

Joint UKBTS / HPA Professional Advisory Committee (¹)

UKBTS General Information 01

List of Evaluations

July 2011

Prepared by: Standing Advisory Committee on Blood Components (SACBC)

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

Background

The Standing Advisory Committee on Blood Components (SACBC) have collated a list of evaluations performed with 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.

Contacts:

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(¹) **Joint United Kingdom Blood Transfusion Services and Health Protection Agency Professional Advisory Committee**

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Database of evaluations in UK Blood Services for SACBC from February 2004

NHSBT FENWAL REPORTS

| Status | Eval. Phase | Pack Code No. | Pack Description | Temperature | Report Date |
|--------|-----------------------------|---|---|-------------|-------------|
| N/A | 0 | Amicus crescendo | | | 10/06/04 |
| N/A | 1 | Amicus crescendo | | | 28/02/05 |
| N/A | 2 | Amicus crescendo | | | 11/09/06 |
| A | 0 | ALYX red cell collector | | | 22/04/04 |
| A | 1 | ALYX red cell collector | | | 28/12/04 |
| A | 2 | ALYX red cell collector | | | 10/11/06 |
| A | 0 | Intercept Platelet Pathogen Inactivation system | | | |
| A | 1 | Intercept Platelet Pathogen Inactivation system | | | 29/01/03 |
| A | 2 | Intercept Platelet Pathogen Inactivation system | | | 27/02/03 |
| A | 0 | PlasmPure filter PLO | | | 18/09/03 |
| N/A | 1 | PlasmPure filter PLO | | | Abandoned |
| A | Minor change Evaluation | R8478 | Reduction in size of red cell pack from 450 ml to 400ml | | 22/06/04 |
| A | | | Move production of R7019, R2094 and R7011 packs from La Chatre to Haina | | 22/06/04 |
| A | 1 | Improved plasma filter | | | 22/10/04 |
| N/A | 2 | Improved plasma filter | | | Abandoned |
| N/A | 1 | Improved plasma filter | | | Abandoned |
| A | 1 | Improved plasma filter | | | 19/01/05 |
| A | Minor change, no validation | FGR2094, FGR7011 and FGR7019 packs | Change sterilisation method from 'Gamma' to 'ebeam' | | 26/06/07 |
| A | 1 | FGR 8477 | Overnight Hold Project | | 29/01/08 |
| A | 2 | FGR 8478 | Overnight Hold project | | 07/04/08 |
| A | 1 | FGR 8477 | Repeat validation at extended ambient overnight hold (18 hour) | | 27/10/08 |
| | 2 | FGR 8477 | Repeat validation at extended ambient overnight hold (18 | | 27/01/09 |

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| | | | hour) | | |
| A | 0 | Amicus v3.1 | | | 23/04/09 |
| | | | | | |
| A | Validation approved by NBPSAG | | | | |
| NA | Not approved for use by NBPSAG | | | | |
| • | Validation ongoing | | | | |

NHSBT NBPI REPORTS

| Status | Eval. Phase | Pack Code No. | Pack Description | Temperature | Report Date |
|--------|-------------|-----------------------------------|--|------------------------|-------------|
| A | 0 | Plasma filter | | | 06/01/04 |
| A | 1 | Plasma filter | | | 16/05/03 |
| A | 1 | Plasma filter | | | 03/08/05 |
| N/A | 2 | Plasma filter | | | 01/03/06 |
| N/A | 2 | Plasma filter | | | 01/03/06 |
| N/A | Trial | Compomat G4 | Validation of Pooled platelets prepared from low volume Buffy coats prepared on a Compomat | | 19/01/05 |
| A | 1 | WB in-line filter | Improved filter | 4°C | 27/09/05 |
| A | 1 | WB in-line filter | Improved filter | Ambient | 25/07/06 |
| A | 0 | Compostop CS | Platelet processing and leucodepletion system | | 01/11/05 |
| A | 1 | Compostop CS | Platelet processing and leucodepletion system | | 16/11/05 |
| A | 1 | Compostop CS | Platelet processing and leucodepletion system | | 15/12/05 |
| A | 2 | Compostop CS | Platelet processing and leucodepletion system | | 15/12/05 |
| A | 1 | NPBI/PALL prion reduction devices | | | 18/04/05 |
| A | 0 | Whole Blood packs (T3949) | Improved WB filter | | 30/04/07 |
| A | 0 | Whole blood PUS filter T3949 | Change to filter coating | | 19/09/07 |
| A | 1 | Whole Blood packs (T3949) | Improved WB filter | Ambient Overnight Hold | 30/05/08 |

