

# Joint UKBTS / NIBSC Professional Advisory Committee (1)

## UKBTS General Information 01

### List of Evaluations

February 2004

*Prepared by:* The technical sub committee of the SACBC

*This document will be reviewed whenever further information becomes available, and at least annually. Please continue to refer to the website for in-date versions.*

### Explanation

The technical sub committee of the SACBC have collated a list of evaluations performed within the UK blood Services. This is made available so that unnecessary duplication of work can be avoided. If details of the reports are required it will be necessary to contact the lead person in an individual service who will discuss what can be made available, which may incur a cost if copies of reports are required. Up to date in-use information may also be available for products that have been introduced into service. It is not intended that information will be made available to commercial suppliers from this database.

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# Joint UKBTS / NIBSC Professional Advisory Committee <sup>(1)</sup>

## UKBTS General Information 01

### List of Evaluations

February 2004

## Database of evaluations in UK blood services for SACBC TG

### NBS BAXTER REPORTS

Statu s	Eval. Phase	Pack Code No.	Pack Description	Temperature	Report Date
A	1	R7481	BAT Triple	4°C (Overnight Hold)	9.3.99
A	2	R7481	BAT Triple	4°C (Overnight Hold)	14.6.99
A	1	R7481	BAT Triple	4°C (Overnight Hold)	5.4.99
A	2	R7481	BAT Triple	4°C (Overnight Hold)	1.7.99
A	1	R7490 (RZ2000 Filter)	OA Triple	4°C (Overnight Hold)	1.7.99
A	2	R7490 (RZ2000 Filter)	OA Triple	4°C (Overnight Hold)	1.10.99
A	1	R7490 (RZ2000 Filter)	OA Triple	Ambient	1.7.99
A	1	R7490	OA Triple	4°C (Overnight Hold)	19.7.99
A	1	R7490	OA Triple	Ambient	06.7.99
A	2	R7490	OA Triple	Ambient	11.10.99
A	1	R7103	Optidock Platelet	Ambient	01.7.99
A	2	R7103	Optidock Platelet	Ambient	20.8.99
A	1	PL2410 + integral filter (PLX5)	Optidock Platelet	20 - 24°C	16.6.99
A	2	PL2410 + integral filter (PLX5)	Optidock Platelet	20 - 24°C	8.9.99
A	1	R7223	Standard Double	4°C (Overnight Hold)	24.8.99
A	2	R7223	Standard Double	4°C (Overnight Hold)	24.8.99
A	2	R7489	BAT Triple	4°C (Overnight Hold)	7.2.99
A	1	R7489	BAT Triple	4°C (Overnight Hold)	24.11.99
NA	1	R7489	BAT Triple	Ambient	18.10.99
A	1	R7489	BAT Triple	4°C (Overnight Hold)	29.10.99
NA	1	R7489	BAT Triple	Ambient	29.10.99
A	2	R7489	BAT Triple	4°C (Overnight Hold)	20.12.99
A	1	FGR7014	Dock on Plasma Filter	Ambient	05.4.00
NA	2	FGR7014	Dock on Plasma Filter	Ambient	17.5.00
NA	2	FGR7014	Dock on Plasma Filter	Room Temperature	23.10.00
A	1	FGR7014	Dock on Plasma Filter	Ambient	01.01.00
NA	2	FGR7014	Dock on Plasma Filter	Ambient	01.06.00
A	0	R7413 (PLX5)	Platelet Filter	Ambient	28.4.00
A	0	R7481 (R2000)	Red Cell Filter	4°C (Overnight Hold)	19.4.00
A	0	R7490 (RZ2000)	Whole Blood in-line Filter	4°C (Overnight Hold)	17.4.00

## Joint UKBTS / NIBSC Professional Advisory Committee <sup>(1)</sup>

### UKBTS General Information 01

#### List of Evaluations

February 2004

Statu s	Eval. Phase	Pack Code No.	Pack Description	Temperature	Report Date
A	0	R7455 (RS2000)	Whole Blood in-line Filter	4°C (Overnight Hold)	3.4.00
A	0	FGR7014	Dock on Plasma Filter	Ambient	24.3.00
NA	1	R7490 (small volume trial)	Standard Triple (without bypass line)	4°C	September 2000
A	0	R7489	Soft Bodied LD Filter	4°C	21.9.00
A	1	R7490	Standard Triple (integral needle)	4°C	23.11.00
A	2	R7490	Standard Triple (integral needle) SSC	-	19.01.01
•	0	FGR2003	Label Quadruple Platelet	-	
•	0	R7489 (8435)	Label Soft Body Filter	-	
A	1	R8435	Bottom & Top	4°C	08.01.01
A	1	R8435	Bottom & Top	Ambient	08.01.01
A	2	R8435	Bottom & Top	4°C	May 2001
A	Small trial	R7490	Standard Triple (without bypass line)	4°C	February 2001
NA	Small trial	R7490	Standard Triple	4°C	April 2001
A	1	R7489	Soft Bodied LD Filter	Ambient	04.05.01
A	1	R7489	Soft Bodied LD Filter	4°C	04.05.01
A	2	R8435	Bottom & Top	Ambient	28.06.01
	Small trial	R2094 with longer lines for producing neonatal red cell splits		-	Jun/Jul 2001
A	1	FGR8451B	Blood Pack with SSC	-	23.08.01
A	1	FGR8451B	Blood Pack with SSC	-	23.08.01
A	2	FGR8451B	Blood Pack with SSC	-	12.11.01
A	2	FGR8451B	Blood Pack with SSC	-	12.11.01
	IV	Pouch Packs		23.5°C	5.9.01

