



New Multi-Point Calibration Method for Corgenix Anti-Phospholipid Assays

Testing for anti-phospholipid antibodies associated with thrombosis and related clinical events is well accepted in the clinical lab. In the original anti-cardiolipin (aCL) method described by Harris et al. in 1983, a single source positive patient serum was serially diluted to produce a calibration curve. This was the basis of the Louisville Antiphospholipid Standards (Harris Standard) to which most aCL procedures are traceable, including the first commercial aCL kit, which was developed by Corgenix (formerly REAADS). However, it was observed during assay development that serial dilution of a patient serum often resulted in a sigmoidal (S-shaped) curve rather than a linear curve. Anti-cardiolipin antibodies were also shown to be very heterogeneous. These findings led to the conclusion that aCL testing is at best semi-quantitative, and the decision was made to use a single calibrator in the kit for calculating patient results, rather than a multi-point calibration curve. A single point calibrator for aCL testing has offered reliable patient recovery historically, along with providing cost savings to the laboratory when compared to multi-point calibration. In spite of the advantages of single point calibration with the current Corgenix aCL kit, some laboratories have expressed a preference for multipoint calibration.

In response to these customers and as part of our continuous product enhancement efforts, we are pleased to announce the development of a new kit format for both Corgenix aCL and anti-Phosphatidylserine (aPS) ELISA assays that will allow laboratories the option of using either single or multiple point calibration. Recently cleared by the FDA, the new kit format will include three individual calibrators (with different levels of reactivity) for each isotype (IgG, IgM or IgA). Laboratories will have the choice of using calibrator #3 as a single point calibrator (as in the original kit configuration) or including all three calibrators in their run and utilizing a multi-point linear regression analysis to calculate results (Fig.1). In the studies submitted to the FDA in the 510(k) applications for the new kit format, both methods of calibration were shown to produce similar sample recovery (Fig.2).

The Corgenix aCL and aPS multi-point calibration format is unique in that it utilizes three individual human-source samples as calibrators and sample diluent as a zero point (fourth calibrator) to construct a four-point calibration curve. The use of sera from different patient sources as calibrators provides a better representation of the heterogeneity of these antibodies in a patient population, upon which the reactivity of unknown

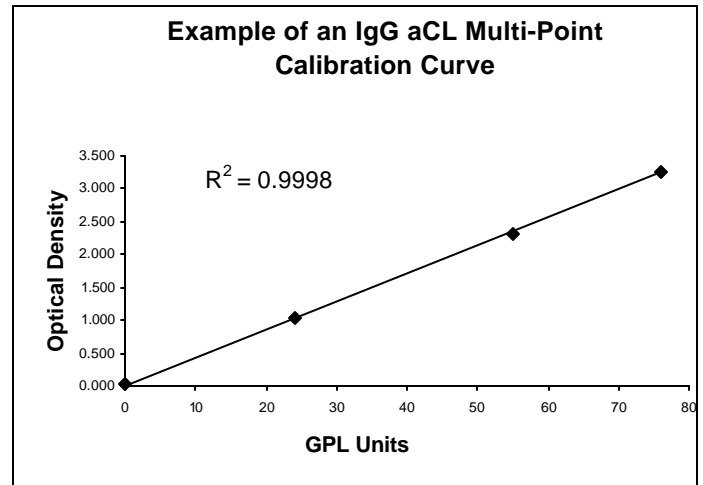


Fig. 1

samples is compared. Also, since the curve type is a linear regression (a straight line), the curve is linear across the entire reportable range of the assay. This is especially important around the assay cutoff, where the log/linear (sigmoidal) calibration curves used in other methods may give discrepant results. As in the previous kit configuration, the calibrators in the Corgenix kit are supplied undiluted and, as specified in the assay procedure, are tested at the same dilutions as kit controls and patient specimens.

Corgenix strives to maintain a leadership position in the field of anti-phospholipid antibody detection while responding to the requests of our customers. With the new aCL and aPS kit format, laboratories may continue to enjoy the cost advantages offered by the single-point analysis or choose the new, equivalent multi-point calibration option.

