



LEIDS UNIVERSITAIR MEDISCH CENTRUM

# *Implementatie van ISBT 128- en Eurocet 128 codering en etikettering voor celtherapie producten*

*LUMC, afdeling IHB- Centrum voor Stamceltherapie*

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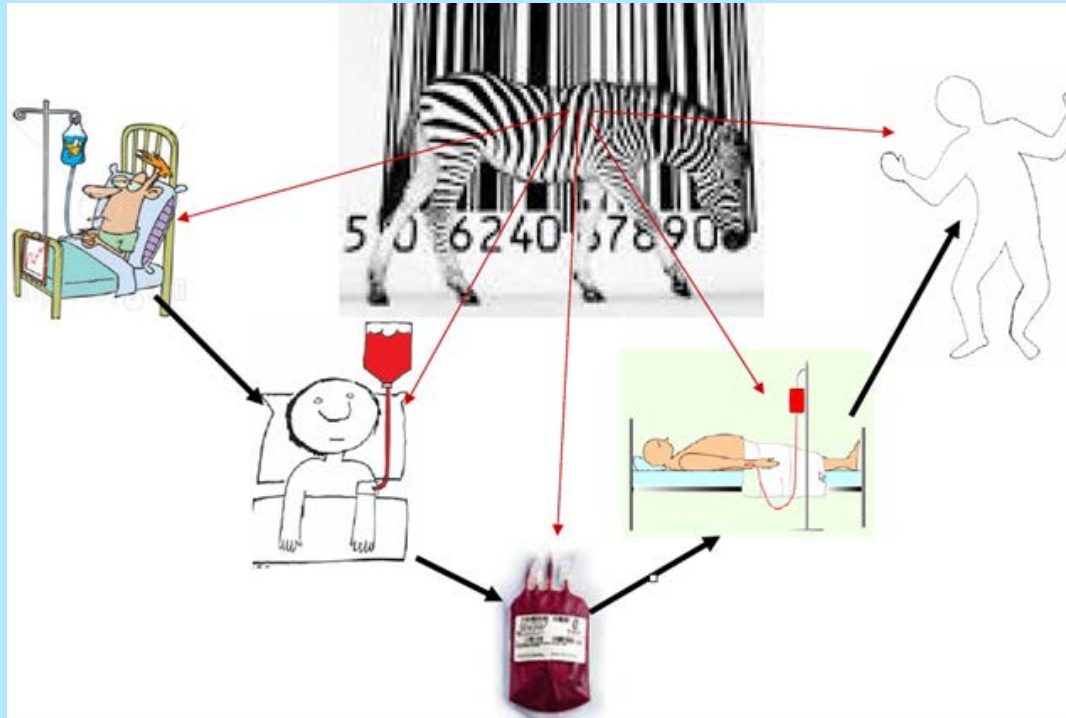
<sup>1</sup> IHB-Centrum voor Stamceltherapie, <sup>2</sup> IHB-HLA, <sup>3</sup> IHB-Bloedtransfusiedienst

6e Haags Hemaferese Symposium 11-04-2014



- Waarom codering van celproducten?
- Celtherapie producten binnen het Centrum voor Stamceltherapie
- Implementatie plan
- Projectuitvoering

- Traceerbaarheid producten vanaf oorsprong t/m toediening



- Vervanging bestaande handmatige systeem

## **JACIE standards**

## **ISBT 128 codering**

- 5<sup>th</sup> edition: Vereist implementatie plan
- 6<sup>th</sup> edition (v.a. 2015): Vereist implementatie van ISBT 128 codering

## **EU Richtlijnen**

## **Eurocet 128 codering**

### **EU Richtlijn 2004/23; Artikel 25**

- De Commissie zet in samenwerking met de lidstaten een uniform Europees coderingssysteem op voor de basisbeschrijving en de eigenschappen van weefsels en cellen.

