Title: CAP Proficiency Tests for Platelet Function (PFPT)

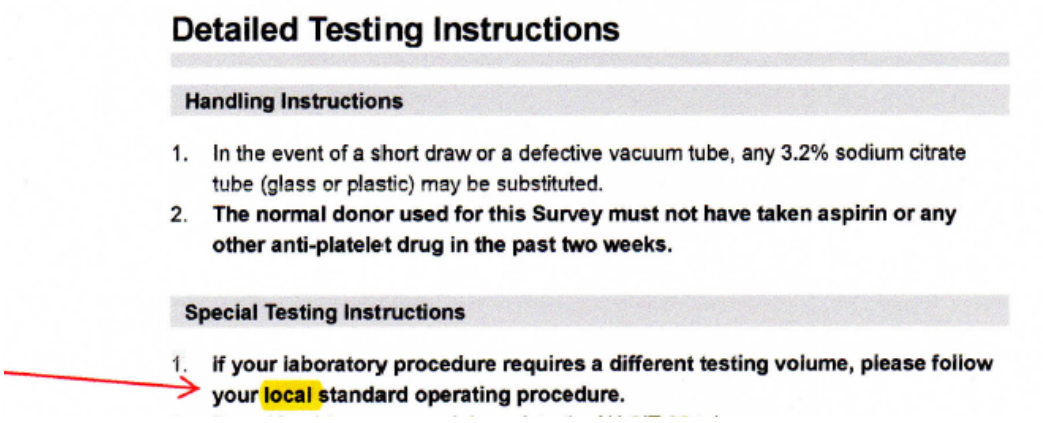
This Supplemental Technical Bulletin (STB) has been developed as a laboratory aid. This STB does not alter, revise or change the information provided in the Technical Bulletin included with the product. In accordance with Good Laboratory Practice and regulatory requirements, each laboratory must develop, validate and implement its own written procedures and expected results.

The PAP 8E and PFPT:

The Kit Instructions (KI) that accompany the PFPT materials are written in a manner intended to include all platelet aggregometers. It is based on the traditional, full volume sample (PRP) size of 450 µL, and agonist concentrations that are different than those of commercially available reagents. Contemporary aggregometers are designed to run microsamples - 250 µL.

Attempting to run a 450 µL sample in a microtest tube or MagneTube™, **MAY NOT** produce an accurate result because the mixing will be suboptimal.

The CAP Resource Committee responsible for this specialty has been made aware of the difficulties the current KI cause their participating laboratories. Recommended changes to the KI that address issues raised by participating laboratories have not been accepted. A minor change has been as a clarification:



Detailed Testing Instructions

Handling Instructions

1. In the event of a short draw or a defective vacuum tube, any 3.2% sodium citrate tube (glass or plastic) may be substituted.
2. **The normal donor used for this Survey must not have taken aspirin or any other anti-platelet drug in the past two weeks.**

Special Testing Instructions

1. **If your laboratory procedure requires a different testing volume, please follow your local standard operating procedure.**

The meaning of "follow your local standard operating procedures" means that the laboratory is suppose to follow the manufacturer's instructions for operating the aggregometer. For the laboratory with a PAP 8E, that means using a 250 µL total volume, and adjusting other materials for use in that total volume.

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Agonist Concentrations:

The agonist concentrations provided with or required for the PFPT testing are often not the same as those that are commercially available. Use the following dilution tables as a guide to adjust Bio/Data ADP, CN 101312, or Epinephrine, CN 101311, to the required concentration.

For ADP, the final concentration of normally reconstituted Bio/Data reagent is 20 uM. See the table below for how to prepare the dilution to reach that final concentration. (use the one in blue type)

ADP	Stock	Saline	Working Conc	Final Conc
Stock	---	---	200 uM	20 uM
1:2 of stock	250 ul	250 ul	100 uM	10 uM
1:4 of stock	125 ul	375 ul	50 uM	5 uM
1:5 of stock	100 ul	400 ul	40 uM	4 uM
1:6.6 of stock	75 ul	425 ul	30 uM	3 uM
1:10 of stock	50 ul	450 ul	20 uM **	2 uM
1:20 of stock	25 ul	475 ul	10 uM	1 uM
1:40 of stock	12 ul	485 ul	5 uM	0.5 uM
1:10 of ** (20 uM)	50 ul of **	450 ul	2 uM	0.2 uM

ADP= 2 x 10^{-4} (200 uM) Makes 500 ul (0.5 mL) **MAKE ALL DILUTIONS WITH 0.85% OR 0.9% SALINE**

For Epinephrine, the final concentration is 100 uM. Follow the table below to reach the 10 uM final concentration (use the one in blue)

EPINEPHRINE	Stock	Saline	Working Conc	Final Conc
Stock	---	---	1000 uM	100 uM
1:2 of stock	100 ul	100 ul	500 uM	50 uM
1:4 of stock	50 ul	150 ul	250 uM	25 uM
1:10 of stock	20 ul	180 ul	100 uM	10 uM
1:20 of stock	10 ul	190 ul	50 uM	5 uM

Epinephrine 1 x 10^{-3} (1000 uM) (Makes 200 ul)

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