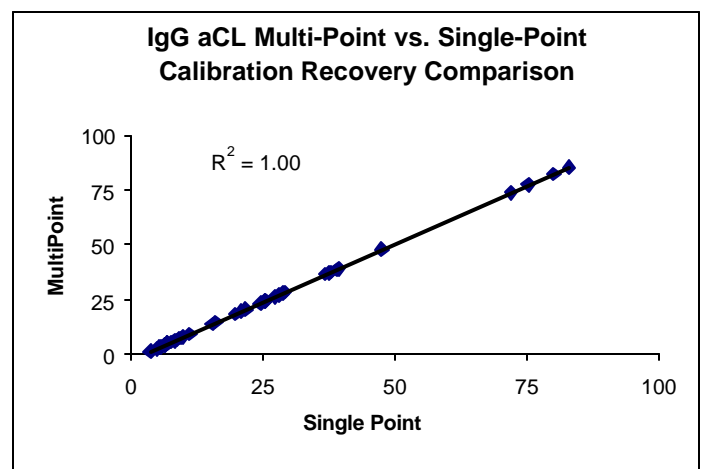


Fig. 2

READER ANNOUNCEMENTS

Increased Reagent Volumes

For the convenience of customers who are running the REAADS kits on an automated microplate processing instrument such as the Dynex DSX™ or Grifols Triturus®, Corgenix has increased the volumes of several reagents in the new anti-Phospholipid kit format. The 96-well kits now include 0.250 mL of each calibrator and control serum, 15 mL of each conjugate, 15 mL of substrate and two 30 mL bottles of wash concentrate. The larger reagent volumes, in addition to the option for multi-point calibration, will be provided at no additional cost to Corgenix customers. These product enhancements have been implemented in the CE Marked REAADS anti-Phospholipid Test Kits, which will be shipping in the near future.

Now Available for Evaluation New vWF:ACT ELISA

The measurement of von Willebrand Factor (vWF) activity levels aids in the differential diagnosis of the two predominant subtypes of von Willebrand Factor Disease, type 1 and type 2. The Ristocetin Cofactor Assay is the most commonly used specialized method for screening vWF activity. However, this test is limited by poor reproducibility.

A new vWF Activity ELISA developed by Corgenix uses a purified monoclonal antibody that recognizes the portion of the vWF molecule that binds platelet glycoprotein Ib. This is the same portion of vWF that is activated by ristocetin in the Ristocetin Cofactor Assay. The REAADS vWF Activity ELISA is valuable for vWF screening due to the objective, accurate and reproducible ELISA procedure. Look for the April 2003 issue of *THE READER* for an update on von Willebrand Disease.

REAADS von Willebrand Factor Activity ELISA

For Investigational Use Only

Product #10826

Considering Automating your ELISA's?

Corgenix is an authorized US distributor of the Dynex DSX™ Automated System, a four-plate ELISA processing system capable of performing multiple assays per plate. The instrument employs a modular design for flexible configuration and has been developed with ease-of-use in mind. The DSX incorporates many features to ensure the quality and security of results and has the performance to handle a wide variety of assays. The DSX offers flexible and reliable sample-in/result-out processing for walk-away automation. Please contact Corgenix Customer Service at 800-729-5661 for additional information. We can offer some helpful suggestions for validating your application programs for the Corgenix assays.

READER PRODUCT FEATURE

REAADS Anti-Cardiolipin (aCL) Semi-Quantitative Test Kits

For In Vitro Diagnostic Use

| | |
|-------------------------|--|
| Assay format - | 96-well microtiter plate (8 x 12 strips) with breakaway wells |
| Sample matrix - | Human serum or plasma collected in 3.2% sodium citrate |
| Sample dilution - | 1:50 |
| Antigen - | Cardiolipin (diphosphatidyl glycerol) |
| Conjugate - | Horseradish peroxidase (HRP) / goat anti-human IgG, IgM or IgA |
| Chromogenic substrate - | TMB (single component) |
| Stopping solution - | 0.36 N Sulfuric acid |
| Assay incubations | |
| Sample - | 15 min @ room temperature |
| Conjugate - | 15 min @ room temperature |
| Substrate - | 10 min @ room temperature |
| Wavelength - | 450 nm |
| Assay calibration - | single point or multi-point curve prepared from 3 serum calibrators included in kit |
| Clinical specificity - | IgG 97%; IgM 96%; IgA 95% |
| Clinical sensitivity - | Unselected SLE: IgG 21%; IgM 10%; IgA 26% |
| | Secondary APS: IgG 45%; IgM 25%; IgA 79% |
| Product numbers: | 023-001: 96 well aCL IgG/IgM 023-002: 288 well aCL IgG/IgM 026-001: 96 well aCL IgA 026-006: 288 well aCL IgA |

UPCOMING EVENTS

March 7-12, 2003: the 60th Anniversary Meeting of the American Academy of Allergy, Asthma and Immunology (AAAAI) will be held in Denver, CO. For more information, call (414) 272-6071 or visit their website at: www.aaaai.org.

March 29-April 1, 2003: the European Association for the Study of the Liver (EASL) will hold their 38th Annual Meeting at the Istanbul Convention and Exhibition Centre in Istanbul, Turkey. Pre-meeting activities will begin on Friday, March 28. Please stop by and visit our booth during the exhibition for the latest information on Hyaluronic Acid. Interested in attending? Log on to their website at: www.easl.ch.

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