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| ■ | 2 | Whole Blood packs (T3949) | Improved WB filter | Ambient Overnight Hold | |
| A | 0 | Compoflow | Collapsible bullet shaped cannula | | 03/09/08 |
| A | 1 | Whole Blood packs (T3949) | Improved WB filter | 4°C | 14/10/08 |
| A | 1 | Whole Blood packs (T3949) | Improved WB filter | Ambient | 14/10/08 |
| ■ | 2 | Whole Blood packs (T3949) | Improved WB filter | 4°C | |
| ■ | 2 | Whole Blood packs (T3949) | Improved WB filter | Ambient | |
| | 1 | T3922 packs | With hard & soft housing filter | Ambient overnight hold | |
| | 0 | T3901 | Dockable plasma filtration system with new flexible filter | | Waiting for Phase 0 information |
| | 0 | T4703 | Platelet processing storage system with new flexible filter | | Waiting for Phase 0 information |
| A | Validation approved by NBPSAG | | | | |
| NA | Not approved for use by NBPSAG | | | | |
| • | Validation ongoing | | | | |

NHSBT PALL REPORTS

| Status | Eval. Phase | Pack Code No. | Pack Description | Temperature | Report Date |
|--------|-------------|----------------------------|--|-------------|-------------|
| A | 0 | ELX platelet storage bag | | | 16/10/03 |
| A | 1 | ELX platelet storage bag | | | 07/07/05 |
| A | 0 | RC Leukotrap RC/WB systems | 42 day storage | | 30/11/04 |
| A | 1 | Prion removal devices | | | 24/11/05 |
| A | 1 | | High efficiency Pre-process filter system for leucocyte removal from Whole Blood | | 08/08/05 |
| A | 1 | | High efficiency Pre-process filter system for leucocyte removal from Whole Blood | | 08/08/05 |
| A | 2 | | High efficiency Pre-process filter system for leucocyte removal | | 12/12/05 |

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| | | | from Whole Blood | | |
| A | 2 | | High efficiency Pre-process filter system for leucocyte removal from Whole Blood | | 01/12/05 |
| A | 1 | | High efficiency In-process filter system for leucocyte removal from Red Cells (BAT) | | 18/01/06 |
| A | 1 | | High efficiency In-process filter system for leucocyte removal from Red Cells (BAT) | | 18/01/06 |
| A | 2 | | High efficiency In-process filter system for leucocyte removal from Red Cells (BAT) | | 18/01/06 |
| A | 2 | | High efficiency In-process filter system for leucocyte removal from Red Cells (BAT) | | 18/01/06 |
| A | 1 | | NPBI/PALL prion reduction devices | | 18/04/06 |
| A | 1 | | Prion removal devices | | 24/11/05 |
| A | 1 | | High efficiency Pre-process filter system for leucocyte removal from Whole Blood | | 08/08/05 |
| A | PQ | Dock on plasma filter (LPS1B1U) | | | 24/04/06 |
| A | IQ/OQ | BAT red cells | | 4°C | 04/04/07 |
| A | 1 | RCB436CU and RLB436CU systems | Move from 'Steam/Stem' to 'Gamma/Steam' sterilisation | Ambient + 4°C | 20/03/07 |
| A | 1 | RCB436CU and RLB436CU systems | Move from 'Steam/Stem' to 'Gamma/Steam' sterilisation | Ambient | 04/04/07 |
| A | 2 | RCB436CU and RLB436CU systems | Move from 'Steam/Stem' to 'Gamma/Steam' sterilisation | Ambient | 27/04/07 |
| A | 2 | RCB436CU and RLB436CU systems | Move from 'Steam/Stem' to 'Gamma/Steam' sterilisation | Ambient | 08/11/07 |
| A | 0 | RCB436CU and RLB436CU packs | New red cell filter (RCM2) | | 15/03/07 |
| A | 1 | RCB436CU and RLB436CU packs | New red cell filter (RCM2) | Ambient | 08/11/07 |
| A | 1 | RCB436CU and | New red cell filter | 4C/Ambient | 22/10/07 |

