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SZABO SCANDIC
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Clonit

MOLECULAR DIAGNOSTICS
AGILITY IS OUR DNA

Clonit srl: history, passion and innovation for Molecular Diagnostics.

Since 1987, Clonit has been focused in developing, manufacturing and distributing of innovative and reliable in Vitro Diagnostic Equipment and Reagents for Molecular Diagnostics.

A deep expertise in Molecular Biology mixed to our strong culture of business ethics make our company a valued partner for laboratories and hospitals around the world.

With our high standard and high performance IVDs portfolio, we aim to improve healthcare by enhancing and supporting the decision-making process, in line with scientific and technological evolution.

Our clinical diagnostic products are used to detect a broad range of diseases in several key areas such as viral, bacterial and fungal infections (including sexually transmitted diseases, transplantation/immunocompromised related infections, tropical diseases, healthcare associated infections), thrombophilia, oncohematology and several genetic disorders.

The company is registered and authorized by the Italian Ministry of the Health for the development, manufacturing and commercialization of Medical Diagnostic devices.

The standardization of internal quality control system and cross-checks in external reference labs, allow Clonit to ensure application of the highest standards of care and quality (ISO 9001 and ISO 13485 Certified). Moreover in May 2022 we obtained the certification of our products according to EU 2017/746 Regulation on In Vitro Diagnostic Medical Devices (IVDR). Certification for Class C products was issued by TÜV SÜD Product Service after a successful two-stage Audit.

We listen carefully to our customers' needs and work closely with health care professionals to transform them into solutions that provide people a better quality of life.

Realtime PCR
Emerging & Tropical Infections

West Nile Virus + Usutu

West Nile virus (WNV), belonging to the antigenic complex of Japanese encephalitis is a pathogen of re-emergence of the genus Flavivirus.
The phylogenetic analysis identified several genetic lines (lineage from 1 to 8). Of these, only lineage 1 and more recently lineage 2 have been associated with significant outbreaks in humans. The quanty WNV allows that allows the detection and quantification of the 3'UTR region of West Nile Virus (WNV), discriminating it from Usutu Virus, also belonging to the Flavivirus family and closely related to WNV.
Given the close phylogenetic correlation between Usutu Virus and WNV, strongly positive Usutu viruses patients could show cross reactivity with West Nile Virus. For this reason, a probe was inserted in the reaction to allow the correct identification of both viral targets.
Most people infected with WNV do not develop clinical signs. In endemic areas the symptomatology is evident in about 20% of the affected subjects, with an influenza-like syndrome characterized by an incubation period of about 2-14 days. Less than 1% has severe neurologic symptomatology classifiable in three main syndromes: meningitis, encephalitis and acute flaccid paralysis.

Product Description	Code	CE Mark	Description
quanty WNV	RT-04	CE IVD	48 Tests

* with Usutu virus differentiation.

USUTU

Among emerging viruses, Usutu virus (USUV) has recently attracted the attention of the scientific community due to its extensive spread in Europe. USUV is a Flavivirus that was first isolated in South Africa in 1959 and maintained in the environment through a typical enzootic cycle involving mosquitoes and birds.
This infection in humans is considered to be most often asymptomatic or to cause mild clinical signs. Nonetheless, a few cases of neurological complications such as encephalitis or meningoencephalitis have been reported. USUV share many features with West Nile virus (WNV). These two viruses co-circulates in numerous European countries: WNV re-emerged in 2015 concomitantly with USUV, and enhanced dual reporting of WNV and USUV outbreaks in 2018 was observed in several European countries. Given that USUV and WNV are genetically, antigenically and epidemiologically closely related, one question is whether such overlaps can influence the associated risks for humans. Co-infections in humans could complicate diagnosis and symptomatology.
Clearly, there is a need to organize standard surveillance measures and early warning systems to detect also USUV activity, and to assess the risk for public health, both at the national and European level.

