

The critical role of diagnostics in transplant programs

Key ways labs affect health systems' readiness

The first human organ was transplanted successfully in 1954. Since then, ongoing medical advances in the prevention and treatment of rejection have led to more successful transplants.

Although it's impossible to eliminate disease transmission in organ transplantation, there are several ways to mitigate risk¹:

- Risk stratification from the donor's medical and social history
- Careful clinical assessment of the donor and the donor organ(s)
- · Laboratory screening of the donor for infection

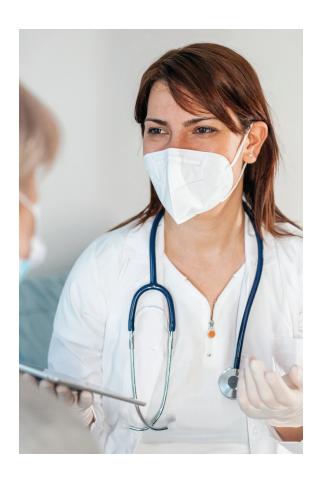
According to the guidelines from the Infectious Diseases Community of Practice of the American Society of Transplantation, unexpected infections occur in approximately 0.2% of solid organ transplant recipients (SOTR). These can include viral pathogens such as HIV, hepatitis C virus (HCV), lymphocytic choriomeningitis virus (LCMV), rabies, or West Nile virus (WNV); fungal infections; or bacterial infections such as *Mycobacterium tuberculosis* or multidrug-resistant (MDR) bacteria.



Currently, **all organ donors in the US must be tested for HCV** with both serology and nucleic acid testing (NAT)¹



It has been estimated that **5% of organ donors have bacteremia** at the time of organ procurement^{1,3,4}



The increasing demand for organ transplants

Today there are many more individuals who could benefit from organ transplantation than there are available organs.

According to Health Resources and Services Administration in 2020, there were nearly **184,000 transplant registrations** in the US, while the number of **organ donors was as low as 18,316.**⁵

Rise in organ failure cases is driving demand⁶

- Increasing number of patients suffering from chronic diseases
- Growing number of blood donors driving demand to ensure donor-recipient compatibility
- Rising geriatric population who are more prone to health problems and organ failure
- Escalating number of injuries from severe road accidents or collisions

Expect more from Quest Diagnostics°

Comprehensive support at all stages of the transplant

From pretransplant testing to monitoring outcomes, the clinical laboratory plays a key role in the success of transplant programs. Just as medical innovation has evolved, health systems should reform expectations of the lab, stretching beyond standard testing.

Pretransplant donor testing

Clinicians and labs work together to achieve 5 main goals of pretransplant screening.

- 1. Identifying infections which may disqualify either the donor or recipient
- 2. Facilitating transplants from donors infected with certain pathogens to recipients who are already infected with those agents (ie, HCV or HIV)
- 3. Identifying and treating active pretransplant infections
- 4. Defining the risk of infection and determining strategies for preventing or mitigating posttransplant infections
- 5. Implementing prophylactic interventions, such as updating vaccination status



Expect more:

- Full menu of transplant testing required for human cells and tissue testing
- FDA-registered lab
- Test results delivered within 24 hours of receipta

Matching donor and recipient testing

Histocompatibility testing including comprehensive cell and tissue panels, and human leukocyte antigen (HLA) testing.



Expect more:

- Prioritized HLA testing that can meet the accelerated timelines of transplants^a
- Tools like a specialized volume calculator can help provide simple specimen requirements for each test in the transplant testing portfolio. As you select multiple tests, the calculator keeps a running tally of the total volume needed, removing any guesswork and streamlining the process

Posttransplant testing

Monitor graft success and guard against potential risk from opportunistic and nosocomial infection in immunosuppressed patients.



Expect more:

- Same-day results for infectious disease screening^a
- Access to longitudinal patient results for insights that can guide long-term care decisions

Health system readiness check:

a transplant diagnostics program that looks at the whole picture

In 2021, there were more organ transplants than ever in a single year,⁷ signaling a positive trend in these life-saving interventions and shining a spotlight on health systems' preparedness.

Redefining expectations of the lab to push the innovation limits of testing and offer comprehensive services can streamline health systems' processes and optimize outcomes of transplant programs.

How well does your lab meet the heightened expectations?