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| | | RLB436CU packs | (RCM2) | | |
| A | 2 | RCB436CU and RLB436CU packs | New red cell filter (RCM2) | Ambient | 08/07/08 |
| A | 2 | RCB436CU and RLB436CU packs | New red cell filter (RCM2) | 4C/Ambient | 01/08/08 |
| A | 1 | WBT packs | Overnight hold project | | 28/01/08 |
| A | 2 | WBT packs | Overnigh hold project | | 28/01/08 |
| A | 1 | RCB436CU and RLB436CU | Wide bore tubing on RC T&B red cell filter systems | | 20/02/08 |
| | 2 | RCB436CU and RLB436CU | Wide bore tubing on RC T&B red cell filter systems | | 16/01/09 |
| A | 0 | PALL RCM3 filter | | | 28/10/08 |
| A | 1 | PALL RCM3 filter | | Ambient | 05/01/09 |
| A | 1 | PALL RCM3 filter | | Ambient overnight | 05/01/09 |
| ■ | 2 | PALL RCM3 filter | | Ambient | |
| ■ | 2 | PALL RCM3 filter | | Ambient overnight | |
| A | Validation approved by NBPSAG | | | | |
| NA | Not approved for use by NBPSAG | | | | |
| • | Validation ongoing | | | | |
| | | | | | |

NHSBT MACOPHARMA REPORTS

| Status | Eval. Phase | Pack Code No. | Pack Description | Temperature | Report Date |
|--------|-------------|-------------------------------------|------------------|-----------------|-------------|
| A | PQ | Dockable PLAS 4 filter (BSV 6000XB) | | | 01/12/04 |
| A | Phase 0 | Modified WB filter | | | 27/07/05 |
| A | Phase 1 | Modified WB filter | | Ambient/Ambient | 05/09/05 |
| A | Phase 1 | Modified WB filter | | 4C/Ambient | 02/09/05 |
| A | Phase 2 | Modified WB filter | | Ambient/Ambient | 27/10/05 |
| A | Phase 2 | Modified WB filter | | 4C/Ambient | 14/11/05 |
| A | Phase 1 | Prion removal devices | | | 27/11/07 |
| N/A | Phase 0 | LXT filter | | | 27/07/05 |
| A | Phase 0 | Improved LXT filter | | | 28/03/08 |
| A | Phase 1 | Improved LXT filter | | Ambient | 04/09/08 |
| A | Phase 1 | Improved LXT filter | | 4C | 04/09/08 |
| • | Phase 2 | Improved LXT filter | | Ambient | |
| • | Phase 2 | Improved LXT filter | | 4C | |
| | Phase 0 | Macotronic plasma illuminator | Version B2 | | |
| A | Phase 1 | LQT6281LB (BAT) | | Ambient O/N | 23/07/2008 |
| • | Phase 2 | LQT6281LB (BAT) | | Ambient O/N | |

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| A | Phase 0 | FQE6280LB (improved LXT filter) | Overnight hold | | 02/09/2008 |
| A | Phase 1 | FQE6280LB (improved LXT filter) | Overnight hold | | 21/10/2008 |
| ■ | Phase 2 | FQE6280LB (improved LXT filter) | Overnight hold | | |
| A | Phase 0 | MacoPharma modified cannula 090320 | New Cannula has a reduced breaking strength and a larger internal diameter | | 04/08/09 |
| | | | | | |
| A | Validation approved by NBPSAG | | A | | |
| NA | Not approved for use by NBPSAG | | NA | | |
| ● | Validation ongoing | | | | |
| | | | | | |

NHSBT OTHER REPORTS

| Status | Eval. Phase | Manufacturer | Pack / Description | Details | Report Date |
|--------|--------------------------------|------------------|---------------------|------------------|-------------|
| A | Phase 0 | Haemonetics | ACP215 RCC washer | | 11/09/07 |
| A | Phase 0 | Haemonetics | 948F DDRC LD filter | | 18/10/07 |
| A | Phase 0 | Haemonetics | Cymbal DDRC | | 23/07/07 |
| A | Phase 0 | Haemonetics | MCS+ DRC in plasma | | 20/11/09 |
| A | Phase 0 | DRK Lyoplas N -w | Freeze dried plasma | For military use | 27/01/10 |
| | | | | | |
| A | Validation approved by NBPSAG | | A | | |
| NA | Not approved for use by NBPSAG | | NA | | |
| • | Validation ongoing | | | | |
| | | | | | |

