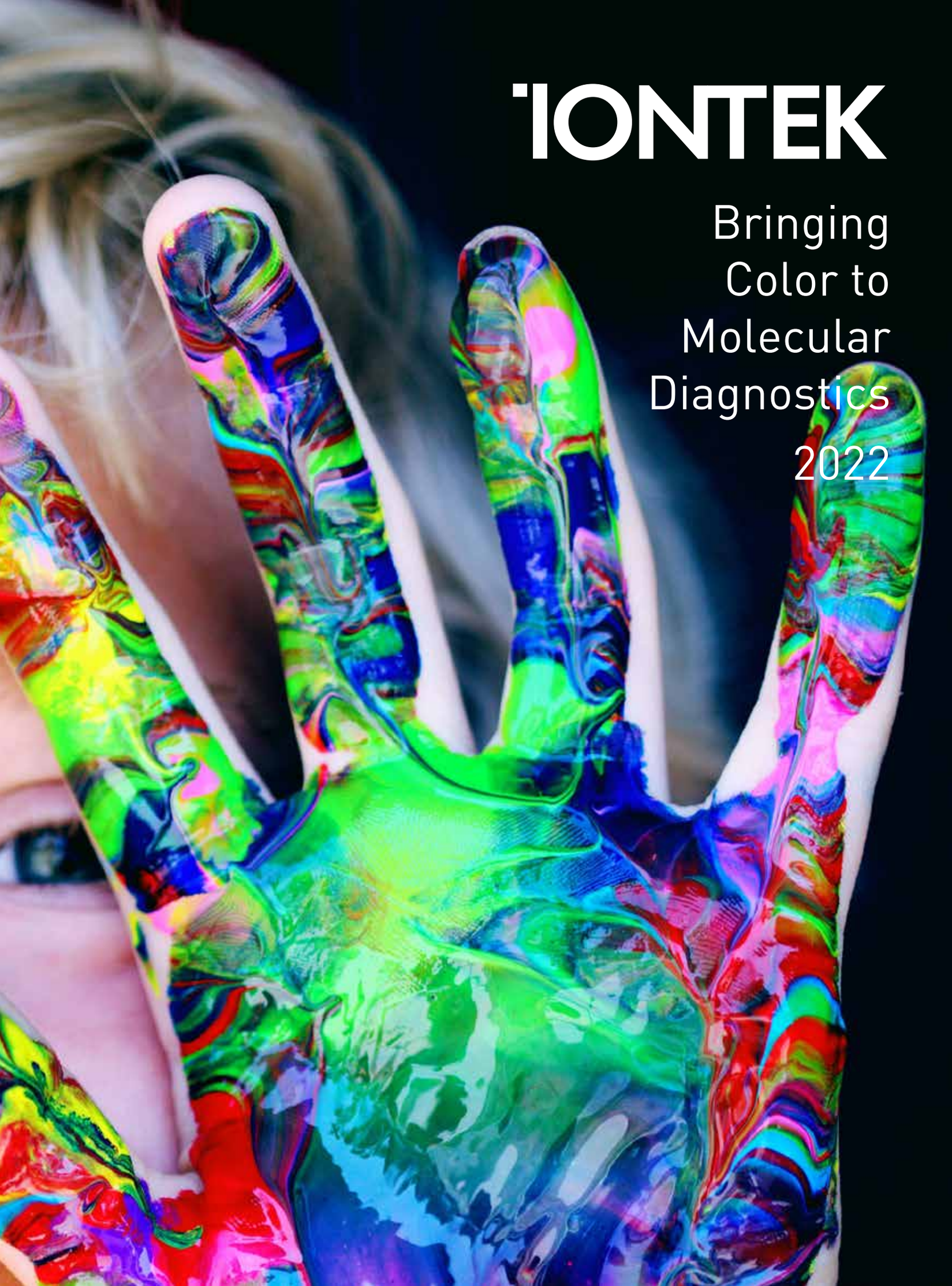


IONTEK

Bringing Color to Molecular Diagnostics 2022

TIONTEK

Bringing Color to Molecular Diagnostics

2022

“At IONTEK, we believe that relentless efforts aligned with innovative biotech are key to changing people’s lives.”

IONTEK has been one of Turkey’s **pioneering Molecular Diagnostic companies starting over 25 years ago.** IONTEK operates under **ISO 9001: 2015 and ISO 13485: 2016** and produces high quality molecular diagnostic tests and services, making use of most advanced techniques and information systems.

The tests design and production facilities are certified under Full Quality Assurance route of the In Vitro Diagnostic Devices Directive 98/79/EC. IONTEK uses its own R&D to produce a wide range of Real-Time PCR tests in the field of molecular microbiology and molecular genetics.

Using Real-Time PCR technology, IONTEK is capable to diagnose and follow the progress of viral diseases such as **Hepatitis B, C, D** and the **HIV**, among many others. With certified test kits, the progression and follow-up of the viral diseases are carried out quantitatively through DNA and RNA.

IONTEK has also developed the **“Fluorion nCoV-19 Real-Time PCR Kit”** to detect the SARS-CoV-2 (COVID-19) virus by which, currently the whole world is seriously affected and caused the death of hundreds of thousand people. In order to distinguish COVID-19 virus from other respiratory infections with similar symptoms, IONTEK has also released a respiratory panel, **CoVIDenza** by producing a rapid and reliable diagnosis for the medical industry as a response to the pandemic. Thanks to the high accuracy and specificity of our diagnostic kits, IONTEK provides an important tool to fight against epidemics.

IONTEK is the first biotechnology company to carry on **DNA production and DNA sequencing services** in Turkey and continues to invest in the training and development of our highly qualified staff in R&D activities. With its state-of-the-art tools, **developing new products for new platforms** and improving the welfare of lives has been IONTEK’s main charter.

Thanks to its highly qualified team, IONTEK also collaborates with education initiatives and research centers as well as private hospitals. It offers its business partners a 25-year experience with competent customer support and a never-ending excitement to create real impact in healthcare.

MOLECULAR DIAGNOSTICS PRODUCTS

FLUORION REAL-TIME PCR KITS

LABORATORY EQUIPMENTS

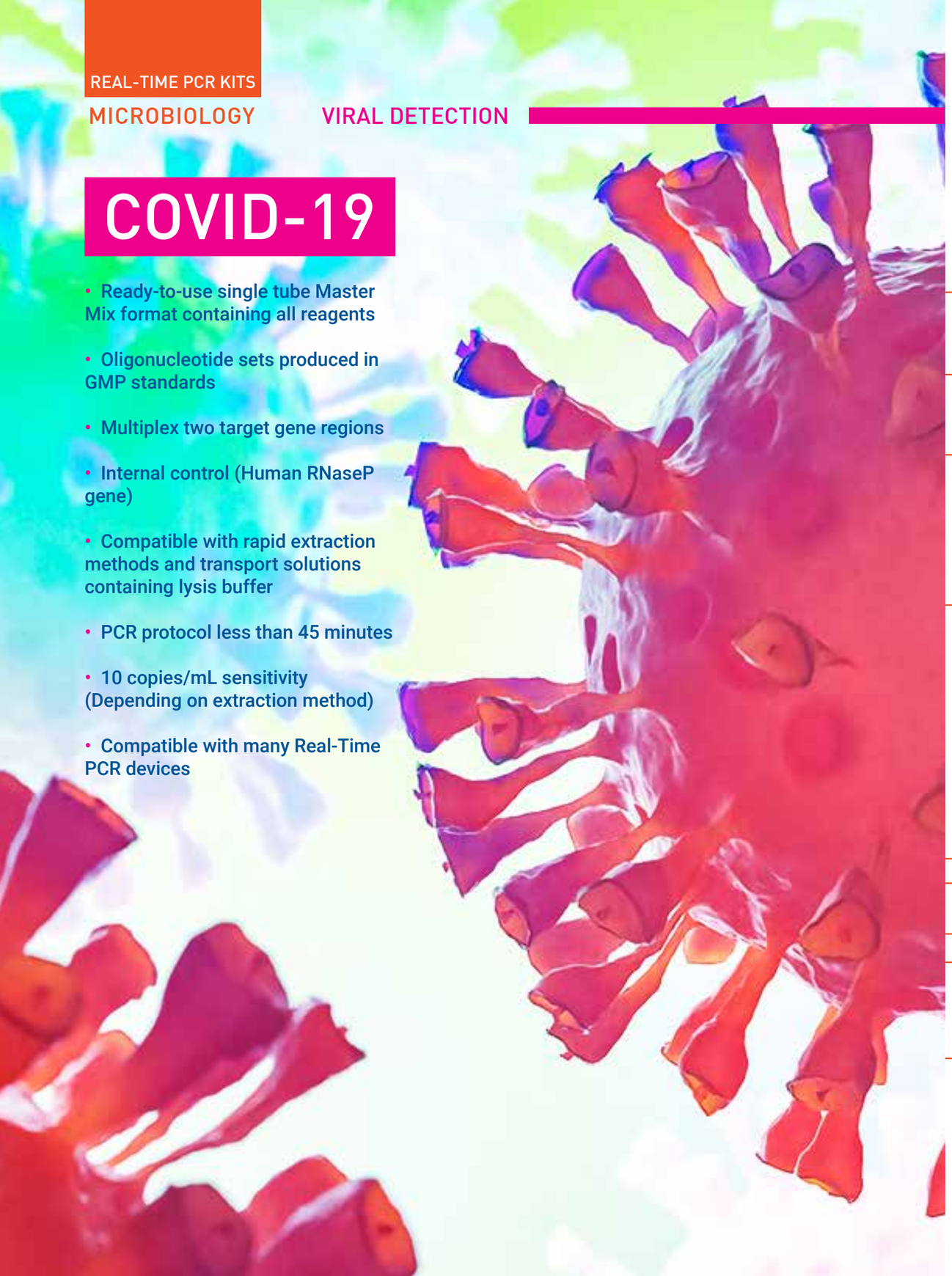
PRODUCTS LIST

FLUORION

REAL-TIME PCR KITS

VIRAL DETECTION

COVID-19



- Ready-to-use single tube Master Mix format containing all reagents
- Oligonucleotide sets produced in GMP standards
- Multiplex two target gene regions
- Internal control (Human RNaseP gene)
- Compatible with rapid extraction methods and transport solutions containing lysis buffer
- PCR protocol less than 45 minutes
- 10 copies/mL sensitivity (Depending on extraction method)
- Compatible with many Real-Time PCR devices

REAL-TIME PCR KITS
MICROBIOLOGY

Fluorion nCoV-19 kit has been developed for the detection of SARS-CoV-2 virus from RNA isolates obtained from human samples.

The positive control in the kit is synthetic DNA. It contains target regions of the N1, N2, and RNAseP genes that are amplified only with the primer-probe sets included in this kit. The content of the positive control tube is not infectious.

