"[With the ImmuKnow assay], we may be able to target early levels of T cell activity after transplant to have an impact on the severity of HCV recurrence."

—Cabrera, et al. *Liver Transpl.* 2009[1]

Being in the Know Gives You Crucial Insight for Individualized Patient Management

- ImmuKnow assay results help you define a range of stable immune function for each of your patients
- ImmuKnow assay results that lie outside an individual patient's defined stable range may help indicate increased risk of infection or rejection
- Combined with individual patients' clinical factors and other routine monitoring tests, ImmuKnow assay results help guide decisions in therapy to avoid over- or under-immunosuppression

“…infectious complications are a major source of morbidity and mortality in transplant recipients…”

—American Society of Transplantation, 2006[6]

You Know About the Risk of Over-immunosuppression

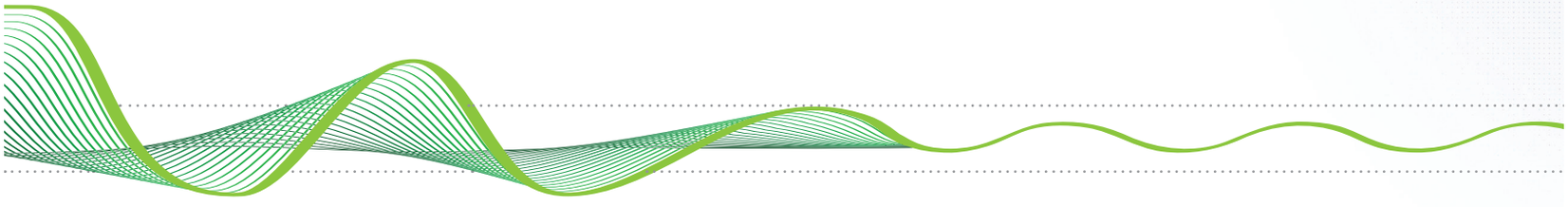
- Potent immunosuppressive drugs have reduced the incidence of allograft rejection while increasing susceptibility to infection and malignancy[2]
- Over-immunosuppressed patients are at increased risk for opportunistic infections, including reactivation of latent viral infections[2]
- 50%-75% of transplant patients will have evidence of microbial invasion in the first year posttransplant[3]
- Immunosuppressant drug labeling must now include stronger warnings about the increased risk for viral infections related to over-immunosuppression[4]
- The FDA recently recommended that transplant patients be monitored closely for signs of over-immunosuppression to reduce the risk of infection[4]
- Immunosuppressant drug monitoring is insufficient for determining the level of immunosuppression or directing changes in treatment regimens[5]

“…serial measurements of the [ImmuKnow] immune cell function assay in kidney transplant recipients might be used to identify patients who require more intensive monitoring for the development of BK virus nephropathy.”

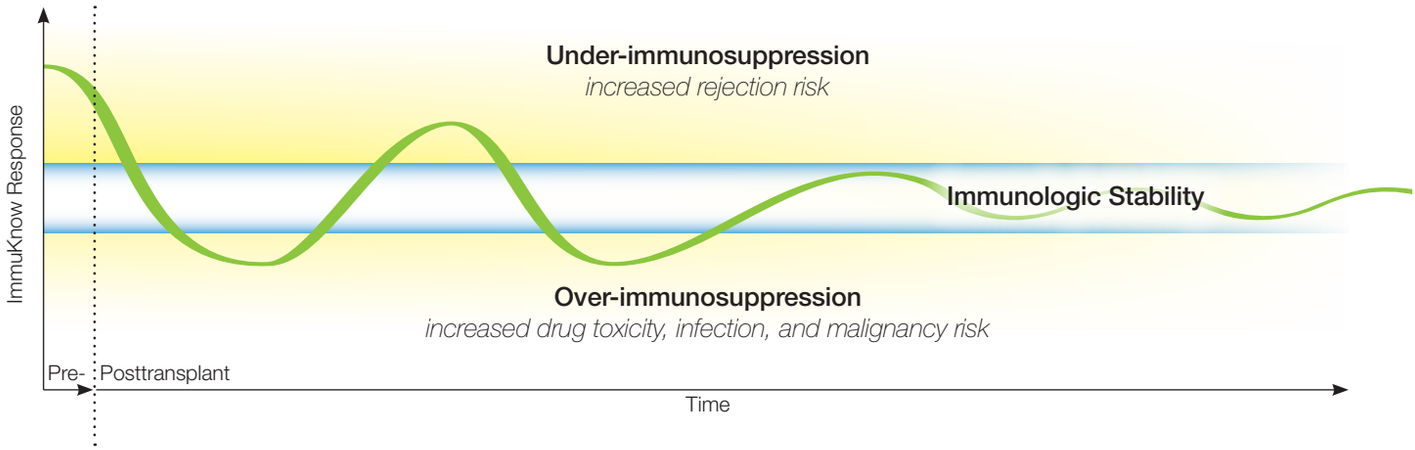
—Batal, et al. *Am J Clin Pathol.* 2008[9]

Assessing Global Immune Function Over Time Puts You in the Know

- ImmuKnow detects changes in CD4 cell ATP production, a known biomarker of global immune function[7,8]
- Used over time, the ImmuKnow assay provides important qualitative information about changes in immune function
- Working from a baseline established for each patient, the ImmuKnow assay is repeated regularly for longitudinal, individualized assessment of changes in global immune status



Longitudinal Assessment of Posttransplant Immune Status



Get to Know ImmuKnow

- ImmuKnow—the only FDA-cleared assay that detects changes in global immune function over time
- Helps identify transplant patients at risk of infection due to over-immunosuppression
- Helps guide decisions in therapy to avoid over- or under-immunosuppression

Patient Immune System Monitoring*†

Time	Interval
Pretransplant	Test as needed to establish baseline values
Months 1-6	Test every 2 weeks
Months 7-12	Test monthly
After Year 1	Perform routine monitoring (at minimum, test quarterly)

*Additional assays may be required in the event of changes in clinical status or posttransplant complications

†Based on therapeutic drug monitoring recommendations described in immunosuppressant agent prescribing information

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"[The ImmuKnow assay] may be useful in identifying [lung transplant] patients with fungal colonization who are at risk for progressing to fungal disease and might benefit from antifungal prophylaxis and close monitoring of immunosuppression."

—Husain, et al. *Transplantation.* 2009[12]

Know the Facts on ImmuKnow

- The utility of the ImmuKnow assay has been well characterized and validated
  - Over 400,000 assays run
  - 25 prospective and interventional studies in more than 1000 transplant recipients
  - More than 120 clinical studies
- To date, global immune status monitoring has been used to:
  - Identify kidney,[10] liver,[1] lung,[11,12] and heart[13] transplant patients with low immune response, which has the potential to lead to infection
  - Define immunologic stability in various solid organ transplant patients[13,14]
  - Longitudinally assess changes in transplant patients' immune status, giving clinicians an additional tool in treatment optimization decisions[1,13-15]
- The ImmuKnow assay is FDA cleared and reimbursable

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Be in the know.
Add ImmuKnow to your transplant patient monitoring test strategy.

In the Know
ImmuKnow®

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