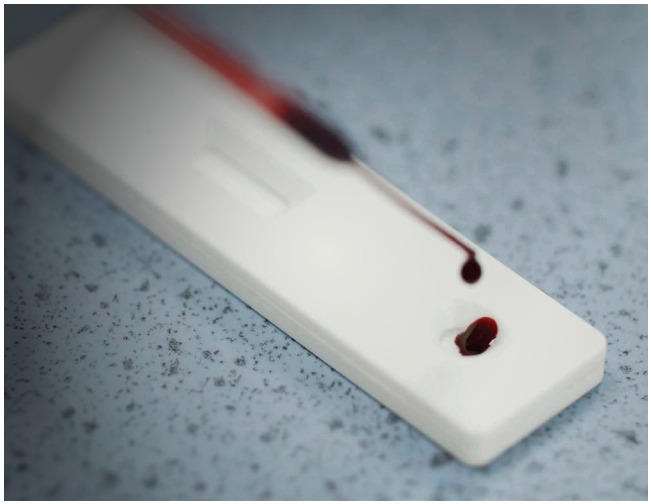

PathFlow®
2021
NOVACYT
GROUP

PathFlow®

Contents



PathFlow® **SARS-CoV-2 IgG**

What is the test?

The assay provides detection of IgG antibodies to SARS-CoV-2 spike (S) protein – receptor binding domain (RBD) and nucleocapsid (N) protein. The test is to aid in the identification of individuals with an adaptive immune response to SARSCoV-2; derived from wild type infection or as a response to vaccination.

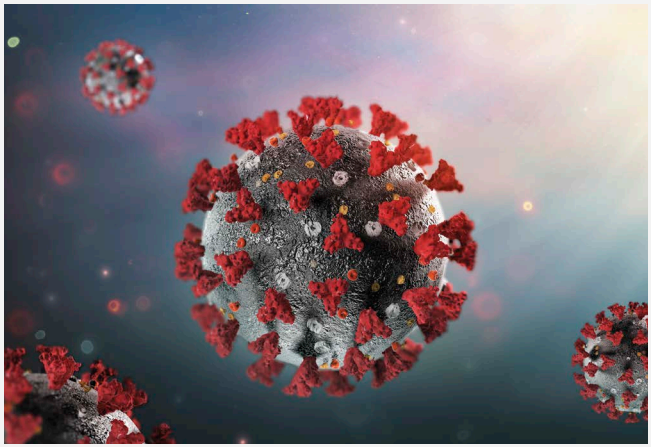
What is the disease?

SARS-CoV-2 belongs to the Coronaviridae family and is closely related to the SARS coronavirus that appeared in 2002/2003[1]. The virus was first identified in humans in Wuhan, China, at the end of 2019 and is transmissible from person to person[2]. The main route of transmission is droplet infection, but infections via aerosols and smear have also been described[2-4]. The incubation period is usually three to seven days, up to a maximum of fourteen days[2]. SARS-CoV-2 infected patients are often asymptomatic or experience only mild symptoms such as a dry cough, fever, and shortness of breath[3,4]. Some of the infected persons develop a severe pneumonia, which can lead to death.

Why use PathFlow?

The PathFlow® SARS-CoV-2 IgG rapid test delivers a high performing and reliable method for the detection of antibodies to the 'S' (RBD) and 'N' proteins of SARS-CoV-2.

PathFlow® offers an easy-to-use solution for antibody testing, without the need for complex levels of equipment or technical knowledge. The assay also provides a rapid turnaround time, with results available from 10-20 minutes. Not only could PathFlow® be used to monitor previous infection prevalence, it may also act as a critical tool to assess vaccine efficacy and subsequent protection offered. The PathFlow® lateral flow testing portfolio entails a broad range of infectious disease diagnostic solutions.



Key features

- Simple to use
- High performing and reliable method
- Detection of antibodies to the 'S' (RBD) and 'N' proteins of SARS-CoV-2
- Results in 10 minutes

Performance	Product Code
Sensitivity – 98%	M598CE
Specificity – 99%	25 tests

PathFlow® **Strep A**

What is the test?

The PathFlow® Strep A Rapid Test Cassette is a rapid test to qualitatively detect the presence of Strep A antigens in throat swab specimens, providing results within 5 minutes.

The test utilizes antibodies specific for whole cell Lancefield Group A *Streptococcus* to selectively detect Strep A carbohydrate antigens in a throat swab specimen.

What is the disease?

Streptococcus pyogenes is an aerobic non-motile grampositive coccus, which contains the Lancefield group A antigens that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis[5].

The bacterium is transmitted via respiratory droplets, hand contact and nasal discharge – patients suffering from streptococcal pharyngitis are infective during the acute phase of illness (7-10 days) and up to 1 week afterwards.

Why use PathFlow?

Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.

PathFlow® Strep A Rapid Test Cassette is a rapid test to qualitatively detect the presence of Strep A antigens in throat swab specimens, providing results from 5 minutes.