## Joint UKBTS / NIBSC Professional Advisory Committee (1)

### UKBTS General Information 01

#### List of Evaluations

**February 2004**

Status	Eval. Phase	Pack Code No.	Pack Description	Temperature	Report Date
A	Operational Evaluation	R7548	Quintuplet WB filter pack for cryo production		10.01.02
A	Operational Evaluation	R7548	Quintuplet WB filter pack for cryo production		15.01.02
A	Operational Evaluation	R7548	Quintuplet WB filter pack for cryo production		15.01.02
A	2	8435	BAT pack	4°C overnight, ambient filtration	13.12.01
A	2	R7490	Sample diversion pouch incorporated as part of SSC assembly		24.05.02
A	Operational Assessment	FGR 8427	Modification of the SSC to incorporate a cap to protect the sample needle		25.03.02

A	Validation approved by NBPSAG
NA	Not approved for use by NBPSAG
•	Validation ongoing

# Joint UKBTS / NIBSC Professional Advisory Committee <sup>(1)</sup>

## UKBTS General Information 01

### List of Evaluations

February 2004

### NBS NBPI REPORTS

Status	Eval. Phase	Pack Code No.	Pack Description	Temperature	Report Date
A	2	T2926	Standard	Ambient	20.9.99
A	1	T2926	Standard	Ambient	7.3.99
A	1	T2926	Standard	4°C (Overnight storage)	14.3.99
A	1	T2926	Standard	4°C (Overnight storage)	15.3.99
A	1	T2926	Standard	Ambient	25.2.99
A	2	T2916	TAB Mini Filter	Ambient	19.3.99
A	2	T2926	Standard	4°C (Overnight Hold)	10.8.99
A	2	T2926	Standard	Ambient	10.8.99
A	1	T2916	B&T Mini Filter	4°C	14.8.00
A	2	T2916	B&T Mini Filter	4°C	2.11.00
A	2	T2926 SSC	Standard SSC	4°C	27.12.00
A	0	T2916	BAT red cell mini filter	-	30.4.00
•	0	T2916	Label BAT Mini Filter		
A	1	T2961	BAT Mini Filter	Ambient	30.11.00
A	1	T2961	BAT Mini Filter	4°C	7.12.00
A	2	T2961	BAT Mini Filter	Ambient	10.01.01
A	1	T2961 SagM	BAT Mini Filter	Ambient	Jan 2001
A	0	T2926	WBF	-	Apr 2000
Status	Eval. Phase	Pack Code No.	Pack Description	Temperature	Report Date
A			NPBI new design of base labels for use on packs provided to the NBS		21.02.02
A	1	T3949	Incorporate sample diversion pouch as part of SSC assembly on all NPBI packs		28.03.02
A	1	T3949	Newly designed clamp on donor line, increased length of specific transfer lines, new filter.	4°C storage overnight, ambient filtration	20.03.02
A	1	T3949	Newly designed clamp on donor line, increased length of specific transfer lines, new filter.	Processed day 0, ambient	05.04.02
A	2	T3949	Whole blood filtration	Overnight 4°C, ambient filtration	12.06.02
A	2	T3949	Whole blood filtration	Processed day 0, ambient	12.06.02

## Joint UKBTS / NIBSC Professional Advisory Committee <sup>(1)</sup>

### UKBTS General Information 01

#### List of Evaluations

**February 2004**

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NA	Not approved for use by NBPSAG
•	Validation ongoing

