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1. PURPOSE

To describe all procedures surrounding cord blood collection: storage and preparation of material, labeling, packaging and sending of the cord blood bag

2. SCOPE

All cord blood collections

3. RESPONSIBILITIES

Maternity ward and operating room nurses

4. REQUIRED MATERIAL

- Collection kit including:
 - Collection bag
 - Disinfectant (2% chlorhexidine / 70% alcohol)
 - Plastic (Ziploc) bag
 - Padded shipping envelope
- Collection file including:
 - Copy of the online registration form for the Public Bank or the consent to directed cord blood donation form (ENR-00139 or 00140)
 - *Collecte de sang de cordon* (Cord blood collection form) or *Collecte de sang de Cordon Dirigé* (Directed Cord Blood Collection)
 - *Étiquette Prélèvement* (Collection Label) or *Étiquette Prélèvement Dirigé* (Directed Collection Label)
 - Donation number labels (IND-00057)
- Shipping box
- Sterile field (not provided)
- Tamper-evident seal
- Thermoregulator bags (4)

5. IDENTIFIERS

N/A

6. PROCEDURE

6.1. GENERAL

- Héma-Québec ensures that the mother has consented to donate and is medically qualified prior to the cord blood collection.
- The cord blood bag must not leave the delivery room or the operating room before all labeling has been completed.
- Use only one cord blood kit per collection.
- Thermoregulator bags must remain in the shipping box provided.
- Material provided by Héma-Québec, including collection bags, disinfectant, documents and labels, is under the responsibility of the delivery unit and the operating room personnel trained on this procedure.
- Regarding any questions, Hema-Quebec Public Cord Blood Bank can be reached at 1-888-666-4362 p.5253.

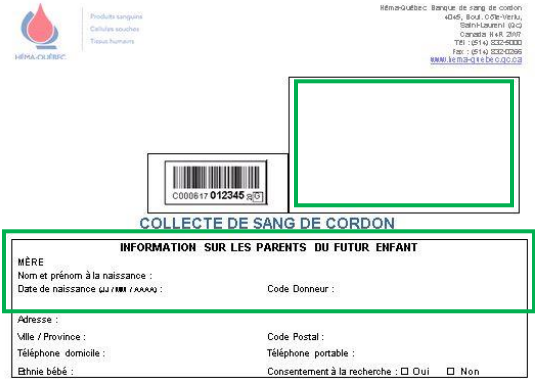


6.2. MATERIAL MANAGEMENT



Steps		Instructions		References
1	Material order	1.1	When needed, complete the order and storage form and transmit it to Héma-Québec Note: The form can be obtained from Hema-Quebec's website at any moment	ENR-02963
2	Material storage	2.1	Upon reception of the material, store it: <ul style="list-style-type: none"> - in a secure restricted area - at room temperature - away from direct heating or sunlight - above the ground to prevent contamination or damage in case of flooding - using the FIFO (first in, first out) or FEFO (first expire, first out) as needed storage system - where only one box is open at any given time. Note: Do not mix different lots in one box	ENR-02963
		2.2	Complete the order and storage form and return in to Héma-Québec	



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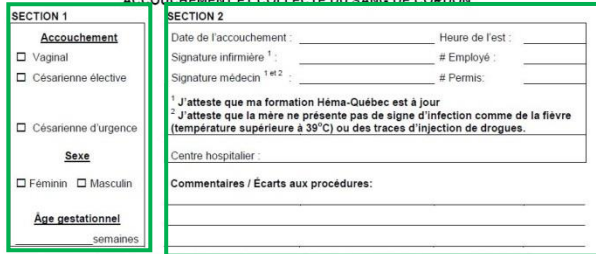
6.3. COLLECTION PREPARATION