Key features

- Rapid detection for the presence of Strep A antigens, providing results from 5 minutes
- Simple and easy to use test, to be used with throat swab samples
- In-built procedural control

Performance	Product Code
Sensitivity – 95.1%	M597CE
Specificity – 97.8%	20 tests

PathFlow® *Streptococcus pneumoniae*

What is the test?

The PathFlow® *S. pneumoniae* Antigen Rapid Test Cassette is a qualitative, membrane-based immunoassay for the detection of *Streptococcus pneumoniae* in human urine specimen.

What is the disease?

Streptococcus pneumoniae, or pneumococcus, is a Gram-positive, alpha-haemolytic (under aerobic conditions) or beta-haemolytic (under anaerobic conditions), facultative anaerobic member of the genus Streptococcus[6].

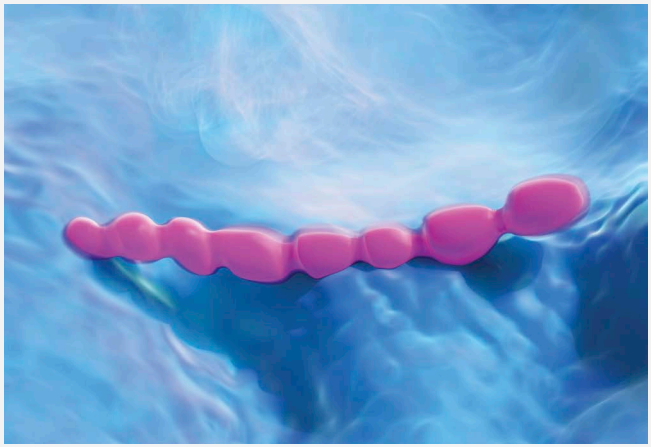
As a significant human pathogenic bacterium *S. pneumoniae* was recognised as a major cause of pneumonia in the late 19th century and is the subject of many humoral immunity studies.

Why use PathFlow?

Typically, bacterial cultivation remains the main diagnostic technique to identify invasive *Streptococcus pneumoniae* – through the growth of bacterium from sterile body fluids (such as blood/spinal fluid).

Cultivation allows for a very accurate diagnosis and can be used to inform appropriate antimicrobial susceptibility however, the process takes time (12-48 hours).

PathFlow® *Streptococcus pneumoniae* rapid test cassette allows for accurate diagnosis to be derived from 15 minutes – providing fast, actionable results.



Key features

- Simple and easy-to-use single step test
- Results available from 15 minutes – considerably faster than traditional culture based diagnostic methods
- In-built procedural control
- Complete system, no additional reagents required

Performance	Product Code
Sensitivity – 90.0%	M594CE
Specificity – 98.9%	10 tests

PathFlow® *Legionella pneumophila*

What is the test?

The PathFlow® *Legionella pneumophila* Rapid Test Cassette is a ready-to-use membrane test based on colloidal gold particles, allowing for the detection of Legionella pneumophila serogroup 1 from a urine sample.

What is the disease?

Legionellosis is a serious pneumonia caused by bacteria of the genus *Legionella,* assigned to the family Legionellaceae.

This family includes 48 species and over 60 serogroups, approximately 20 species are implicated in human disease – predominantly by Legionella pneumophila.

Legionnaires' disease is the major clinical manifestation of Legionella infection, although extra-pulmonary infection and non-pneumonic disease like Pontiac fever can occur.

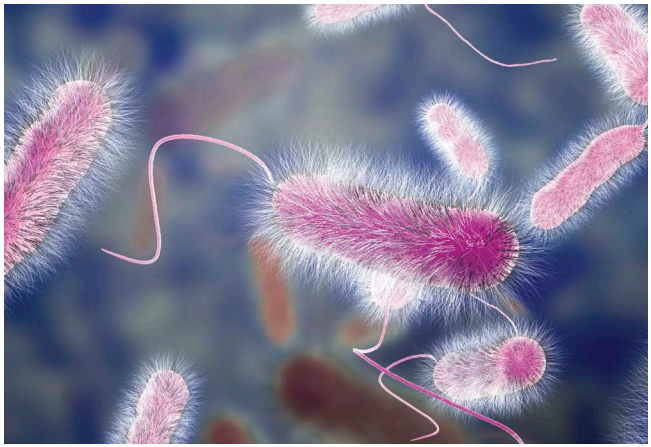
Why use PathFlow?

Diagnosis of legionellosis can be difficult because signs and symptoms are nonspecific and do not distinguish L. pneumophila infections from other common causes of pneumonia.

L. pneumophila infections are considered fairly common, but they are probably underdiagnosed and under-reported.

The underdiagnosis of legionellosis can in part be attributed to the need for rapid, specific and sensitive diagnostic testing methods.

PathFlow® *Legionella pneumophila* allows for rapid and specific diagnosis of *Legionella pneumophila* serogroup 1, providing results from 15 minutes.



