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## Worklist for Issue of frozen products for as starting material for manufacture

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Organisation: Christie Pathology Partnership

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## ISSUING WORKLIST FOR FROZEN CELLS AS STARTING MATERIAL FOR ATMPS

*Please initial when complete. Do not leave blank fields, use N/A if not applicable.*

**Name****Date:****Date of Birth:****BB number****Hospital number****DIN (if applicable)****Batch number****Patient ID**

	Completed by	Checked By
Time of pickup confirmed		
Check release authorised		
Date returned entered in Synergy		
Rack/slot set at 0 (if all cells used)		
Dry shipper received and check list completed		
<b>Packing the Leukapheresis Material and Sentinel Vials in the Cryoport Dry Shipper</b>		
<b>Materials Required for Shipment:</b>		
<b>Supplied by Manufacturer</b>		
Metal Cassettes		
Inner leak-proof polybags		
Absorbent sheets		
Tyvek bags		
<b>Supplied by Courier - Delivered with dry shipper</b>		
Zip ties		
Tamper-evident zip-tie seal		
Dry Shipper Container Label		
Exempt Human Specimen Label		
Tray prepared with dry ice		
Cells removed from tank to dry ice tray <b>Time:</b>		
Patient and harvest details checked on insert and product label for each bag		
Integrity of bag checked		
Remove bag from overwrap		
Place in pre-cooled cassette. <i>Cryobag ports upwards.</i>		
Cassette placed in polybags provided with one absorbent sheet.		



Polybag sealed and folded around the cassette		
Polybag placed in Tyvek bag with cryobag ports facing upwards.		
Tyvek bag sealed and bag folded around the cassette.		
Each bag packed individually as above and placed in metal rack inside internal dry shipper.		
Bag/s placed in rack with spaces in-between (max 4 bags per shipper).		
Cells placed in dry shipper <b>Time:</b>		
Sentinel vials placed inside polybag with one absorbent sheet, air removed and sealed.		
Aliquot polybag placed in Tyvek bag, air removed and sealed.		
Sentinel vials placed in rack		
Lid of inner shipper closed <b>Time:</b>		
Check logger active and flashing green.		
Serialised zip tie applied to inner shipper lid. <b>Zip tie serial no:</b>		
Contents labels attached to outer shipper container.		
Shipper certification form packed in outer pouch of shipper.		
Latches sealed with non-serialised zip ties.		
4 Copies of waybill signed and placed in outer pouch (courier brings these). Keep one copy one for records.		
Handed to courier <b>Time:</b>		
Date and times of packing and shipment recorded on manufacture IT system		