### NBS PALL REPORTS

Status	Eval. Phase	Pack Code No.	Pack Description	Temperature	Report Date
A	1	780-44U	OA Triple	4°C (Overnight Hold)	25.2.99
A	2	780-44U	OA Triple	4°C (Overnight Hold)	25.2.99
A	1	780-44U	OA Triple	Ambient	12.3.99
A	1	780-44U (T2001-9)	OA Triple	Ambient	31.3.99
A	2	780-44U (T2001-9)	OA Triple	Ambient	24.6.99
A	2	LPS1B1U/B2U	Dock on Plasma Filter	Ambient	16.8.99
A	1	LPS1B1U Plasma Filter	Dock on Plasma Filter	Ambient	26.5.99
A	2	LPS1B1U Plasma Filter	Dock on Plasma Filter	Ambient	5.8.99
A	1	780-24U	BAT Triple	Ambient	19.7.99
•	2	780-24U	BAT Triple	Ambient	20.3.00
A	1	789-24U	BAT Triple	Ambient	21.7.99
•	2	780-24U	BAT Triple	Ambient	25.1.00
A	1	RCB410CU	BAT Triple (Euro Pack)	Ambient	12.7.00
A	1	BATI, RCB410CU	BAT Triple	Ambient	15.6.00
A	0	LPS1B1	Plasma Filter		27.3.00
A *	0	MB1	Methylene Blue Removal Filter		6.9.00
A	1	WBT410CU	Whole Blood Filter	4°C	11.12.00
A	2	WBT410CU	Whole Blood Filter	4°C	22.12.00
A *	1	BSV 7001 XB	MB Inactivation and Pall MB Removal		29.8.00
A *	1	BSV 7001 XB	MB Inactivation and Pall MB Removal		4.9.00
*	1b	BSV 7001 XB	MB Inactivation and Pall MB Removal		10.10.00
*	2	BSV 7001 XB	MB Inactivation and Pall MB Removal		22.11.00
*	2	BSV 7001 XB	MB Inactivation and Pall MB Removal		10.11.00
•	O	WBT410CU	Label Phase O		
•	O	RCB410CU	Label Phase O		
A	1	WBT410CU	BAT Triple	Ambient	21.01.01

## Joint UKBTS / NIBSC Professional Advisory Committee (1)

### UKBTS General Information 01

#### List of Evaluations

**February 2004**

A	0	WBF3 Filter	Whole Blood Filter	Ambient / 4°C	16.02.00
A	0	789-24U	Red Cell B&T Triple	Ambient / 4°C	10.5.99
A	1	WBT410CU	Whole Blood Integral Filter	Room Temp	24.01.01
NA	2	WBT410CU	Whole Blood Integral Filter	Room Temp	03.10.01
A	1	RCB433CU	BATi	Ambient	20.01.01
A	1	WBT410CU	Whole Blood Integral Filter	Overnight hold at 4°C	05.02.01
A	0	789-44U	WBF2 Filter	-	11.01.99
<b>Status</b>	<b>Eval. Phase</b>	<b>Pack Code No.</b>	<b>Pack Description</b>	<b>Temperature</b>	<b>Report Date</b>
•		All PALL blood collection systems	Change wording and format for blood pack base labels		

A	Validation approved by NBPSAG
•	Validation ongoing

\* c/o SPIC PIB GROUP

## Joint UKBTS / NIBSC Professional Advisory Committee (1)

### UKBTS General Information 01

#### List of Evaluations

February 2004

### NBS MACOPHARMA REPORTS

Status	Eval. Phase	Pack Code No.	Pack Description	Temperature	Report Date
A	1	FQF6261B	OA Triple	Ambient	5.8.99
A	2	FQF6261B	OA Triple	Ambient	13.9.99
A	1	FQF6261B	OA Triple	4°C (Overnight Hold)	23.8.99
A	1	FQF6261B	OA Triple	4°C (Overnight Hold)	22.10.99
A	1	FQF6261B	OA Triple	Ambient	11.10.99
A	2	FQF6261B	OA Triple	4°C (Overnight Hold)	15.11.99
NA	1	FQF6261B	OA Triple	4°C (Overnight Hold)	5.10.99
NA	1	FQF6261B	OA Triple (longer filtration line)	4°C (Overnight Hold)	22.10.99
A	1	6260PB-NPE	BAT pack with integrated removal filters for plasma and red cell concentrates	Ambient	21.9.00
•	2	6260PB-NPE	BAT pack with integrated removal filters for plasma and red cell concentrates	4°C	20.2.01
A	1	6260PB-NPE	BAT pack with integrated removal filters for plasma and red cell concentrates	4°C (Overnight)	12.10.00
•	2	6260PB-NPE	BAT pack with integrated removal filters for plasma and red cell concentrates	Ambient	17.11.00
A	1	NPE 6260 PB	BAT pack with integrated removal filters for plasma and red cell concentrates	Ambient	December 2000
A	1	NPE 6260 PB	BAT pack with integrated removal filters for plasma and red cell concentrates	4°C	January 2001
A	1 & 2	FQF6261 PB	SSC (Heat Sealing)		January 2001
A	1 & 2	FQF6261 PB	SSC (Stripping)		January 2001
A	1 & 2	FQF6261 PB	SSC (Close Clipping)		January 2001
NA	1 & 2	FQF6261 PB	SSC (not stripping)		January 2001
A	2	NPE 6260	SSC (stripping)		January 2001
A	O	Leucoflex PLAS4	BAT Plasma Filter		1999
A	2	NPE6260PB	BAT	Ambient	March 2001
A	Acceptance Testing	LQT6260PB	BAT	4°C	June 2001

## Joint UKBTS / NIBSC Professional Advisory Committee (1)

### UKBTS General Information 01

#### List of Evaluations

**February 2004**

Status	Eval. Phase	Pack Code No.	Pack Description	Temperature	Report Date
NA	1	PROT 0245 (LST2)	Whole blood filter	Ambient	19.11.01
NA	1	PROT 0245 (LST2)	Whole blood filter	4°C storage, Ambient filtration	October 2001
NA	Acceptance Testing (1)	PROT 0245 (LST2)	Whole blood filter	4°C storage, Ambient filtration	December 2001
A	0	PROT 0245 (LST2)	Whole blood filter		15.03.02
A	1	LCR5 Quadruple CPP/SAGM Bactivam	Sample diversion pouch incorporated as part of SSC assembly		22.03.02
A	2	LQT 6261LB	Sample diversion pouch incorporated as part of SSC assembly		30.04.02