Product Description	Code	CE Mark	Description
Quanty Usutu	RT-20	CE IVD	48 Tests

CHIKUNGUNYA E ZIKA

Chikungunya fever is a mosquito-borne viral disease transmitted by Aedes sp., particularly A. aegypti and A. albopictus. It is caused by infection with Chikungunya virus, an alphavirus from the Togaviridae family. There are three distinct genotypes of CHIKV: genotype-1 Asian, genotype-2 Eastern/Central/Southern African (ECSA), and genotype-2 Western African. The ECSA genotype has been the dominant strain throughout Asia and the islands and countries in the Indian Ocean over the last decade.

The clinical characteristics of Chikungunya include acute onset of fever which may last up to two weeks and painful, potentially debilitating, polyarthritis in adults which may last for up to a year following infection. Most CHIKV diagnostics are performed based on clinical outcomes; however, it can be difficult to differentiate CHIKV infection from other arboviruses, since the symptoms are very similar. Laboratory tests are critical for distinguishing this infection from other acute febrile illnesses, and viral isolation can be performed for detection of CHIKV. The ZikaVirus (ZIKV) it's a RNA virus of the Flaviviridae family, with single positive filament. In humans this virus causes the Zika Fever which is transmitted mainly by bites from mosquitos (Ae. aegypti e Ae. Albopictus), through infection from biological fluids or sexual intercourse and from mother to fetus. In this last event an increased incidence of teratogens effects (microcephalia and cerebral defects) may happens, specially if the infection occurs in the first quarter of the pregnancy.

Product Description	Code	CE Mark	Description
quanty Chikungunya	RT-05	CE IVD	48 Tests
quanty Zika	RT-40	CE IVD	48 Tests

Realtime PCR
Emerging & Tropical Infections

DENGUE

Dengue is a mosquito-borne viral infection causing flu-like illness, and occasionally develops into a potentially lethal complication called Severe Dengue, a leading cause of serious illness and death among children in some Asian and Latin American countries.
The global incidence of Dengue has grown dramatically in recent decades: about half of the world's population is now at risk. It is found in tropical and sub-tropical climates worldwide, mostly in urban and semi-urban areas. There is no specific treatment for Dengue/Severe Dengue, but early detection and access to proper medical care lowers fatality rates below 1%. Dengue virus belongs to the Flaviviridae family and there are 4 distinct, but closely related, serotypes of the virus that cause dengue (DEN-1, DEN-2, DEN-3 and DEN-4).
The Clonit Dengue Serotyping system is a qualitative test that allows identification of Dengue Virus focusing on the identification of the 4 serotypes, because recovery from infection by one provides lifelong immunity against that particular serotype. However, cross-immunity to the other serotypes after recovery is only partial and temporary.
Subsequent infections (secondary infection) by other serotypes increase the risk of developing severe dengue.

Product Description	Code	CE Mark	Description
Dengue Serotyping	RT-03	CE IVD	48 Tests

Product Description	Code	CE Mark	Description
Malaria Panel	RT-61	CE IVD	24 Tests Multiplex Detection and Identification of P. falciparum, P. malariae, P. vivax and P. ovale
Malaria Screening	RT-66	CE IVD	48 Tests
Malaria panel 2.0	RT-61v2	CE IVD	with P.Knowlesi
Leishmania spp	RT-63	CE IVD	48 Tests
quanty Leishmania	RT-63q	CE IVD	48 Tests
quanty ZEBOV	RT-35	RUO	48 Tests
quanty Monkeypox	RT-103	RUO	48 Tests

Transplantation Panel
Manual solutions

Clonit

Product Description	Code	CE Mark	Description
quanty Adenovirus	RT-34	CE IVD	48 Tests
quanty BK	RT-32	CE IVD	48 Tests
quanty CMV	RT-12	CE IVD *	48 Tests
quanty EBV	RT-13	CE IVD	48 Tests
quanty Enterovirus	RT-33	CE IVD	48 tests
quanty HHV-6	RT-30	CE IVD	48 Tests
quanty HHV-7	RT-29	CE IVD	48 Tests
quanty HHV-8	RT-31	CE IVD	48 Tests
quanty HSV-1	RT-18/1	CE IVD	48 Tests
quanty HSV-2	RT-18/2	CE IVD	48 Tests
quanty HSV 1-2	RT-18S	CE IVD	48 test multiplex
quanty Parvo B19	RT-17	CE IVD	48 Test
quanty JCV	RT-24	CE IVD	48 Tests
quanty VZV	RT-23Q	CE IVD	48 Tests
Varicella Zoster Virus	RT-23	CE IVD	48 test qualitative