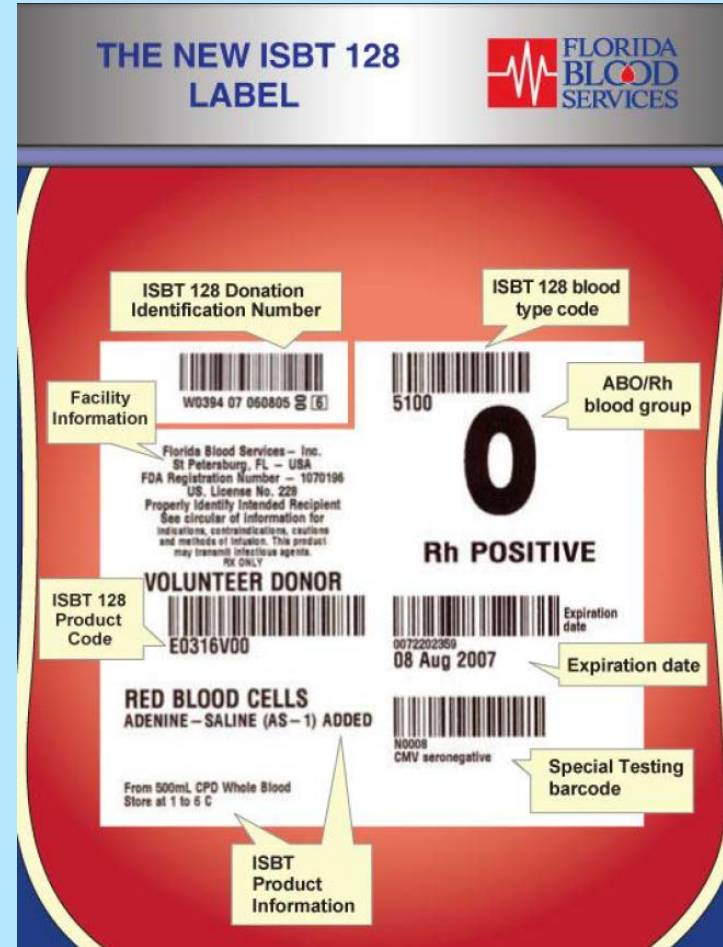
### **EU Richtlijn 2006/86; Artikel 10:**

- In de weefselinstelling wordt aan al het gedoneerde materiaal een eenduidige Europese identificatiecode toegekend, om een correcte identificatie van de donor en de traceerbaarheid van al het gedoneerde materiaal te garanderen en informatie te verstrekken over de voornaamste kenmerken en eigenschappen van de weefsels en cellen.

### **TRIP Biovigilantie symposium November 2013**

- Bijeenkomst van Eurocet 128 consortium, Ministerie VWS en werkvloer

Al sinds jaren voor bloedproducten



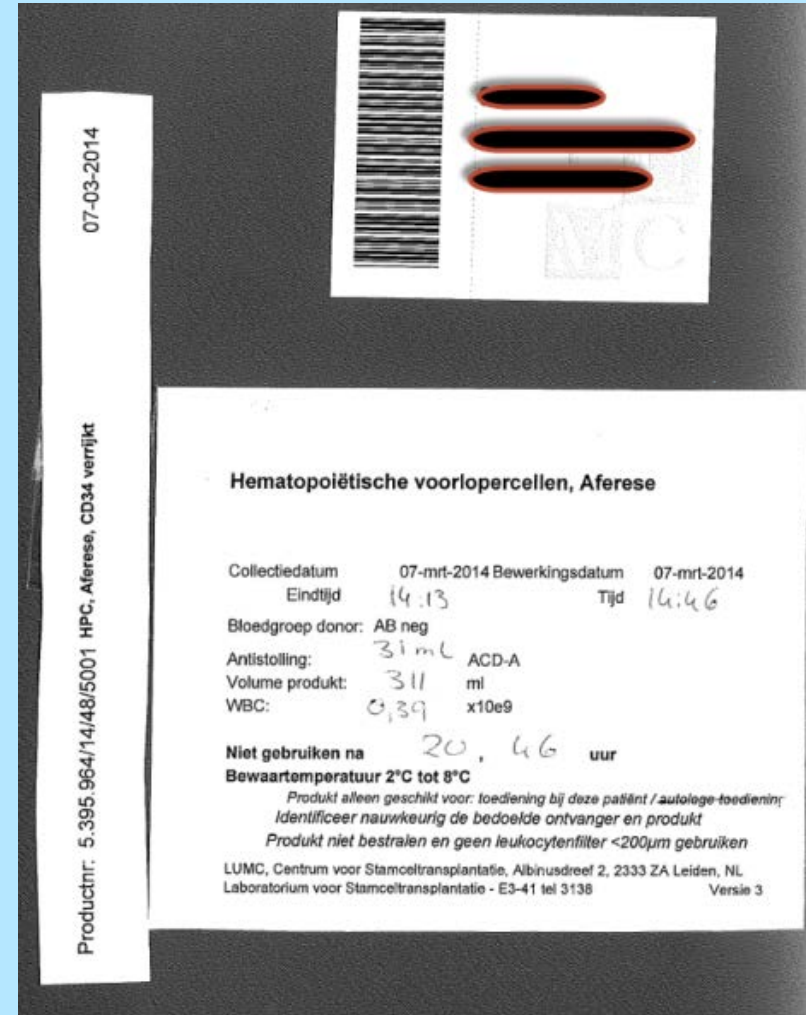
## SEC = Single European Coding

**SEC: NL028714N002113999817 A00S20920A020140731**

- Product is ISBT 128 labeled
  - Product description code is S2092
  - Division code is A0 Bijv. Cryo-porties voor autologe stamceltransplantatie
  - Expiry date is 31 Jul 2014
  