A	Validation approved by NBPSAG
NA	Validation not approved by NBPSAG
•	Validation ongoing

## Joint UKBTS / NIBSC Professional Advisory Committee (1)

### UKBTS General Information 01

#### List of Evaluations

February 2004

### NBS MISCELLANEOUS REPORTS

Status	Eval. Phase	Description	Temperature	Report Date
-	-	Field Validation of the next generation blood cell separator : Amicus Separator	-	1999
-	2	COBE Trima Cell Separator	-	11.5.99
-	-	COBE Spectra Platelet Bag Sample and Twist Off Recepter	-	March 99
A	1	Haemonetics	4°C	15.9.00
-	0	Base Label Validation – SOP	4°C, 22°C, -40°C	Dec 2000
	-	Automatic Side Tube Stripping Validation	-	2000
	-	Label Validation - Terumo LGF456E13	-	2000
	-	NPBI Compodock Validation Report	-	2000
A	-	Validation of equipment bioelettronica BagPRESS BIO45	-	29.9.00 7.7.01
A	-	Validation of the new Optipress II for the processing of conventional double blood packs.	-	Nov 1999
	-	Validation of blood administration set compatibility with packs in current use within the NBS	-	June 2000
	-	Addendum to Validation of blood administration set compatibility....	-	31.10.00
	-	Base label Validation of the Biofil Bio-P bag.	-	15.11.00
A	-	Specification for demand printed blood group and product labels.	-	Dec 2000
	-	Validation of Spectra Harness Needleguards StD – Apheresis	-	Dec 2000
	-	Harness specification for Apheresis Technology	-	Jan 2001
NA	0	Haemonetics 942UKF Red Cell Harness – Base Label	-	29.01.01
A	-	Leuko Reduction Cart, Sarstedt Tube Stripper, Line Stripper - ITL	-	Apr 2001
A	-	Dental/Optical Chairs – Lab Validation	-	29.01.01
A	-	Vista Tec Protective Faceshield – report on trial	-	May 2001
A	-	Validation on thicker walled tubing on Baxter Blood Packs	-	08.12.00
	3	Cobe Trima Automated Blood Collection System	-	Dec 2000
	-	Baxter Optipress Heatsealers	-	25.04.01
	-	Macopharma Heatsealer	-	25.04.01
	-	Haemonetics MCS+ Platelet Protocol	-	13.12.00
	-	MCS+ machine revision C.1 for the collection of double dose platelets	-	1.8.00
-	-	MCS+ version C in collection of double dose platelets when programmed for a set number of cycles	-	21.11.00
-	-	T-ACE Blood Processor : Pall (Terumo)	-	02.12.99
-	-	Protocol for Baxter Modified In-line Sample Site Coupler	-	July 2001
-	-	Protocol for the Validation of the in line sample pouch system	-	July 2001
		Specification for the replacement of blood irradiators in NL	-	28.09.01

## Joint UKBTS / NIBSC Professional Advisory Committee <sup>(1)</sup>

### UKBTS General Information 01

#### List of Evaluations

**February 2004**

Status	Eval. Phase	Description	Temperature	Report Date
A	0	Terumo WBSP Filter – RCC and Plasma Products Only	-	06.09.00
-	-	Haemonetics MCS+ employing the revision C.1 and C.3 (high speed LDP) with continuous filtration	-	13.2.01
-	-	Validation to establish the suitability for routine use of the Fresenius NPBI Compodock Sterile Connecting Device.	-	11.6.01
A	-	PALL Metrologic Voyager (MS9500 Series) barcode scanner and stand	-	31.10.01
A	-	PALL Metrologic Voyager (MS9500 Series) barcode scanner and stand	-	20.10.01
A	-	Blank PM labels for demand printing for blood group and component labels with Baxter Packs	-	25.10.01
A	-	Blank PM labels for demand printing for blood group and component labels with MacoPharma Packs	-	25.10.01
A	-	Blank PM labels for demand printing for blood group and component labels with Baxter Packs	-	16.10.01
A	-	Blank PM labels for demand printing for blood group and component labels with Baxter and MacoPharma Packs	-	22.10.01
A	-	Validation of the Thermogenesis Plasma Thawer (MT210 10 bag capacity) for use in the Methylene Blue Photoinactivation System	-	26.11.01
•	1	Haemonetics Platypus needle guard and Samplelok sampling adaptor for the collection of post donation samples	-	21.03.02
NA	Operational Evaluation	RadTag blood irradiation indicator label.	-	November 2001
NA	-	Baxter Helmer Plasma Thawer DH8 (8 bag capacity)	-	18.01.02
A	0	Baxter Opti II software upgrade	-	31.01.02
A	1	Baxter Opti II software upgrade	-	20.02.02
A	Functional Evaluation	Baxter Opti II software upgrade	-	10.01.02
A	2	Baxter Opti II software upgrade	-	28.05.02
A	BSI Report	Baxter Opti II software upgrade	-	12.04.02
NA	BSI Report	Haemonetics TCD B40 Sterile Connection Device	-	14.02.02
A	BSI Report	Haemonetics TCD B40 Sterile Connection Device	-	05.03.02
A	1	Haemonetics TCD B40 Sterile Connection Device	-	21.03.02
NA	2	Haemonetics TCD B40 Sterile Connection Device	-	30.05.02
A	BSI Report	NBPI Compodock Sterile Connection Device	-	11.05.01
NA	1	NBPI Compodock Sterile Connection Device	-	23.05.02
A	1	NBPI Compodock Sterile Connection Device	-	09.05.02
NA	2	NBPI Compodock Sterile Connection Device	-	30.05.02
NA	1	Terumo Whole blood platelet saving filter	Ambient	08.05.02
A	1	Gambro SSC on dual arm kit	-	28.03.05
A	-	Change over to thicker walled tubing on the donor line of Baxter blood packs	-	07.02.02