*NB.0318

Transplantation panel
WalkAway Automation

Product Description	Code	CE Mark	Description
quanty Adenovirus_qs	QS-34	CE IVD	96 Tests - QIASymphony SP/AS Application
quanty BK_qs	QS-32	CE IVD	96 tests - QIASymphony SP/AS application
quanty CMVqs	QS-12	CE IVD	96 Tests - QIASymphony SP/AS Application
quanty EBVqs	QS-13	CE IVD	96 Tests - QIASymphony SP/AS Application
quanty Enterovirus_qs	QS-33	CE IVD	96 Tests - QIASymphony SP/AS application
quanty HSV-1qs	QS-18/1	CE IVD	96 Tests - QIASymphony SP/AS application
quanty HSV 1-2qs	QS-18s	CE IVD	96 Tests - QIASymphony SP/AS application
quanty HSV-2qs	QS-18/2	CE IVD	96 Tests - QIASymphony SP/AS application
quanty HHV-6qs	QS-30	CE IVD	96 Tests - QIASymphony SP/AS application
quanty HHV-7qs	QS-29	CE IVD	96 Tests - QIASymphony SP/AS application
quanty HHV-8qs	QS-31	CE IVD	96 Tests - QIASymphony SP/AS application
quanty JCVqs	QS-24	CE IVD	96 Tests - QIASymphony SP/AS application
quanty Parvo B19qs	QS-17	CE IVD	96 Tests - QIASymphony SP/AS application
quanty VZVqs	QS-23	CE IVD	96 Tests - QIASymphony SP/AS application

Realtime PCR Hepatitis Virus

Clonit

Hepatitis is an inflammation of the liver. It can be developed as a result of alcoholism or medications but is most commonly caused by viral infection. Five distinct hepatitis viruses have been identified: A, B, C, D and E. Together they affect about 400 million people worldwide. Viral hepatitis A and E are food- and water-borne infections that can result in acute outbreaks in communities with unsafe water and poor sanitation. HDV infection is linked to HBV infection.

Hepatitis E is a liver disease caused by the Hepatitis E virus (HEV). HEV infection usually results in a self-limited, acute illness. Although rare in developed countries, locally acquired HEV infection can result in acute hepatitis with tendency to progress to chronic hepatitis mainly among solid organ transplant recipients. The unique characteristics of HEV is that it displays different clinical and epidemiologic profile depending on where the infection is acquired which is mainly due to the viral genotype. There are four genotypes of HEV, each displaying different epidemiological and clinical characteristics between developing and developed countries. Hepatitis E virus is usually spread by the fecal-oral route. The most common source of HEV infection is fecally contaminated drinking water. In developing countries, HEV genotypes 1 and 2 are spread by fecally contaminated drinking water. In developed countries sporadic cases of HEV genotype 3 have occurred following consumption of uncooked/undercooked pork or deer meat.

Consumption of shellfish was a risk factor in a recently described outbreak in a cruise ship. HEV genotype 4, detected in China, Taiwan, and Japan, has also been associated with foodborne transmission.

Product Description	Code	CE Mark	Description
quanty HDV	RT-49	RUO	48 Tests
quanty HAV	RT-02	CE IVD	48 Tests
quanty HEV	RT-41	CE IVD	24 Tests

Realtime PCR
Respiratory Infections

Respiratory infections are among the top ten causes of death worldwide and represent a main cause of pediatric outpatient consultations in the industrialized world. A quick and sensitive diagnostic test is critical for immediate diagnosis and treatment of the patient and for preventing further spreading of the infections.

