

# HIV Patient Management Solutions

Your mission for timely HIV monitoring impacting treatment decisions in regions hardest hit by the disease, is what drives Beckman Coulter Solutions.

## AQUIOS CL

The AQUIOS CL Load & Go flow cytometer is an all-in-one solution that incorporates automated loading, sample preparation, reagent management, barcode scanning, data analysis, and full LIS connectivity.

- **Reducing** potential user error by eliminating numerous manual steps to set up and run.
- **Enhanced productivity** with high-throughput performance by eliminating the least efficient features of existing systems.
- **Learn in as little as one day** for skilled flow cytometrists with computer based training videos.

## AQUIOS PLG

This comprehensive suite of innovative products provides highly effective monitoring tools that can be taken closer to patients to accelerate time-to-treatment.

- **Integrated fully automated sample preparation system** - no sample preparation necessary, reducing operator exposure to biohazards.
- **72 h post draw testing window** - percent & absolute CD4 values on aged patient specimens to support even your remote blood draw needs.
- **Simple, affordable testing** - takes CD4 monitoring to new places.
- **Less than 35 minutes to %CD4 and absolute CD counts (7)** - gives healthcare workers critical information while the patient is still on site.
- **From 20 to 150 tests per day** - a flexible instrument that meets your workflow requirements in centralized and more remote healthcare facilities.

## AQUIOS TETRA

In addition to basic CD4 testing, and following exactly the same Load & Go principle, AQUIOS CL offers additional options for advanced immunophenotyping:

- T cells (CD45/CD4/CD8/CD3)
- B- and NK cells (CD45/CD56+CD16/CD19/CD3)



WHO prequalified

The AQUIOS CL Flow cytometer and associated reagents are CE marked. AQUIOS CL with Tetra-1 has been accepted for the WHO list of prequalified in vitro diagnostic products.

## REVOLUTIONIZING LABORATORY WORKFLOW\*

### The DxN VERIS Molecular Diagnostics System

At Beckman Coulter Diagnostics, we are moving healthcare forward by bringing more than 80 years of automation and innovation history in the clinical diagnostics laboratory to the molecular diagnostics arena.

## DESIGNED TO IMPROVE LABORATORY EFFICIENCY AND ACHIEVE FASTER RESULTS

### SIMPLICITY AT WORK

- With single-sample random access, individual samples can be loaded at any time, eliminating batch processing
- The closed system limits the potential for contamination by using uracil-DNA glycosylase (UDG) in the qPCR vessel to digest uracil-containing amplicons created in previous PCR reactions
- Internal process controls provide assurance that the extraction and PCR amplification is performing within established parameters
- Minimal expertise is required, maximizing your laboratory staff's potential laboratory flexibility
- The DxN VERIS can be operational in less than 10 minutes
- It features onboard storage and refrigeration for up to 20 assays
- It delivers fast test results in as low as 70 minutes for DNA assays, 110 minutes for RNA assays
- The system can be operational 24/7 with fewer steps, faster results
- One system delivers a LEAN workflow—integrating nucleic acid extraction and purification, reaction setup, real-time PCR amplification and detection, and results interpretation

### FROM SAMPLE TO RESULT IN JUST THREE STEPS

- 1 LOAD SAMPLES INTO SYSTEM\*\*
- 2 CLICK "START"
- 3 VIEW RESULTS



\* DxN VERIS product line is CE marked. DxN VERIS product line has not been submitted to U.S. FDA and is not available in the U.S. market.  
DxN VERIS Molecular Diagnostics System is also known as VERIS Molecular Diagnostics System and VERIS MDx System.

\*\* Evidence for this brochure regarding DxN:

- 2015 Reports by Global Nexus for DxN VERIS
- Whittaker D. Enhancing productivity and improving service provision in the virology department. Pathology in Practice. 2015; 16 (3)
- Whittaker D. EuroMedLab June 2015 Recorded presentation: An EU laboratory perspective, U.K.

\*\*Loading of consumables may be required.

## PUTTING THE POWER OF SCIENCE WHERE IT'S NEEDED MOST

Drawing from our history as leading biomedical life science companies, we've collaborated with healthcare leaders to develop breakthrough HIV monitoring solutions that contribute directly to the treatment process. Your mission for timely HIV monitoring impacting treatment decisions in regions hardest hit by the disease, is what drives Beckman Coulter. At Beckman Coulter, we're bringing a world of CARES to a world in need.