## Joint UKBTS / NIBSC Professional Advisory Committee <sup>(1)</sup>

### UKBTS General Information 01

#### List of Evaluations

**February 2004**

A	Stores Assessment	MacoPharma new carton for all blood packs, with and without filter		12.03.02
A	Assessment	MacoPharma – standardise SAGM formulation		18.03.02
A		Whole Blood Transportation Bag		24.05.02
NA		Becton Dickinson FACS Sample Processor SP-1		14.06.02
A		Validation of Coulter LH 750 Haematology Analyser		June 2002
A		Acceptance Testing of Beckman Coulter Haematology Analyser LH750		28.05.02
A		Acceptance Testing of Beckman Coulter Haematology Analyser LH750		16.07.02
•		Implementation of Autologous Tears as a Standard NBS product for the service		
A		Production of Platelet Pools using Dry Buffy Coat Method in M&SW Centres		10.06.02
A		Production of Platelet Pools using Dry Buffy Coat Method in M&SW Centres		13.06.02
A		Production of Platelet Pools using Dry Buffy Coat Method in M&SW Centres		17.06.02
A		Validation of BD and Coulter Flow Cytometer reagents using new protocols for BD and Coulter Flow Cytometers		July 2001
A		Change to protocols for use of BD and Coulter reagents in BD and Coulter machines		05.07.02
•		Replacement spike/drip chamber assembly for Spectra and Trima tubing sets		
•		Validation of blank labels/donation ID sets for National purchase contract		
•		Replace plasma bags on Haemonetics platelet harnesses – 600ml bag to be replaced by 800ml bag		
A		Validation of Gambro packs as third pack in the production of Triple Dose Cobe Apheresis platelets		12.06.02
•		Provision of AB serum for Pancreatic Islet Transplantation		
•		Baxter bar code readable batch numbers on all packs		
•		Validation of Baxter Cannula Breaker		
•		Validation of Baxter Automated R7019 Platelet Filtration Processing		
A	1 & 2	Validation of Gambro Trima cell separators for the collection of 3 adult therapeutic doses of platelets		11.07.02
A		Closed system for the recovery of Frozen Red Cells		15.08.02
•		Validation of MacoPharma removable and re-openable clamp		
•		PULSE product reference tables updated to include codes for Lymphocytes		
•		Implementation of a single heat seal throughout processing of components		
A		MacoPharma changes to peelable overwrap		

# Joint UKBTS / NIBSC Professional Advisory Committee (1)

## UKBTS General Information 01

### List of Evaluations

February 2004

NA		Validation of B Coonan LD Trolley 2000		23.07.02
•		Validation of NPBI Electric LD Trolley		
•		Validation of Metrologic Scanner software upgrade		
•		Validation of Computype laser printed donation ID sets		
A				

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NA
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# Joint UKBTS / NIBSC Professional Advisory Committee (1)