	Innovation and technology that can accelerate critical decisions	
	Latest in HLA transplant testing technology that delivers fast results (24 hours for donor testing and within 8-12° hours for posttransplant testing	
	HLA donor/recipient matching	
	Posttransplant infectious disease testing	
	Access to longitudinal patient results for insights that can guide long-term care decisions	
En	d-to-end support that can help optimize outcomes	
	Dedicated transplant services team that is specially trained to:	
	☐ Address specific testing needs	
	☐ Deliver proactive customer notifications	
	☐ Track specimens, coordinate medical/scientific consultations	
	Seamless access to ordering and results across your health system with LIS/EHR connectivity	
	Access to MDs and PhDs ready to help guide test selection and interpret results	
Inf	rastructure that helps balance care with cost	
	Comprehensive transplant testing portfolio to help support testing needs across the transplant journey	
	Ample testing locations are accessible to patients	
	Extensive health plan coverage	
	Flexible billing to simplify reimbursement	

Above and beyond

Expertise in cancer screening

Cancer screening in SOTRs is crucial as there is a reported 2- to 3-fold increased risk of cancer-specific mortality compared with the general population.⁸

A single source with a comprehensive cancer test menu; board-certified pathologists, dermatologists, and medical experts; leading technology; and committed customer service can help with early detection and insights that may improve outcomes

Agility to address major healthcare developments

The impact of the SARS-CoV-2 (COVID-19) pandemic on solid organ transplants has been profound. In the US, approximately 75% of SOTRs diagnosed with COVID-19 required hospital admission.⁹

Adaptive testing programs—including molecular diagnostic tests, antibody serology tests, and cotesting panels for differential diagnosis of COVID-19, flu, RSV, and other respiratory infections—can help expedite the right treatment



Quest Diagnostics is an **industry leader in laboratory diagnostics and information services with clinical experts, resources, and services** to help optimize your transplant program and power better outcomes for recipients.

- Complete diagnostic menu from routine to specialized
- Dedicated transplant services team
- Broad health plan coverage with most major insurers makes testing more accessible and can encourage adherence
- Over 2,250 Patient Service Centers nationwide makes it easier for patients to follow through with testing
- Prioritized testing meets the accelerated timelines of transplants, with results provided within 24 hours for donor testing and within 8-12^a hours for posttransplant testing

- Patient assistance programs for those who qualify help ensure that uninsured patients receive care, with each case handled personally
- Quanum® Lab Services Manager platform and connectivity with over 800 EHR systems help you manage all your lab testing needs
- 650+ MDs, PhDs, and genetic counselors are available for consultation on test selection and results interpretation^b

References

- 1. Wolfe CR, Ison MG; On behalf of the AST Infectious Diseases Community of Practice. Donor derived infections: Guidelines from the American Society of Transplantation Infectious Diseases

 Community of Practice. Clin Transplant. 2019;33:e13547. doi.org/10.1111/ctr13547
- Community of Practice. Clin Transplant. 2019;33:e13547. doi.org/10.1111/ctr.13547

 2. Malinis M, Boucher HW, for the AST Infectious Diseases Community of Practice. Screening of donor and candidate prior to solid organ transplantation—Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019;33(9):e13548. doi: 10.1111/ctr.13548
- Lumbreras C, Sanz F, González A, et al. Clinical significance of donor-unrecognized bacteremia in the outcome of solid-organ transplant recipients. Clin Infect Dis. 2001;33(5):722-726. doi:10.1086/322599
- 4. Singh N. Impact of donor bacteremia on outcome in organ transplant recipients. Liver Transpl. 2002;8(10):975-976. doi:10.1053/jlts.2002.0080975
- 5. HRSA. Detailed description of data: Patients on the waiting list vs transplants performed by organ (2021). Published March 2022. Accessed June 13, 2022. https://www.organdonor.gov/learn/organ-donation-statistics/detailed-description#fig1
- 6. Imarc. Transplant diagnostics market share, size, growth, opportunity and forecast 2022-2027. Accessed May 19, 2022. https://www.imarcgroup.com/transplant-diagnostics-market
- 7. Organ transplant trends. UNOS. Published January 11, 2022. Accessed May 18, 2022. https://unos.org/news/2021-all-time-records-organ-transplants-deceased-donor-donation 8. Dharia A, Boulet J, Sridhar VS, et al. Cancer screening in solid organ transplant recipients: a focus on screening liver, lung, and kidney recipients for cancers related to the transplanted
- organ. Transplantation: 2022; 106(1):e64-e65. doi:10.1097/TP.00000000000003773

 9. Heldman MR, Kates OS. COVID-19 in solid organ transplant recipients: a review of the current literature. Curr Treat Options Infect Dis. Epub June 29, 2022. doi:10.1007/s40506-021-00249-6

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^a 8-12 hour resulting for most assays when shipped via FedEx with a Quest shipping kit. Turnaround time is determined from when Quest receives the sample, not from when the blood draw is taken.

^b Pretransplant testing guidance should be referred to our Chantilly FDA-registered transplant testing laboratory. Additional testing guidance, including posttransplant testing, can be provided by our dedicated Quest MDs and PhDs.