SAMPLE TYPE	TARGET	SENSITIVITY
• Bronchoalveolar Lavage • Nasopharyngeal Swab • Orofarengeal Swab	SARS-CoV-2	10 copies/mL

KIT SPESIFICATIONS	
Intended Use	Qualitative detection of Coronavirus 2019 (COVID-19) SARS-CoV-2, in patients with COVID-19 symptoms (e.g. fever, cough, shortness of breath), using lower respiratory tract (bronchoalveolar lavage (BAL), tracheal aspirate) and/or upper respiratory tract (nasopharyngeal and oropharyngeal fluids, nasal swab) samples.
Analitycal Specificity *(in vitro analysis)*	**DOES NOT** cross-react with the below pathogens: SARS-CoV, Adenovirus, Influenza A, Influenza B, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, *Candida albicans,* RSV A, RSV B, Rhinovirus, *Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis,* Hepatitis B, Hepatitis C, Hepatitis Delta, Human Immunodeficiency Virus, Cytomegalovirus, Epstein-Barr Virus, JCV, BKV, Human Papilloma Virus, Parvovirus, Herpes Simplex Virus, *Mycobacterium tuberculosis, Aspergillus spp., Brucella abortus, Brucella melitensis, Brucella canis and Brucella suis, E.coli O157, Salmonella spp., Listeria monocytogenes*
Analitycal Specificity *(in silico analysis)*	**DOES NOT** cross-react with the below pathogens: SARS-CoV, MERS-CoV, Human coronaviruses (HCoV-229E, HCoV-OC43, HCoV-NL63, HCoV-HKU1), Adenovirus, Influenza C, Influenza A, Influenza B, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parechovirus, *Candida albicans, Corynebacterium diphtheriae,* Legionella non-pneumophila, *Bacillus anthracis, Moraxella catarrhalis, Neisseria elongata, Neisseria meningitides,* RSV A, RSV B, Rhinovirus, *Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus salivarius,* Leptospirosis, *Chlamydia psittaci, Coxiella burnetii* (Q-Fever), *Staphylococcus epidermidis,* Enterovirus, *Haemophilus Influenzae, Mycobacterium tuberculosis, Bordetella parapertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila,* Hepatitis B, Hepatitis C, Hepatitis Delta, Human Immunodeficiency Virus, Cytomegalovirus, Epstein-Barr Virus, JCV, BKV, Human Papilloma Virus, Parvovirus, Herpes Simplex Virus, *Mycobacterium tuberculosis, Aspergillus spp., Brucella abortus, Brucella melitensis, Brucella canis and Brucella suis, E.coli O157, Salmonella spp., Listeria monocytogenes*
Specificity	100.00%
Target Regions	N1 and N2 regions of nucleocapsid gene of SARS-CoV-2 virus Human RNaseP gene (internal control)
Reaction Duration	~45 min. (may change depending on the Real-Time PCR instrument)
Storage Conditions	• Products should be stored at -20°C or below. • It is recommended not to freeze-thaw products more than three times. In cases where more freeze-thaw is required, solutions should be aliquoted and stored at -20°C or lower following the first thaw. • Detection mixes are light-sensitive. Aliquoted reagents must be protected from light.

Item	Cat. No.	Pack Size
nCoV-19 QLP 2.1 Real-Time PCR Kit CE-IVD	M1350102-3	100 tests
nCoV-19 QLP 2.1 Real-Time PCR Kit CE-IVD	M1350102-5	1000 tests

HBV

Hepatitis B Virus, a member of the Hepadnaviridae, is an enveloped virus with a partially double-stranded DNA genome. The infection can be asymptomatic or symptomatic, which starts with anorexia, vague abdominal discomfort, nausea and vomiting, sometimes arthralgias and rash, often progressing to jaundice. Fever may be absent or mild; severity ranges from inapparent cases to fatal acute hepatic necrosis, or chronic infection. Long term fatality rate is 2-3% due to cancer or cirrhosis of the liver; 95% of adult infections are self limited. The mode of transmission is through percutaneous or permucosal exposure to infectious body fluids (blood, blood products, cerebrospinal fluid, serum-derived fluids, saliva, semen, vaginal fluids, unfixed tissues and organs), indirect contact with contaminated items in the laboratory; commonly spread by contaminated needles, syringes and other equipment; contamination of wounds or lacerations; exposure of mucous membranes; sexual contact, household contact, perinatal transmission from mother to infant, nosocomial exposure.

Fluorion HBV QNP 2.0 Real-Time PCR Kit is based on the real-time PCR principle. The pathogen is detected using fluorescent dyes that are incorporated into oligonucleotide probes. The assay utilizes the 5' exonuclease activity of Taq Polymerase to cleave a dual-labeled fluorescent hydrolysis probe during the extension phase of PCR.

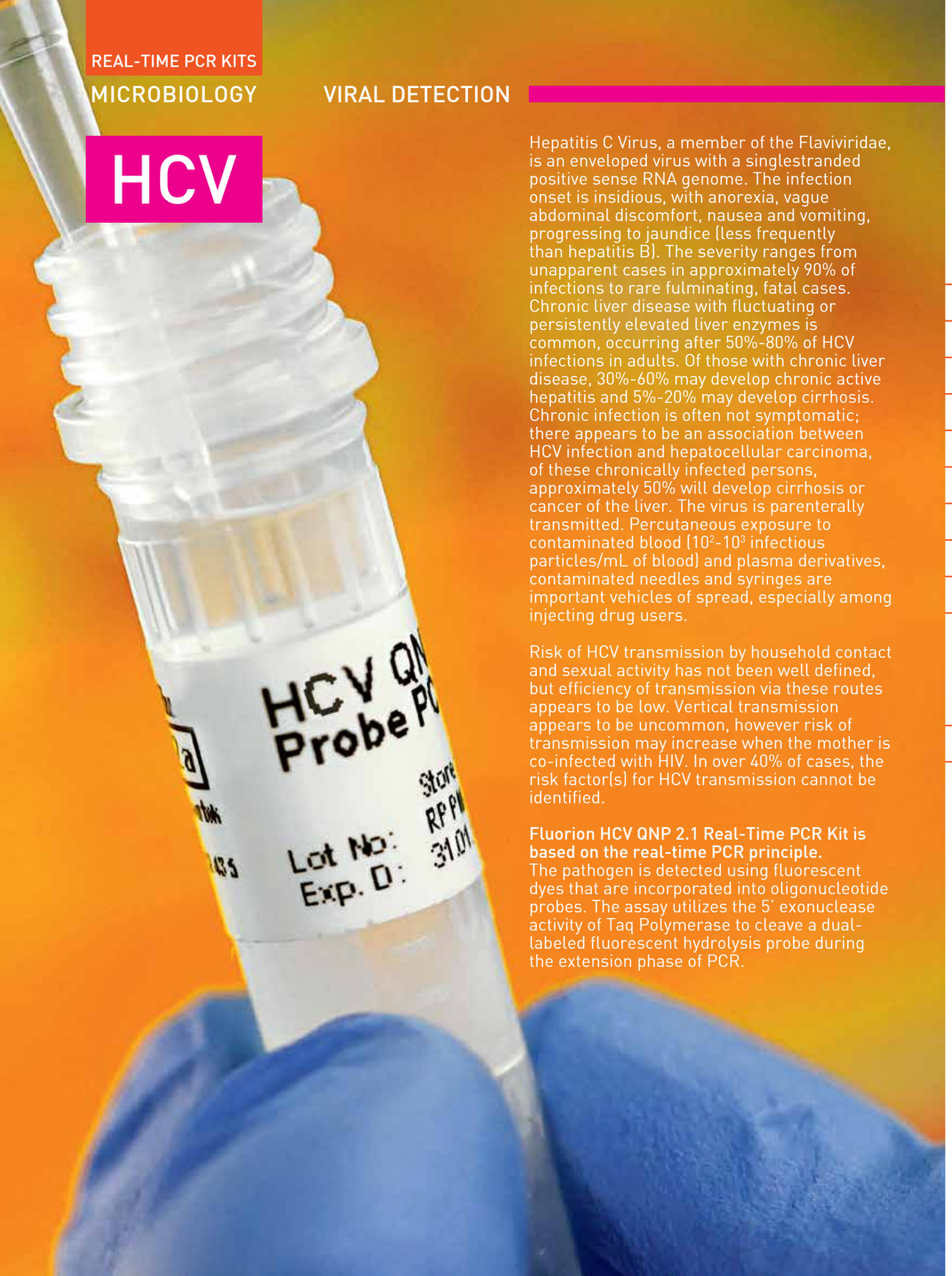
Principle of the Test	Quantification of HBV
Technology	Real-Time PCR with hydrolysis probes
Gene Target	HBV DNA polymerase gene
Detected Genotypes	Genotypes A-F
Specimen Type	Serum
Limit of Detection	10 IU/ml
Dynamic Range of Quantification	$2x10^1$-$2x10^9$ IU/ml
Controls	Inhibition and extraction control, negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	**Extraction** Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) **Amplification** Fluorion Detection System (Iontek)*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
HBV QNP 2.0 Real-Time PCR Kit CE-IVD	M0010202-2	50 tests
HBV QNP 2.0 Real-Time PCR Kit CE-IVD	M0010202-3	100 tests

VIRAL DETECTION

HCV



Hepatitis C Virus, a member of the Flaviviridae, is an enveloped virus with a singlestranded positive sense RNA genome. The infection onset is insidious, with anorexia, vague abdominal discomfort, nausea and vomiting, progressing to jaundice (less frequently than hepatitis B). The severity ranges from unapparent cases in approximately 90% of infections to rare fulminating, fatal cases. Chronic liver disease with fluctuating or persistently elevated liver enzymes is common, occurring after 50%-80% of HCV infections in adults. Of those with chronic liver disease, 30%-60% may develop chronic active hepatitis and 5%-20% may develop cirrhosis. Chronic infection is often not symptomatic; there appears to be an association between HCV infection and hepatocellular carcinoma, of these chronically infected persons, approximately 50% will develop cirrhosis or cancer of the liver. The virus is parenterally transmitted. Percutaneous exposure to contaminated blood (10^2-10^3 infectious particles/mL of blood) and plasma derivatives, contaminated needles and syringes are important vehicles of spread, especially among injecting drug users.

Risk of HCV transmission by household contact and sexual activity has not been well defined, but efficiency of transmission via these routes appears to be low. Vertical transmission appears to be uncommon, however risk of transmission may increase when the mother is co-infected with HIV. In over 40% of cases, the risk factor(s) for HCV transmission cannot be identified.

Fluorion HCV QNP 2.1 Real-Time PCR Kit is based on the real-time PCR principle.
The pathogen is detected using fluorescent dyes that are incorporated into oligonucleotide probes. The assay utilizes the 5' exonuclease activity of Taq Polymerase to cleave a dual-labeled fluorescent hydrolysis probe during the extension phase of PCR.

