



**GTI. DIAGNOSTICS**

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June 2008

**RE: PF4 Confirmatory Procedure**

20925 Crossroads Circle, Suite 200  
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TO: All GTI Diagnostics PF4 ENHANCED® and PF4 IgG™ Customers

FROM: GTI Diagnostics Technical Support

As many of you are aware, recent events in China have affected the supply of heparin in the U.S.

Both the GTI Diagnostics PF4 ENHANCED® and PF4 IgG™ kits include a heparin confirmatory procedure which requires 10,000 unit/mL heparin in a saline solution. The liquid heparin solution is currently on backorder for many companies. We do not know if this is only a temporary inconvenience or long term.

To assist our customers, we are providing a sample procedure for using heparin sodium in a powdered form which is available through most scientific supply companies (i.e. VWR, Fisher Scientific). The heparin sodium tested at GTI Diagnostics was from VWR, Manufactured by JT Baker, Cat No JTM916-0. It was at a concentration of 175 units/mg in a 1 gram vial.

- Contact the supplier to obtain the concentration of the heparin sodium.
- Rehydrate the vial of heparin to a concentration of 100,000 U/ml.
- Example: To a vial containing 1 gram of heparin powder (175 U/mg) add 1.75 mLs of saline solution (0.85%).
- Swirl periodically to mix. This may take 30 – 45 minutes to completely dissolve into solution.
- This stock solution will be at a concentration of 100,000 U/mL.
- Add 100µL of stock solution to 900µL of saline (0.85%). This solution will be at a concentration of 10,000 U/mL. Caution: the stock solution is very viscous. Pipet slowly by releasing the pipet plunger in a slow, steady motion and resting the pipet tip below the liquid level to allow the solution to continue to rise to the level of 100µL. When dispensing the stock solution in saline, rinse the pipet tip several times.
- Mix well by vortexing.
- This will be the starting heparin solution (10,000 U/mL) in the PF4 Confirmatory Procedure.



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Four positive samples were tested comparing liquid heparin at 10,000 U/mL to powdered heparin sodium prepared as above. Both solutions were diluted to a final concentration of 100 units/mL in Specimen Diluent per the PF4 Confirmatory Procedure.

Results were as follows:

Sample ID	PF4 Screen (OD)	Liquid heparin in saline at 100 U/mL (OD)	% inhibition (OD)	Powdered heparin in saline suspension at 100 U/mL (OD)	% inhibition (OD)
A	0.511	0.179	81%	0.184	80%
B	2.553	0.270	93%	0.291	92%
C	0.441	0.103	99%	0.100	100%
D	3.407	0.297	94%	0.509	88%
Pos Ctl.	2.006	0.046	103%	0.046	103%
Neg Ctl.	0.101				

As you can see, both heparin solutions resulted in comparable inhibition.

If you have any questions regarding this protocol, please feel free to contact Technical Support at 1.800.233.1843.