Steps		Instructions		References	
1	Document preparation	1.1	Verify the content of the collection file: <ul style="list-style-type: none"> - Copy of the online registration form or consent for directed donation - <i>Collecte de sang de cordon (dirigé)</i> - <i>Étiquette</i> prélèvement (<i>dirigé</i>) - Donation number labels 	Online registration form or ENR-00139 (00140) IND-00057	
		1.2	If incomplete, notify Héma-Québec's Cord Blood Bank		
		1.3	Verify the identity of the mother and make sure it matches the online registration form or consent for directed donation and collection form, then adressograph  Note: The signature of the document certifies that the verification was performed	  Héma-Québec Banque de sang de cordon 4040, boulevard Henri Bouffard, Québec (QC) Canada H4K 2H5 Tél : (514) 322-5000 Fax : (514) 322-5005 www.hema-quebec.ca	<i>Collecte de sang de cordon (dirigé)</i> Online registration form or ENR-00139 (00140)
		1.4	Insert the online registration form or consent to directed donation to the mother's hospital file	Online registration form or ENR-00139 (00140)	



Steps		Instructions		References
2	Collection material preparation	2.1	Fetch the collection kit material: - Collection bag - Disinfectant - Plastic (Ziploc) bag - Padded shipping envelope	
		2.2	Place gauze pads and disinfectant (2% chlorhexidine / 70% alcohol) on the sterile field	
		2.3	Make sure the collection bag and the disinfectant is not expired 	
		2.4	Tear open the aluminum envelope and, if possible, keep the collection bag in its transparent plastic overwrap during the collection 	

6.4. COMPLETION OR INTERRUPTION OF COLLECTION


Steps		Instructions		References
1	Collection bag	1.1	Ensure that the needle protector is locked in place, covering the needle	
		1.2	If it has not been already done by the physician: - Break the cannula from the anticoagulant pouch - Open the proximal blue clamp - Roll the anticoagulant pouch up onto itself to empty the anticoagulant into the collection line - Close the proximal blue clamp and permanent red clamp Otherwise, skip to step 1.3	
		1.3	Make sure the clamps are closed	






Steps		Instructions		References
1	Collection bag (continued)	1.4	<p>Invert the bag, back and forth, 10 times to mix the anticoagulant with the cord blood</p> <p>IMPORTANT : This step must be performed as soon as possible after the collection to prevent blood clots formation. If the situation provides the opportunity, start the inversions of the pouch during the collection.</p>	
2	Document	2.1	<p>Fill out sections 1 and 2</p> <div data-bbox="578 653 1170 905" data-label="Form">  <p>SECTION 1</p> <p>Accouchement</p> <p><input type="checkbox"/> Vaginal</p> <p><input type="checkbox"/> Césarienne éleative</p> <p><input type="checkbox"/> Césarienne d'urgence</p> <p>Sexe</p> <p><input type="checkbox"/> Féminin <input type="checkbox"/> Masculin</p> <p>Âge gestationnel</p> <p>_____ semaines</p> <p>SECTION 2</p> <p>Date de l'accouchement : _____ Heure de l'est : _____</p> <p>Signature infirmière ¹ : _____ # Employé : _____</p> <p>Signature médecin ^{1 et 2} : _____ # Permis : _____</p> <p>¹ J'atteste que ma formation Héma-Québec est à jour</p> <p>² J'atteste que la mère ne présente pas de signe d'infection comme de la fièvre (température supérieure à 39°C) ou des traces d'injection de drogues.</p> <p>Centre hospitalier : _____</p> <p>Commentaires / Écarts aux procédures : _____</p> <p>_____</p> <p>_____</p> <p>Anticoagulant contenu dans le dispositif de prélèvement : CPD - 21mL pour collecte de 200mL (MacoPharma)</p> <p>PFN-00026 : Procédures surrounding cord blood collection</p> <p>PFN-00027 : Procédures entourant la collecte du sang de cordon</p> </div>	<p>✓ Collecte de sang de cordon (dirigé)</p>
		2.2	<p>If applicable, add the following comments:</p> <ul style="list-style-type: none"> - Interruption of the collection procedure - Problem with the mother or the infant during birth - Physical anomalies of the infant such as additional digits (toes or fingers), missing digits or any visible congenital anomalies. <p><u>Anomalies concerning the mother:</u></p> <ul style="list-style-type: none"> - Abnormal vital signs - Signs of at-risk behaviours - Signs of viral or bacterial infection (such as septicemia) - Past medical history - Any other pertinent information that might alter the quality and safety of the cord blood product 	<p>✓ Collecte de sang de cordon (dirigé)</p>
		2.3	<p>Document any incident (adverse event or deviation to this procedure)</p>	<p>✓ Collecte de sang de cordon (dirigé)</p>