REAL-TIME PCR KITS
MICROBIOLOGY

Principle of the Test	Quantification of HCV
Technology	Real-Time PCR with hydrolysis probes
Gene Target	5' UTR
Detected Genotypes	Genotypes 1-6
Specimen Type	Serum
Limit of Detection	26 IU/ml
Dynamic Range of Quantification	$2x10^2$-$2x10^{10}$ IU/ml
Controls	Inhibition and extraction control, negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	**Extraction** Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) **Amplification** Fluorion Detection System (Iontek)*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
HCV QNP 2.1 Real-Time PCR Kit CE-IVD	M0020202-2	50 tests
HCV QNP 2.1 Real-Time PCR Kit CE-IVD	M0020202-3	100 tests

HIV

AIDS, or acquired immune deficiency syndrome, is caused by the Human Immunodeficiency Virus (HIV). First reported in 1981 in the United States, AIDS has become a major worldwide epidemic. By killing or impairing cells of the immune system, HIV progressively destroys the body's ability to fight infections and certain cancers. Individuals diagnosed with AIDS are susceptible to life-threatening diseases called opportunistic infections, which are caused by microbes that usually do not cause illness in healthy people. HIV-1 is classified as a lentivirus in a subgroup of retroviruses. The genetic material is single-stranded RNA. HIV converts its RNA into DNA and inserts into the host cell's DNA. Two closely related retroviruses, HIV-1 and HIV-2, have been identified as causing AIDS in different geographic regions. HIV-1 causes most cases of AIDS in the Western Hemisphere, Europe, Asia, and Central, South, and East Africa; HIV-2 is the principal agent of AIDS in West Africa and appears less virulent than HIV-1. At the end of 2016, there were approximately 36.7 million people living with HIV according to WHO. CDC has estimated that approximately 40,000 persons become infected with HIV each year. Measuring human immunodeficiency virus type 1 (HIV-1) RNA in plasma has enabled the pathophysiology of the infection to be studied, and this parameter, which directly reflects viral replication, is the main prognostic factor for the evolution of the disease. It is the only evidence for mother-to-child transmission, since maternal antibodies present in infant serum hamper antibody-screening assays. The HIV-1 RNA level is the most valuable marker for predicting disease progression in nontreated patients and is highly useful for evaluating the effectiveness of antiretroviral drug therapy.

Fluorion HIV QNP 1.1 Real-Time PCR Kit is based on the real-time PCR principle. The pathogen is detected using fluorescent dyes that are incorporated into oligonucleotide probes. The assay utilizes the 5' exonuclease activity of Taq Polymerase to cleave a dual-labeled fluorescent hydrolysis probe during the extension phase of PCR.

REAL-TIME PCR KITS
MICROBIOLOGY

Principle of the Test	Quantification of HIV
Technology	Real-Time PCR with hydrolysis probes
Gene Target	LTR
Detected Genotypes	HIV-1 group M genotypes (A-H)
Specimen Type	Serum
Limit of Detection	60 IU/ml
Dynamic Range of Quantification	$2x10^{10}$-$2x10^{2}$ IU/ml
Controls	Inhibition and extraction control, negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	**Extraction** Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) **Amplification** Fluorion Detection System (Iontek)*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
HIV-1 QNP 1.1 Real-Time PCR Kit CE-IVD	M0290202-2	50 tests
HIV-1 QNP 1.1 Real-Time PCR Kit CE-IVD	M0290202-3	100 tests

CMV

Cytomegalo Virus, a member of the Herpesviridae, is an enveloped virus with a double-stranded linear DNA genome. Infection is common and usually asymptomatic. The most severe form is congenital with severe generalized infection involving central nervous system and liver accompanied by lethargy, convulsions, jaundice, pneumonitis and encephalitis. For severely affected infants neonatal case fatality rate is high. Inapparent infections can be observed later in life, which are mononucleosis-like but without pharyngitis. Reactivation, infection, or reinfection may occur in immunocompromised patients (bone marrow and other transplants). Pneumonitis, hepatitis and retinitis are most common manifestations in this group. The distribution of the infection is worldwide. It is acquired early in developing countries. In developed areas serum antibodies is observed in 40% of adults and in developing countries the occurrence is 100%. The infection rate is higher in women. Immunodeficient patients (fetus, newborn, immunocompromised) are at higher risk. The mode of transmission is through intimate exposure by cutaneous or mucosal contact with infectious tissues, secretions or excretions (urine, saliva, breast milk, cervical secretions, semen). Infection of the fetus in the uterus and postnatal infection at delivery is possible. Blood transfusion is a common cause of post-transfusion mononucleosis (about 3% risk). The virus can also be transmitted through organ transplantation.

Fluorion CMV QNP 3.0 Real-Time PCR Kit is based on the real-time PCR principle. The pathogen is detected using fluorescent dyes that are incorporated into oligonucleotide probes. The assay utilizes the 5' exonuclease activity of Taq Polymerase to cleave a dual-labeled fluorescent hydrolysis probe during the extension phase of PCR.

Principle of the Test	Quantification of CMV
Technology	Real-Time PCR with hydrolysis probes
Gene Target	DNA polymerase
Detected Genotypes	All major genotypes
Specimen Type	Serum
Limit of Detection	48 copies/ml
Dynamic Range of Quantification	$2x10^{10}$-$2x10^{2}$ Copies/ml
Controls	Inhibition and extraction control, negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	Extraction Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) Amplification Fluorion Detection System (Iontek)*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
CMV QNP 3.0 Real-Time PCR Kit CE-IVD	M0380202-2	50 tests
CMV QNP 3.0 Real-Time PCR Kit CE-IVD	M0380202-3	100 tests

HDV

Hepatitis D is an infective disease caused by Hepatitis Delta Virus (HDV). The symptoms may include fever, jaundice, fatigue, appetite loss, abdominal pain, nausea, joint pain, tea colored urine.

HDV infection may either be acquired as a coinfection with Hepatitis B Virus (HBV), or as a super infection in individuals with existing HBV infection. In both coinfection and superinfection, HDV infection results in more severe complications, such as a higher risk of liver failure (in acute infections) and a higher risk of liver cancer (in chronic infections) compared to infection with HBV alone. Though it is rare in developed countries, HDV presents a health risk in countries where Hepatitis B is more common; mostly in Mediterranean, Middle Eastern, African and South American countries.

HDV can propagate only in the presence of HBV. Having a genetic material composed of only 1.7 kb circular RNA, HDV is the smallest virus known to infect humans. Since 70% of the nucleotide sequence is self-complementary, the HDV genome forms a partially double stranded RNA structure which is described as rod-like.

Fluorion HDV QNP 1.0 Real-Time PCR Kit is based on the real-time PCR principle. The pathogen is detected using fluorescent dyes that are incorporated into oligonucleotide probes. The assay utilizes the 5'exonuclease activity of Taq Polymerase to cleave a dual-labeled fluorescent hydrolysis probe during the extension phase of PCR.

Principle of the Test	Quantification of HDV
Technology	Real-Time PCR with hydrolysis probes
Gene Target	Structural antigen gene
Detected Genotypes	HDV genotypes 1-7
Specimen Type	Serum
Limit of Detection	400 IU/ml
Dynamic Range of Quantification	$1x10^{10}$-$1x10^{3}$ IU/ml
Controls	Inhibition and extraction control, negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	Extraction Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) Amplification Fluorion Detection System (Iontek)*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
HDV QNP 1.0 Real-Time PCR Kit CE-IVD	M0060202-2	50 tests
HDV QNP 1.0 Real-Time PCR Kit CE-IVD	M0060202-3	100 tests

EBV

Epstein-Barr Virus (EBV) is a member of the herpesvirus family and is one of the most common human viruses. The virus occurs worldwide, and most people become infected with EBV sometime during their lives. Infants become susceptible to EBV as soon as maternal antibody protection (present at birth) disappears. Many children become infected with EBV, and these infections usually cause no symptoms or are indistinguishable from the other mild, brief illnesses of childhood. In developed countries, many persons are not infected with EBV in their childhood years. When infection with EBV occurs during adolescence or young adulthood, it causes infectious mononucleosis 35% to 50% of the time. Symptoms of infectious mononucleosis are fever, sore throat, and swollen lymph glands. Sometimes, a swollen spleen or liver involvement may develop. Heart problems or involvement of the central nervous system occurs only rarely, and infectious mononucleosis is almost never fatal. Although the symptoms of infectious mononucleosis usually resolve in 1 or 2 months, EBV remains dormant or latent in a few cells in the throat and blood for the rest of the person's life. Periodically, the virus can reactivate and is commonly found in the saliva of infected persons. This reactivation usually occurs without symptoms of illness. EBV also establishes a lifelong dormant infection in some cells of the body's immune system. A late event in a very few carriers of this virus is the emergence of Burkitt's lymphoma and nasopharyngeal carcinoma. EBV appears to play an important role in these malignancies, but is probably not the sole cause of disease.

Fluorion EBV QNP 1.0 Real-Time PCR Kit is based on the real-time PCR principle. The pathogen is detected using fluorescent dyes that are incorporated into oligonucleotide probes. The assay utilizes the 5' exonuclease activity of Taq Polymerase to cleave a dual-labeled fluorescent hydrolysis probe during the extension phase of PCR.

Principle of the Test	Detection and quantification of EBV
Technology	Real-Time PCR with hydrolysis probes
Gene Target	Long internal repeat region 1
Detected Genotypes	All major genotypes
Specimen Type	Serum
Limit of Detection	50 IU/ml
Dynamic Range of Quantification	$5x10^2$-$5x10^9$ IU/ml
Controls	Inhibition and extraction control, negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	**Extraction** QIAamp MinElute Virus Spin Kit (Qiagen), Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) **Amplification** Fluorion Detection System (Iontek)*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
EBV QNP 1.0 Real-Time PCR Kit CE-IVD	M0360202-2	50 tests
EBV QNP 1.0 Real-Time PCR Kit CE-IVD	M0360202-3	100 tests

PARVOVIRUS B19

Parvovirus B19 is the only member of the Parvoviridae family which has been identified as a human pathogen. This DNA virus, preferentially infects and destroys precursor erythroid cells in the bone marrow.

B19 infections are very common, and most adults have serum IgG antibodies against this virus. Infection is transmitted through contact with infected respiratory secretions (saliva, sputum or nasal mucus); mother to fetus; parenterally by transfusion of blood and blood products.
Parvovirus B19 infection in healthy hosts is either asymptomatic or results in the common viral exanthem, erythema infectiosum which is also known as "Fifth Disease" that affects children, or in acute arthropathy. Following an incubation period of 6-18 days, Fifth Disease is manifested by a brief period of non-specific symptoms including mild fever, malaise, headache and pruritus. After this stage, which may be asymptomatic in some patients, viremia ends and a new phase characterized by rash, arthritis and arthralgias, begins. Recovery is usually spontaneous and it rarely leads to complications such as anemia, ancephalopathy, arthritis or pneumoniae. Individuals with impaired bone marrow or immune function are uniquely susceptible to B19 infections. Infection in patients with chronic haemolytic diseases (such as sickle cell anemia) may lead to transient aplastic crisis or persistent viraemia with chronic anaemia.

Fluorion PARVOVIRUS QNP 1.0 Real-Time PCR Kit is based on the real-time PCR principle. The pathogen is detected using fluorescent dyes that are incorporated into oligonucleotide probes. The assay utilizes the 5' exonuclease activity of Taq Polymerase to cleave a dual-labeled fluorescent hydrolysis probe during the extension phase of PCR.