## UKBTS General Information 01

### List of Evaluations

February 2004

### WELSH BLOOD SERVICE VALIDATIONS

Status	Eval. Phase	Pack Code No.	Pack Description	Temperature	Report Date
A	0	780-44U WBF2	Whole Blood	AMBIENT	19/2/99
A	1	780-44U WBF2	Whole Blood	AMBIENT	19/2/99
NT*	2	780-44U WBF2	Whole Blood	AMBIENT	19/2/99
A	0	R7455 RS2000	Whole Blood	AMBIENT	19/2/99
NA	1	R7455 RS2000	Whole Blood	AMBIENT	19/2/99
NT	2	R7455 RS2000	Whole Blood		
A	0	NPBI 2915	Whole Blood	AMBIENT	19/2/99
A	1	NPBI 2915	Whole Blood	AMBIENT	19/2/99
NT	2	NPBI 2915	Whole Blood		
A	0	780-44U WBF2	Whole Blood	Overnight hold @ 4 <sup>0</sup> C & filtered @ 4 <sup>0</sup> C	19/2/99
A	1	780-44U WBF2	Whole Blood	Overnight hold @ 4 <sup>0</sup> C & filtered @ 4 <sup>0</sup> C	19/2/99
NT***	2	780-44U WBF2	Whole Blood		
A	0	R7455 RS2000	Whole Blood	Overnight hold @ 4 <sup>0</sup> C & filtered @ 4 <sup>0</sup> C	19/2/99
A**	1	R7455 RS2000	Whole Blood	Overnight hold @ 4 <sup>0</sup> C & filtered @ 4 <sup>0</sup> C	19/2/99
NT	2	R7455 RS2000	Whole Blood		
A	0	NPBI 2915	Whole Blood	Overnight hold @ 4 <sup>0</sup> C & filtered @ 4 <sup>0</sup> C	19/2/99
A	1	NPBI 2915	Whole Blood	Overnight hold @ 4 <sup>0</sup> C & filtered @ 4 <sup>0</sup> C	19/2/99
NT	2	NPBI 2915	Whole Blood		
A	0	725-94U	CPD-A1 Whole Blood for NN	Ambient	19/5/99
A	1	725-94U	CPD-A1 Whole Blood for NN	Ambient	19/5/99
A	2	725-94U	CPD-A1 Whole Blood for NN	Ambient	19/5/99
A	0	725-94U	CPD-A1 Whole Blood for NN	Overnight hold @ 4 <sup>0</sup> C & filtered @ 4 <sup>0</sup> C	19/5/99
A	1	725-94U	CPD-A1 Whole Blood for NN	Overnight hold @ 4 <sup>0</sup> C & filtered @ 4 <sup>0</sup> C	19/5/99
A	0	725-94U	CPD-94U Whole Blood for NN irradiated day 5	Ambient & overnight hold	11/6/99
A****	2	725-94U	CPD-A1 Whole Blood for NN	Overnight hold @ 4 <sup>0</sup> C & filtered @ 4 <sup>0</sup> C after 11:15am	10/9/99

## Joint UKBTS / NIBSC Professional Advisory Committee (1)

### UKBTS General Information 01

#### List of Evaluations

February 2004

A**	One gross failure @ $2.64 \times 10^9$	
NT*	Introduced into routine use with 3778 data points available	
A	Validation approved by WBS	
NA	Validation not approved by WBS	
NT	Not tested	
NT***	Introduced into routine use but withdrawn after confidence lost in process.	Introduced into routine use but withdrawn after confidence lost in process 26/2/01.

## Joint UKBTS / NIBSC Professional Advisory Committee <sup>(1)</sup>

### UKBTS General Information 01

#### List of Evaluations

February 2004

### WELSH BLOOD SERVICE VALIDATIONS

Status	Eval. Phase	Pack Code No.	Pack Description	Temperature	Report Date
A	0	789-24U RCM-1	BAT SYSTEM WET BC	AMBIENT	19/2/99
A	1	789-24U RCM 1	BAT SYSTEM WET BC	AMBIENT	19/2/99
A	2	789-24U RCM-1	BAT SYSTEM WET BC	AMBIENT	19/2/99
A	0	R7416 R2000	BAT SYSTEM WET BC	AMBIENT <sup>1</sup>	19/2/99
NA	1	R7416 R2000	BAT SYSTEM WET BC	AMBIENT <sup>1</sup>	19/2/99
NT	2	R7416 R2000	BAT SYSTEM WET BC	Operationally not acceptable & Residual RBC insufficient	
A	0	NPBI 2916	BAT SYSTEM WET BC	AMBIENT	19/2/99
NA	1	NPBI 2916	BAT SYSTEM WET BC	AMBIENT	19/2/99
NT	2	NPBI 2916	BAT SYSTEM WET BC	Residual RBC insufficient	
A	0	789-24U RCM-1	BAT SYSTEM DRY BC	WB Overnight hold @ 4 <sup>0</sup> C then processed & filtered @ ambient	19/2/99
A	1	789-24U RCM 1	BAT SYSTEM DRY BC	WB Overnight hold @ 4 <sup>0</sup> C then processed & filtered @ ambient	19/2/99
A	2	789-24U RCM-1	BAT SYSTEM DRY BC		
A	0	R7416 R2000	BAT SYSTEM DRY BC	WB Overnight hold @ 4 <sup>0</sup> C then processed & filtered @ ambient	19/2/99
A	1	R7416 R2000	BAT SYSTEM DRY BC	WB Overnight hold @ 4 <sup>0</sup> C then processed & filtered @ ambient	19/2/99
NT	2	R7416 R2000	BAT SYSTEM DRY BC		
A	0	NPBI 2916	BAT SYSTEM DRY BC	WB Overnight hold @ 4 <sup>0</sup> C then processed & filtered @ ambient	19/2/99
A	1	NPBI 2916	BAT SYSTEM DRY BC	WB Overnight hold @ 4 <sup>0</sup> C then processed & filtered @ ambient	19/2/99
NT	2	NPBI 2916	BAT SYSTEM DRY BC		

A	Validation approved by WBS
NA	Validation not approved by WBS
NT	Not tested
1	
NT***	Introduced into routine use but withdrawn after confidence lost in process.

