



Akers Biosciences, Inc.

Heparin / PF4 Antibody Serum Panel Frequently Asked Questions

Please Consult the Product Package Insert Prior to Use

Storage and Reagent Handling

Q. How should the Heparin / PF4 Antibody Serum Panel be stored?

A. As noted in the Package Insert, serum panel members should be stored at -70°C or colder. These conditions are required to maintain antibody stability and achieve the labeled expiration dating.

If serum panel members and/or aliquots are stored above -70°C, the samples may not perform per classification and can only be used for informational purposes – not quality control. The labeled expiration dating would also be invalidated.

Q. I don't have a -70°C freezer, do you have any suggestions for meeting my Quality Control needs?

A. First, if possible, borrow space from another department who may have a -70°C or colder freezer. The control material is very small and doesn't take up much space.

Although controls should be assayed as required by your laboratory's standard quality control policy, the Heparin/PF4 Serum Panel Package Insert recommends that the Laboratory run controls upon receipt of a new lot of PIFA[®]/PAIFA[®] Heparin/PF4 Rapid Assays devices (referred to as "PIFA devices") and after running 100 devices within the same lot. As unit-use devices, Quality Control samples can be run somewhat infrequently.

Some customers have found the following approach helpful. Since your distributor may not provide lot-specific information when you place your order for PIFA devices, when it is time to reorder, also order a new serum panel. Run controls upon receipt of your shipment, even if there are no patient samples in queue. This should keep you in compliance until the next shipment (depending on the QC policy of your laboratory).

If you wish to run controls more frequently, proceed to produce control sample aliquots. The samples can be run for informational use only, not strictly as a control. Certain customers may find the additional experience in reading results beneficial.

Q. Why should I use a quick thaw procedure?

A. Proteins will precipitate out of frozen specimens if they are thawed at room temperature. The quick thaw procedure should minimize protein shedding. Our serum panel is frozen and comes on dry ice but it is processed under strict specifications in order to avoid the formation of particulates. Particulates could potentially interfere with the PIFA device.



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Q. If I don't have a water bath capable of maintaining 30-37°C, can I use a heating block?

A. Yes, your heating block should maintain 30-37°C. Exercise care when performing the quick thaw. Be careful not to overheat the samples as this will cause damage to the HPF4 antibodies.

Q. What happens if I forget about the control and it is heated for an extended period of time?

*A. More than likely, the positive sample will **not** perform per classification. The proteins contained in the HPF4 positive sample will degrade if exposed to excessive heat and they will not activate the reagent in the PIFA device. There is 150µl sample volume in each cryovial. This volume can quickly be overheated. The negative control will still work per classification but it is not a true indicator of device performance due to protein degradation.*

Q. The cryovial contains such a small volume, how can I accurately mix it?

*A. Inversion is **not** the mixing method of choice! We suggest the vial be vortexed or manually flicked several times to ensure mixing. It is important to have a homogenous dispersal of antibody throughout the sample.*

Q. After I thaw the sample, how soon should I use it?

A. It is best to use the sample immediately after thaw to maximize antibody reactivity. It is possible to keep the thawed sample at 2 to 8°C for a maximum of eight (8) hours prior to use. Remember: controls that have been kept refrigerated should warm to room temperature prior to use. This should take approximately thirty (30) minutes.

Q. What do I do with the remaining sample?

A. When using HPF4 serum panel members from ABI, it is imperative to avoid multiple freeze-thaw cycles. Once thawed, divide each panel member into single use aliquots. Aliquots should be flash frozen, stored at -70° C and should only be subjected to one additional freeze-thaw cycle.

When you are done using the initial sample, separate the remaining volume into 40µL single use aliquots and return these back into frozen conditions (-70° C). At a minimum, each panel member has 150µL starting volume. We recommend using the smallest possible cryovials for storage. If a 40µL aliquot is stored in a large volume tube, it is difficult to recover volume as the sample often coats the sides of the tube. It is also more prone to freezer burn due to the increased surface area. You should get one QC run and at least three (3) aliquots from each control vial. Pipetting technique will affect the yield obtained from each vial.

Q. What is meant by "Follow aseptic techniques" during the aliquot procedure?

A. To protect the sample aliquot from bacterial contamination follow standard aseptic techniques. This would include use of sterile pipet tips and cryovials. A bacterially contaminated sample may non-specifically block the membrane filtration system leading to false positives.



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Q. Aliquotting is a bother; can't I just freeze/thaw the same sample?

A. No! Repeated freeze cycles may diminish antibody activity. The Heparin/PF4 Antibody Serum Panel members should only be exposed to two (2) freeze/thaw cycles.

Results Interpretation

Q. What happened to the Certificate of Quality (Cof Q) data for individual panel members?

A. The C of Q data used to be on the back of the Heparin/PF4 Antibody Serum Panel package insert. This data can now be accessed by visiting www.akersbiosciences.com/products/coa.php. Data is provided for informational purposes and is listed by Lot Number. If you wish to be mailed or faxed a copy of this information, contact technical service at +1.856.848.2116 (US: 1-800-451-TEST).

Q. Can I use a control from another Heparin/PF4 test kit with the Heparin/PF4 Rapid Assay devices?

A. No! Most controls are plasma based. Plasma or converted plasma is not suitable to test with this assay and should not be used.

Q. What happens if my Heparin/PF4 antibody proficiency testing sample is plasma?

A. It cannot be run on the Heparin/PF4 Rapid Assay devices per manufacturer specifications. Most likely, it will give an inaccurate result.

Q. What can I do in the above circumstance?

A. If this happens, consult your survey and the governing body to clarify their requirements. It may be possible to blindly run an appropriately gathered characterized patient sample.

Q. If the HPF4 serum panel members are frozen, why can't I use my frozen specimens?

A. If not handled meticulously, freezing and thawing will decrease antibody activity, and could cause a positive sample to produce a negative test result. Freezing/thawing may also cause certain proteins to precipitate out of solution, and cause other microparticulates or debris to form. These particulates can clog the pores in the membrane filter system in the test device, and could cause a negative sample to produce a positive test result. ABI manufactures our serum panel members under very strict guidelines to avoid the formation of any particulates and interfering substances.

Q. I'm using such a small volume of control (30µL), does the temperature really matter?

A. Yes! The overall temperature of both the control and the devices is very important. They should both warm to room temperature for a minimum of 30 minutes prior to use. The colder the reagent/sample mixture, the more slowly the antibody/antigen reaction occurs.



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Q. I'm just a little short in the volume of control I have, can I run it anyway?

A. No, an incorrect amount of sample can affect the test result!