Principle of the Test	Detection and quantification of Parvovirus
Technology	Real-Time PCR with hydrolysis probes
Gene Target	NS-1 gene
Detected Genotypes	All major genotypes
Specimen Type	Serum
Limit of Detection	90 IU/ml
Dynamic Range of Quantification	$1.5x10^2$-$1.5x10^8$ IU/ml
Controls	Inhibition and extraction control, negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	**Extraction** QIAamp MinElute Virus Spin Kit (Qiagen), Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) **Amplification** Fluorion Detection System (Iontek)*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
Parvovirus B19 QNP 1.0 Real-Time PCR Kit CE-IVD	M0410202-2	50 tests
Parvovirus B19 QNP 1.0 Real-Time PCR Kit CE-IVD	M0410202-3	100 tests

BKV

BK Virus (BKV) is a nonenveloped, double-stranded DNA virus of the polyomavirus family that primarily affects immunocompromised people. The virus is ubiquitous in human populations worldwide. BKV becomes latent in the urinary tract after primary infection. In the context of immunosuppressive therapy, BKV can cause nephropathy in renal transplant recipients, resulting in tubulointerstitial lesions known as polyomavirus-associated nephropathy (PVAN) or, more specifically, BKV nephropathy (BKVN).

BKVN is one of the most common viral diseases affecting renal allografts. Specific and potent antiviral drugs to treat active BKV infections are not available, thus requiring patient screening and early diagnosis of BKVN. Measurement of BKV loads in the urine and plasma is a powerful clinical tool for identifying patients at risk for developing BKVN and for monitoring response to therapy. Quantitative Real Time PCR is ubiquitous and reliable method for early diagnosis of BKVN.

Fluorion BKV QNP 1.0 Real-Time PCR Kit is based on the real-time PCR principle. The pathogen is detected using fluorescent dyes that are incorporated into oligonucleotide probes. The assay utilizes the 5' exonuclease activity of Taq Polymerase to cleave a dual-labeled fluorescent hydrolysis probe during the extension phase of PCR.

Principle of the Test	Detection and quantification of BK Virus
Technology	Real-Time PCR with hydrolysis probes
Gene Target	Small T-Antigen gene
Detected Genotypes	All major genotypes
Specimen Type	Serum, plasma, urine
Limit of Detection	32 copies/ml
Dynamic Range of Quantification	$1x10^1$-$1x10^8$ copies/ml
Controls	Inhibition and extraction control, negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	**Extraction** QIAamp MinElute Virus Spin Kit (Qiagen), Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) **Amplification** Fluorion Detection System (Iontek)*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
BKV QNP 1.0 Real-Time PCR Kit CE-IVD	M0610202-2	50 tests
BKV QNP 1.0 Real-Time PCR Kit CE-IVD	M0610202-3	100 tests

JCV

Human JC Virus (JCV) non-enveloped virus with a circular double-stranded-DNA genome of the polyomavirus family. JCV infection is widespread in the human population and primary infection usually occurs during childhood. After primary infection, the virus undergoes lifelong latency in the kidneys and replicates the progeny being excreted into the urine via an unknown reactivated mechanism.

JCV is the causative agent of the neurological disease progressive multifocal leukoencephalopathy, which occurs in immunocompromised patients. Infection of oligodendrocytes and astrocytes leads to relentlessly progressive demyelination, usually with death in 3 to 9 months.

Fluorion JCV QNP 1.0 Real-Time PCR Kit is based on the real-time PCR principle. The pathogen is detected using fluorescent dyes that are incorporated into oligonucleotide probes. The assay utilizes the 5' exonuclease activity of Taq Polymerase to cleave a dual-labeled fluorescent hydrolysis probe during the extension phase of PCR.

Principle of the Test	Detection and quantification of JC virus
Technology	Real-Time PCR with hydrolysis probes
Gene Target	Small T-Antigen gene
Detected Genotypes	All major genotypes
Specimen Type	Serum, plasma, urine
Limit of Detection	45 copies/ml
Dynamic Range of Quantification	$4x10^1$-$4x10^9$ copies/ml
Controls	Inhibition and extraction control, negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	**Extraction** QIAamp MinElute Kit (Qiagen), Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) **Amplification** Fluorion Detection System (Iontek)*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
JCV QNP 1.0 Real-Time PCR Kit CE-IVD	M0620202-2	50 tests
JCV QNP 1.0 Real-Time PCR Kit CE-IVD	M0620202-3	100 tests

HSV

Human Herpesviruses are a family of eight DNA viruses which naturally occur in humans. They consist of Herpes simplex virus type 1 (HSV-1), Herpes simplex virus type 2 (HSV-2), Varicella-zoster virus (VZV), Cytomegalovirus (CMV), Epstein–Barr virus (EBV), Human herpesvirus 6 (HHV-6), Human herpesvirus 7 (HHV-7), and Kaposi sarcoma-associated herpesvirus (KSHV or HHV-8). HSV infections are transmitted by the transfer of infected secretions through direct contact.

Gingivostomatitis, symptomatic primary infection of the oral cavity usually caused by HSV-1, occurs most frequently in small children. Recurrent HSV-1 infections are most frequently manifested as cold sores that usually appear near the lip. HSV-1 is also the main cause of Herpes simplex keratitis, which is frequently accompanied by conjunctivitis and may lead to visual impairment. Genital herpes is most frequently caused by HSV-2. While some of the infections are completely cured, others are recurrent. Neonatal HSV infections are mostly caused by HSV-2 and usually result from contact of the fetus with infected maternal secretions during delivery. Neonatal HSV infection may result in; a) Skin, Eye and Mouth Disease, b) Encephalitis, and c) Disseminated Infection.

Fluorion HSV QLP 2.1 Real-Time PCR Kit is based on the real-time PCR principle. The pathogen is detected using fluorescent dyes that are incorporated into oligonucleotide probes. The assay utilizes the 5' exonuclease activity of Taq Polymerase to cleave a dual-labeled fluorescent hydrolysis probe during the extension phase of PCR.

Principle of the Test	Detection and genotyping of HSV
Technology	Real-Time PCR with hydrolysis probes
Gene Target	DNA polymerase
Detected Genotypes	HSV-1 and HSV-2
Specimen Type	Serum, plasma
Limit of Detection	HSV 1: 100, HSV 2: 10 copies/ml
Controls	Inhibition and extraction control, negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	**Extraction** QIAamp MinElute Kit (Qiagen), Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) **Amplification** Fluorion Detection System (Iontek)*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
HSV QLP 2.1 Real-Time PCR Kit CE-IVD	M0580302-2	50 tests
HSV QLP 2.1 Real-Time PCR Kit CE-IVD	M0580302-3	100 tests

MTBC

Mycobacterium tuberculosis is a gram positive, non-spore forming bacteria and it is the major cause of tuberculosis in human. It is an important cause of disability and death in many parts of the world despite the decreased mortality and morbidity rates. The portal entry is the lung. The pathogen is carried as airborne particles (droplet nuclei). Exposure to airborne bacilli from sputum of infected persons, direct invasion of mucous membranes or breaks in skin, bovine tuberculosis from exposure to infected cattle are major modes of transmission. The bacteria are communicable as long as bacilli are discharged in sputum, extrapulmonary tuberculosis (except laryngeal tuberculosis) is generally not communicable.

Tuberculosis may involve multiple organs such as the lung, liver, spleen, kidney, brain, and bone. In some patients, pulmonary macrophages are unable to contain the bacilli and are overwhelmed, leading to a clinically apparent infection. This is more common in patients who are immunocompromised, notably the population with HIV/AIDS.

The primary infection usually has no symptoms. 95% of individuals will have healing of their primary tuberculous lesions with no further evidence of disease. Disseminated disease develops in the minority whose immune systems do not successfully heal the primary infection.

Fluorion MTBC QLP 2.1 Real-Time PCR Kit is based on the real-time PCR principle. The pathogen is detected using fluorescent dyes that are incorporated into oligonucleotide probes. The assay utilizes the 5' exonuclease activity of Taq Polymerase to cleave a dual-labeled fluorescent hydrolysis probe during the extension phase of PCR.

Principle of the Test	Detection of MTBC
Technology	Real-Time PCR with hydrolysis probes
Gene Target	Insertion sequence
Detected Genotypes	Whole M. Tuberculosis complex family
Specimen Type	Serum, plasma, sputum, CSF, alveolar lavage
Limit of Detection	800 copies/ml
Controls	Inhibition and extraction control, negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	Extraction QIAamp DNA Mini Kit (Qiagen), Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) Amplification Fluorion Detection System (Iontek)*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
MTBC QLP 2.1 Real-Time PCR Kit CE-IVD	M0030102-2	50 tests
MTBC QLP 2.1 Real-Time PCR Kit CE-IVD	M0030102-3	100 tests

VRE

Enteroccocci are bacteria that are normally present in the human intestines and in the female genital tract and are often found in the environment. These bacteria can sometimes cause infections. Vancomycin is an antibiotic that is used to treat some drug-resistant infections caused by enterococci. In some instances, enterococci have become resistant to this drug and thus are called Vancomycin-Resistant Enterococci (VRE).

VRE has become an important clinical concern, and it is now accepted as an emerging problem in hospitals. In enterococci, two principal phenotypes of acquired vancomycin resistance have been described, VanA and VanB. Strains with VanA phenotype possess high level resistance to both vancomycin and teicoplanin, whereas strains with VanB phenotype possess only moderate to high levels of vancomycin resistance. The main reservoir for these genes are *E. faecium* and *E. faecalis* Rapid and accurate identification of VRE is crucial in the treatment of infected patients, to allow selection of appropriate antimicrobial treatment and to implement appropriate infection control procedures. Confirmation of VRE with Real-time PCR technology is much more rapid than conventional PCR or phenotype based methods.

Fluorion VRE QLP 1.0 Real-Time PCR Kit is based on the real-time PCR principle. The pathogen is detected using fluorescent dyes that are incorporated into oligonucleotide probes. The assay utilizes the 5' exonuclease activity of Taq Polymerase to cleave a dual-labeled fluorescent hydrolysis probe during the extension phase of PCR.

Principle of the Test	Detection of VRE
Technology	Real-Time PCR with hydrolysis probes
Gene Target	vanA and vanB genes
Detected Genotypes	All vancomycin resistant genotypes
Specimen Type	Serum, plasma
Limit of Detection	100 copies/ml
Controls	Inhibition and extraction control, negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	Extraction QIAamp DNA Mini Kit (Qiagen), Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) Amplification Fluorion Detection System (Iontek)*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
VRE QLP 1.0 Real-Time PCR Kit CE-IVD	M0630102-2	50 tests
VRE QLP 1.0 Real-Time PCR Kit CE-IVD	M0630102-3	100 tests

FLUORION CoVIDenza

Fluorion Covidenza kit has been developed for the detection and separation of SARS-CoV-2, Influenza A and Influenza B viruses from RNA isolates obtained from human samples.

The positive control in the kit is synthetic DNA. It contains target regions of the N1, N2, M2, NS1 and RNAseP genes that are amplified only with the primer-probe sets included in this kit. The content of the positive control tube is not infectious.

