



Akers Biosciences, Inc.

Heparin/PF4 Antibody Serum Panel

Intended Use

The Heparin/Platelet Factor 4 Antibody Serum Panel is an assayed control, intended for use as a serum QC control to monitor and evaluate precision and accuracy of the (qualitative) PIFA® Heparin/PF4 Rapid Assay. Included are both confirmed positive and negative control panel members.

The panel members enable the users to evaluate their PIFA® Heparin/PF4 Rapid Assay test systems and provide comprehensive data for comparative analysis.

Summary and Explanation

Controls (also known as “Quality Control (QC) Materials”) are solutions for which an expected analyte concentration or antibody determination has been established. Good Laboratory Practices necessitate the use of controls to test and verify the performance of test systems. Laboratories should follow guidelines concerning the use of controls set forth by their national accrediting bodies, as well as state and/or local authorities.

The panels are assembled from its repository of frozen serum samples, with reactivity as determined by the (FDA approved) GTI® PF4 Enhanced® ELISA test currently available within the United States and verified against current lots of the PIFA® Heparin/PF4 Rapid Assay. Samples are chosen to provide a broad range of reactivity levels.

Reagents

Confirmed positive and negative Heparin/Platelet Factor 4 frozen human sera, packaged cryovials, ready to use. No preservatives are added.

All blood is collected in the USA from human donors in FDA licensed centers & tested with FDA approved test kits.

For *In Vitro* Diagnostic Use Only

Warnings and Precautions

The serum control panels have not been inactivated.

- All human source materials used in the preparation of the Heparin/Platelet Factor 4 Antibody Serum Panels have been tested and found negative for antibody to HIV and HCV, HIV-1 RNA, HCV RNA, Syphilis and detection of Hepatitis B Surface Antigen by FDA approved methods.
- No test method can provide total assurance that Hepatitis B Virus, Hepatitis C Virus, Human Immunodeficiency Virus or other infectious agents are absent. Thus, all blood products are handled at the bio-safety level 2 as recommended by the CDC/NIH Manual: Bio-Safety in Microbiological and Biomedical Laboratories for potentially infectious human serum or blood specimens.
- Discard all components according to local regulations.

Limitations

Certificate of Quality data can be accessed by visiting www.akersbiosciences.com/products/coa.php. Data provided is for informational purposes and is ordered by Lot Number. Akers Biosciences, Inc. (ABI) does not claim that comparative results (on the GTI® PF4 Enhanced® ELISA test) can be duplicated exactly. According to the GTI® PF4 Enhanced® ELISA test Package Insert, the O.D. readings obtained from duplicate tests should fall within $\pm 20\%$ of the mean of the two values.

Storage & Reagent Handling

The Heparin/Platelet Factor 4 Antibody Serum Panel members should be stored frozen at -70°C (-94°F) or colder. Use before the expiration date listed on the cryovial label.

To initiate use of a Serum Panel member, use the following quick-thaw procedure: thaw sample in a water bath with temperatures between $30-37^{\circ}\text{C}$ ($86-98^{\circ}\text{F}$) for approximately 1-2 minutes. Mix sample well prior to use. To maximize antibody reactivity, use immediately after thawing; serum can be refrigerated $2-8^{\circ}\text{C}$ ($36-46^{\circ}\text{F}$) for a maximum of eight (8) hours prior to use. Specimens that have been refrigerated should warm to room temperature prior to use.

After obtaining the desired serum specimen(s), the remaining serum may be divided into single use aliquots for ease of use and to avoid continued freeze-thaw cycles. For optimum recovery, please use small volume cryovials, similar to the cryovial used by ABI to package each original serum panel member.

NOTE: Follow aseptic techniques

Aliquots should be flash frozen and stored at -70°C (-94°F) or colder and should only be subjected to one additional freeze-thaw cycle. Repeated freeze-thaw cycles may diminish antibody reactivity. Use care when thawing an aliquot; excessive heat, combined with a small sample volume, can easily damage the control material.

Materials Provided

Two types of kit configurations are available, specifically for use on the PIFA® Heparin/PF4 Rapid Assay test systems.

2 Member QC Panel

This panel consists of 1 positive and 1 negative sera. These are normally used for routine quality checks and to help determine if technical errors or reagent failures have occurred.