### REFERENCES

1. WHO (2015): HIV/AIDS Fact Sheet No. 360. World Health Organization, Geneva.
2. UNAIDS (2014): 90-90-90: An ambitious treatment target to help end the AIDS epidemic. Joint United Nations Programme on HIV/AIDS (UNAIDS), Geneva, pp. 1-33.
3. WHO (2013): Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infections. World Health Organization, Geneva, pp. 28-30.
4. Cassim N et al. (2014): Estimating Implementation and Operational Costs of an Integrated Tiered CD4 Service including Laboratory and Point of Care Testing in a Remote Health District in South Africa. PLoS ONE 9(12): e115420.
5. Glencross DK et al. (2002): CD45-assisted PanLeucogating for accurate, cost-effective dual-platform CD4+ T-cell enumeration. Cytometry 50: 69-77.
6. WHO (2015): Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. World Health Organization, Geneva.
7. 7. PLG: B43671: System Guide\_PLG Application for the AQUIOS CL Flow Cytometer



**BECKMAN COULTER**  
A Danaher Company

Danaher is a global science & technology innovator committed to helping our customers solve complex challenges and improve quality of life worldwide. Our world class brands are leaders in some of the most demanding and attractive industries. A globally diverse team of 71,000 associates, we are united by our culture and operating system, the Danaher Business System, which is our competitive advantage.

The Life Science and Diagnostic segment consists of seven operating companies: Beckman Coulter Life Sciences, SCIEX, Leica Microsystems, Pall, Molecular Devices, Beckman Coulter Diagnostics, Leica Biosystems and Radiometer. We are global in reach, but local in service and support and in our collaborative approach to meeting your needs.



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## BECKMAN COULTER CARES INITIATIVE

A GLOBAL INITIATIVE IN SUPPORT OF THE FIGHT AGAINST HIV/AIDS AND RELATED CO-INFECTIONS

SCIENCE  
SERVING  
HUMANITY



# BECKMAN COULTER CARES

Science Serving Humanity

More than 30 years after HIV/AIDS first appeared, there are an estimated 37 million cases worldwide with nearly 70% of HIV+ patients living in Sub Saharan Africa followed by Southeast Asia, Latin America and Eastern Europe. The vast majority of individuals affected by HIV are in low and middle income countries. More than 3 million children were infected by HIV positive mothers during pregnancy, childbirth or breastfeeding (1).

## A LEGACY OF SERVING HUMANITY

The worldwide need for effective assessment and treatment is more urgent than ever, and Beckman Coulter is part of the solution. Beckman Coulter helped pioneer the use of flow cytometry to confront the emerging threat of HIV/AIDS in the 1980s. Beckman Coulter introduced the manual CD4 counting test for use with a microscope for labs without access to flow cytometry. At Beckman Coulter Diagnostics & Life Sciences, we are moving healthcare forward by bringing more than 80 years of automation and innovation history in the clinical diagnostics laboratory from Flow cytometry to the molecular diagnostics arena.

## BECKMAN COULTER JOINS THE FIGHT

By focusing on innovative, yet affordable solutions for HIV monitoring, Beckman Coulter supports the **UNAIDS 90-90-90 target** to ensure that by the year 2020, 90% of people living with HIV will know their HIV status, 90% of people with diagnosed HIV infection will receive sustained antiretroviral therapy, and 90% of all people receiving antiretroviral therapy will have viral suppression (2).

## THE CARES INITIATIVE

The CARES initiative was launched and driven by a social and civic responsibility to support the fight against HIV/AIDS. Public and private partnerships are being explored to identify areas for Beckman Coulter to contribute for the broader purpose. We seek to develop alliances with non-governmental organizations (NGO's), implementing partners, and health policy organizations to align our efforts.

Beckman Coulter is meeting tomorrow's needs today by our commitment to leading the fight against HIV through the development of innovative solutions for the monitoring of CD4+ lymphocyte depletion and viral load levels. Our simple, robust and sustainable tests have been made available to thousands of patients and allow the Health Departments to channel more funds towards better treatment programs.



Photo: Courtesy of D.K. Glencross

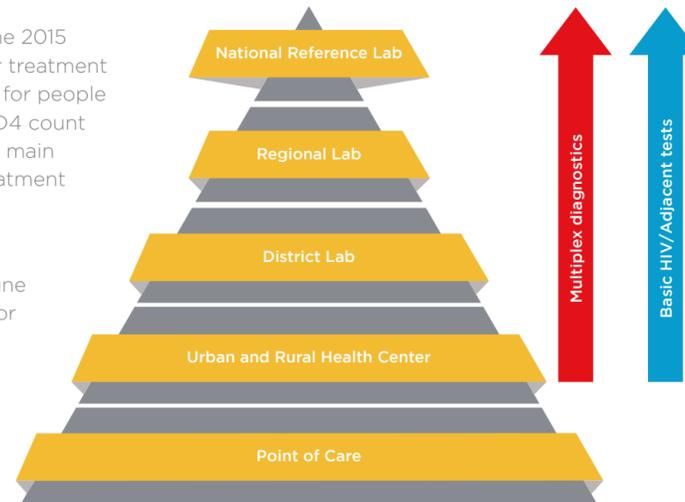


## WHO GUIDELINES

The 2013 WHO guidelines, and the 2015 revision thereof, call for an earlier treatment with antiretroviral therapy (ART) for people infected with HIV, and identify CD4 count and viral load analysis as the two main technologies to monitor ART treatment initiation and follow-up (3; 6).

This requires countries to build capacity for the analysis of immune system integrity, and especially for CD4 analysis platforms that can be used in both centralized and regional healthcare facilities.

Tiered laboratory network and workload requirements. Please see reference (4) for additional information.