REAL-TIME PCR KITS
MICROBIOLOGY

FLUORION CoVIDenza

SAMPLE TYPE	TARGET	SENSITIVITY
• Bronchoalveolar Lavage • Nasopharyngeal Swab • Orofarengeal Swab	SARS-CoV-2 Influenza A Influenza B	10 copies/mL

KIT SPESIFICATIONS	
Intended Use	Qualitative detection and discrimination of Coronavirus 2019 (COVID-19) SARS-CoV-2, Influenza A and Influenza B viruses in patients with COVID-19 or influenza-like clinical symptoms (e.g. fever, cough, shortness of breath), using lower respiratory tract (bronchoalveolar lavage (BAL), tracheal aspirate) and/or upper respiratory tract (nasopharyngeal and oropharyngeal fluids, nasal swab) samples.
Analitycal Specificity *(in vitro analysis)*	**DOES NOT** cross-react with the below pathogens: SARS-CoV, Adenovirus, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, *Candida albicans,* RSV A, RSV B, Rhinovirus, *Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis,* Hepatitis B, Hepatitis C, Hepatitis Delta, Human Immunodeficiency Virus, Cytomegalovirus, Epstein-Barr Virus, JCV, BKV, Human Papilloma Virus, Parvovirus, Herpes Simplex Virus, *Mycobacterium tuberculosis, Aspergillus spp., Brucella abortus, Brucella melitensis, Brucella canis and Brucella suis, E.coli O157, Salmonella spp., Listeria monocytogenes*
Analitycal Specificity *(in silico analysis)*	**DOES NOT** cross-react with the below pathogens: SARS-CoV, MERS-CoV, Human coronaviruses (HCoV-229E, HCoV-OC43, HCoV-NL63, HCoV-HKU1), Adenovirus, Influenza C, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parechovirus, *Candida albicans, Corynebacterium diphtheriae,* Legionella non-pneumophila, *Bacillus anthracis, Moraxella catarrhalis, Neisseria elongata, Neisseria meningitides,* RSV A, RSV B, Rhinovirus, *Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus salivarius,* Leptospirosis, *Chlamydia psittaci, Coxiella burnetii* (Q- Fever), *Staphylococcus epidermidis,* Enterovirus, *Haemophilus Influenzae, Mycobacterium tuberculosis, Bordetella parapertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila,* Hepatitis B, Hepatitis C, Hepatitis Delta, Human Immunodeficiency Virus, Cytomegalovirus, Epstein-Barr Virus, JCV, BKV, Human Papilloma Virus, Parvovirus, Herpes Simplex Virus, *Mycobacterium tuberculosis, Aspergillus spp., Brucella abortus, Brucella melitensis, Brucella canis and Brucella suis, E.coli O157, Salmonella spp., Listeria monocytogenes*
Specificity	100.00%
Target Regions	N1 and N2 regions of nucleocapsid gene of SARS-CoV-2 virus, M2 gene of Influenza A virus, NS1 gene of Influenza B virus Human RNaseP gene (internal control)
Reaction Duration	~45 min. (may change depending on the Real-Time PCR instrument)
Storage Conditions	• Products should be stored at -20°C or below. • It is recommended not to freeze-thaw products more than three times. In cases where more freeze-thaw is required, solutions should be aliquoted and stored at -20°C or lower following the first thaw. • Detection mixes are light-sensitive. Aliquoted reagents must be protected from light.

Item	Cat. No.	Pack Size
CoVIDenza QLP 1.0 Real-Time PCR Kit CE-IVD	M1360102-2	50 tests
CoVIDenza QLP 1.0 Real-Time PCR Kit CE-IVD	M1360102-3	100 tests

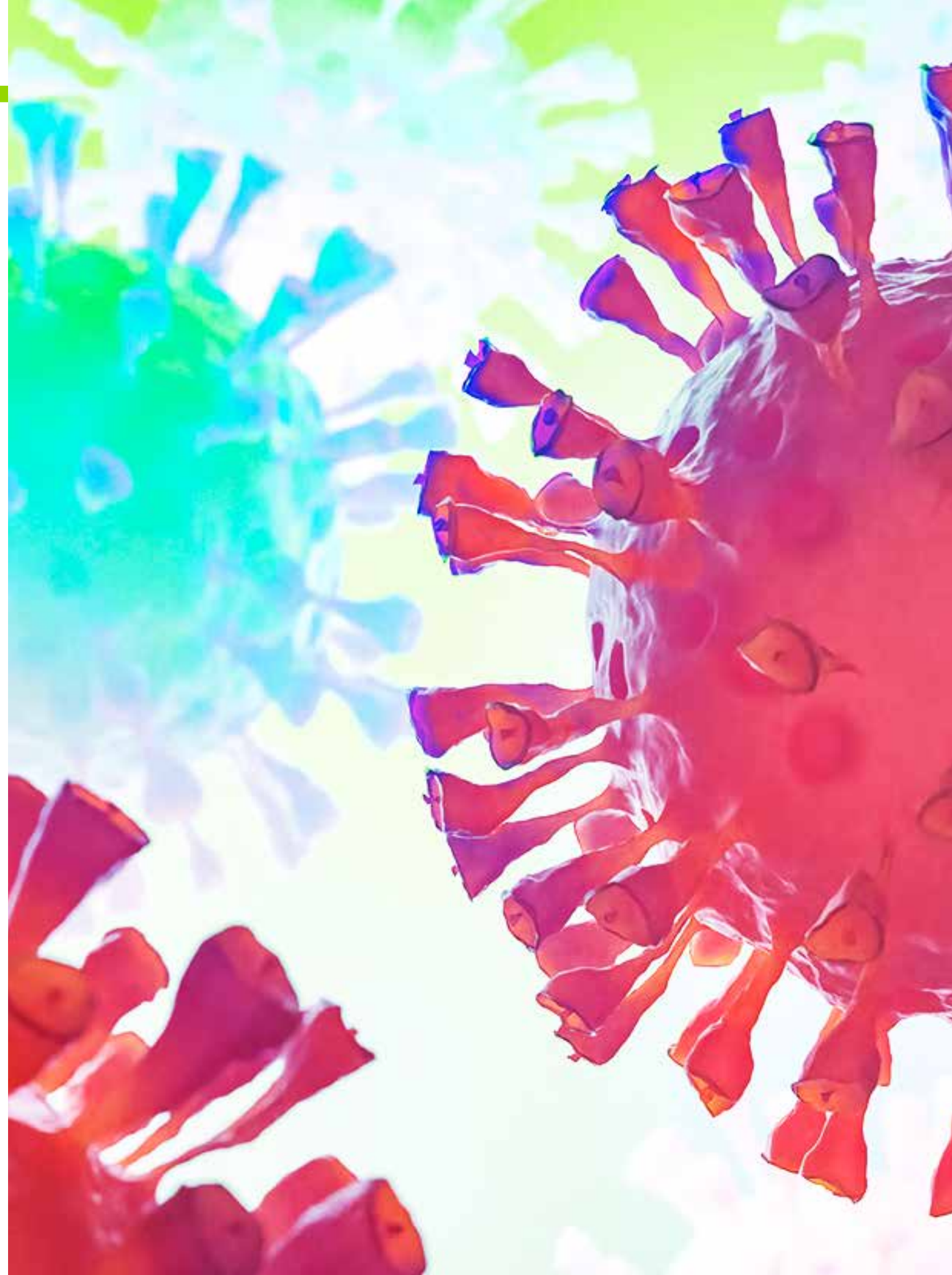
FLUORION CoVIDenza+

SAMPLE TYPE	TARGET	SENSITIVITY
• Bronchoalveolar Lavage • Nasopharyngeal Swab • Orofarengeal Swab	SARS-CoV-2 Influenza A Influenza B RSV and/or Rhinovirus*	10 copies/mL

	KIT SPESIFICATIONS
Intended Use	Qualitative detection and discrimination of Coronavirus 2019 (COVID-19) SARS CoV-2, Influenza A, Influenza B, RSV and Rhinovirus viruses in patients with COVID-19, influenza or common cold like symptoms (e.g. fever, cough, shortness of breath), using lower respiratory tract (bronchoalveolar lavage (BAL), tracheal aspirate) and/or upper respiratory tract (nasopharyngeal and oropharyngeal fluids, nasal swab) samples.
Analitycal Specificity *(in vitro analysis)*	**DOES NOT** cross-react with the below pathogens: SARS-CoV, Adenovirus, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, *Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus, Staphylococcus epidermidis,* Hepatitis B, Hepatitis C, Hepatitis Delta, Human Immunodeficiency Virus, Cytomegalovirus, Epstein-Barr Virus, JCV, BKV, Human Papilloma Virus, Parvovirus, Herpes Simplex Virus, Mycobacterium tuberculosis, *Aspergillus spp., Brucella abortus, Brucella melitensis, Brucella canis and Brucella suis, E.coli O157, Salmonella spp., Listeria monocytogenes*
Analitycal Specificity *(in silico analysis)*	**DOES NOT** cross-react with the below pathogens: SARS-CoV, MERS-CoV, Human coronaviruses (HCoV-229E, HCoV-OC43, HCoV-NL63, HCoV-HKU1), Adenovirus, Influenza C, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parechovirus, *Candida albicans, Corynebacterium diphtheriae, Legionella non-pneumophila, Bacillus anthracis, Moraxella catarrhalis, Neisseria elongata, Neisseria meningitides, Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus salivarius, Leptospirosis, Chlamydia psittaci, Coxiella burnetii (Q- Fever), Staphylococcus epidermidis, Enterovirus, Haemophilus Influenzae, Mycobacterium tuberculosis, Bordetella parapertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila,* Hepatitis B, Hepatitis C, Hepatitis Delta, Human Immunodeficiency Virus, Cytomegalovirus, Epstein-Barr Virus, JCV, BKV, Human Papilloma Virus, Parvovirus, Herpes Simplex Virus, *Mycobacterium tuberculosis, Aspergillus spp., Brucella abortus, Brucella melitensis, Brucella canis and Brucella suis, E.coli O157, Salmonella spp., Listeria monocytogenes*
Specificity	100.00%
Target Regions	N1 and N2 regions of nucleocapsid gene of SARS-CoV-2 virus, M2 gene of Influenza A virus, NS1 gene of Influenza B virus, G Protein of RSV 5′ UTR region of Rhinovirus Human RNaseP gene (internal control)
Reaction Duration	~45 min. (may change depending on the Real-Time PCR instrument)
Storage Conditions	• Products should be stored at -20°C or below. • It is recommended not to freeze-thaw products more than three times. In cases where more freeze-thaw is required, solutions should be aliquoted and stored at -20°C or lower following the first thaw. • Detection mixes are light-sensitive. Aliquoted reagents must be protected from light.

