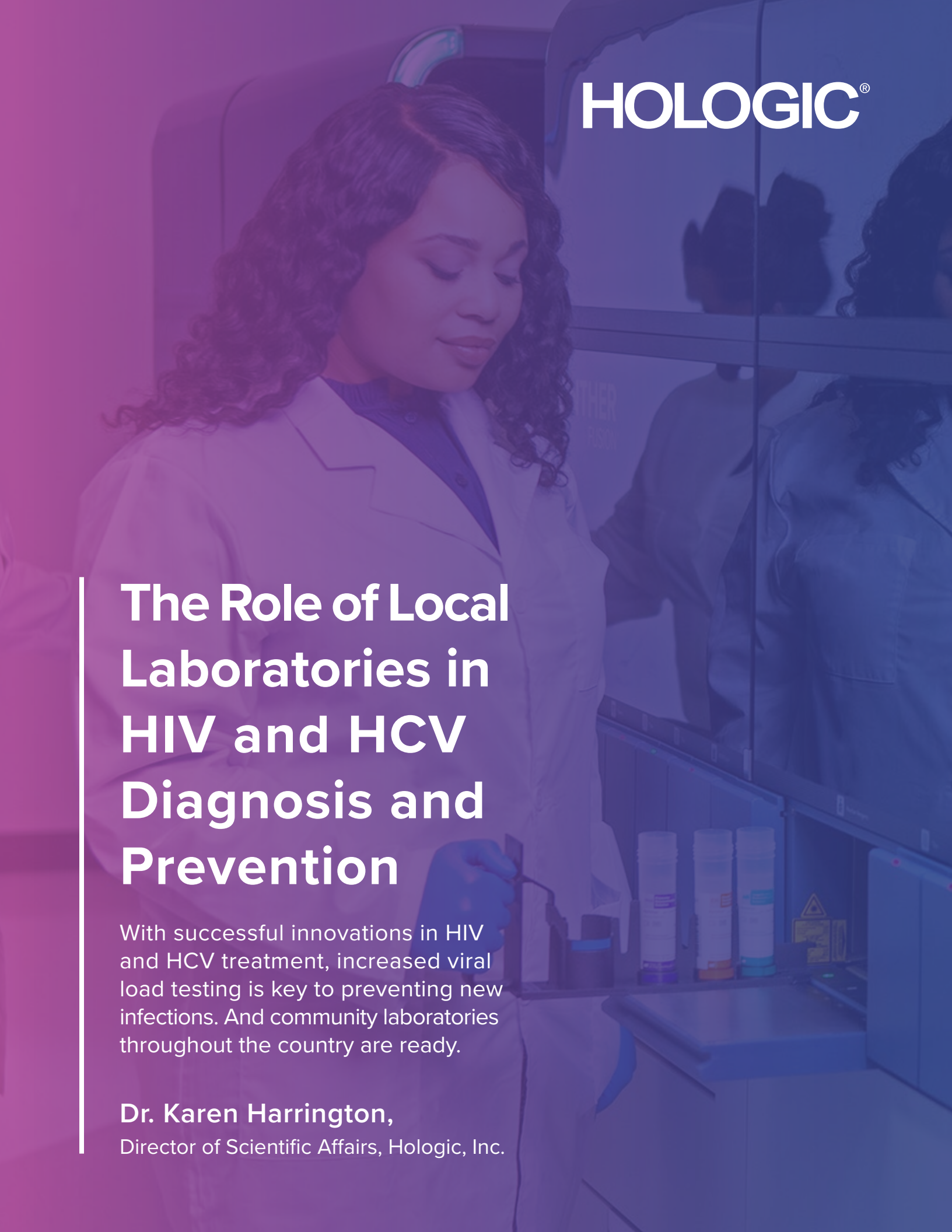

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# The Role of Local Laboratories in HIV and HCV Diagnosis and Prevention

With successful innovations in HIV and HCV treatment, increased viral load testing is key to preventing new infections. And community laboratories throughout the country are ready.

