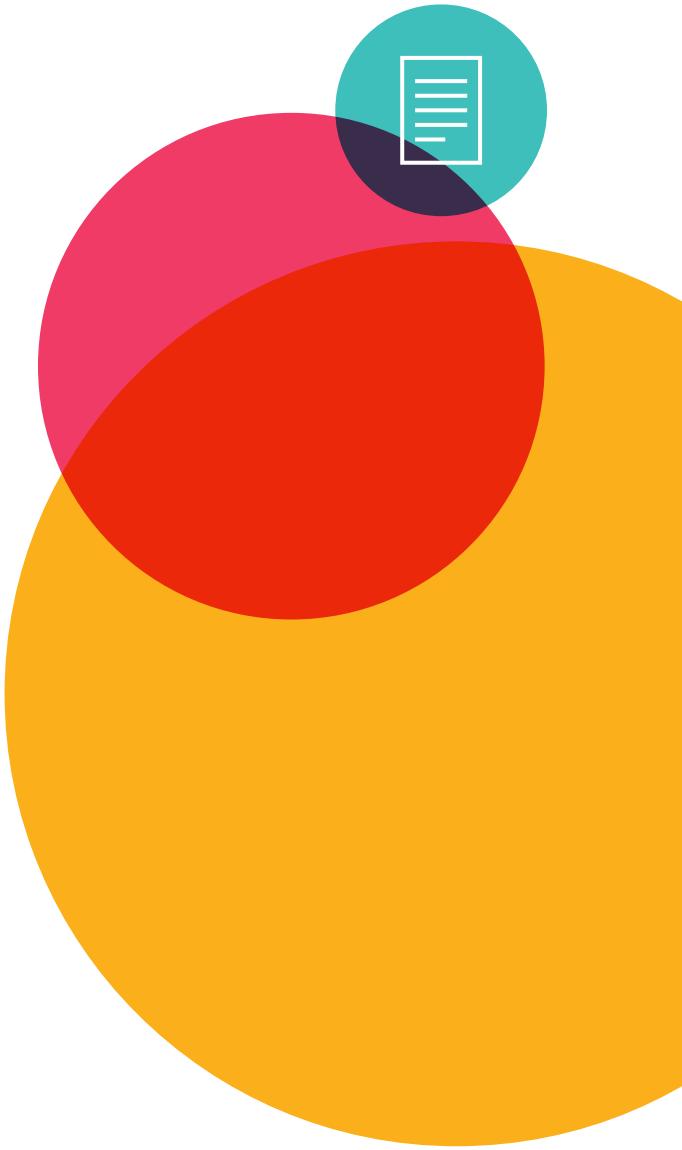
Serology testing

Infectious disease antibody screening



Summary

› Multiplex infectious disease testing
› Minimal hands-on steps with co-flow protocols
› Short time to result by real-time reaction monitoring

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Infectious disease

The invasion of the host body by infectious agents may cause severe sickness. Such agents include parasites, viruses, bacteria, viroids, prions etc. Typically, the host reacts through an immune response against agent specific antigens presented by the pathogens. The detection of the resulting antibodies in the blood of infected hosts is used in the diagnosis of infection.

Multiplex infectious disease panel

For a selection of infectious agents, a multiplex Evalution™[1] serology prototype assay was developed. The assay detects and measures antibodies against different types of pathogens present in the blood of postinfected specimens (table 1). For each infectious agent, one or multiple antibody antigens were coupled to differently encoded microparticles. After coupling these were mixed to provide a multiplex panel and loaded into the microchannels of an Evalution cartridge.

Disease	Causative agent	Type	Antigen(s)
Chagas disease	Trypanosoma cruzi	Parasite	ND*
Hepatitis B	HBV	Virus	Core + Core Delta
Hepatitis C	HCV	Virus	ND*
Aids	HIV	Virus	gp41 + p24
Adult T-cell leukemia	HTLV	Virus	ND*
Syphilis	Treponema palladium	Bacteria	ND*

*ND: not disclosed

Evalution assay performance

Over 100 clinically characterized reference samples including 10 to 20 positive samples for each indication were analyzed using the Evalution multiplex assay following a typical end-point assay workflow [table 2]. The assay shows to be highly specific for the infectious agent or its antigen [figure 1]. In such assay format, total assay times do not exceed 30 minutes with minimal hands-on time and steps. The total assay time can be further reduced by making use of a co-flow procedure with real-time assay monitoring [table 2][figure 2].

Workflow	Total assay time	Hands-on time
End-point workflow	**30 minutes**	**<5 minutes**
Sample loading	20 min	
Wash	1 min	
Labelled anti-human antibody	5 min	
Wash	1 min	
Fluorescent reading	<5 min	
Co-flow kinetic workflow	**<15 minutes**	**<2 minutes**
Sample premixed with labelled anti-human antibody + real-time monitoring		

[1] The Evalution platform is intended for research use only. Not for use in diagnostic procedures.