Product Description	Code	CE Mark	Description
M. tuberculosis Complex	EBR019032	CE IVD	32 Tests
Mycoplasma pneumoniae	EBR012032	CE IVD	32 Tests
Adenovirus	EBR008032	CE IVD	32 Tests
Legionella spp.	EBR011032	CE IVD	32 Tests
Legionella pneumophila	EBR007032	CE IVD	32 Tests
Mycobacterium avium Complex	EBR010032	CE IVD	32 Tests
quanty RSV A/B	RT-47	CE IVD	48 Tests

SARS-COV-2

Coronavirus disease 2019 (COVID-2019) is caused by a novel coronavirus known as Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) and was identified as a pandemic by the World Health Organization (WHO) on March 11, 2020. SAR-CoV2 is an enveloped, non-segmented, positive sense RNA virus that is included in the sarbecovirus, ortho corona virinae subfamily which is broadly distributed in humans. Patients infected with the virus usually shows flu-like symptoms, such as fever (in over 90% of cases), dry cough (over 80% of cases), fatigue, shortness of breath (about 20% of cases) and difficulty of breathing (about 15% of cases).
All the Clonit COVID-19 kits are qualitative or quantitative tests that allow the identification, by means of Real Time PCR, of different regions of N gene (nucleocapsid phosphoprotein) of SARS-CoV-2 in subjects with suspected COVID-19 infection. Furthermore, Clonit COVID-19 Kits allow a simultaneous evaluation swabs suitability using endogenous internal control amplification.

Product Description	Code	CE Mark	Description
quanty Covid-19 v2	RT-25v2	CE IVD	96 Tests (N1,N2) one tube
Covid 19 HT Screen	RT-25HT	CE IVD	96 Tests (N1,N2) one tube
Covid 19 HT Screen 501	RT-25HT501	CE IVD	N1,N2, S gene

Product Description	Code	CE Mark	Description
Covid Variant Catcher	RT-27	CE IVD	69-70del, E484K and N501Y
Covid UltraVariant Catcher	RT-27v2	CE IVD	L452R, E484K, E484Q and N501Y

Product Description	Code	CE Mark	Description
Flu A/Flu B/ SARS-CoV-2	RT-26	CE IVD	96 Tests

Realtime PCR
Sexually Transmitted Diseases

Sexually transmitted diseases (STDs) are the most widespread diseases in the world. The most frequently reported STDs are caused by Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis and Mycoplasmas. Diagnosis of STDs is problematic as they often cause no specific symptoms. Due to its rapidity and sensitivity, molecular diagnostics is becoming a worldwide standard in this field.

Product Description	Code	CE Mark	Description
Trichomonas vaginalis	EBR038032	CE IVD	32 Tests
Mycoplasma hominis	EBR015032	CE IVD	32 Tests
Ureaplasma urealyticum	EBR016032	CE IVD	32 Tests
Neisseria gonorrheae	EBR018032	CE IVD	32 Tests
Mycoplasma genitalium	EBR027032	CE IVD	32 Tests
Multiplex CT/ NG	RT-44	CE IVD *	48 Tests
Chlamydia trachomatis	RT-22	CE IVD *	48 Tests

*NB.0318

Realtime PCR Pregnancy Management

Clonit

Toxoplasmosis is a parasitic disease caused by the parasite Toxoplasma gondii. Toxoplasmosis infections usually cause no symptoms in adult humans. Sometimes infected people may encounter a few weeks or months of mild influenza-like illness such as muscle pain, lymphadenopathy, and in a few cases they develop eye problems. Only to those who have a weak immune system, may experience severe symptoms such as convulsions and a lack of coordination capacity.
If a woman is infected during pregnancy, a condition known as "congenital toxoplasmosis" can affect the unborn child. Toxoplasmosis is usually contracted after eating poorly cooked food containing cysts, with the contact with the feces of an infected cat and transmission from mother to child during pregnancy. Rarely the disease is transmitted as a result of a blood transfusion, or spreads between people. The parasite is known to reproduce sexually in felines. However, it is able to infect the majority of warm-blooded animals, including humans. Diagnosis is typically made by testing the blood for the presence of antibodies or by testing the amniotic fluid in the presence of parasite DNA.

Product Description	Code	CE Mark	Description
quanty TOXO	RT-94	CE IVD *	48 Tests

*NB.0318

Measles is a highly contagious respiratory disease caused by a virus. It can result in serious health complications, such as pneumonia and encephalitis (swelling of the brain), and even cause death.
Rubella is a viral infection that affects unvaccinated children and young adults. If an unvaccinated woman gets rubella while pregnant – especially in her first three months – serious consequences can result, including miscarriages, fetal deaths, still births, and having infants born with congenital rubella syndrome (CRS).

