated with Hemochromatosis: C282Y, H63D and S65C.

Highlights

- Detects the main mutations that are the consensus worldwide.
- Easy interpretation.
- Differentiates heterocygosis and homozygosis.

Results



LACTOSTRIP

Test for the genotyping of polymorphisms associated with lactase persistence

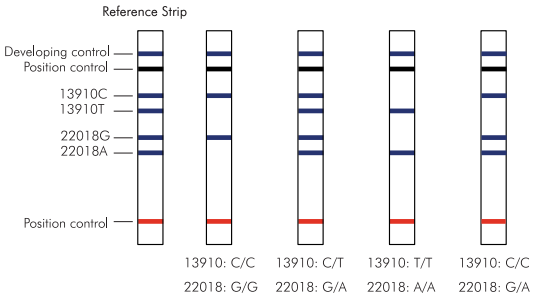
The frequency of the lactase activity persistence varies from >90% in northern Europe populations to 50% in southern Europe and Middle East, 5-20% in African populations not devoted to pasturage and 1% in Asia. Lactose intolerance presents with diverse symptoms, from the most typical (abdominal pain and distension, flatulence, diarrhea) to many others as nausea, vomiting, headache, poor concentration, severe tiredness, muscular and joint pain, etc.

LactoStrip is a test based on the reverse hybridization technique designed for the detection of two MCM6 gene polymorphisms associated with the persistence of lactase activity in adults: C/T 13910 and G/A 22018.

Highlights

- Detects the main mutations that are the consensus worldwide.
- Easy interpretation.
- Differentiates heterocygosis and homozygosis.

Results



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THROMBOSTRIP

Test for the genotyping of point mutations associated with Thrombosis risk

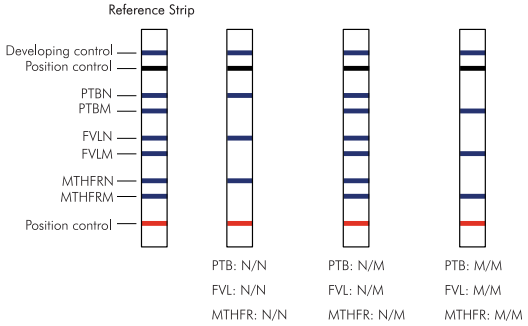
Venous thrombosis is one of the three most frequent cardiovascular diseases, and might be partially determined by genetic predisposition. Several mutations have been found, that affect mainly blood coagulation cascade factors. Among them, G1691A mutation in the coagulation Leiden's factor V is found in 20-60% of thrombosis patients. Other mutations as G20210A in prothrombin gene (factor II, PTB) and C677T in methylenetetrahydrofolate reductase gene (MTFH) have also been described.

ThromboStrip is a test based on the reverse hybridization technique designed for the detection of 3 point mutations associated with venous thrombosis risk: G1691A (FVL), G20210A (PTB) and C677T (MTHFR).

Highlights

- Detects the main mutations that are the consen sus worldwide.
- Easy interpretation.
- Differentiates heterocygosis and homozygosis.

Results



YCHROMSTRIP

Test for the detection of microdeletions in the azoospermia factor (AZF) of the Y chromosome causing azoospermia and oligospermia

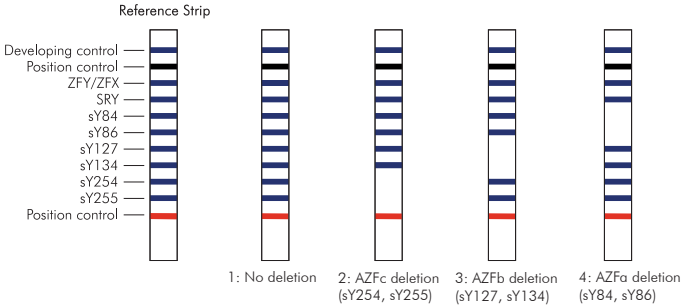
The male factor is responsible for 30-50% of cases of infertility problems, and 10-20% are attributed to azoospermia or oligospermia, casused by deletions in the Azospermia Factor (AZF) located on chromosome Y. The diagnosis of these microdeletions is important because carrier subjects are refractory to any treatment used to remedy such disorder. Besides, if a pregnancy is achieved, the resulting children will inherit these deletions and will present fertility problems like their fathers.

YchromStrip is a test based on the reverse hybridization technique designed for the detection of six STSs located in three different regions of the AZF: AZFa (sY84 and sY86), AZFb (sY127 and sY134) and AZFc (sY254 and sY255).

Highlights

- Detects the main deletions as indicated by EMQN guidelines.
- Easy interpretation.
- Analysis of 2 non-polymorphic STS from each of the 6 regions to increase the accuracy.

Results



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

Sales and Technical information: sales@operon.es

www.operon.es