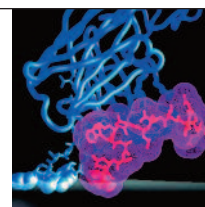




SeraCare Technical Bulletin 0901: Multi-Analyte Controls

Q: Why is there a wide range of ACCURUN® 1 multi-analyte control products?



A: Because test methods with similar sensitivity for anti-HIV and other analytes produce different results with controls. In the development of anti-HIV assays, manufacturers use different approaches to formulate a test that will detect an HIV-infected individual's immune response.

Among the differences:

- Antigens: viral lysate, synthetic or recombinant proteins, a combination
- Sample dilution
- Conjugates
- Assay conditions: temperature, incubation time, etc.

Test kits are also designed to optimize detection of early antibodies, which generally have lower antigen affinity than antibodies produced later in the immune response.

Our research and development showed clearly that one control cannot meet the specifications of all anti-HIV assays.

A control that provided a consistent low positive result with one test method was so low that it was frequently negative with another method, or so high that it couldn't really be considered a low positive control with a third method. Yet, all three of these tests could be similar in their ability to detect early seroconversion in patient samples, a required characteristic for anti-HIV test methods.

To monitor test methods over time, across kit lots and in different laboratories, independent controls for antibody tests must be made in large batches or lots, often by diluting a pool of high titer samples with antibody negative plasma.

Pools of high-titer samples will contain a mixture of mostly later, high-affinity antibodies to multiple antigenic sites or epitopes.

Since test kits have different mixtures of epitopes or antigenic sites, their responses to a single formulation of a control such as ACCURUN 1 will differ.

[See Table 1, next page.](#)

This phenomenon could be observed in any test that yields a single response (signal or specimen absorbance to cutoff ratio or s/co) for a group of molecular entities, and antibody tests or serologies are the most common example of this category.

The ACCURUN 1 series was formulated specifically for different test methods or automated instrument systems, to provide a low positive control for each analyte/method/instrument combination.

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Table 1: SeraCare Multi-Analyte Control Products

As shown below, a wide variety of multi-analyte control products were developed because SeraCare research clearly showed that one control will not meet the specifications of all anti-HIV assays.

Analyte	Platform/ Product*	Target Assays**	IVD/CE	Fill Size	Cat No
Anti-HIV-1/2, Anti-HTLV I/II, Anti-HBc, Anti-HCV, HBsAg	ACCURUN 1 Series 2400	Abbott Prism®	IVD, CE	12 x 3.5 mL	A001-2408-P
Anti-HIV-1/2, Anti-HTLV I/II, Anti-HBc, Anti-HCV, HBsAg	ACCURUN 1 Series 2500	Abbott Prism®	IVD, CE	12 x 3.5 mL	A001-2508-P
Anti-HIV-1/2, Anti-HTLV I/II, Anti-HBc, Anti-HCV, HBsAg, Anti-CMV	ACCURUN 1 Series 2600	Abbott AxSYM®, Abbott AxSYM® Plus	IVD, CE	3 x 5 mL 12 x 3.5 mL	A001-2603-P A001-2608-P
Anti-HIV-1/2, Anti-HTLV I/II, Anti-HBc, Anti-HCV, HBsAg, Anti-CMV	ACCURUN 1 Series 3000	Sanofi Diagnostics GENSCREEN®	IVD, CE	3 x 5 mL	A001-3003-P
Anti-HIV-1/2, Anti-HTLV I/II, Anti-HBc, Anti-HCV, HBsAg, Anti-CMV	ACCURUN 1 Series 4000	bioMerieux VIDAS® HIV DUO ULTRA	IVD, CE	3 x 5 mL	A001-4003-P
Anti-HIV-1/2, Anti-HTLV I/II, Anti-HBc, Anti-HCV, HBsAg, Anti-CMV	ACCURUN 1 Series 4100	Murex EIA	IVD, CE	3 x 5 mL	A001-4103-P
Anti-HIV-1/2, Anti-HTLV I/II, Anti-HBc, Anti-HCV, HBsAg, Anti-CMV	ACCURUN 1 Series 4400	Bio-Rad Genetic Systems™ EIA	IVD	3 x 5 mL 12 x 3.5 mL	A001-4403-P A001-4408-P
Anti-HIV-1/2, Anti-HTLV I/II, Anti-HBc, Anti-HCV, HBsAg, Anti-CMV	ACCURUN 1 Series 5100	Abbott EIA	IVD, CE	1 x 5 mL 3 x 5 mL 12 x 3.5 mL	A001-5101-P A001-5103-P A001-5108-P
Anti-HIV-1/2, Anti-HTLV I/II, Anti-HBc, Anti-HCV, HBsAg, Anti-CMV	ACCURUN 1 Series 5600	Roche Elecsys®	IVD, CE	6 x 3.5 mL	A001-5605-P
Anti-HIV-1/2, Anti-HTLV I/II, Anti-HBc, Anti-HCV, HBsAg, Anti-CMV	ACCURUN 1 Series 8100	Dade Behring Enzygnost®	IVD, CE	3 x 5 mL 12 x 3.5 mL	A001-8103-P A001-8108-P
Anti-HIV-1/2, Anti-HTLV I/II, Anti-HBc, Anti-HCV, HBsAg, Anti-CMV, HIV-1 Ag, Anti-Syphilis	ACCURUN 1 Negative Control	Abbott HIVAB®	IVD, CE	1 x 5 mL 12 x 3.5 mL	A001-1001-N A001-1008-N

* Many products have been tested on multiple platforms. Please inquire

** Based on Anti-HIV-1/2 target assay

IVD For *in vitro* diagnostic use
CE Complies with EU standards



For more information or to place an order, contact SeraCare customer service at 800.676.1881 or visit our eCatalog at www.seracarecatalog.com