**Dr. Karen Harrington,**
Director of Scientific Affairs, Hologic, Inc.

When the SARS-CoV-2 emergency overwhelmed centralized laboratories throughout the U.S. with sudden, high demand for quick test results, hospital and community laboratories across the country responded by developing or expanding their in-house testing capabilities. New investments in automated systems running fast, accurate nucleic acid amplification tests (NAATs) were instrumental in reducing COVID-19 spread by identifying infections quickly.[1] Now that the emergency has passed, these laboratories are ideally situated to expand their in-house testing to other epidemics: Human Immunodeficiency Virus (HIV) and Hepatitis Virus.

The community laboratories—small-to-medium-sized—and hospital laboratories have effectively decentralized a large volume of molecular diagnostic testing capacity. As a result, the post-pandemic community laboratory now brings essential testing closer to people living with, or at risk of, HIV infection at a pivotal time. With the federal government setting ambitious agendas to achieve a 90% decrease in new HIV infections and eradication of HCV infection in the U.S. by the year 2030,[2-3] the availability of more widely distributed virology testing infrastructure will be catalytic in those efforts.

**The installation of multiple diagnostic platforms in molecular laboratories reduces the necessity to send samples out to a reference laboratory. Community laboratories are located closer to the patients. They belong at the forefront of the fight against HIV and HCV, yielding significant benefits for patients, clinicians, and laboratory professionals:**

1. **They provide rapid results to clinicians who prescribe HIV drug therapies;**
2. **Their proximity to care is critical to achieve the goal to eradicate HCV;**
3. **They grow the talent and insights needed for strong collaborative work with in-network virologists and clinicians by bringing viral load (VL) testing in-house.**

This is an exciting time in virology, and community laboratories have already made investments in the technology needed to meet the moment. Now is the time to capitalize on those investments.

**With ambitious federal agendas to decrease HIV and eradicate HCV infections, this is an exciting time in virology. Community laboratories have already made investments in the technology needed to expand viral load testing to meet the moment. Now is the time to capitalize on those investments.**

# 1. The Local Laboratories at the Forefront in the Fight Against HIV Infection

To meet the national Ending the HIV Epidemic (EHE) objective of 3,000 new HIV-1 infections per year by 2030,[2,‡] prevention of new infection numbers will have to increase substantially.[4] This means more testing overall, and ideally it means testing performed by laboratories that are more involved with those living with HIV to drive a broader reach.

To reach the infection reduction target, the Centers for Disease Control and Prevention (CDC) estimates that in the U.S., 95% of HIV-infected persons will need to be receiving ART and at least half of all eligible persons will need to be receiving PrEP.[2] This increase in both antiretroviral regimens can only be supported by regular and responsive monitoring testing with highly sensitive and reliable assays for detection and VL. Fortunately, the community laboratory with expanded molecular testing capacity can offer fast turnaround time (TAT) as well as direct consultation with clinicians.

Because a significant number of new of HIV infections are transmitted by people who do not know their status,[5] diagnosing infection at the early acute stage and intervening with ART as soon as possible is an essential strategy in preventing transmission.[6] Diagnosis through confirmation of HIV infection (or non-infection) with a reliable, accurate, and highly sensitive NAAT assay is a service many community laboratories can now offer with rapid TAT where it is needed. Beyond confirmation of infections, running molecular assays for detection and VL are the best options when monitoring people on ART or PrEP medications.

**Testing Recommendations for ART and PrEP[7-8]**

| Treatment | Testing Recommendations | Testing Intervals |
|---|---|---|
| **ART** | Those on ART should be tested for **VL quantification** until an undetectable status is achieved | Every 4-8 weeks |
| | Those on ART should be tested for **VL quantification** to confirm viral suppression | Every 3-6 months for two years |
| | | Every ~6 months following |
| **PrEP** | Those on oral PrEP medication should be tested for HIV infection by an **HIV antigen/antibody assay and an HIV-1 RNA assay** | Every 3 months |
| | Those on injectable PrEP should be tested for HIV infection by an **HIV antigen/antibody assay and an HIV-1 RNA assay** | One month after first injection |
| | | Every 2 months beginning with the third injection |

‡ Projected populations were calculated using 2021 data. CDC. Ending the HIV Epidemic in the U.S. (EHE). Centers for Disease Control and Prevention. Last reviewed June 9, 2023. Accessed June 25, 2023. https://www.cdc.gov/endhiv/ehe-progress/index.html

