

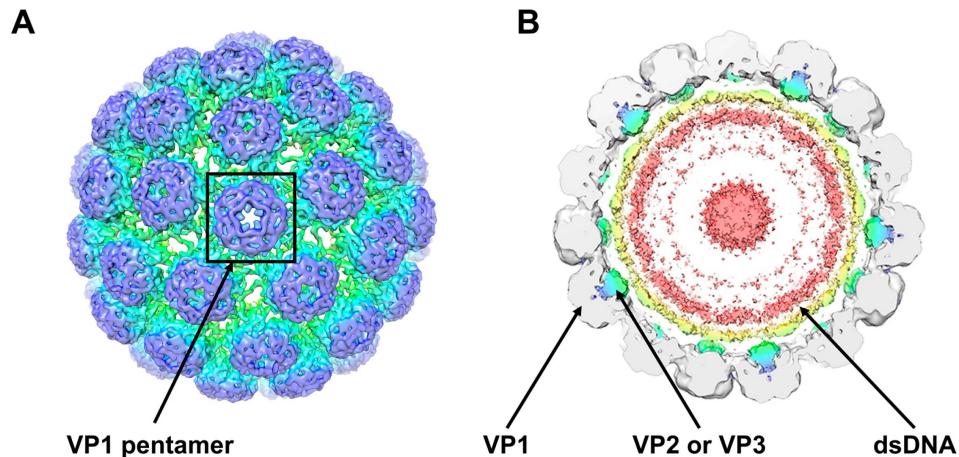


Anti-BKV IgG ELISA

BK virus (BKV) Human polyomavirus 1

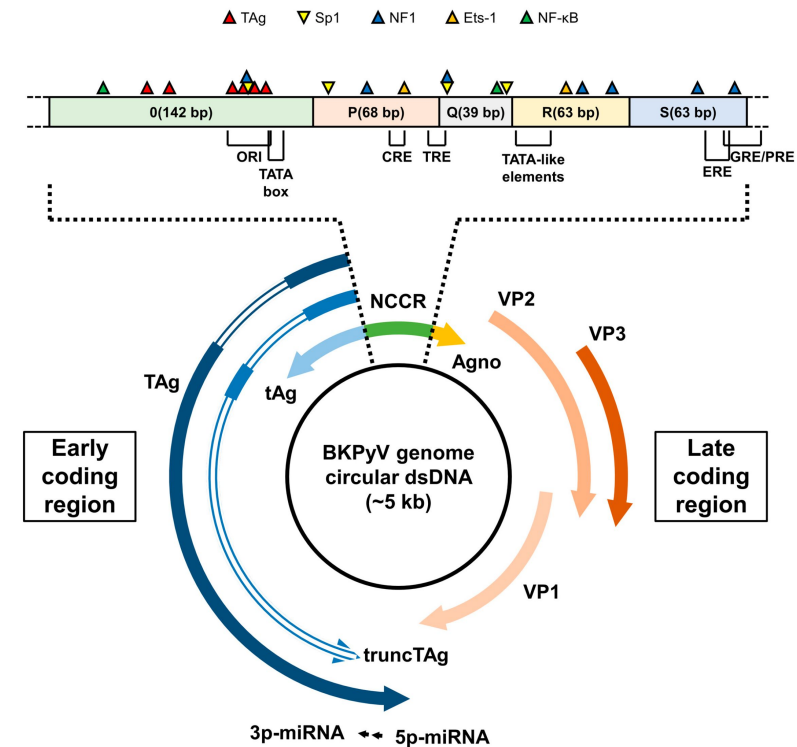
The **BK virus (BKV)** was first isolated in **1971**, by **Gardner et al.**, after inoculation of Vero cells with urine samples from a **39-year-old Sudanese male with the initials B.K.**, who had undergone renal transplantation because of chronic pyelonephritis and advanced renal failure.

It shares a **75% sequence homology with JCV** and **69% - SV40**.



BKV replicates only in human or monkey cells.

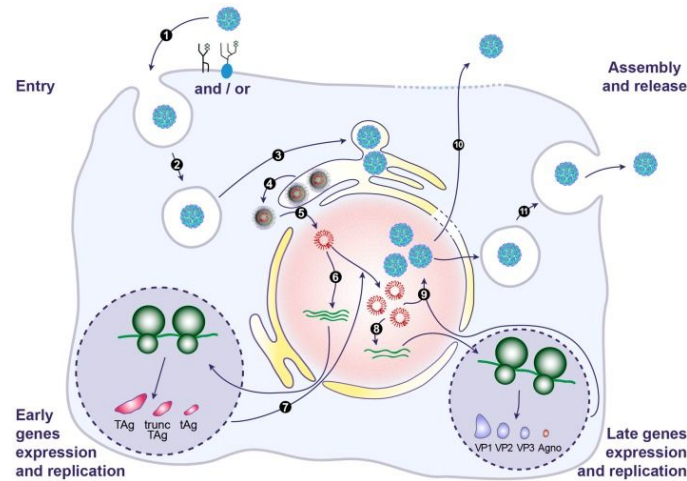
5kb closed circular double-stranded DNA



1. BKV life cycle.

- **Binding of BKV to target cells**
- Internalization
- Viral genome transportation to nucleus
- Viral DNA replication
- Virion assembly
- Cell lysis and virions release