- Coding system identifier for ISBT 128 : A
- ISBT 128 Product Description Code : 00S2092
- Split number : 0A0
- Expiry date (ISO format) : 20140731





# Historie Productidentificatie binnen IHB-CST

- Etiketten ontworpen in Microsoft-office Word
- Bijhouden voorraad etiketten op werkvloer
- Handmatige invoer van gegevens op etiket
- Handmatig versiebeheer en archief



# Celtherapie producten binnen het CST



		Afname	Ontvangst	Bewerking	Uitgifte
PBSC	autoloog	X	X	X	X
	Allogeen verwant	X	X	X	X
	Allogeen onverwant	 X	X	X	X
Mononucleaire cellen/ Lymfocyten	Allogeen verwant, Autoloog	X	X	X	X
	Allogeen onverwant	 X	X	X	X
Granulocyten	Allogeen	X	X	X	X
Stamcellen uit beenmerg	autoloog	X	X	X	X
	Allogeen verwant	X	X	X	X
	Allogeen onverwant	 X	X	X	X
Beenmerg t.b.v. MSC	Allogeen onverwant	X	X	X	X
Navelstreng-bloed	Allogeen onverwant	 X	X	X	X





# Implementatieplan

- Vaststellen projectgroep: Hemaferese, Stamcellab, IHB arts, ICT, Kwaliteitsfunctionaris

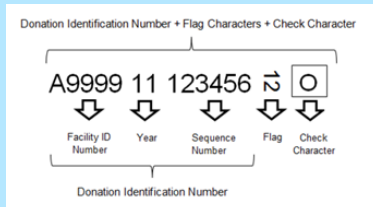
- Onderzoek naar geschikt softwareprogramma →



- IHB-CST registratie bij ICCBBA (beheerd ISBT 128 internationale informatie)



- Invulling geven aan karakters DIN



# Implementatieplan

- Aanschaffen etiketten en printer



- Inrichting GLIMS module



- Validatie

- Implementatie



# Implementatieplan

- Inventarisatie productnamen en bewerkingen.
  - Waar nodig ontbrekende productnamen, bewerkingen geregistreerd bij ICCBBA