People living with HIV may receive hundreds of tests through a lifetime of HIV monitoring. For instance, from initial HIV-1 diagnosis, it can take up to six months to develop the correct ART regimen (and longer for some patients)[9] before most people living with HIV achieve durable viral suppression (<200 copies/ml) and, eventually, undetectable = untransmittable (U=U) status.[10] Because maintaining U=U may depend upon an individual's personal circumstances (e.g., consistent access to care, economic status, medical literacy, and treatment adherence), the laboratory team that can combine repeat testing with data history in consultation with clinicians, will be effective and responsive at ensuring optimal treatment.

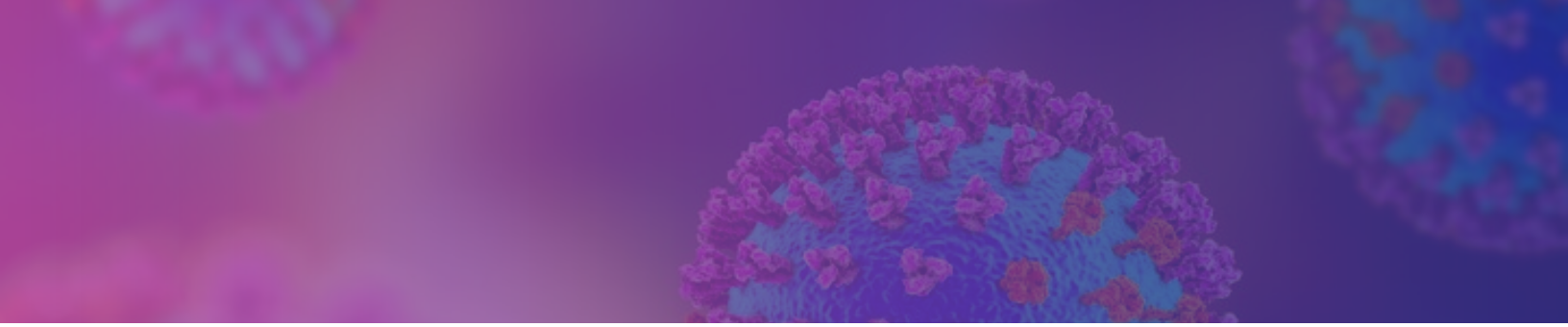
Further, stigmas against HIV persist. It is critical that people living with HIV feel supported by their clinical team. **In this regard, in-house HIV and HCV molecular testing cannot only provide the volume of testing needed but help maximize the benefits of therapies by offering a timely level of personalized care.**

With innovative treatments, accurate tests and supportive clinicians and laboratory teams, living a full life while also living with HIV is a reality for many people around the world. But this encouraging achievement comes with new challenges as health care systems confront the first generation of people living with HIV into their senior years.[11] Once again, the community laboratory with in-house molecular testing will play an essential role for those living with HIV.

As of 2016, more than half the U.S. HIV-positive population was age 50 or older, and that number is expected to be around 70% by the year 2030.[12] We cannot adequately predict how diagnostic methods might need to be adapted to provide the best care. What is known is that even with viral suppression, HIV infection over time causes or exacerbates conditions already associated with aging.[12]

HIV infection is known to be associated with accelerated aging and increased rates of cardiovascular, renal, neurocognitive, oncological, osteoporotic, and liver disease; and as the population of older persons living with HIV grows, clinicians will need to balance immunosuppression with emergent co-morbidities, potential drug interactions, and quality-of-life counseling.[12] The Ryan White HIV/AIDS Program of the Health Resources and Services Administration (HRSA) recommends a multidisciplinary approach involving all members of a health care team—one that is familiar with community resources—to address the social, physical, and psychological considerations associated with aging and HIV.[11] At the heart of those teams will be local laboratory professionals.