NHSBT PATHOGEN INACTIVATION REPORTS

| Status | Eval. Phase | Manufacturer. | Description | Details | Report Date |
|------------------|--|---------------|--|---------|-------------|
| N/A [#] | Phase 0 | Cerus | Intercept Plasma | | 03/07/09 |
| N/A [#] | Phase 0 | Cerus | Intercept Platelets in plasma and/or PSM | | ? |
| N/A [#] | Phase 0 | Caridian BCT | Mirasol Platelets in plasma | | 01/02/10 |
| | | | | | |
| A | Validation approved by NBPSAG | | | A | |
| NA | Not approved for use by NBPSAG | | | NA | |
| NA [#] | Not approved for use incase manufacturer takes this as approval to proceed / implement | | | | |
| • | Validation ongoing | | | | |

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WELSH BLOOD SERVICE VALIDATIONS

| Status | Eval. Phase | Pack Code No. | Pack Description | Temperature | Report Date |
|--------|-------------|---|---|----------------------------------|---------------|
| A | 0 | Baxter ALYX2 RBC collection system | Red cells collected in ACD-A, stored in SAG-M | "Apheresis" collection | February 2004 |
| A | 0 | Evaluation of Pall <i>Leukotrap</i> Affinity Prion Reduction Filter | WBT434CU packs | Ambient and overnight hold @ 4°C | April 2005 |
| A | 0 | WBT434CEU | Pall Line II evaluation (Ascoli) | Ambient and overnight hold @ 4°C | June 2005 |
| A | 1 | WBT434CEU | Pall Line II evaluation (Ascoli) | Ambient and overnight hold @ 4°C | August 2005 |
| A | 2 | WBT434CEU | Pall Line II evaluation (Ascoli) | Ambient and overnight hold @ 4°C | October 2005 |
| A | 0/1 | RCB434CEU | Pall Line II evaluation (Ascoli) | Ambient and overnight hold @ 4°C | March 2006 |
| A | Small trial | Effect of irradiation in split packs | Neonatal split packs | | February 2007 |
| A | 1 | RCB434CEU (wide-bore" collection packs | BAT system DRY BC | Ambient and overnight hold @ 4°C | June 2007 |
| A | 1 | RCB434CEU units with RCM2 filter | BAT system DRY BC | Ambient and overnight hold @ 4°C | October 2007 |
| A | 2 | RCB434CEU units with RCM2 filter | BAT system DRY BC | Ambient and overnight hold @ 4°C | |
| A | 1 | RCB436CEU packs | BAT system DRY BC | Ambient and overnight hold @ 4°C | March 2008 |
| A | 1 | Macopharma P_CAPT filter | Prion reduced red cell filter | Day 1 filtration | August 2010 |
| A | 1 | RCB436CU3 | PALL BAT system with RCM3 filter | Ambient and overnight hold @ 4°C | May 2010 |
| A | 1 | R8477 and R8478 | Fenwal T/T and BAT systems | Ambient and overnight hold @ 4°C | November 2008 |
| A | 2 | R8477 and R8478 | Fenwal T/T and BAT systems | Ambient and overnight hold @ 4°C | January 2009 |
| A | 0 | Pall prion/LD reduction filter | WBT436CEU, RCB436CU2 | Ambient and overnight hold @ | January 2009 |

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| | | | | 4°C | |
|-----------------|--|-------------------------------------|--|--|---------------|
| * | 0/1 | 000777132 777800001 777800401 | Eval. of LD Hyperconcentrated Platelets collected on – (a) Cobe Spectra (b) Cobe Trima (c) Cobe Trima Accel | | February 2005 |
| A | 0 | ATSBC1EU | Pack for the storage of buffy coat-PCs for up to 7 days | | December 2004 |
| A | | ATSBC1EU | Evaluation of CD62P and PS levels in 8 – 14 day old pooled PCs | | August 2004 |
| A | Small trial | C08049167b | Method for suspending apheresis PCs in PAS (SSP+) | | June 2008 |
| A | | ATSBC1EU | Evaluation of pooled PC prepared from dry buffy coats | | June 2008 |
| A | | NFP1EU | Evaluation of Pall PC storage pack for use as “third pack” for apheresis triple doses | | May 2011 |
| A | | WBT436CEU and RCB436CU3 | Pall top/top and BAT | Overnight hold of whole blood at ambient temperature | June 2011 |
| A | Validation approved by WBS | | | | |
| NA ¹ | Validation not approved by WBS due to breakaway H&S problems | | | | |
| NT | Not tested | | | | |
| IP | | | | | |