Key features

- Complete system, no additional reagents required
- Simple and easy to use
- Rapid result offered. Available after 15 minutes
- In-built procedural control
- Differential detection of Legionella pneumophila serotype 1 from other serotypes and Legionella spp

Performance	Product Code
Sensitivity – 97.6%	M593CE
Specificity – >99.9%	25 tests

PathFlow® **Calprotectin**

What is the test?

The **PathFlow®** Calprotectin is a lateral flow immunoassay for the detection of calprotectin – a potential indicator to aid in the correct diagnosis of inflammatory gastrointestinal disorders.

What is the disease?

Calprotectin (MRP-8/MRP-14 or S100A8/A9 heterocomplex) is named after the calcium-binding proteins it's formed by[7].

The expression of these proteins is largely confined to the intracellular fluid (cytosol) of neutrocytes and monocytes (white blood cells), accounting for approximately 60% of their total soluble proteins.

During periods of inflammation, calprotectin is released from activated neutrocytes and can also be released upon cell damage/death.

This release of calprotectin results in higher levels being present in-patient stools which can directly relate to the severity of inflammation.

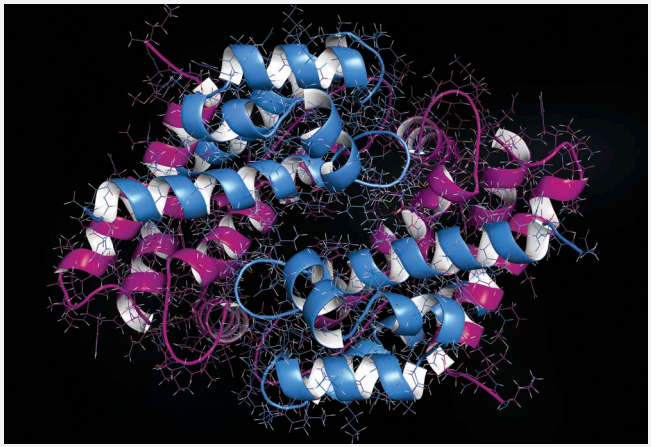
Why use PathFlow?

Faecal calprotectin testing is recommended by NICE to aid distinguishing between inflammatory bowel diseases (such as Crohn's disease/ulcerative colitis) and non-inflammatory bowel diseases (IBS).

These conditions can cause similar symptoms; however, Crohn's disease and ulcerative colitis can also lead to serious complications, so their differential diagnosis is imperative.

Many people with irritable bowel syndrome have unnecessary invasive hospital investigations before their condition is diagnosed.

PathFlow® Calprotectin allows for the potential of a differential diagnosis of IBS, without the need for such invasive investigations.



Key features

- Complete system, no additional reagentsrequired
- Simple and easy to use
- Rapid result offered. Available after 5 minutes
- In-built procedural control
- Can be used with both solid and liquid faecal specimens

Performance	Product Code
Sensitivity – 97.8%	M589CE
Specificity – 99%	10 tests

PathFlow® **Adenovirus**

What is the test?

The PathFlow® Adenovirus antigen Rapid Test Cassette is a qualitative membrane-based immunoassay for the detection of adenovirus antigen in eye conjunctive swabs, throat swabs and nasal swabs.

What is the disease?

Although there are a variety of viruses that can cause infections in the lower respiratory tract (for example, Influenza & RSV) adenovirus are often the most common[8].

Alongside respiratory tract infection, adenovirus have also been implicated in diseases affecting the ocular and gastrointestinal systems.

Human adenoviruses are so far classified into 7 species: HAdV-A to G including a wide range of serovars.

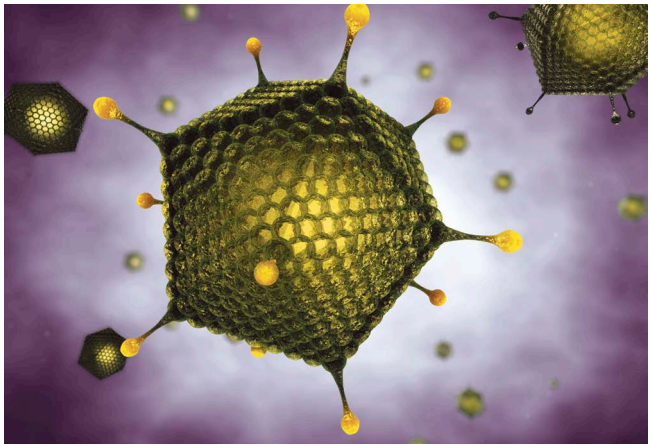
Why use PathFlow?

The differential diagnosis of various forms of conjunctivitis (viral, bacterial, allergic) is often difficult as they manifest similar symptoms.

Cell culture in combination with immunofluorescence is the historical “gold standard” for identifying adenovirus in conjunctival specimens.

Virus isolation requires an intensive process, technical expertise and may take up to 3 weeks to complete.

PathFlow® Adenovirus allows for a rapid method of accurate diagnosis to allow for more appropriate patient management and to control the risk of spreading infections within healthcare institutions.