## Joint UKBTS / NIBSC Professional Advisory Committee (1)

### UKBTS General Information 01

#### List of Evaluations

February 2004

### WELSH BLOOD SERVICE VALIDATIONS

Status	Eval. Phase	Pack Code No.	Pack Description	Temperature	Report Date
A	0	RCB-410CU RCM-1	BAT SYSTEM WET BC	AMBIENT	31/7/00
A	2	RCB-410CU RCM-1	BAT SYSTEM WET BC	AMBIENT	12/9/00
A	0	RCB-410CU RCM-1	BAT SYSTEM DRY BC	WB Overnight hold @ 4 <sup>0</sup> C then processed & filtered @ ambient	31/7/00
NA <sup>1</sup>	2	RCB-410CU RCM-1	BAT SYSTEM DRY BC	WB Overnight hold @ 4 <sup>0</sup> C then processed & filtered @ ambient	9/11/00
A	0	WBT-410CU WBF3	Whole Blood	AMBIENT	26/9/00
A	2	WBT-410CU WBF3	Whole Blood	AMBIENT	11/12/00
A	0	WBT-410CU WBF3	Whole Blood	Overnight hold @ 4 <sup>0</sup> C & filtered @ Ambient	7/11/00
A	1	WBT-410CU WBF3	Whole Blood	Overnight hold @ 4 <sup>0</sup> C & filtered @ Ambient	23/1/01
IP	0	WBT-410AU WBF3	CPD-A1 Whole Blood for NN	AMBIENT	
NT	2	WBT-410AU WBF3	CPD-A1 Whole Blood for NN	AMBIENT	
IP	0	WBT-410AU WBF3	CPD-A1 Whole Blood for NN	Overnight hold @ 4 <sup>0</sup> C & filtered @ 4 <sup>0</sup> C after 11:15am	
NT	2	WBT-410AU WBF3	CPD-A1 Whole Blood for NN	Overnight hold @ 4 <sup>0</sup> C & filtered @ 4 <sup>0</sup> C after 11:15am	
			<b>MISCELLANEOUS</b>		
A		Bio 45A bagpress	But not in routine use		8/12/99
A	1	Amicus			16/8/99
A	2	Amicus			6/12/99
A	0/1	777800151	Eval. Of Cobe Trima for LD Single Dose Platelets and Single RBC		15/8/02
A	0/1	000777132	Eval. Of Cobe Spectra for LD Hyperconcentrated Platelets		31/8/01
A	0/1	F4R2316	Eval. Of Baxter Amicus Crescendo for LD Plateletpheresis		17/7/02
A	0/1	F4R2316	Process qual. of Baxter Amicus Crescendo for LD Plateletpheresis		22/8/02
NA	2	F4R2316	Eval. Of Baxter Amicus LD Plateletpheresis from new manufacturing plant		22/8/02
A	0/1	777800001	Eval. Of Cobe Trima for LD Plateletpheresis		12/9/02

# Joint UKBTS / NIBSC Professional Advisory Committee (1)

**UKBTS General Information 01**

**List of Evaluations**

**February 2004**

A	2	777800001	Process qual. Of Cobe Trima for LD Plateletpheresis		12/902
*	0/1	000777132 777800001 777800401	Eval. of LD Hyperconcentrated Platelets collected on – (a) Cobe Spectra (b) Cobe Trima (c) Cobe Trima Accel		
*	0/1	777800401	Eval. Of Cobe Trima Accel for LD Plateletpheresis		
*	2	777800401	Process qual. Of Cobe Trima Accel for LD Plateletpheresis		

A	Validation approved by WBS
NA <sup>†</sup>	Validation not approved by WBS due to breakaway H&S problems
NT	Not tested
IP	