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SNBTS VALIDATIONS – BLOOD PACK / LD FILTERS

| Status | Eval. Phase | Pack Code No. | Pack Description | Temperature | Report Date |
|--------|----------------------------------|---------------|------------------|-------------|-------------|
| | | | | | |
| A | Validation approved by SNBTS | | | | |
| NA | Validation NOT approved by SNBTS | | | | |

| Validation Number | Title | Date Completed |
|-------------------|---|----------------|
| VD 002/04 | Process Validation of Pooled Cryoprecipitate | Jan 2004 |
| VD 004/04 | Validation of Upgrade on Compodock MKII Sterile Connecting Device | Feb 2004 |
| VD 008/04 | Validation of Orbisac Process | Mar 2004 |
| VD 013/04 | Validation of Terumo TSCDII Sterile Connecting Device | Aug 2004 |
| VD 014/04 | Validation of Terumo BP-KIT for the Preparation of BCD Platelet Components at West BTC | Oct 2004 |
| VD 019/04 | Validation of Heraeus 6000i Cryofuge Centrifuge | Dec 2004 |
| VD 010/05 | Validation of Porteus Fabrication 4°C Cryoprecipitate Preparation Waterbath | June 2005 |
| VD 011/05 | Process Qualification of Gambro Trima Accel Single Stage Enhancement | July 2005 |
| VD 012/05 | Validation of Thermogenesis Plasma Thawer | Feb 2006 |
| VD 013/05 | Process Validation of Pooled Cryoprecipitate Component Using MacoPharma Pooling Pack (VSE80004XQ) | July 2005 |
| VD 017/05 | Validation of MacoPharma Packs (LQT6281LB) | Nov 2005 |
| VD 020/05 | Intercept Platelet Validation (Baxter Protocol 451-P-A-NIV) | Sept 2005 |
| VD 003/06 | Validation of Terumo BP-Kit for Preparation of BCD Platelet Components | Feb 2006 |
| VD 019/06 | Procedural Qualification of Baxter Plateletpheresis Harness C Type F4R2337 with Integral Sample Pouch | July 2006 |
| VD 023/06 | Operational Validation of NPBI Pack Type T3922 (Top and Bottom with CRC filter) | Sept 2006 |
| VD 026/06 | Operational Validation of NPBI pack Type T4002 Compostop Platelet Pooling System | Oct 2006 |
| VD 032/06 | Validation of Thermo TSCDII Sterile Connecting Device | Oct 2006 |
| VD 027/07 | Validation of new Fresenius Hemocare Compomat G4 Blood Processing Equipment | July 2007 |
| VD 017/08 | In Vitro Evaluation of MacoPharma P-CAPT Prion Removal Device (PSE3080XB) using SAGM RCCs from Fresenius Kabi (T3922) B&T Blood Packs | June 2008 |
| VD 020/08 | Validation of Helmer Platelet Incubator (PC4200i) | July 2008 |
| VD 031/08 | Validation of Insulated Transport Boxes | Nov 2008 |
| VD 032/09 | Qualification of Pall Top and Top WB Filter System (Pack Type WBT436 Cell) | Aug 09 |
| VD 033/09 | Qualification of PalTop and Bottom CRC Filter System (Pack | Aug 09 |

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| | Type RCB436CU3) | |
| VD 034/09 | Qualification of Pall Platelet Filter System (Pack Type ATSBC1ESU) | Aug 09 |
| VD 039/09 | Terumo TSCDII Upgrade | Oct 09 |
| VD 059/09 | Qualification of MacoPharma Top and Top WB Filter (Pack Type FQE6280LB) | Dec 09 |
| VD 060/09 | Qualification of MacoPharma Top and Bottom Filter System (Pack Type LQT6281LB) | Dec 09 |
| VD 061/09 | URS for Procurement of Rapid Plasma Blood Component Freezer | Aug 10 |
| VD 004 10 | Validation of Becton Dickinson FACS Calibur Flow Cytometer | Aug 10 |
| VD 006 10 | Qualification of Fresenius Compostop BC Pool Processing with MacoPharma LQT6281LB packs | March 2010 |
| VD 010/10 | Validation of Haemonetics ACP 215 Cell Washer | On-going |
| VD 021/10 | Validation of MacoPharma P-CAPT Prion Removal Devive USING SAGM RCC from MacoPharma blood Top and Top Packs (FQE6280LB) | Aug 2010 |

NIBTS VALIDATIONS

[illegible]