* Please contact for optional requests

Item	Cat. No.	Pack Size
CoVIDenza Plus QLP 1.0 Real-Time PCR Kit CE-IVD	M1370102-2	50 tests
CoVIDenza Plus QLP 1.0 Real-Time PCR Kit CE-IVD	M1370102-3	100 tests



DİKKAT

FV LEIDEN

Factor V Leiden is a genetic disorder inherited in an otosomal dominant manner. The disorder results in 50% of the familial thrombophilia cases. Thrombophilia is a term used to describe a group of conditions in which there is an increased tendency, for excessive clotting. The development of a blood clot is called thrombosis. The vascular system includes both the venous system (the veins that deliver blood from the tissues to the heart) and the arterial system (the system that delivers blood from the heart to the tissues). Thrombotic episodes may occur in either system. The severity of the symptoms depend on the part of the vascular system in which they occur, the extent of the clot and whether the clot breaks off and travels to another part of the body (e.g. the lungs—pulmonary embolus, the brain—embolic stroke, etc). Several types of conditions have been identified which may lead to dangerous clots. These conditions may be present at birth (congenital or inherited) or may occur as a result of another condition (acquired). Thrombophilia affects a large number of individuals in the world. The most common mutation associated with inherited thrombosis in the Caucasian population is the Factor V Leiden mutation, which leads to resistance to activated protein C. A point mutation at position 1691 of the Factor V gene, renders the gene product resistant to degradation by APC (activated protein C), which results in excessive clotting.

Heterozygotes for the Factor V Leiden mutation have an approximately 5 to 10-fold increased risk for venous thrombosis.

Principle of the Test	Detection of the Factor V Leiden G1691A mutation
Technology	Real-Time PCR with hydrolysis probes
Gene Target	Factor V Leiden
Detected Genotypes	Wild type and mutant
Specimen Type	Whole blood
Minimum DNA Concentration	50 ng/ul DNA
Controls	Negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	**Extraction** QIAamp DNA Blood Mini Kit (Qiagen), Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) **Amplification** Fluorion Detection System (Iontek), MIC*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
Factor V Leiden (G1691A) QLP 4.0 Real-Time PCR Kit CE-IVD	G0990402-2	50 tests
Factor V Leiden (G1691A) QLP 4.0 Real-Time PCR Kit CE-IVD	G0990402-3	100 tests

REAL-TIME PCR KITS
MOLECULAR GENETICS

FACTOR II KIT (PROTHROMBIN)

Thrombophilia is a term used to describe a group of conditions in which there is an increased tendency, for excessive clotting. The development of a blood clot is called thrombosis. The vascular system includes both the venous system (the veins that deliver blood from the tissues to the heart) and the arterial system (the system that delivers blood from the heart to the tissues). Thrombotic episodes may occur in either system. The severity of the symptoms depend on the part of the vascular system in which they occur, the extent of the clot and whether the clot breaks off and travels to another part of the body (e.g. the lungs—pulmonary embolus, the brain—embolic stroke, etc). Several types of conditions have been identified which may lead to dangerous clots. These conditions may be present at birth (congenital or inherited) or may occur as a result of another condition (acquired).

Thrombophilia affects a large number of individuals in the world. The most common mutation associated with inherited thrombosis in the Caucasian population is the Factor V Leiden mutation, which leads to resistance to activated protein C. The second most common mutation associated with hereditary thrombosis is the G20210A mutation in the prothrombin (Factor II) gene, which is associated with high plasma prothrombin levels.

Heterozygous carriers of the prothrombin 20210 G-A mutation have an estimated 3 to 8-fold increased risk for venous thrombosis.

Principle of the Test	Detection of the Factor II G20210A mutation
Technology	Real-Time PCR with hydrolysis probes
Gene Target	Factor II
Detected Genotypes	Wild type and mutant
Specimen Type	Whole blood
Minimum DNA Concentration	50 ng/ul DNA
Controls	Negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	**Extraction** QIAamp DNA Blood Mini Kit (Qiagen), Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) **Amplification** Fluorion Detection System (Iontek), MIC*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
Prothrombin (G20210A) QLP 4.0 Real-Time PCR Kit CE-IVD	G1000402-2	50 tests
Prothrombin (G20210A) QLP 4.0 Real-Time PCR Kit CE-IVD	G1000402-3	100 tests

MTHFR 1298 KIT

Thrombophilia is a term used to describe a group of conditions in which there is an increased tendency, for excessive clotting. The development of a blood clot is called thrombosis. The vascular system includes both the venous system (the veins that deliver blood from the tissues to the heart) and the arterial system (the system that delivers blood from the heart to the tissues). Thrombotic episodes may occur in either system. The severity of the symptoms depend on the part of the vascular system in which they occur, the extent of the clot and whether the clot breaks off and travels to another part of the body (e.g. the lungs—pulmonary embolus, the brain—embolic stroke, etc). Several types of conditions have been identified which may lead to dangerous clots. These conditions may be present at birth (congenital or inherited) or may occur as a result of another condition (acquired).

Thrombophilia affects a large number of individuals in the world. The most common mutation associated with inherited thrombosis in the Caucasian population is the Factor V Leiden mutation, which leads to resistance to activated protein C. The second most common mutation associated with hereditary thrombosis is the G20210A mutation in the prothrombin (Factor II) gene, which is associated with high plasma prothrombin levels.

Another risk factor for venous thrombosis is increased plasma homocysteine level, which is associated with homozygosity for a nucleotide variants in the methylenetetrahydrofolate reductase (MTHFR) gene. The MTHFR 677 C-T variant (leading to an alanine to valine substitution) and the 1298 A-C variant (leading to a glutamic acid to alanine substitution) result in a thermolabile enzyme and decreased production of folate, which is a cofactor required for homocysteine remethylation.

Principle of the Test	Detection of the MTHFR A1298C mutation
Technology	Real-Time PCR with hydrolysis probes
Gene Target	MTHFR
Detected Genotypes	Wild type and mutant
Specimen Type	Whole blood
Minimum DNA Concentration	50 ng/ul DNA
Controls	Negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	Extraction QIAamp DNA Blood Mini Kit (Qiagen), Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) Amplification Fluorion Detection System (Iontek), MIC*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
MTHFR (A1298C) QLP 4.0 Real-Time PCR Kit CE-IVD	G1030402-2	50 tests
MTHFR (A1298C) QLP 4.0 Real-Time PCR Kit CE-IVD	G1030402-3	100 tests

REAL-TIME PCR KITS
MOLECULAR GENETICS

MTHFR 677 KIT

Thrombophilia is a term used to describe a group of conditions in which there is an increased tendency, for excessive clotting. The development of a blood clot is called thrombosis. The vascular system includes both the venous system (the veins that deliver blood from the tissues to the heart) and the arterial system (the system that delivers blood from the heart to the tissues). Thrombotic episodes may occur in either system. The severity of the symptoms depend on the part of the vascular system in which they occur, the extent of the clot and whether the clot breaks off and travels to another part of the body (e.g. the lungs—pulmonary embolus, the brain—embolic stroke, etc). Several types of conditions have been identified which may lead to dangerous clots. These conditions may be present at birth (congenital or inherited) or may occur as a result of another condition (acquired).

Thrombophilia affects a large number of individuals in the world. The most common mutation associated with inherited thrombosis in the Caucasian population is the Factor V Leiden mutation, which leads to resistance to activated protein C. The second most common mutation associated with hereditary thrombosis is the G20210A mutation in the prothrombin (Factor II) gene, which is associated with high plasma prothrombin levels.

Another risk factor for venous thrombosis is increased plasma homocysteine level, which is associated with homozygosity for a nucleotide variant in the methylenetetrahydrofolate reductase (MTHFR) gene. The MTHFR 677 C-T variant (leading to an alanine to valine substitution) results in a thermolabile enzyme and decreased production of folate, which is a cofactor required for homocysteine remethylation.

Principle of the Test	Detection of the MTHFR C677T mutation
Technology	Real-Time PCR with hydrolysis probes
Gene Target	MTHFR
Detected Genotypes	Wild type and mutant
Specimen Type	Whole blood
Minimum DNA Concentration	50 ng/ul DNA
Controls	Negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	Extraction QIAamp DNA Blood Mini Kit (Qiagen), Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) Amplification Fluorion Detection System (Iontek), MIC*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
MTHFR (C677T) QLP 4.0 Real-Time PCR Kit CE-IVD	G1010402-2	50 tests
MTHFR (C677T) QLP 4.0 Real-Time PCR Kit CE-IVD	G1010402-3	100 tests

PAI KIT

Plasminogen activator inhibitor-1(PAI-1), or serpin E1, is a serine protease inhibitor (serpin) encoded by the human SERPINE1 gene. PAI-1 is a major inhibitor of fibrinolysis, a process that prevents blood clots from growing and becoming problematic. Increased PAI-1 activity results in depressed fibrinolytic activity resulting in elevated risk for thrombosis (formation of blood clots).

The normal (wild-type) promoter for the PAI-1 gene contains a tract of five consecutive G residues. However, there a mutant form of the PAI-1 promoter that have been identified that only contains four consecutive G residues. This mutant promoter causes higher amounts of PAI-1 to be made, compared to the wild-type. Increased amounts of PAI-1 inhibit more tPA and uPA and, therefore, inhibits fibrinolysis more than the wild-type gene, resulting in elevated risk of thrombosis.

Homozygous wild-type (5G/5G) – Normal PAI-1 activity and normal risk of thrombosis Heterozygous (4G/5G) – Increased PAI-1 activity resulting in depressed fibrinolysis and increased risk of thrombosis. Homozygous mutant (4G/4G) – Significantly increased PAI-1 activity resulting in depressed fibrinolysis and increased risk of thrombosis.

This genotype result is one factor affecting thrombosis risk, and other genetic and clinical factors should also be considered. Multiple thrombosis risk factors are usually additive. Additional risk factors for development of thrombosis include: Older age, surgery, obesity, prolonged travel, immobility, hospitalization, oral contraceptive use, hormonal replacement therapy, pregnancy, and malignancy.

Principle of the Test	Detection of the PAI-1 4G-5G mutation
Technology	Real-Time PCR with hydrolysis probes
Gene Target	PAI-1
Detected Genotypes	Wild type and mutant
Specimen Type	Whole blood
Minimum DNA Concentration	50 ng/ul DNA
Controls	Negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	Extraction QIAamp DNA Blood Mini Kit (Qiagen), Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) Amplification Fluorion Detection System (Iontek), MIC*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
PAI-1 (4G/5G) QLP 4.0 Real-Time PCR Kit CE-IVD	G1020402-2	50 tests
PAI-1 (4G/5G) QLP 4.0 Real-Time PCR Kit CE-IVD	G1020402-3	100 tests

REAL-TIME PCR KITS
MOLECULAR GENETICS

HLA B27 KIT

The human leukocyte antigen HLA-B27 is strongly associated with spondyloarthropathies (SpA), a group of inflammatory rheumatic diseases including ankylosing spondylitis (AS). HLA-B27 is found in 90–95% of AS patients. It is also found in a lower proportion of patients with reactive arthritis and some forms of psoriatic arthritis (PsA). Twenty-four HLA-B27 subtypes have been detected and differ only by a small number of nucleotide substitutions within exons 2 and 3 of the HLA-B27 gene. Although the exact mechanism determining disease susceptibility is still unknown, testing for HLA-B27 is a valuable tool for the diagnosis of AS and SpA.