**Those living with HIV can achieve durable viral suppression (<200 copies/ml) and, eventually, undetectable = untransmittable (U=U) status.[10]**



## 2. The Local Laboratories at the Forefront in the Fight Against Hepatitis-C and STIs

According to the CDC, incidence of acute HCV infection in the U.S. more than doubled since 2013 and increased 15% between 2019 and 2020.[13] Although intravenous (IV) drug use is the most common means of transmission,[14] other HCV risk factors correspond with risk for HIV infection. The HCV prevalence data are concerning enough that in 2022, the Division of Viral Hepatitis (DVH) arm of the CDC, in cooperation with the Association of Public Health Laboratories (APHL), announced a grant to support laboratories in at least 12 states seeking to add or expand NAAT testing for the virus.[15]

The community laboratory running a broad menu of assays is well equipped to support testing for HCV and STIs, which are more prevalent among persons at risk for—or already infected with—HIV. For instance, after initial screening for *Neisseria gonorrhea* (NG), *Chlamydia trachomatis* (CT), syphilis, and *Trichomoniasis vaginalis* (TV), it is recommended that anyone receiving HIV-related therapies be re-tested for these STIs at least annually, and some individuals every 3-6 months depending on risk factors and/or local prevalence data.[16]

Left untreated, 70% - 80% of acute HCV infection becomes chronic, and 15% - 30% of chronic infections will progress to liver disease and cirrhosis.[17] Fortunately, an HCV infection is curable in more than 95% of individuals who receive timely treatment,[18] which again places laboratory testing in the foreground—especially because both new and chronic HCV may be asymptomatic. **The 8- to 12-week treatment[14] is best supported by a local laboratory that establishes baseline VL and provides follow-up testing to ensure sustained virologic response and endpoint cure.[19]**

## 3. An Increased Number of Community Laboratories are Becoming Viral Load Experts

Laboratory directors and managers understand the decades-long challenge to address staff attrition in the industry. But the community laboratories with new virology capabilities are now better equipped to foster an exceptional work environment and reinvigorate the careers of existing and future members of the team.[20] Two of the leading considerations when laboratory professionals are deciding where to work are efficiency and opportunities for continued learning. And the community laboratory with state-of-the-art systems can offer both.

Running primary tubes on a broad menu of assays with automated systems reduces repetitive labor and saves time. Laboratories using transcription-mediated amplification (TMA) assays detect the RNA amplicon, reducing the risk of carry-over contamination.[21] Time saved can be re-invested in training personnel.

The laboratory running superior tests, providing fast TAT, and with a staff who knows its patient population is more likely to provide relevant and insightful laboratory reports. **When more members of the laboratory team can provide knowledgeable support to clinicians, the patients benefit, and so do the laboratory professionals as they grow in their careers.**

## Conclusion

Despite the setbacks caused by the COVID-19 pandemic in infectious disease surveillance, testing, and care, it did stimulate advancements and upgrades to laboratories' automated platforms. Many community laboratories that previously sent their HIV and HCV viral load testing out to reference labs today have the technology, expertise, and desire to offer virology testing in-house. When combined with consolidated menus and automated, off-hours operation, these laboratories can meet rising demand without higher costs or reduction in quality, maximizing recently adopted platforms to bring essential VL assays closer to patients.

HCV is curable for nearly everyone who receives timely treatment, and the most recent WHO guidelines on HIV now state with greater certainty than ever that undetectable VL means zero chance of transmission.[22] When clinicians prescribing antiviral treatments are backed by reliable and insightful laboratory test results, patients build trust in their care team. This increased send of connection more often leads to higher willingness to undergo timely testing, accept treatment, and remain compliant. Together, patients, clinicians, and local laboratories have a great chance to achieve the goal to dramatically reduce HIV-1 and HCV infections by the end of this decade.


Author's Biography

### Dr. Karen Harrington

Karen Harrington, PhD, HCLD (ABB) is Director of Scientific Affairs at Hologic, Inc. Dr. Harrington has more than 20 years of experience in molecular diagnostics having worked in research and development and clinical and regulatory affairs, successfully taking several molecular IVD products through clinical trials, FDA approval and commercialization. Harrington received her BS in Biology from Marquette University and her PhD in Molecular Genetics from Georgia State University. Dr. Harrington is also certified as a High-complexity Clinical Laboratory Director by the American Board of Bioanalysis and has directed CLIA/CAP accredited clinical laboratories performing molecular-based infectious disease and oncology testing.

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