6 Member Qualification Panel

This panel consists of 5 positive and 1 negative sera. These are normally used for qualifying and evaluating the PIFA® Heparin/PF4 Rapid Assay test systems where a broad range of reactivity levels is desired. They provide data for comparative analysis in regard to sensitivity, specificity, reproducibility, and lot-to-lot variability.

Materials Not Provided

If a decision is made to divide the panel members into smaller aliquots, the following supplies will be needed:

- Micropipettor for measuring aliquot sample
- Small Volume cryovials capable of withstanding temperatures of $30-37^{\circ}\text{C}$ ($86-98^{\circ}\text{F}$) for approximately 1-2 minutes (conditions for thawing in a water bath), and flash freezing with storage temperatures at -70°C (-94°F)

Results Interpretation

Serum control panel members are identified as positive and negative. These are selected for specific use on the PIFA® Heparin/PF4 Rapid Assay test.

QC requirements should be performed in conformance with local, state, and/or federal regulations or accreditation requirements.

Expected Values

All serum panel members undergo continued testing from selection of bulk material through the aliquoting process. Samples are chosen to provide a broad range of reactivity levels. All testing is performed in parallel according to the manufacturer's directions for the GTI® PF4 Enhanced® ELISA test system where test results showing O.D. values of greater than 0.400 are regarded as positives.

A "positive" identified serum panel has O.D. values equal to or greater than 0.500 as determined on the GTI® PF4 Enhanced® ELISA test. A "negative" identified serum panel has O.D. values less than or equal to 0.320 as determined on the GTI® PF4 Enhanced® ELISA test.

Performance Claims

Studies were performed to evaluate the performance of the Heparin/Platelet Factor 4 Antibody Serum Panels for reproducibility (stability, including freeze-thaw), and precision.

Study #1 was performed to test the reproducibility of the Heparin/Platelet Factor 4 Antibody Serum Panel through repetition of the testing procedure utilizing the PIFA® Heparin/PF4 Rapid Assay in conjunction with the GTI® PF4 Enhanced® ELISA assay. This study also provided data supporting the ability of the Heparin/Platelet Factor 4 Antibody Serum Panel to remain stable after a number of freeze thaw cycles to mimic panel member handling conditions when utilized in the field. Included in the study were "borderline" samples that are near the cutoff range for positive and/or negative.

From testing each of the characterized samples in duplicate over a period of five days through varying number of freeze-thaw cycles, the Heparin/Platelet Factor 4 Antibody Serum Panel consistently produced expected results from the PIFA® assay. In addition, the results consistently correlate with the O.D. values received when samples were run on the GTI® PF4 Enhanced® ELISA assay, including the ability of the serum panel member to remain stable through numerous freeze-thaw cycles.

Reproducibility

GTI® PF4 Enhanced® ELISA Assay

	Positive	Negative
PIFA® Heparin/ PF4 Rapid Assay	40	0
	0	20

Study #2 was conducted to support the quality of the serum panel members processed for use with the PIFA® Heparin/PF4 Rapid Assay. Included in the study were "borderline" samples that are near the cutoff range for positive and/or negative.

THE USER MUST VALIDATE MORE THAN 1 ADDITIONAL FREEZE-THAW

From testing each of the characterized samples in multiple formats and consistently receiving the expected results from the PIFA® assay, the data reflects the precision provided by the assay. In addition, the results consistently correlate with the O.D. values received when samples were run on the GTI® PF4 Enhanced® ELISA assay, illustrating the ability of the serum panel member to deliver appropriate results through multiple testing procedures.

Precision

GTI® PF4 Enhanced® ELISA Assay

	Positive	Negative
PIFA® Heparin/ PF4 Rapid Assay	30	0
	0	20

References:

- 1 Guidance for Industry – Points to consider Guidance Document on Assayed and Unassayed Quality Control Material. <http://www.fda.gov/cdrh/ode/99.html>
- 2 GTI® PF4 Enhanced® ELISA Assay Package Insert. Catalog X-HAT13 or X-HAT45. <http://www.gtidiagnostics.com>

*GTI is a registered trademark of Genetic Testing Institute Corporation, Waukesha, WI

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Index of Symbols

	Attention, see instructions for use		Tests per kit		Manufacturer
	For in vitro diagnostic use only		Use by		Do not reuse
	Store at -70°C		Lot Number		Catalog #

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