Key features

- Simple and easy to use system
- Differential detection of adenovirus from other diseases preventing similar symptoms
- Rapid results offered; positive results may be visible from as little as 3 minutes
- Can be used with multiple sample types, including eye conjunctive swabs and throat/nasopharyngeal swabs

Performance	Product Code
Sensitivity – 98.6%	M592CE
Specificity – 98.1%	20 tests

PathFlow® *C. diff* GDH & TOX A/B

What is the test?

The PathFlow® *C. difficile* GDH & Tox A/B Combi Cassette simultaneously detects three distinct antigens in faecal specimens for *C. difficile;* GDH, Toxin A and Toxin B.

What is the disease?

Clostridium difficile is an opportunistic anaerobic bacterium that can grow in the intestine once normal flora has been altered by antibiotics[9] [10] [11].

Toxigenic strains of *C. difficile* can cause infection (*Clostridium difficile* infection – CDI) through the production of two toxins; Toxin A (tissue-damaging enterotoxin) and/or Toxin B (cytotoxin).

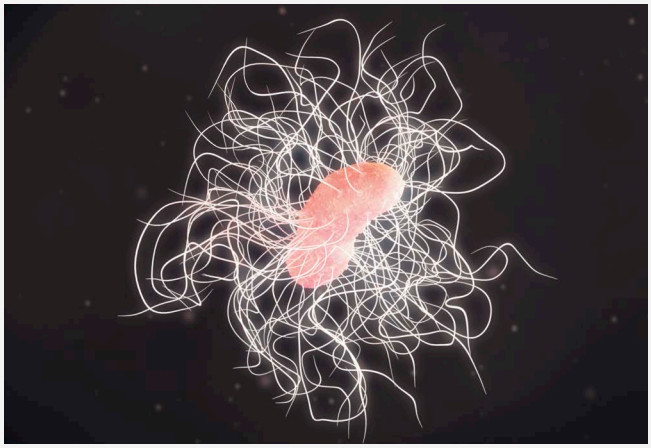
Why use PathFlow?

The PathFlow® *C. difficile* GDH and Tox A/B Combi Cassette allows for the rapid and accurate detection of *C. difficile,* with test results available after 10 minutes.

The ability to conduct simultaneous GDH/Tox A&B testing coupled with rapid provision of results allows for *Clostridium difficile* infections to be managed more effectively.

Key features

- Complete system, no additional reagents required and provides concurrent detection
- Simple and easy to use
- Rapid result offered. Available after 10 minutes or within 10-20 minutes
- Can be used for both solid and liquid specimens.
- In-built procedural control
- Ability to rapidly identify *C. difficile* is key for patient care



Performance – Tested vs. another leading commercial rapid test
GDH
Sensitivity – 98.7%
Specificity – 98.3%
Accuracy – 98.5%
Tox A&B
Sensitivity – 98.2%
Specificity – 98.6%
Accuracy – 98.5%
Product Code
M588CE
25 tests

PathFlow® *H. pylori*

What is the test?

The PathFlow® *H. pylori* Cassette a qualitative, lateral flow immunoassay for the detection of *H. pylori* antigens in human faeces specimens.

What is the disease?

H. pylori is a small, spiral-shaped bacterium that lives in the surface of the stomach and duodenum.

It is implicated in the aetiology of a variety of gastrointestinal diseases, including duodenal and gastric ulcers, non-ulcer dyspepsia and active and chronic gastritis.

Why use PathFlow?

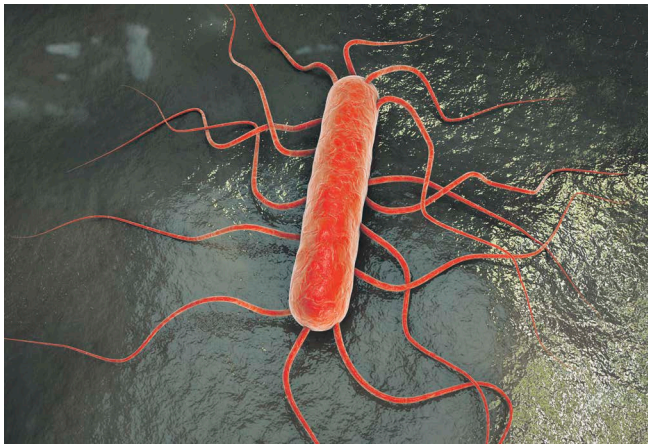
Both invasive and non-invasive methods are used to diagnose *H. pylori* infection in patients with symptoms of gastrointestinal disease.

Specimen-dependent and costly invasive diagnostic methods include gastric or duodenal biopsy followed by urease testing (presumptive), culture, and/or histologic staining[12].

Non-invasive methods include faecal antigen testing, serological testing and UBT (urea breath test).

The UBT is the most expensive diagnostic technique and serological testing does not distinguish past and current infections.

The PathFlow® *H. pylori* Antigen Cassette provides a non-invasive method, for the qualitative detection of *H. pylori* antigens in human faeces allowing for a more cost effective, rapid diagnostic procedure.