Product Description	Code	CE Mark	Description
quanty Measles	RT-06	CE IVD	48 Tests
quanty Rubella	RT-39	RUO	48 Tests
Measles/Rubella	RT-21	RUO	48 Tests

Realtime PCR Nosocomial Infections

Clostridium difficile has been recognized as an increasingly important cause of nosocomial diseases. The C. difficile infections or CDI are the leading cause of infectious diarrhea in hospitals worldwide. The major virulence factors of C. difficile are thought to be toxin A and toxin B produced by the pathogen.

Product Description	Code	CE Mark	Description
Clostridium difficile Toxin A- Toxin B	EBR026032	CE IVD	32 Tests

Acinetobacter baumannii, once considered an opportunistic and low-category pathogen, is today one of the most challenging nosocomial pathogens due to the emergence and widespread of antibiotic resistance. Detection of OXA-type carbapenamases-mediated acquired resistance by testing the blaOXA-51, blaOXA-58, blaOXA-23, blaOXA-24, blaOXA-143-genes and IsAba1-blaOxa51-junction is therefore becoming a very important tool for monitoring resistance spreading.

Product Description	Code	CE Mark	Description
A. baumannii MDR OXA Genotyping	EBR040032	CE IVD	32 Tests

Oncohematology Panel

The new molecular assays are based on a one-step Real-Time RT-PCR protocol starting from peripheral blood or bone marrow samples and can be performed on the most common Real-Time PCR Systems.
These tests represents an important tool in the screening of Acute Myeloid Leukemia and provide useful information for the diagnosis and prognosis even in situations with low starting material. They help patients to be assigned to the appropriate risk group for management and therapy.

Product Description	Code	CE Mark	Description
PML-RARA t(15;17) (q22;q21)	RT-100	CE IVD	24 test
AML1-ETO t(8;21) (q22;q22)	RT-101	CE IVD	24 test
Inv(16)(p13q22) - CBFB-MYH11	RT-102	CE IVD	24 test

Realtime PCR Cardiovascular Diseases

Thrombophilia represents a predisposition to form clots inappropriately. It is caused by abnormalities in blood consistency, determined by modified levels and activity of coagulation factors that participate in the "coagulation cascade". Thrombotic events are increasingly recognized as a significant source of mortality and morbidity. Predisposition to form clots is a multifactorial disease: it derives from genetic factors, acquired changes in the clotting mechanism, or, more commonly, an interaction between genetic and acquired factors. A significant proportion of the population has a detectable abnormality, but most of these only develop thrombosis in the presence of additional environmental risk factors. Clonit's assays provide a complete coverage of frequent as well as rare mutations in genes related to the coagulation pathway reported to constitute risk factors for thrombophilia.

	Target	Code	CE Mark	Description
Factor II	G20210A	EER028032QS*	CE IVD	32 Tests
		EER037032	CE IVD	32 Tests
Factor V	R306T Cambridge	EER024032	CE IVD	32 Tests
	G1691A	EER027032QS*	CE IVD	32 Tests
		EER038032	CE IVD	32 Tests
	H1299R	EER031032QS*	CE IVD	32 Tests
		EER041032	CE IVD	32 Tests
	Y1702C	EER047032	CE IVD	32 Tests
Factor XIII	V34L	EER022032	CE IVD	32 Tests
MTHFR	C677T	EER029032QS*	CE IVD	32 Tests
		EER039032	CE IVD	32 Tests
	A1298C	EER030032QS*	CE IVD	32 Tests
		EER040032	CE IVD	32 Tests
MTRR	A66G	EER042032	CE IVD	32 Tests
MTR	A2756G	EER043032	CE IVD	32 Tests
PAI-1	675 promoter 4G/5G	EER053032	CE IVD	32 Tests
HPA-1 a/b	HPA-1 a/b	EER048050	CE IVD	50 Tests
		EER048032QS*	CE IVD	32 Tests
Beta-Fibrinogen	Beta-Fibrinogen	EER049050	CE IVD	50 Tests
		EER049032QS*	CE IVD	32 Tests

* WalkAway automation on QiaSymphony

Pharmacogenomic

WARFARINE METABOLISM

Warfarin is the treatment of choice in the management of venous thromboembolic disease. The wide interindividual variability in warfarin response is influenced by some genetic variants: in particular, a single nucleotide polymorphism (SNP) in the Vitamin K Epoxide Reductase Complex Subunit 1 (VKORC1) known as VKORC1 (1639G>A) that is an important determinant of the initial Warfarin dosage, and two SNPs found in the cytochrome P450 enzyme gene CYP2C9 known as CYP2C9*2 (C430T) and CYP2C9*3 (A1075C).