Serological techniques such as the microlymphocytotoxicity test (MLCT), flow cytometry (FC) and enzyme immunoassays (EIA) are usually used for the routine typing of HLA-B27. However, these techniques require fresh blood samples (viable cells) because they are based on the detection of cell surface structures by antibodies and are thus sensitive to downregulation or conformational changes of the HLA-B27 glycoprotein. Moreover, serological methods lack specificity especially in the presence of antigens that cross-react with HLA-B27, such as HLA-B7. Therefore, several molecular methods that do not require viable cells and are more accurate have been developed for HLA-B27 genotyping. These methods include PCR restriction length polymorphism, polymerase chain reaction with sequence-specific primers (PCR-SSP), hybridization with specific oligonucleotide probes (PCR-SSO), ligationbased typing (LBT) and sequence- based typing (SBT).

The development of real-time PCR was an important technical improvement permitting the detection and quantification of PCR products during thermal cycling. Real-time PCR is a powerful tool for gene expression analysis, genotyping, pathogen detection/ quantification and mutation screening.

Principle of the Test	Detection of the HLA B27 ALLELE
Technology	Real-Time PCR with hydrolysis probes
Gene Target	HLA B27
Detected Genotypes	HLA B27
Specimen Type	Whole blood
Minimum DNA Concentration	50 ng/ul DNA
Controls	Negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	Extraction QIAamp DNA Blood Mini Kit (Qiagen), Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek) Amplification Fluorion Detection System (Iontek), MIC*
Status	For in vitro diagnostic use

* Please contact for other instruments

Item	Cat. No.	Pack Size
HLA B27 QLP 1.0 Real-Time PCR Kit CE-IVD	G0570102-2	50 tests
HLA B27 QLP 1.0 Real-Time PCR Kit CE-IVD	G0570102-3	100 tests

MEAT SPECIES IDENTIFICATION

Meat products can be composed of different sources. The composition and ratio of each meat species should be documented on the cover of the package. The variability of meat prices in different regions can cause fraudulent production using undeclared meat species and ratios. The most frequent meat species used are cow, sheep, pig, horse, donkey, turkey and chicken. Former meat species identification techniques include protein electrophoresis or immunological methods. These techniques have a drawback in analyzing complex cooked products since proteins denature upon cooking. DNA is a much stable molecule compared to proteins. Even if DNA may be broken by heat modern molecular techniques are still capable of detecting it. Moreover, in contrast to proteins, DNA can be found in all organs and tissues.

Techniques like hybridization, PCR and PCR-RFLP have been frequently used for meat species identification. However, these techniques are not suitable for analyzing mixtures. On the other hand, Real-Time PCR is especially suitable for mixtures and cooked products, since the target region used for amplification is considerably short (50-150 bp), which enables the analysis of degraded material.

Principle of the Test	Meat Species Identification
Technology	Real-Time PCR with hydrolysis probes
Gene Target	CYTOCHROME B
Detected Species	Cow, sheep, pig, horse, donkey, turkey and chicken
Specimen Type	Meat, tissue
Limit of Detection	0.001% of mixture
Controls	Negative control, positive control
Storage Condition	Below -20 °C
Necessary Equipment	**Extraction** QIAamp DNA Mini Kit (Qiagen), Fluorion i12, i24/i12 Nucleic Acid Extraction Kit (Iontek), ExiPrep 16 Plus (Bioneer) Extraction System Exiprep Tissue Genomic DNA Kit **Amplification** Fluorion Detection System (Iontek), MIC*
Status	RUO

* Please contact for other instruments

Item	Cat. No.	Pack Size
Meat. Spec. Ident. QLP 1.0 Real-Time PCR Kit RUO	F0560102-2	50 tests
Meat. Spec. Ident. QLP 1.0 Real-Time PCR Kit RUO	F0560102-3	100 tests

LABORATORY EQUIPMENT

FLUORION i-SERIES

The Fluorion i-series extraction systems are innovative compact magnetic bead based benchtop workstations for flexible fully-automated isolation of nucleic acids from up to 24 samples.

Usage of pre-filled reagent cartridges and disposable consumables enable a true walk-away automation and high quality extraction.

The systems provide error-free identification with barcode scanner, pre-installed protocols with free updating, ready to use prefilled reagents and all required labware for all sample types. Isolation of pure nucleic acids from a variety of sample types can be performed in 35-50 min. The systems are equiped with UV decontamination and high cross-contamination protection.

Item	Cat. No.	Description	Pack Size
Fluorion i12	FZP01001	Bench-top auto extractor for rapid purification of nucleic acids from 1-12 biological samples	1 instrument and barcode reader
Fluorion i24	FZP01003	Bench-top auto extractor for rapid purification of nucleic acids from 1-24 biological samples	1 instrument and barcode reader

FLUORION

AUTOMATED EXTRACTION KITS

Item	Cat. No.	Description	Pack Size
Fluorion i12 Blood DNA Extraction Kit (200)	FZP02001	For extracting genomic DNA from mammalian whole blood, peripheral blood mononuclear cell, or buffy coat **Sample volume range: up to 400 µL**	1 kit (48 extractions) *including all required plastic disposables*
Fluorion i12 Blood DNA Extraction Kit (1200)	FZP02002	For extracting genomic DNA from mammalian whole blood, peripheral blood mononuclear cell, or buffy coat **Sample volume range: up to 400 µL**	1 kit (48 extractions) *including all required plastic disposables*
Fluorion i12 Viral Nucleic Acid Extraction Kit	FZP02003	For extracting viral nucleic acids from plasma, serum or cell-free body fluids **Sample volume range: up to 400 µL**	1 kit (48 extractions) *including all required plastic disposables*
Fluorion i12 Tissue DNA Extraction Kit	FZP02004	For extracting genomic DNA from a variety of animal tissues, swap and blood stain	1 kit (48 extractions) *including all required plastic disposables*
Fluorion i12 Cultured Cell DNA Extraction Kit	FZP02005	For extracting genomic DNA from up to $5x10^6$ cultured cells	1 kit (48 extractions) *including all required plastic disposables*
Fluorion i12 Bacterial DNA Extraction Kit	FZP02006	For extracting genomic DNA from Bacteria	1 kit (48 extractions) *including all required plastic disposables*
Fluorion i12 HPV DNA Extraction Kit for Swab samples	FZP02007	For extracting HPV DNA from swab sample	1 kit (48 extractions) *including all required plastic disposables*
Fluorion i12 TB DNA Extraction Kit for Swab samples	FZP02008	For extracting ***Mycobacterium tuberculosis*** DNA from sputum, pulmonary and cultured samples	1 kit (48 extractions) *including all required plastic disposables*
Fluorion i12 FFPE DNA Extraction Kit for Swab samples	FZP02009	For extracting genomic DNA from formalin-fixed, paraffin-embedded tissue (FFPE) samples	1 kit (48 extractions) *including all required plastic disposables*
Fluorion i12 Forensic DNA Extraction Kit for Swab samples	FZP02010	For extracting genomic DNA from a wide range of forensic and human identity samples, such as casework or crime-scene samples, dried blood, bone, and sexual assault samples, swabs, and filters.	1 kit (48 extractions) *including all required plastic disposables*
Fluorion i12 Viral/ Pathogen Nucleic Acids Extraction Kit A	FZP02011	For extracting viral DNA/RNA and pathogen DNA from cell free samples	1 kit (48 extractions) *including all required plastic disposables*
Fluorion i12 Viral/ Pathogen Nucleic Acids Extraction Kit B	FZP02012	For extracting viral DNA/RNA and pathogen DNA from swab samples	1 kit (48 extractions) *including all required plastic disposables*
Fluorion i12 Viral RNA Extraction Kit	FZP02013	For extracting viral RNA from plasma or serum.	1 kit (48 extractions) *including all required plastic disposables*
Fluorion i12 Plant DNA Extraction Kit	FZP02014	For extracting gDNA from plant	1 kit (48 extractions) *including all required plastic disposables*
Fluorion i12 Total RNA Extraction Kit	FZP02015	For extracting total RNA from a variety of sample types	1 kit (48 extractions) *including all required plastic disposables*
Fluorion i12 Viral Nucleic Acid Extraction Kit 800	FZP02016	For extracting viral nucleic acids from plasma, serum or cell-free body fluids **Sample volume range: up to 800 µL**	1 kit (48 extractions) *including all required plastic disposables*

PRODUCTS LIST

FLUORION REAL-TIME PCR KITS

MICROBIOLOGY

	VIRAL			
1	Fluorion HCV QNP 2.1	Hepatitis C Virus QUANTITATIVE	IVD-CE	M0020202
2	Fluorion HDV QNP 1.0	Hepatitis Delta Virus QUANTITATIVE	IVD-CE	M0060202
3	Fluorion HIV-1 QNP 1.1	Human Immunodeficiency Virus-1 QUANTITATIVE	IVD-CE	M0290202
4	Fluorion HBV QNP 2.0	Hepatitis B Virus QUANTITATIVE	IVD-CE	M0010202
5	Fluorion CMV QNP 3.0	Human Cytomegalovirus QUANTITATIVE	IVD-CE	M0380202
6	Fluorion H1N1 QLP 2.0	H1N1 QUALITATIVE	RUO	M0480102
7	Fluorion EBV QNP 1.0	Epstein-Barr Virus QUANTITATIVE	IVD-CE	M0360202
8	Fluorion Parvovirus B19 QNP 1.0	Parvovirus B19 QUANTITATIVE	IVD-CE	M0410202
9	Fluorion HSV QLP 2.1	Herpes Simplex Virus 1/2 QUALITATIVE	IVD-CE	M0580302
10	Fluorion HCV Genotyping 1.0	Hepatitis C Virus 1/2/3/4 Genotyping	RUO	M0490302
11	Fluorion BK-JC QLP 1.0	BK Virus- JC Virus QUALITATIVE	IVD-CE	M0540102
12	Fluorion BKV QNP 1.0	BK Virus QUANTITATIVE	IVD-CE	M0610202
13	Fluorion JCV QNP 1.0	JC Virus QUANTITATIVE	IVD-CE	M0620202
14	Fluorion RSV QLP 1.0	Respiratory Syncytial Virus QUALITATIVE	IVD-CE	M1400102
15	Fluorion Influenza A/B QLP 1.0	Influenza A and Influenza B Viruses QUALITATIVE	IVD-CE	M1410102
16	Fluorion nCoV-19 QLP 2.1	SARS-CoV-2 QUALITATIVE	IVD-CE	M1350102
	RESPIRATORY PANELS			
1	Fluorion CoVIDenza QLP 1.0	SARS-CoV-2 and Influenza A and B Viruses QUALITATIVE	IVD-CE	M1360102
2	Fluorion CoVIDenza QLP 1.0	SARS-CoV-2, Influenza A and B Viruses and Respiratory Syncytial Virus QUALITATIVE	IVD-CE	M1370102
3	Fluorion CoVIDenza Plus QLP 2.0	SARS-CoV-2, Influenza A and B Viruses, Respiratory Syncytial A and B Viruses, and Rhinovirus QUALITATIVE	IVD-CE	M1380102
4	Fluorion CoVIDenza Plus QLP 3.0	SARS-CoV-2, Influenza A and B Viruses, Respiratory Syncytial Virus, and Rhinovirus QUALITATIVE	IVD-CE	M1390102
	BACTERIAL			
1	Fluorion MTBC QLP 2.1	*Mycobacterium tuberculosis* QUALITATIVE	IVD-CE	M0030102
2	Fluorion Brucella QLP 2.0	Brucella spp. QUALITATIVE	RUO	M0070102
3	Fluorion VRE QLP 1.0	*Vancomycin-resistant Enterococcus spp. QUALITATIVE*	IVD-CE	M0630102
4	Fluorion MRSA QLP 1.0	*Methicillin-resistant Staphylococcus aureus QUALITATIVE*	IVD-CE	M0350102
5	Fluorion Ureoplasma QLP 1.0	*Ureoplasma spp. QUALITATIVE*	RUO	M0530102
	FUNGAL			
1	Fluorion Aspergillus QLP 1.0	*Aspergillus spp. QUALITATIVE*	IVD-CE	M0510102