6.5. LABELING

Steps		Instructions		References
1	Verification	1.1	Verify concordance of 	<i>Collecte de sang de cordon (dirigé)</i> <i>Étiquette prélèvement (dirigé)</i> IND-00057
2	Labeling	2.1	Complete the information	<i>Étiquette prélèvement (dirigé)</i>
		2.2	In the mother's presence, affix the cord blood bag label without covering the bar code lot number with as little contact as possible with the plastic of the bag 	<i>Étiquette prélèvement (dirigé)</i> IND-00057

6.6. PACKAGING AND SHIPPING

Steps		Instructions		References
1	Packaging	1.1	Place the cord blood bag into a plastic (Ziploc) bag	
		1.2	Expel any air and seal, then put into the shipping envelope	
		1.3	Activate the temperature logger and place it with the cord blood bag in the shipping envelope  Note: The logger is used to monitor the temperature during transport and may be inside or outside of the plastic bag containing the cord blood bag.	

1	Packaging (continued)	1.4	Add the documents and remaining labels (keep one for shipping identification) into the shipping envelope	<i>Collecte de sang de cordon (dirigé)</i> IND-00057																
		1.5	Seal the shipping envelope																	
2	Cord blood shipping	2.1	As soon as possible, place the shipping envelope on the 2 thermoregulator bags at the bottom of the shipping box, then cover with the 2 other thermoregulator bags 	ENR-03749 IND-00057																
		2.2	Apply a collection label for each CBU packaged <table border="1" data-bbox="581 745 1222 892"> <thead> <tr> <th colspan="4">Section réservée au Centre hospitalier</th> </tr> </thead> <tbody> <tr> <td>1</td> <td></td> <td>2</td> <td>Numéro de prélèvement</td> </tr> <tr> <td>3</td> <td>Numéro de prélèvement</td> <td>4</td> <td>Numéro de prélèvement</td> </tr> <tr> <td>5</td> <td>Numéro de prélèvement</td> <td colspan="2"># Commande :</td> </tr> </tbody> </table>		Section réservée au Centre hospitalier				1		2	Numéro de prélèvement	3	Numéro de prélèvement	4	Numéro de prélèvement	5	Numéro de prélèvement	# Commande :	
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2.3	Place up to a maximum of five collection kits per box, inserted between the thermoregulator bags (only one envelope will contain a temperature logger)																			
2.4	Fasten the strap on the shipping box and affix a tamper-evident seal 																			
2.5	Carry the box to the location designated for outgoing parcels																			