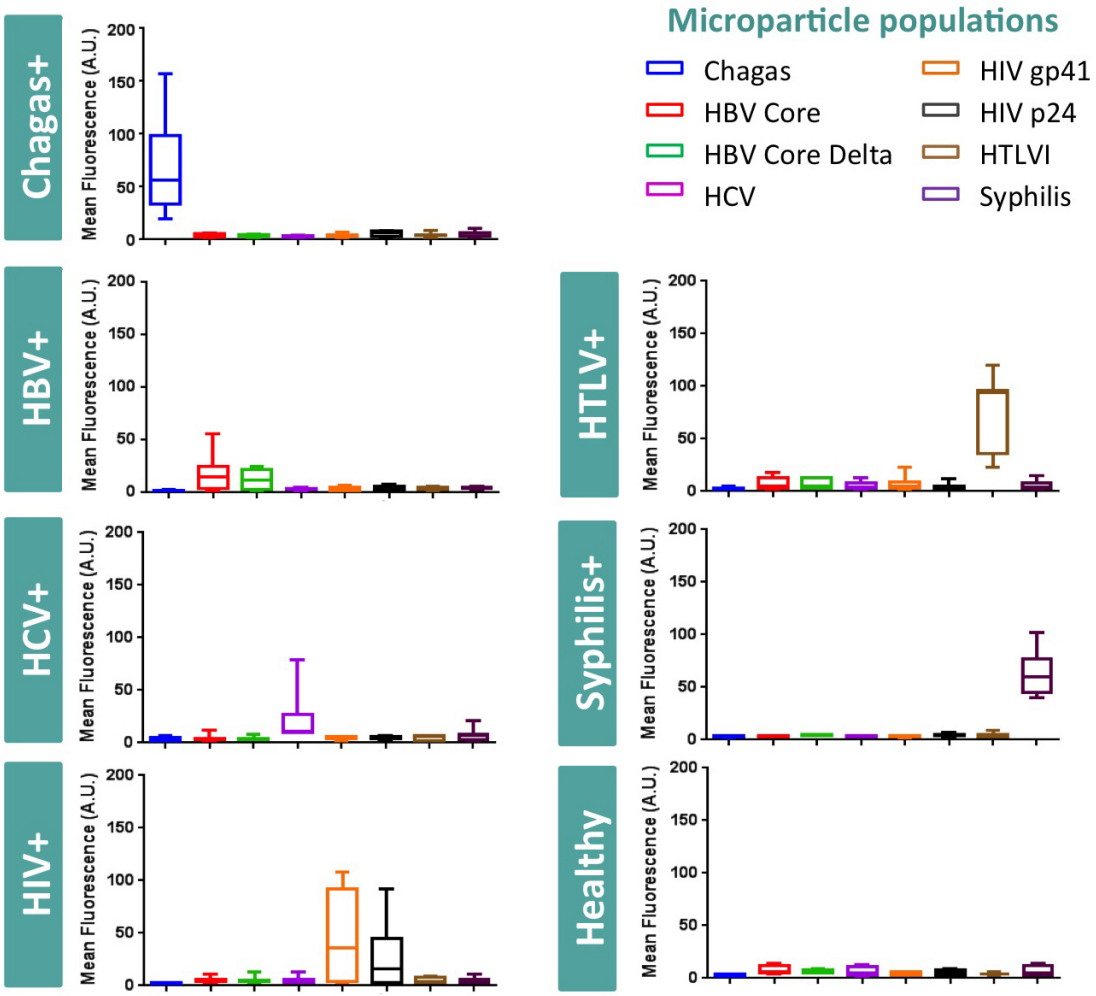

Figure 1: End-point detection of postinfection

The Evalution infectious disease panel was tested using over 100 clinical reference samples including 10-20 positives for each indication. Each microchannel was loaded with a population of differently encoded microparticles, each code representing a specific agent antigen. Captured epitope-specific antibodies were detected using a fluorescently labeled anti-human antibody. For each clinical sample, one microchannel is needed to provide all measurements.

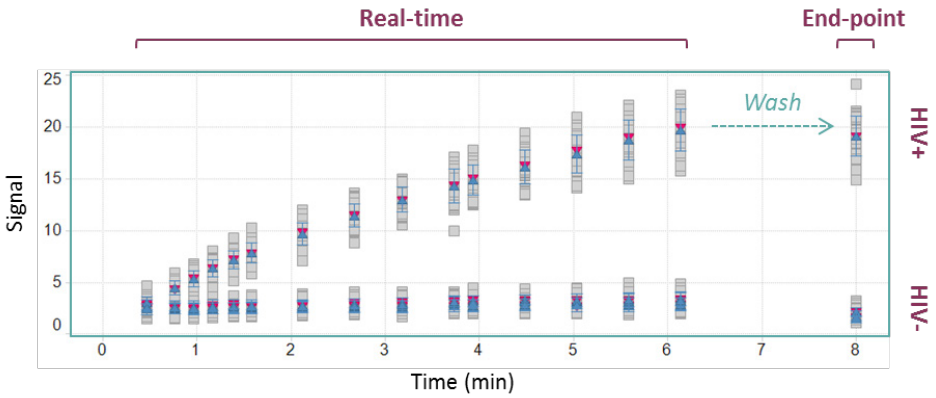

Figure 2: Co-flow with real-time monitoring reduces total assay time to a minimum

Identical assay cartridges as those used for the end-point detection are used in a co-flow protocol with real time kinetic measurements. Samples were premixed with the fluorescently labeled anti-human antibody before introduction into the microchannel. Fluorescent buildup was recorded in real time and data shown for the HIV p24 coated microparticles. By using the slope at origin, the monitoring time can be as low as 2 minutes for high titer samples. The threshold required for positive calling of an infection will finally determine the analysis time.

MyCartis at a glance

The big revolution in healthcare today is that we are finally realizing that we are all equal, but not identical. MyCartis is convinced that the future of healthcare lies in personalization. Our goal is to deliver innovative solutions for fast and cost effective identification of a patient's signature. By building bridges between research and medical practices we are increasing the level of health and the quality of life for everyone. We dedicate ourselves to improve healthcare for future generations.

Evalution™ at a glance

› Powerful tool for assay development and biomarker analysis
› Broad range of applications
› Single platform, different analytes
› Simple workflows with minimal handling
› High sensitivity and broad dynamic range for robust measurements
› Competitive cost per data point

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