## Joint UKBTS / NIBSC Professional Advisory Committee (1)

### UKBTS General Information 01

#### List of Evaluations

February 2004

### SNBTS VALIDATIONS – BLOOD PACK / LD FILTERS

Status	Eval. Phase	Pack Code No.	Pack Description	Temperature	Report Date
A	0/1/2	FQF&DLE6260PB	MacoPharma in-line WB filter LST1	Ambient	Feb 1998
NA	0	RS2000	Baxter in-line WB filter	Ambient & overnight at 4 <sup>o</sup> C	Nov 1998
NA	0	RZ200	Baxter in-line CRC filter	Ambient	Nov 1998
A	0	780-94U	Pall in-line WB filter WBF 2	Amb(at various times)& 24hrs at 4 <sup>o</sup> C	Jan 1999
A	1	780-94U	Pall in-line WB filter WBF 2	Amb(at various times)& 24hrs at 4 <sup>o</sup> C	Jan 1999
A	2	780-94U	Pall in-line WB filter WBF 2	Amb(<8hrs post collect.)& 24hrs at 4 <sup>o</sup> C	Jan 1999
A	0	ATSBC1U	Pall AutoStop plt filter	Ambient	June 1999
A	1	ATSBC1U	Pall AutoStop plt filter	Ambient	June 1999
A	2	ATSBC1U	Pall AutoStop plt filter	Ambient	June 1999
A	0	789 -94U	Pall in-line CRC filter RCM 1	Ambient	June 1999
A	1	789 -94U	Pall in-line CRC filter RCM 1	Ambient	June 1999
A	2	789 -94U	Pall in-line CRC filter RCM 1	Ambient	June 1999
A	0	MBT/FL	MacoPharma MBT of FFP	Ambient	May 2000
A	1	Autologous donor pack	MacoPharma in-line WB filter LSD1	Ambient	Oct 1999
A	1	Autologous donor pack	MacoPharma in-line WB filter LSD1	Ambient	Jan 2000
A	1	LPS1B?2U	Pall dock-on plasma filter	Ambient	Jan 2000
A	1&2	RZ2000 (R7490)	Baxter in-line WB filter Sepacell	Amb(at various times post collection)	Jun 00&Jan 01
A	1&2	T&B Quad R8453	Baxter in-line CRC filter Sepacell	Ambient	Mar 01
A	2	T2926	NPBI in-line WB filter Composelect	Amb(at various times post collection)	June 2000
A	0	T2915	NPBI in-line WB filter Compoflex	Ambient	Feb 1999
A	1	T2915	NPBI in-line WB filter Compoflex	Ambient	Feb 1999
A	2	T2915	NPBI in-line WB filter Compoflex	Ambient	Feb 1999
A	0		NPBI dock-on platelet filter	Ambient	1999
A	1		NPBI dock-on platelet filter	Ambient	1999
A	2		NPBI dock-on platelet filter	Ambient	1999
A	0	T&B Quad pack	NPBI in-line CRC filter	Ambient	1999
A	1	T&B Quad pack	NPBI in-line CRC filter	Ambient	1999
A	2	T&B Quad pack	NPBI in-line CRC filter	Ambient	
A		MBT/FL	MacoPharma MBT of fresh plasma	Ambient	Sept 2000
A	0	2964	NPBI in-line CRC filter(small type)	Ambient	Oct 2000

## Joint UKBTS / NIBSC Professional Advisory Committee (1)

### UKBTS General Information 01

#### List of Evaluations

**February 2004**

A	Validation approved by SNBTS
NA	Validation NOT approved by SNBTS

### SNBTS VALIDATIONS - MISCELLANEOUS

Status	Eval. Phase	Pack Code No. Pack Description	Temperature	Report Date
A	0	Eval. of COBE Trima for LD Plateletpheresis	N/A	AUG 1998
A		Validation of NPBI COMPOCOOL System	N/A	AUG 1998
A		Process qual. of Haemonetics MCS+ LD Plateletpheresis	N/A	AUG 1999
A		Eval. of Trima & MCS+ to achieve Adult+Neonatal LD Platelet Components	N/A	JULY 1999
A		Process qual. on NPBI COMPODOCK SCD	N/A	MARCH 2000
A		Eval. of MacoPharma Sample Pouch/Inoc.Needle in Platelet Sterility Testing	N/A	SEPT 2000
A		Eval. of Pall Medical Sample Pouch/Inoc.Needle in Platelet Sterility Testing	N/A	SEPT 2000
A		Eval. of NPBI Sample Pouch/Inoc.Needle in Platelet Sterility Testing	N/A	OCT 2000
A	0	Eval. of BAXTER Amicus for LD Plateletpheresis	N/A	Early 1999
A	2	Process qual. of COBE Trima for LD Plateletpheresis	Also ABE	Beg 2001
A	2	Process qual. of BAXTER Amicus LD Plateletpheresis	Also INV /GLA	JAN 2001
A	2	Process qual. on NPBI COMPODOCK SCD		MAR 1999
A	2	Process qual. on NPBI COMPOMIXERS		2000

A	Validation approved by SNBTS
NA	Validation NOT approved by SNBTS

## Joint UKBTS / NIBSC Professional Advisory Committee <sup>(1)</sup>

### UKBTS General Information 01

#### List of Evaluations

February 2004

### NIBTS VALIDATIONS

Statu s	Eval. Phase	Pack Code No.	Pack Description	Temperature	Report Date
	1	789-24U RCM-1	BAT SYSTEM DRY BC	Ambient	6/9/99
	1	780-44U WBF 2	Whole Blood	Ambient & 4°C	6/6/99
	1	NPBI T2916	BAT	Ambient	6/6/99
	1	NPBI 2926	Whole Blood	Ambient & 4°C	6/6/99
	1	Baxter 7490	Whole Blood	Ambient & 4°C	6/6/99
	1	NPBI Q9007	BAT	Ambient	October 2000
	1	Baxter FGR 7489	BAT	Ambient	December 2000
	1	Baxter R7490	Whole Blood	Ambient & 4°C	December 2000

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<sup>(1)</sup> **Joint United Kingdom Blood Transfusion Services and National Institute for Biological Standards and Control Professional Advisory Committee**