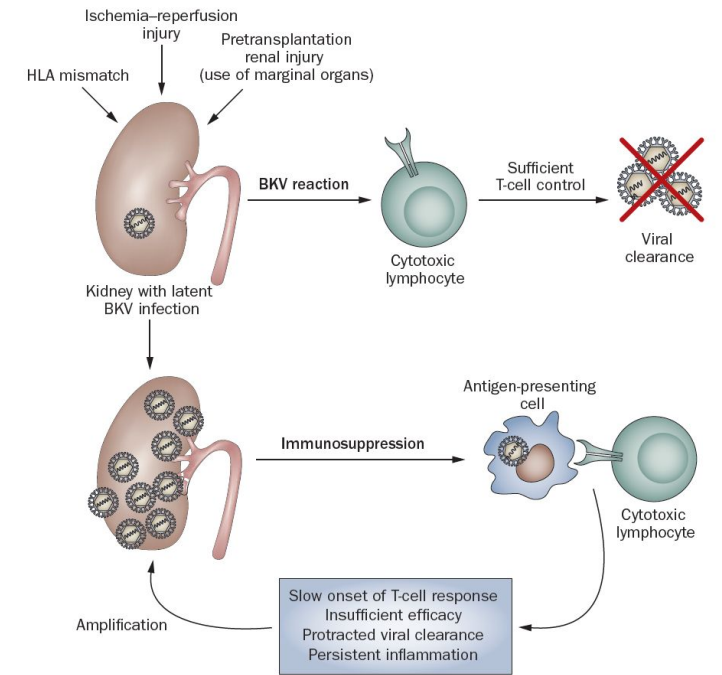
1. BKV life cycle



2. Clinical outcome of BKV reactivation.

- Insufficient or only partial T-cell-mediated responses
- Persistent intragraft inflammation
- Cytotoxic T cells migrate into the inflamed area and attack graft cells
- Tissue damage further increases intragraft inflammation

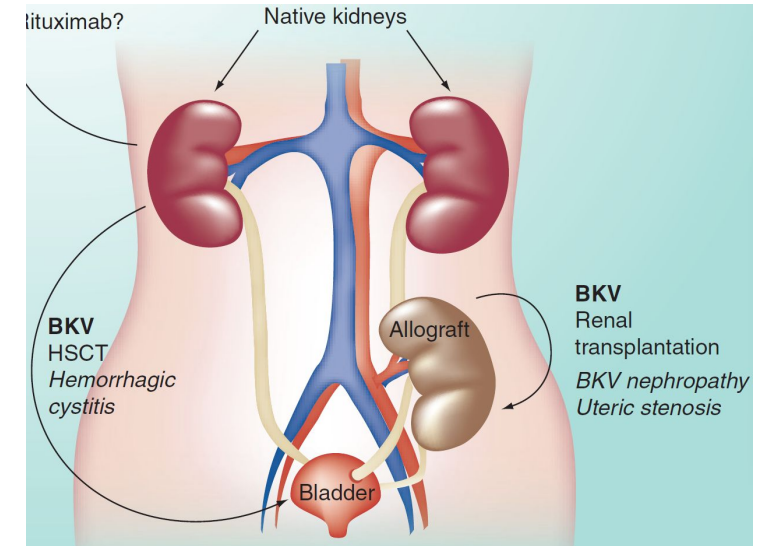
2. Clinical outcome of BKV reactivation



3. BKV associated diseases.

BKV-associated nephropathy (BKVAN)

Uteric stenosis (ureteral stricture) is a narrowing of the tube carrying urine from the kidney to the bladder, causing functional obstruction, pain, and potentially kidney damage. Hemorrhagic cystitis is a severe, painful bladder inflammation characterized by diffuse bleeding (hematuria)



3. BKV associated diseases

The **BK virus (BKV)** — is very common in humans.

Primary infection usually occurs in **early childhood**. Studies show that **around 70% of children are infected by the age of 10**.

In most healthy people, the infection causes **no symptoms or only mild respiratory illness**.

After that, the virus **does not disappear**. Instead, it remains **latent (inactive)** in the body, mainly in the **kidneys and urinary tract cells**.

For many years, it stays quiet.

BK polyomavirus (BKV) is a member of the Polyomaviridae family of double-stranded DNA viruses.

The BK virus (BKV) — also called Human polyomavirus 1 — is very common in humans. In fact, most people become infected during childhood, often without even knowing it.

The virus was first identified in 1971, and its name comes from the initials of the first patient from whom it was isolated.

What happens after infection?

Primary infection usually occurs in **early childhood**. Studies show that **around 70% of children are infected by the age of 10**. In most healthy people, the infection causes **no symptoms or only mild respiratory illness**. After that, the virus does not disappear. Instead, it remains **latent (inactive)** in the body, mainly in the **kidneys and urinary tract cells**.
For many years, it stays quiet.

When does it become a problem?

The situation changes in **immunocompromised patients**, especially **kidney transplant recipients**.