	Product Description	Code	CE Mark	Description
VKORC1	1639G>A	EER054050	CE IVD	50 Tests
		EER054032QS*	CE IVD	32 Tests
CYP2C9*2	430C>T	EER055050	CE IVD	50 Tests
		EER055032QS*	CE IVD	32 Tests
CYP2C9*3	1075A>C	EER056050	CE IVD	50 Tests
		EER056032QS*	CE IVD	32 Tests

* WalkAway automation on QiaSymphony

ABACAVIR HYPERSENSITIVITY - HLA-B*5701 ALLELE

Abacavir is an antiviral drug belonging to the class of Nucleoside Reverse Transcriptase Inhibitors (NRTI). It is used in combination with other antiretroviral agents in the treatment of patients infected by human immunodeficiency virus (HIV), the cause of Acquired Immunodeficiency Syndrome (AIDS). Most importantly, HIV-positive patients must be monitored for the presence of
HLA-B*5701 allele before treating them with Abacavir. Indeed, Abacavir must not be given to patients bearing HLA-B*5701 allele, unless any other therapeutic option is not available.

Product Description	Code	CE Mark	Description
HLA-B*5701 Allele	EER052032	CE IVD *	32 Tests

* NB.0318

Realtime PCR Genetic Diseases

CELIAC DISEASE

Celiac disease is a serious autoimmune disease that occurs in genetically predisposed people where the ingestion of gluten leads to damage in the small intestine. It is estimated to affect 1 in 100 people worldwide. The presence of certain HLA alleles explains at least 40% of the disease heritability. Performing an accurate HLA typing allows to evaluate the greater or lesser predisposition of an individual to develop intolerance. The main genetic risk factor is localized in the HLA-DQ region and is represented by DQ2 heterodimer coded by HLA-DQA1*05 and DQB1*02 genes. The presence of DQB1 * 02 and DQA1 * 05 determines the DQ2.5 haplotype, at greater risk. The presence of DQB1 * 02 and DQA1 * 02 determines the DQ2.2 haplotype, at lower risk. Subjects affected by celiac disease, negative for HLA-DQ2, mostly show the DQ8 heterodimer encoded by the genes HLA-DQA1 * 03 and DQB1 * 0302. The presence of one of the predisposing HLA combination determines an increased risk of Celiac Disease, while the absence of the same makes the development of the disease quite unlikely. The Clonit Celiac Disease kit is a test that allows the identification of HLA DQ2 (DQ2.2 and DQ2.5), DQ8, and also HLA DR3, DR4, DR7, DR11 and DR12 haplotypes. Identification of DR haplotypes does not modify the disease risk that depends exclusively on the DQA1 and DQB1 loci, but their determination can help as a validation of the results, due to the close linkage disequilibrium between DR and DQ The test is integrated with a dedicated software that allows a fast and accurate identification of the haplotypes in the analyzed patients.

Product Description	Code	CE Mark	Description
Gluten DQuick DResolution	RT- 59v3	CE IVD *	48 Tests
Plug-in Analyze Software	PL-01	CE IVD	

* NB.0318

LACTOSE INTOLERANCE

Many adults have a genetically caused deficiency of the enzyme lactase (LCT gene) which results in intestinal disorders on consumption of milk or milk products. The two main polymorphisms associated with lactose intolerance are LCT -13910C/T and LCT -22018G/A, located in the regulatory region of the lactase gene. According to current knowledge, homozygous carriers of the wild type variants -13910C/C and -22018G/G develop lactose intolerance, while heterozygous carriers of the polymorphisms -13910C/T and -22018G/A only show corresponding symptoms in stress situations or with intestinal infections.