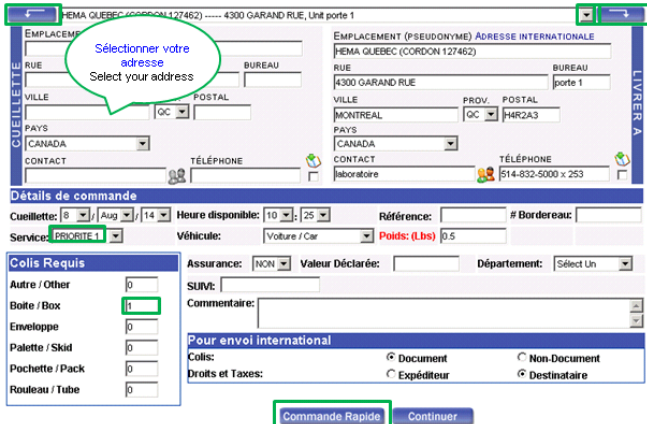



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Steps	Instructions	References															
<p>2 Cord blood shipping (continued)</p>	<p>2.6 Ship the box to Héma-Québec as soon as possible via www.planetecourrier.com</p> <p>Account # : 20030903 Web ID : hema05 Password : planete</p>  <p>Note: Hema-Quebec has a maximum of 48 hours to freeze a cord blood following its collection.</p> <p>2.7 Document the order number</p>  <table border="1" data-bbox="581 1325 1224 1465"> <thead> <tr> <th colspan="3">Section réservée au Centre hospitalier</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Numéro de prélèvement</td> <td>2</td> <td>Numéro de prélèvement</td> <td>3</td> <td>Numéro de prélèvement</td> </tr> <tr> <td>4</td> <td>Numéro de prélèvement</td> <td>5</td> <td>Numéro de prélèvement</td> <td colspan="2"># Commande :</td> </tr> </tbody> </table>	Section réservée au Centre hospitalier			1	Numéro de prélèvement	2	Numéro de prélèvement	3	Numéro de prélèvement	4	Numéro de prélèvement	5	Numéro de prélèvement	# Commande :		<p>ENR-03749</p>
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<p>3 Collection files shipping</p>	<p>3.1 Put the collection files in a shipping box (or in a sealed envelope on the top of the box) to preserve the mother's confidential information.</p>																



7. APPENDICES

N/A

8. REFERENCES

- Cord blood collection bag REF MSC1200PU MacoPharma NOTEURO121 (Rev03_20190611 and Rev04_20201021)

9. LIST OF MODIFICATIONS

SECTION	MODIFICATIONS	JUSTIFICATION	ORIGIN OF INFORMATION
3	Addition of « and operating room »	The procedure is applicable to nurses of the operating room that participate in cord blood collection following a caesarean delivery	S/O
6.1 6 th arrow	Addition of contact information for Hema-Quebec Public Cord Blood Bank	Contact information for interaction between the cord blood collection site and the cord blood bank	NetCord-FACT Standard B3.1.6
6.2 Step 1.1	Addition of a note	The personnel did not know where to find the document.	AUD-I00378 AEX-2768-EXP
6.2 Step 2.1	Addition of good inventory management practices notions	Expired disinfectants were found in storage inventory.	AUD-F01064 AEX-2741-EXP/ AUD-I00378 AEX-2767-EXP
6.3 Step 1.3	Replacement that it is the signature of the document that proves the verification, not the adressography	The adressography is not always done by the nurse that does the final verification of the documents	PFN-00026[13]
6.3 Step 1.4	Replacement of « Insert » with « Integrate »	Clarification	S/O
6.3 Step 2.3	Addition of « and the disinfectant »	The disinfection used to disinfect the umbilical cord must not be expired	S/O
6.4 Step 1.2	Addition of a new step	The temperature logger was not packaged as described in the document (outside of the plastic bag)	AUD-I00379 AEX-2770-EXP/ PFN-00028[6]
6.4 Step 1.4	Removal of « gently », replacement of « 4-5 » by « 10 » inversions and addition of « if the situation provides the opportunity, start the inversions of the pouch during the collection. »	To prevent blood clot formation in the product.	PFN-00026[13]
6.6 Step 1.2	Movement of the step	To maintain a logic sequence following the change of step 1.3	6.6 Étape 1.3
6.6 Step 1.3	Replacement of « plastic bag » with « shipping envelope » Addition of « and may be inside or outside of the plastic bag containing the cord blood bag. »	The temperature logger was not packaged as described in the document (outside of the plastic bag)	AUD-I00379 AEX-2770-EXP



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SECTION	MODIFICATIONS	JUSTIFICATION	ORIGIN OF INFORMATION
6.6 Step 1.5	Addition of « shipping »	Clarification	S/O
6.6 Step 2.6	Addition of « Hema-Quebec has a maximum of 48 hours to freeze a cord blood following its collection »	Give information to the collection center in order to prevent shipping of a box to close to the deadline freezing	S/O
References	Addition of insert revision Rev04_20201021	Update of current version	ENR-02840[5]
Reference : OC-08148			

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