Because these patients must take **immunosuppressive therapy** to protect the transplanted organ, the immune system becomes weaker. This can allow the **latent BK virus to reactivate**.

When reactivation occurs, it may lead to **BK virus-associated nephropathy (BKVAN)**, a serious complication that can cause **graft dysfunction or even graft loss in up to 30% of cases**.

Another challenge: **there are currently no effective antiviral drugs for BKV**. The main strategy to control infection is often **reducing immunosuppression and restoring the patient's immune response**.

Key facts clinicians should know

- **BK viraemia** (virus in urine) occurs in up to **30% of patients**
- **BK viraemia** (virus in blood) occurs in **10-20% of patients**
- **BKV-associated nephropathy** develops in about **3% of kidney transplant recipients**

Risk factors may come from three main sources:

- The donor
- The recipient
- The transplant procedure itself

Is viral load monitoring enough?

Today, most transplant centers rely on **BKV DNA viral load testing using qPCR** for routine monitoring. While this approach is important, **the incidence of BKV-associated nephropathy has remained stable**, even with regular screening. This suggests that **viral load alone does not give the full picture**.



After kidney transplantation, **30–40% of patients develop early BK virus (BKV) replication.**

BKV infection can lead to **BKV-associated nephropathy (BKVAN)**

This may cause **graft dysfunction and even graft loss.**

■ After kidney transplantation, **30-40% of patients develop early BKV replication**



Key Facts Clinicians Should Know!

**BK viruria
(virus in urine) occurs
in
up to 30%
of patients**

**BK viraemia
(virus in blood) occurs
in
10–20% of patients**

**BKV-associated
nephropathy develops
in about 3% of kidney
transplant recipients**

Key Risk Factors!

DONOR

RECIPIENT

SURGERY

Is Viral Load Monitoring Enough?

- Today, most transplant centers rely on **BKV DNA viral load testing using qPCR** for routine monitoring.
- While this approach is important, **the incidence of BKV-associated nephropathy has remained stable**, even with regular screening.
- This suggests that **viral load alone does not give the full picture**.

THE BEST APPROACH IS TO EVALUATE VIRAL LOAD MONITORING TOGETHER WITH BKV-IgG. This provides a **better understanding of the patient's immune status**, helps **identify high-risk patients earlier**, and allows clinicians to **adapt monitoring and management strategies**.

Why BKV-specific IgG matters

- BKV-specific IgG antibodies reflect the patient's immune response to the virus.
- **High donor BKV-IgG levels** are strongly linked to **post-transplant BK viremia and BKVAN**.
- **Recipients without BKV-IgG antibodies** have a **higher risk of infection after transplantation**.

• **The highest risk profile occurs when there is:
High donor BKV-IgG + Low recipient BKV-IgG + Low BKV-specific cellular immunity**

- Tracking **BKV IgG antibodies** can significantly improve how we **predict infection risk and protect kidney grafts**.

VIDIA is currently the only company in the world that manufactures a dedicated anti-BKV IgG ELISA test

- **Qualitative and semiquantitative determination** of IgG antibodies
- Uses **recombinant species-specific BKV antigens**
- **Reliable and reproducible results**
- **Color-coded ready-to-use reagents** for easier workflow
- **Room temperature incubation** for convenient laboratory handling
- Helps clinicians **assess risk before transplantation and monitor patients after the procedure.**



Key Benefits of the VIDITEST anti-BKV IgG ELISA kit

- ✓ **Qualitative and semiquantitative evaluation** of BKV IgG antibodies
- ✓ Supports **pre-transplant serological testing**
- ✓ Enables **accurate monitoring of BKV infection in transplant patients**
- ✓ Provides **standardized and high-quality results**

With **anti-BKV IgG ELISA – VIDITEST**, laboratories have access to a **specialized diagnostic tool designed to support safer and more precise kidney transplant monitoring.**

Summary

1. **The BK virus (BKV)** is very common in humans. Most people become infected during childhood, often without even knowing it.
2. **BK virus–associated nephropathy (BKVAN)**, a serious complication that can cause **graft dysfunction or even graft loss in up to 30% of cases**.
3. **There are currently no effective antiviral drugs for BKV.** The main strategy to control infection is often **reducing immunosuppression and restoring the patient’s immune response**.
4. Today, most transplant centers rely on **BKV DNA viral load testing using qPCR** for routine monitoring. While this approach is important, **the incidence of BKV-associated nephropathy has remained stable**, even with regular screening. This suggests that **viral load alone does not give the full picture**.
5. The best approach is to **combine BKV viral load monitoring with BKV-specific IgG testing**. This provides a **better understanding of the patient’s immune status**, helps **identify high-risk patients earlier**, and allows clinicians to **adapt monitoring and management strategies**.
6. **VIDIA is currently the only company in the world that manufactures a dedicated anti-BKV IgG ELISA test**, providing laboratories and transplant centers with a specialized tool to evaluate immune response to BK virus.
7. **anti-BKV IgG ELISA test can significantly improve how we predict infection risk and protect kidney grafts.**



THE WAY TO THE CORRECT RESULTS...