Product Description	Code	CE Mark	Description
Lactose Intolerance	RT-11	CE IVD	48 Tests (C13910T Mutation)
Lactose Intolerance	RT-37	CE IVD	48 Tests (C13910T and G22018A Mutations)

Realtime PCR
Genetic Diseases

HEREDITARY HAEMOCHROMATOSIS

Hereditary haemochromatosis is an inherited disorder of iron metabolism potentially resulting in injury and organ failure. The disease is a consequence of different mutations in the HFE gene, which is involved in intracellular iron transport, that in turn causes disorders such as: cirrhosis, hepatoma, heart failure, arhythmia, infectious diseases and diabetes.

	Product Description	Code	CE Mark	Description
HFE	C282Y	EER032032QS*	CE IVD	32 Tests
		EER044032	CE IVD	32 Tests
	H63D	EER033032QS*	CE IVD	32 Tests
		EER045032	CE IVD	32 Tests
	S65C	EER034032QS*	CE IVD	32 Tests
		EER046032	CE IVD	32 Tests

* WalkAway automation on QiaSymphony

APOE

The apolipoprotein E (ApoE) is a 299 aminoacid glycoprotein synthesized in the liver and nervous system, in surrenal gland, gonads, kidney, musculus striatum and spleen. The three possible alleles of ApoE (E2,E3, E4) encode for the E2, E3 ed E4 isoforms respectively. In the brain Apo E plays a crucial role in the development and repairment of neuronal structures. Moreover, Apo E is involved in the pathogenesis of the either late onset, familiar or sporadic Alzheimer's Disease.

	Product Description	Code	CE Mark	Description
ApoE	ApoE*E2 (Cys112-Cys158) ApoE*E3 (Cys112-Arg158) ApoE*E4 (Arg112-Arg158)	EER018032	CE IVD	32 Tests

GILBERT'S SYNDROME

Gilbert's syndrome is caused by decreased hepatic levels of the enzyme glucuronosyltransferase. As this enzyme is responsible for the glucuronidation (conjugation) of bilirubine in the liver, reduced activity of the glucuronosyltransferase leads to the accumulation of unconjugated bilirubin in the circulation. It is not a rare disease: 3-10% of the population presents this condition.

	Product Description	Code	CE Mark	Description
UGT1A1	6TA/7TA	EER025032	CE IVD	32 Tests

ANKYLOSING SPONDYLITIS

Product Description	Code	CE Mark	Description
HLA-B*27	RT-53	CE IVD *	48 Tests

* NB.0318

CARDIOVASCULAR DISEASES

RHYMA TEST CVD STRIP TEST is based on Reverse Hybridization Technology.
It is a multiplex assay for the detection of the following 5 different thrombophilia-related mutations in blood samples: **R506Q (Factor V Leiden), H1299R (HR2 haplotype), G20210A (Factor II- Prothrombin), C677T (MTHFR), A1298C (MTHFR)**

Product Description	Code	CE Mark	Description
Rhyma Test CVD	EES001020	CE IVD	20 Strips
Rhyma Test CVD for automatic instrument	EES001020D	CE IVD	20 Strips
Rhyma Test HFE	EES006020	CE IVD	20 Strips

Y CHROMOSOME MICRODELETIONS

Infertility is a major health problem affecting 10-15% of couples seeking to have children and a male factor can be identified in about half of these cases. A significant proportion of infertile males are affected either by oligozoospermia or azoospermia. The recent growth of assisted reproduction techniques has led to the identification of Y chromosome microdeletions into AZF regions correlated to non-obstructive azoospermia, Men with deletions in AZFa and AZFb regions show severe defects in spermatogenesis, whereas deletions of AZFc region can be compatible with residual spermatogenesis. These Clonit tests are based on Gel Electrophoresis and Reverse Hybridization techniques.

Product Description	Code	CE Mark	Description
Rhyma Test IVF AZF	EES003020	CE IVD	20 Strips
Rhyma Test IVF AZF for automatic instrument	EES003020D	CE IVD	20 Strips
Chromosome Y Microdeletion	EDP003024	CE IVD	40 Strips

official distributor

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