Key features

- Complete system, no additional reagents required
- Simple and easy to use; only two steps involved
- Rapid result offered. Available after 10 minutes or within 10-20 minutes
- Can be used for both solid and liquid specimens
- In-built procedural control
- Non-invasive test allowing for rapid detection of *H. pylori* infections to create effective treatment solutions

Performance	Product Code
Sensitivity – 98.8%	M587CE
Specificity – 98.4%	25 tests

PathFlow® **Influenza A&B**

What is the test?

The PathFlow® Flu A/B Combi is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in nasopharyngeal swab, throat swab or nasal aspirate specimens; including (but not exclusive to) subtypes A/H1N1, A/H3N2 and A/H5N1.

What is the disease?

Influenza (commonly known as 'flu') is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus[13].

Seasonal influenza outbreaks occur each year during the autumn and winter months. Type A viruses are typically more prevalent then type B and are associated with the most serious epidemics; whilst type B infections are usually milder – type C is also only usually associated with mild symptoms or asymptomatic carriage.

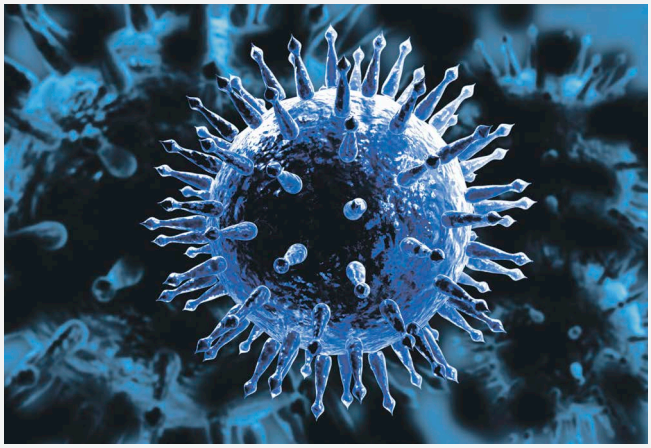
Why use PathFlow?

The gold standard of laboratory diagnosis is 14-day cell culture; however, results are often obtained too late in the clinical course for effective patient intervention.

The PathFlow® Flu A/B Combi qualitatively detects presence of Influenza A and/or Influenza B antigen in nasopharyngeal/ throat swab or nasal aspirate specimens.

Key features

- Complete system, no additional reagents required.
- Simple and easy to use
- Rapid result offered. Available after 15 minutes or within 15-20 minutes
- Can be used for nasopharyngeal swab samples, throat swab samples and nasal aspirate
- In-built procedural control
- Early diagnosis of influenza A/B is paramount in a clinical environment; enabling for the ability to provide greater levels of patient care and management



Performance – Tested vs. RT-PCR Nasopharyngeal Swab Specimen	
Type A	**Type B**
Sensitivity – 99.0%	Sensitivity – 97.7%
Specificity – 98.9%	Specificity – 99.0%
Accuracy – 98.5%	Accuracy – 98.6%
Throat Swab Specimen	
Type A	**Type B**
Sensitivity – 95.1%	Sensitivity – 94.2%
Specificity – 99.3%	Specificity – 99.4%
Accuracy – 98.1%	Accuracy – 97.8%
Nasal Aspirate Specimen	
Type A	**Type B**
Sensitivity – 100%	Sensitivity – 97.9%
Specificity – 99.2%	Specificity – 99.4%
Accuracy – 99.3%	Accuracy – 98.8%
Product Code	
M591CE	
25 tests	

PathFlow® **Rotavirus/Adenovirus**

What is the test?

The PathFlow® Rota/Adeno Combi Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of rotavirus and adenovirus in human faeces; the test utilises antibodies specific for rotavirus and adenovirus to selectively detect rotavirus and adenovirus from specimens.

What is the disease?

Acute diarrhoea disease in young children is a major cause of morbidity worldwide and is a leading cause of mortality in developing countries; rotavirus is the most common agent responsible for acute gastroenteritis, followed by enteric adenoviruses (primarily Ad40 & Ad41)[14] [15].

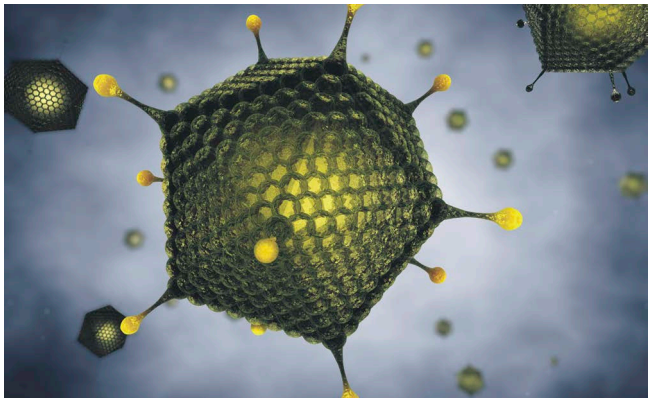
Rotavirus infections occur frequently during winter months, they may be endemic (confined to a population) or may spread widely (epidemic). Infections affecting some thousand people have been reported; In the case of hospitalised children with acute enteritis, up to 50% of the samples examined are rotavirus positive.