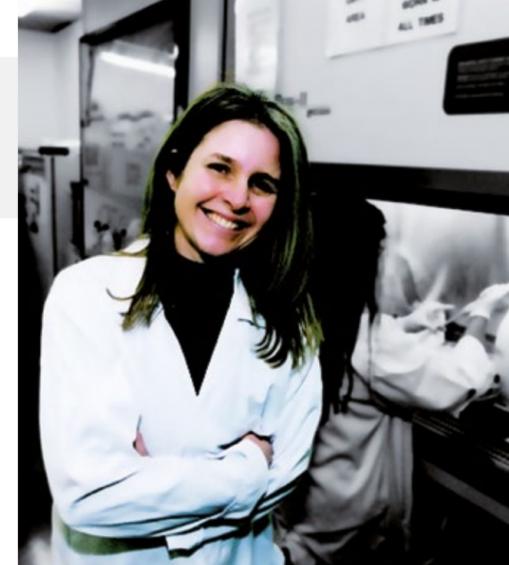


## TIERED LABORATORY NETWORKS

Laboratories are the backbone of the entire public health system, and standardization is the key to success in order to facilitate collaboration and communication between them.

Within a tiered public healthcare system, near-patient testing in many cases still means high-throughput testing, combined with centralized data collection and storage requirements.

While basic peripheral testing sites usually need to rely on Point of Care testing due to infrastructural challenges, all other laboratory categories require state-of-the-art solutions that meet flexible workload requirements and automated integrated approaches.



"With many years in the field, I saw the need for a HIV/AIDS test that's both accurate and cost-effective. By applying scientific knowledge in a new way, we found it. And now, the PLG-CD4 test is bringing better care to millions of patients worldwide."  
Professor Debbie Glencross  
Photo: Courtesy of D.K. Glencross

## THE PLG CD4 TEST STORY

Monitoring CD4 lymphocyte counts is essential in providing critical information that impacts patient care. CD4 monitoring allows caregivers to know when the disease transforms and stage its progression so they can implement the most appropriate intervention.

Beckman Coulter has been providing cost effective solutions to monitor CD4 status in resource limited countries for several decades. The mounting HIV problem in these regions of the world has led to innovative solutions with a mission to deliver patient care.

An example of innovative solutions driven by need is the breakthrough 'PanLeucoGating' (PLG) story from South Africa. Developed by the University of the Witwatersrand, a leading South African research institute, PLG CD4 was adopted in response to the urgent need for simple, rapid, accurate, and low-cost CD4 results in primarily centralized labs that monitor large numbers of HIV patients. The benefits were clear: According to the South African National Health Laboratory Service (NHLS), large-scale use of PLG CD4 has the potential to reduce the cost of HIV/AIDS monitoring (5).

PLG CD4 was subsequently licensed to Beckman Coulter for manufacturing and worldwide distribution — with provision that the technology be priced affordably for resource limited countries. Beckman Coulter remains a proud partner to the NHLS. Today Beckman Coulter's legacy and passion for science and innovation to improve healthcare manifests itself within the CARES Initiative.

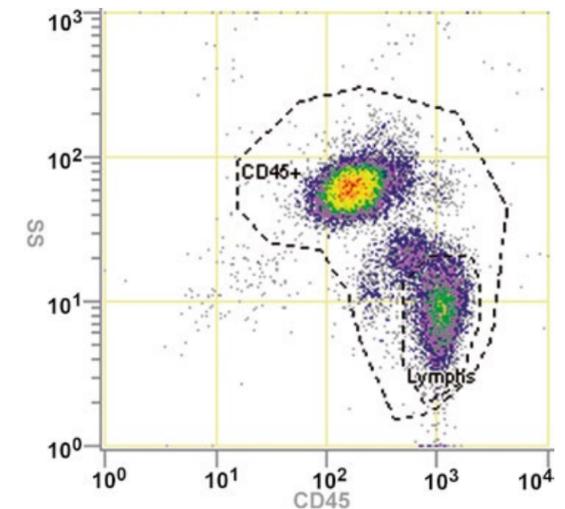
## AFFORDABLE, RELIABLE TESTING

By focusing on the most essential parameters for monitoring HIV therapies, PLG CD4 addresses cost, complexity, and the time previously required by labor-intensive processes to provide busy laboratories with an affordable, high-performance monitoring solution that also offers standardization and simplicity. Its efficient operation takes CD4 testing to new places (5).

### Advantages of PLG CD4:

- 2-colour pre-optimized reagent for PanLeucoGating (CD45/CD4)
- Provides both CD4% and absolute counts
- Extends to accommodate sample age up to 72 hours.

The PLG 'Africa Gate' that identifies lymphocytes, monocytes, and granulocytes based on CD45 expression and cell complexity (side scatter).



A sample plot from the peripheral blood of a normal donor is shown, depicting all white blood cells (CD45+), as well as a region to identify the lymphocyte (Lymphs) subpopulation for further analysis of CD4 cells. The name 'Africa Gate' stems from the form of the region that is used to identify all white blood cells.