MOLECULAR GENETICS

1	Fluorion FVL 4.0	Factor V Leiden Mutation DETECTION	IVD-CE	G0990402
2	Fluorion MTHFR C677 T QLP 4.0	MTHFR C677T Mutation DETECTION	IVD-CE	G1010402
3	Fluorion MTHFR A1298C QLP 4.0	MTHFR A1298C Mutation DETECTION	IVD-CE	G1030402
4	Fluorion Prothrombin G20210A QLP 4.0	MTHFR (Factor II/G20210A) Mutation DETECTION	IVD-CE	G1000402
5	Fluorion PAI-1 4G-5G QLP 4.0	PAI-1 4G/5G Deletion Mutation DETECTION	IVD-CE	G1020402
6	Fluorion HLA B27 QLP 1.0	HLA-B27 Mutation DETECTION	IVD-CE	G0570102
7	Fluorion IL28B QLP 1.0	Interleukin 28B Mutation DETECTION	IVD-CE	G0680402
8	Fluorion HFE H63D QLP 1.0	Hereditary Hemochromatosis H63D Mutation DETECTION	RUO	G0470402

*Fluorion Factor V Leiden (G1691A) QLP 4.0, Fluorion Prothrombin (G20210A) QLP 4.0, MTHFR (A1298C) QLP 4.0, MTHFR (C677T) QLP 4.0, PAI-1 (4G/5G) QLP 4.0 kits have common PCR protocol.

FOOD

1	Fluorion Meat Spec. Ident. QLP 1.0**	Meat Species IDENTIFICATION	RUO	F0560102
	• PORK (Sus scrofa) DNA IDENTIFICATION QLP 1.0*	PORK DNA IDENTIFICATION	RUO	F1070102
	• BOVINE (Bos taurus) DNA IDENTIFICATIN QLP 1.0*	BOVINE DNA IDENTIFICATION	RUO	F1080102
	• HORSE (Equus caballus) DNA IDENTIFICATION QLP 1.0*	HORSE DNA IDENTIFICATION	RUO	F1090102
	• SHEEP (Ovis aries) DNA IDENTIFICATION QLP 1.0*	SHEEP DNA IDENTIFICATION	RUO	F1100102
	• CHICKEN (Gallus gallus) DNA IDENTIFICATION QLP 1.0*	CHICKEN DNA IDENTIFICATION	RUO	F1110102
	• TURKEY (Meleagris gallopavo) DNA IDENTIFICATION QLP 1.0*	TURKEY DNA IDENTIFICATION	RUO	F1120102
	• DONKEY (Equus asinus) DNA IDENTIFICATION QLP 1.0*	DONKEY DNA IDENTIFICATION	RUO	F1130102
2	Fluorion Listeria monocytogenes QLP 1.0	*Listeria monocytogenes* QUALITATIVE	RUO	F0970102
3	Fluorion Salmonella QLP 1.0	*Salmonella spp.* QUALITATIVE	RUO	F0520102
4	Fluorion GMO QLP 1.0	GMO DETECTION	RUO	F0500102

*Can be ordered separately.
**Fluorion Meat Species Identification Kit contains detection mixes for each 7 species.

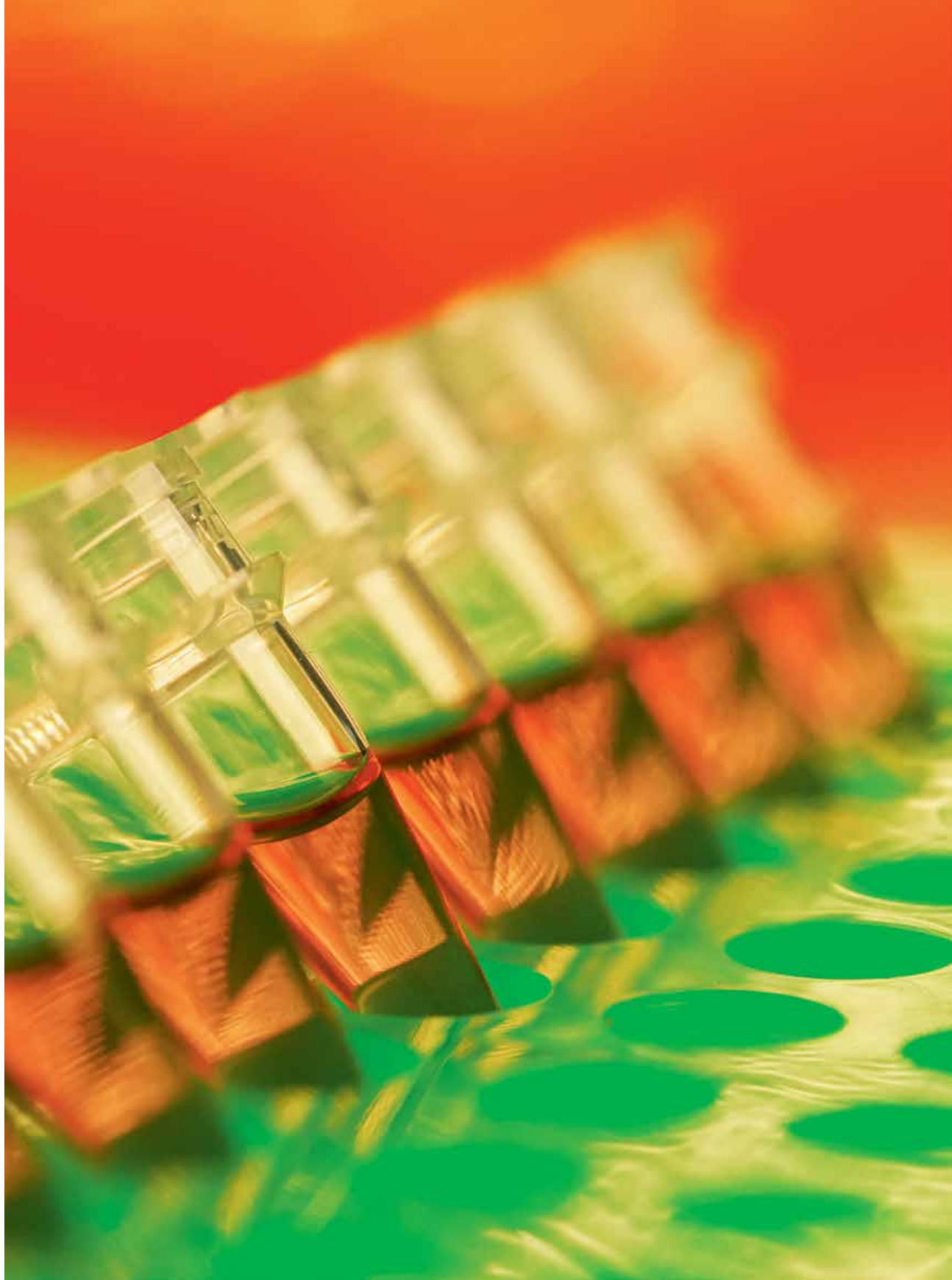
LABORATORY EQUIPMENT

	Real-Time PCR			
1	FDS-48	Fluorion Detection System-48	48 sample capacity	D001001
2	FDS-96	Fluorion Detection System-96	96 sample capacity	D001002
	Extraction Systems			
1	Fluorion	i12 Extraction System	1-12 Extraction	FZP01001
2	Fluorion	i24 Extraction System	1-24 Extraction	FZP01003

FLUORION

AUTOMATED EXTRACTION KITS

	Extraction Kits			
1	Fluorion i12	Blood DNA Extraction Kit (200)	For extracting genomic DNA from mammalian whole blood, peripheral blood mononuclear cell, or buffy coat **Sample volume range: up to 400 µL**	FZP02001
2	Fluorion i12	Blood DNA Extraction Kit (1200)	For extracting genomic DNA from mammalian whole blood, peripheral blood mononuclear cell, or buffy coat **Sample volume range: up to 400 µL**	FZP02002
3	Fluorion i12	Viral Nucleic Acid Extraction Kit	For extracting viral nucleic acids from plasma, serum or cell-free body fluids **Sample volume range: up to 400 µL**	FZP02003
4	Fluorion i12	Tissue DNA Extraction Kit	For extracting genomic DNA from a variety of animal tissues, swap and blood stain	FZP02004
5	Fluorion i12	Cultured Cell DNA Extraction Kit	For extracting genomic DNA from up to $5x10^6$ cultured cells	FZP02005
6	Fluorion i12	Bacterial DNA Extraction Kit	For extracting genomic DNA from Bacteria	FZP02006
7	Fluorion i12	HPV DNA Extraction Kit for Swab samples	For extracting HPV DNA from swab sample	FZP02007
8	Fluorion i12	TB DNA Extraction Kit for Swab samples	For extracting Mycobacterium tuberculosis DNA from sputum, pulmonary and cultured samples	FZP02008
9	Fluorion i12	FFPE DNA Extraction Kit for Swab samples	For extracting genomic DNA from formalin-fixed, paraffin-embedded tissue (FFPE) samples	FZP02009
10	Fluorion i12	Forensic DNA Extraction Kit for Swab samples	For extracting genomic DNA from a wide range of forensic and human identity samples, such as casework or crime-scene samples, dried blood, bone, and sexual assault samples, swabs and filters.	FZP02010
11	Fluorion i12	Viral/Pathogen Nucleic Acids Extraction Kit A	For extracting viral DNA/RNA and pathogen DNA from cell free samples	FZP02011
12	Fluorion i12	Viral/Pathogen Nucleic Acids Extraction Kit B	For extracting viral DNA/RNA and pathogen DNA from swab samples	FZP02012
13	Fluorion i12	Viral RNA Extraction Kit	For extracting viral RNA from plasma or serum	FZP02013
14	Fluorion i12	Plant DNA Extraction Kit	For extracting gDNA from plant	FZP02014
15	Fluorion i12	Total RNA Extraction Kit	For extracting total RNA from a variety of sample types	FZP02015
16	Fluorion i12	Viral Nucleic Acid Extraction Kit 800	For extracting viral nucleic acids from plasma, serum or cell-free body fluids **Sample volume range: up to 800 µL**	FZP02016



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