Adenoviruses have been isolated throughout the world and can cause diarrhoea in children year-round, frequently seen in children less than two years of age. Further studies indicate adenoviruses are associated with 4-15% of all hospitalised cases of viral gastroenteritis.

Why use PathFlow?

Diagnostic techniques such as electron microscopy (EM) and nucleic acid hybridisation are expensive and labour-intensive.

The PathFlow® Rota/Adeno Combi Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of rotavirus and adenovirus in human faeces, providing results from 10 minutes – offering an easy-touse, rapid alternative.



Key features

- Complete system, no additional reagents required
- Simple and easy to use
- Rapid result offered. Available after 10 minutes or within 20 minutes
- In-built procedural control
- Can be used with both solid and liquid faecal specimens
- Simultaneous testing for rotavirus and adenovirus

Performance – Tested vs. Latex Agglutinationt
Rotavirus
Sensitivity – 97.3%
Specificity – 97.1%
Accuracy – 97.2%
Adenovirus
Sensitivity – 95.2%
Specificity – 97.7%
Accuracy – 96.8%
Product Code
M595CE
25 tests

PathFlow® **RSV**

What is the test?

The PathFlow® RSV is a qualitative, lateral flow immunoassay for the detection of Respiratory Syncytial Virus nucleoproteins in nasopharyngeal swab or nasal aspirate specimens.

What is the disease?

Respiratory Syncytial Virus (RSV), is a common cause of respiratory tract infection and a major cause of respiratory illness in infants and young children (such as bronchiolitis and pneumonia).

Almost all children are infected with RSV at least once by the time they are 2-3 years old.

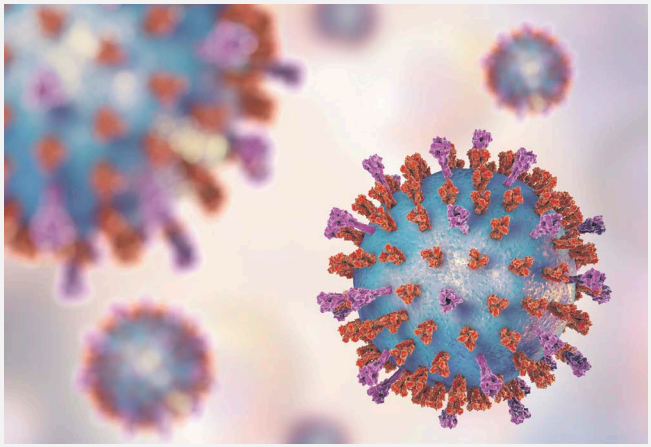
Why use PathFlow?

RSV can be detected in human respiratory samples by a variety of methods, including; virus culture testing and cell culture confirmation, enzyme immunoassay (EIA) and immunofluorescent assay. Although tissue culture remains the diagnostic test standard, it requires culture facilities and can take a considerable amount of time to complete; potentially reducing the ability to make appropriate patient care decisions.

The RSV Rapid Test Cassette qualitatively detects the presence of Respiratory Syncytial Virus antigen in nasopharyngeal swab or nasal aspirate specimens, providing results after 15 minutes, allowing for decision making to be conducted much sooner than alternative methods.

Key features

- Complete system, no additional reagents required
- Simple and easy to use
- Rapid result offered. Available after 15 minutes or within 15-20 minutes
- In-built procedural control
- Can be used with both nasopharyngeal swabs and nasal aspirate specimens



Performance – Tested vs. Tested vs. RT-PCR
Nasopharyngeal Swab Specimen
Sensitivity – 92.7%
Specificity – 98.0%
Accuracy – 95.6%
Nasal Aspirate Specimen
Sensitivity – 92.6%
Specificity – 98.5%
Accuracy – 96.0%
Product Code
M590CE
25 tests

PathFlow® Norovirus

What is the test?

The PathFlow® Norovirus Cassette is a qualitative, lateral flow immunoassay for the detection of norovirus in human faeces.

What is the disease?

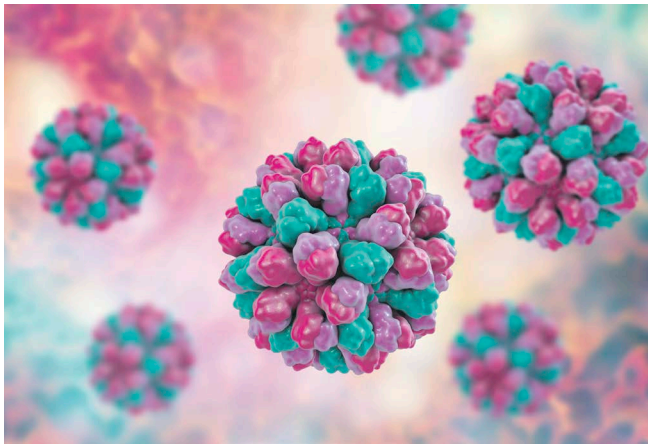
Noroviruses (NoV) are a genetically diverse group of single stranded RNA, nonenveloped viruses belonging to the Caliciviridae family.

Three genogroups have been identified with the genus norovirus. Genogroup 1 and genogroup 2, associated with human infections and genogroup 3, associated with bovine and porcine infection.

Why use PathFlow?

The PathFlow® Norovirus Cassette provides rapid test results allowing for improved decision-making abilities; improving patient management and outcomes.

Swift norovirus identification and detection is pivotal for the prevention and management of outbreaks; especially in a clinical/healthcare environment.



Key features

- Complete system, no additional reagents required.
- Simple and easy to use
- Rapid result offered. Available after 15 minutes or within 20 minutes
- In-built procedural control
- Can be used with both solid and liquid faecal specimens.
- Simultaneous testing for genogroups 1 & 2
- Point-of-care ICD test

Performance	Product Code
Sensitivity – 95.7%	M596CE
Specificity – 91.7%	25 tests

PathFlow® **Mononucleosis**

What is the test?

Qualitative detection of Infectious Mononucleosis from whole blood, serum or plasma patient samples.

What is the disease?

Infectious Mononucleosis (IM), also known as glandular fever, is caused by the Epstein-Barr virus, a member of the herpes virus family. Symptoms of IM are fever, sore throat and swollen lymph glands. In very rare cases, heart or central nervous system problems may arise from infection.

Why use PathFlow?

PathFlow® Mononucleosis is a qualitative, lateral flow immunoassay for the detection of IM heterophile antibodies in whole blood, serum or plasma.

PathFlow® Mononucleosis allows for the differential diagnosis of Infectious Mononucleosis in cases where it may otherwise be diagnosed as cytomegalovirus infection, or streptococcal pharyngitis. Although cytomegalovirus infection is normally managed in much the same way as IM, in pregnant women it can have a very different outcome for the mother's unborn child. Also, diagnosis of IM can prevent the over-prescribing of antibiotics that are usually offered as a result of streptococcal pharyngitis.

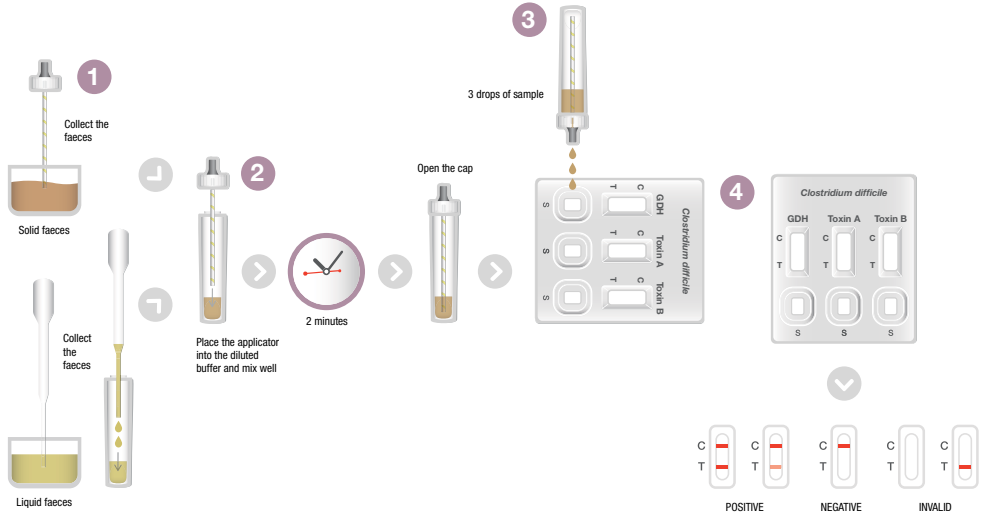
Key features

- A complete detection system, no additional reagents required
- Simple to use, only two steps involved
- Rapid – result offered. Available after 5 minutes or within 5 - 10 minutes
- Works on multiple sample types
- In-built procedural control

Performance	Product Code
Sensitivity – 97.6%	M120CE
Specificity – 97.8%	25 tests

Example Procedure Guides

Faecal Specimen Procedure Guide



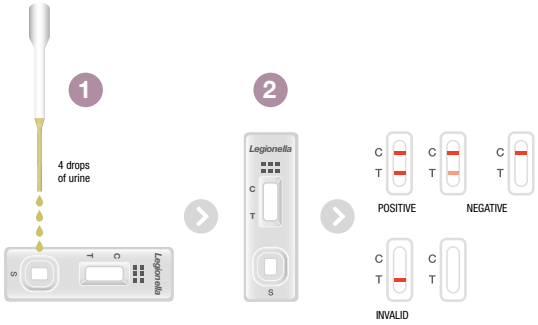
STEP 1. Collect the faecal specimen; the assay will produce optimum results if performed 6 hours within collection.

STEP 2. Solid Specimens – Unscrew the cap of the specimen collection tube and collect approximately 50mg of faeces. Liquid Specimens – Hold the dropper vertically, aspirate faecal specimens and then transfer 2 drops of liquid specimen (approximately 80µl) into specimen collection tube. Tighten cap on collection tube, then mix vigorously and leave for 2 minutes. Bring the pouch up to room temperature, remove test cassette from the foil pouch and use it ASAP.

STEP 3. Hold the specimen collection tube upright and unscrew the cap. Invert the tube and transfer 3 full drops of specimen to each well on the testing cassette.

STEP 4. Read the result after 10 minutes, do not read after 20 minutes.

Urine Specimen Procedure Guide



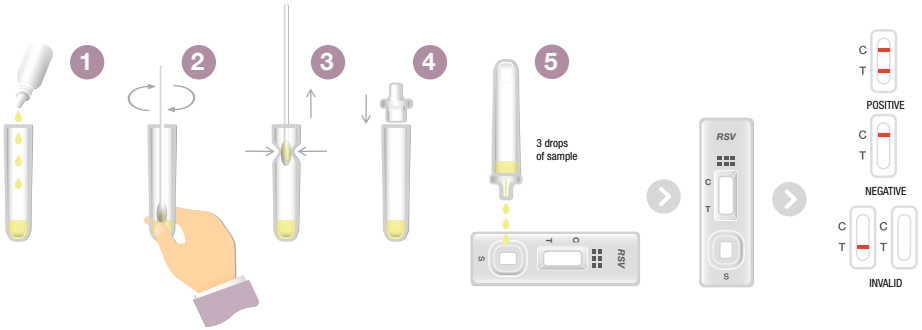
STEP 1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.

STEP 2. Swirl the urine sample gently to mix before testing.

STEP 3. Add 4 drops of homologised urine sample to the sample well.

STEP 4. Wait for the colour line to appear. Read the results at 15 minutes, do not interpret the results after 20 minutes.

Respiratory Specimen Procedure Guid



STEP 1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Place the extraction tube in the workstation – hold the reagent bottle upside down and squeeze the bottle to let the solution drop into the extraction tube, adding 10 drops.

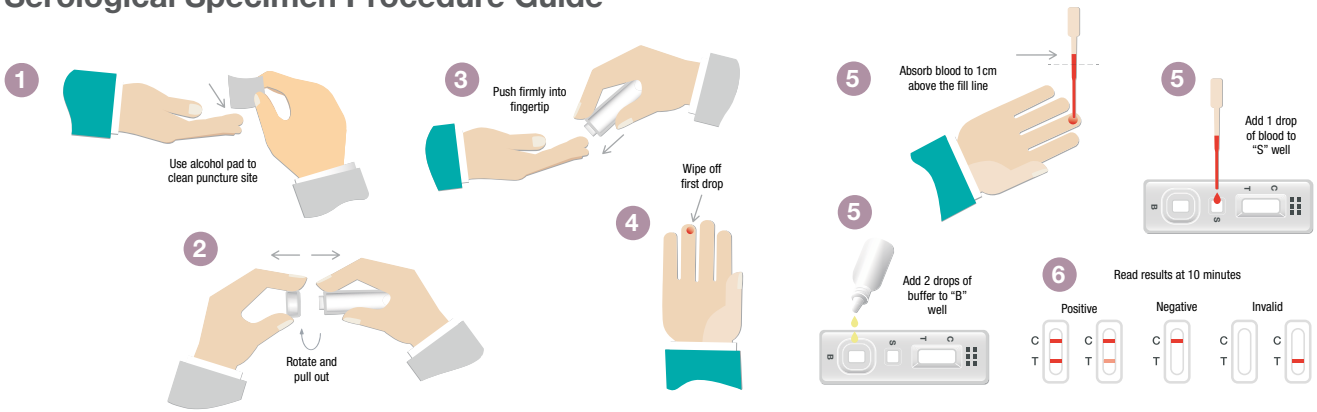
STEP 2. Place the swab specimen in the extraction tube, rotate the swab for approximately 10 seconds.

STEP 3. Remove the swab while squeezing the swab head against the inside of the extraction tube.

STEP 4. Fit the dropper tip on top of the extraction tube.

STEP 5. Add three drops of the solution to the sample well and start the timer. Read the result at 15 minutes and do not interpret after 20 minutes.

Serological Specimen Procedure Guide



STEP 1. Use alcohol pad to clean the fingertip of the middle finger or ring finger as the puncture site.

STEP 2. Carefully rotate and pull off the lancet cap.

STEP 3. Push the sterile lancet firmly into the fingertip of the middle finger.

STEP 4. Wipe off the first drop of blood. To increase blood flow, use the thumb and forefinger to gently apply pressure around the puncture site.

STEP 5. Hold the dropper vertically, draw the blood to 1cm above the fill line and transfer 1 full drop of blood (approximately 20µl) to the specimen well (S), then add 2 drops of buffer (approximately 80µl) to the buffer well (B), and start the timer.

STEP 6. Wait for the coloured line(s) to appear. Read results at 10 minutes. Do not interpret the result after 20 minutes.

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