1	Class en Modifier	Core conditions	Manipulation	Cryoprotect	3rd party compo	Other Additives
2	HPC, Marrow	Heparin/XX/rt				Other additives: Yes
3	HPC, Marrow	Heparin/XX/rt				Other additives: Yes
4	HPC, Marrow	Citrate+Heparin/XX/rt				Other additives: Yes
5	HPC, Marrow	Heparin/XX/rt	buffy coat enriched			Other additives: Yes
6	HPC, Marrow	Heparin/XX/rt	buffy coat enriched			
7	HPC, Marrow	Heparin/XX/rt	T/B cell reduced			Other additives: Yes
8	Cryopreserved HPC, Marrow	Citrate+Heparin/XX/rt<=150C	buffy coat enriched	10% DMSO	3rd party comp: yes	Other additives: Yes
9	Thawed HPC, Marrow	Citrate+Heparin/XX/rtrefg	buffy coat enriched	10% DMSO	3rd party comp: yes	Other additives: Yes
10	Thawed washed HPC, Marrow	Citrate/XX/rtrefg	buffy coat enriched		3rd party comp: yes	Other additives: Yes
11	HPC, Marrow	Citrate+Heparin/XX/rt	Mononuclear cells enriched			Other additives: Yes
12	HPC, Marrow	Citrate+Heparin/XX/rt	T/B cell reduced			Other additives: Yes
13	HPC, Marrow	NS/XX/rt	CD34 enriched		3rd party comp: yes	Other additives: Yes
14	Cryopreserved HPC, Marrow	Citrate+Heparin/XX/rt<=150C	Mononuclear cells enriched	10% DMSO	3rd party comp: yes	Other additives: Yes
15	Thawed HPC, Marrow	Citrate+Heparin/XX/rtrefg	Mononuclear cells enriched	10% DMSO	3rd party comp: yes	Other additives: Yes
16	Thawed washed HPC, Marrow	Citrate/XX/rtrefg	Mononuclear cells enriched		3rd party comp: yes	Other additives: Yes
17	TC, Marrow	Citrate+Heparin/XX/rt	Mononuclear cells enriched			Other additives: Yes
18	TC-BLINDED STUDY	NS/XX/rt				Other additives: Yes
19	Cryopreserved TC, Marrow	Citrate+Heparin/XX/rt<=150C	Mononuclear cells enriched	10% DMSO	3rd party comp: yes	Other additives: Yes
20	Thawed TC, Marrow	Citrate+Heparin/XX/rtrefg	Mononuclear cells enriched	10% DMSO	3rd party comp: yes	Other additives: Yes
21	Thawed washed TC, Marrow	Citrate/XX/rtrefg	Mononuclear cells enriched		3rd party comp: yes	Other additives: Yes
22	TC, Marrow	Heparin/XX/rt	Mononuclear cells enriched		3rd party comp: yes	Other additives: Yes
23	TC-BLINDED STUDY	Heparin/XX/rt	Mononuclear cells enriched		3rd party comp: yes	Other additives: Yes
24	TC-MSC	None/XX/rt	Cultured		3rd party comp: yes	Other additives: Yes
25	TC-MSC	None/XX/rt	Cultured		3rd party comp: yes	Other additives: Yes
26	Cryopreserved TC-MSC	Citrate/XX/rt<=150C	Cultured	10% DMSO	3rd party comp: yes	Other additives: Yes
27	Cryopreserved TC-MSC	Citrate/XX/rt<=150C	Cultured	10% DMSO	3rd party comp: yes	Other additives: Yes
28	Thawed TC-MSC	Citrate/XX/rtrefg	Cultured	10% DMSO	3rd party comp: yes	Other additives: Yes
29	Thawed washed TC-MSC	Citrate/XX/rtrefg	Cultured		3rd party comp: yes	Other additives: Yes
30	Noq biospoken	Heparin/XX/rt	Buffy coat removed			
31	Noq biospoken	Citrate+Heparin/XX/rt	Buffy coat removed			
32	TC, APHERESIS	Citrate/XX/rt				
33	TC-T CELLS	Citrate/XX/rt				
34	TC-T CELLS	Citrate/XX/rt				Other additives: Yes
35	TC-T CELLS	NS/XX/rt	CD6 reduced		3rd party comp: yes	Other additives: Yes
36	Cryopreserved TC-T CELLS	Citrate/XX/rt<=150C		10% DMSO	3rd party comp: yes	Other additives: Yes
37	Thawed TC-T CELLS	Citrate/XX/rtrefg		10% DMSO	3rd party comp: yes	Other additives: Yes
38	HPC, APHERESIS	Citrate/XX/rt				
39	HPC, APHERESIS	Citrate/XX/rt	T/B cell reduced			Other additives: Yes
40	Cryopreserved HPC, APHERESIS	Citrate/XX/rt<=150C		10% DMSO	3rd party comp: yes	Other additives: Yes
41	Thawed HPC, APHERESIS	Citrate/XX/rtrefg		10% DMSO	3rd party comp: yes	Other additives: Yes
42	Thawed washed HPC, APHERESIS	Citrate/XX/rtrefg			3rd party comp: yes	Other additives: Yes
43	HPC, APHERESIS	Citrate/XX/rt	Plasma reduced			
44	HPC, APHERESIS	Citrate/XX/rt	Plasma reduced			Other additives: Yes
45	HPC, APHERESIS	Citrate/XX/rt	T/B cell reduced			Other additives: Yes
46	Cryopreserved HPC, APHERESIS	Citrate/XX/rt<=150C	Plasma reduced	10% DMSO	3rd party comp: yes	Other additives: Yes
47	Thawed HPC, APHERESIS	Citrate/XX/rtrefg	Plasma reduced	10% DMSO	3rd party comp: yes	Other additives: Yes
48	Thawed washed HPC, APHERESIS	Citrate/XX/rtrefg	Plasma reduced		3rd party comp: yes	Other additives: Yes
49	HPC, APHERESIS	NS/XX/rt	CD34 enriched		3rd party comp: yes	Other additives: Yes
50	HPC, APHERESIS	NS/XX/rt	CD34 enriched		3rd party comp: yes	Other additives: Yes
51	Cryopreserved HPC, APHERESIS	Citrate/XX/rt<=150C	CD34 enriched	10% DMSO	3rd party comp: yes	Other additives: Yes
52	Thawed HPC, APHERESIS	Citrate/XX/rtrefg	CD34 enriched	10% DMSO	3rd party comp: yes	Other additives: Yes
53	Apheresis, PLATELETS	ACD-A/XX/20-24C				
54	Apheresis, GRANULOCYTES	ACD-A/XX/rt				
55	Apheresis, GRANULOCYTES	ACD-A/XX/rt				
56	Apheresis, GRANULOCYTES	ACD-A/XX/rt	RBC reduced by sedimentation			
57	Apheresis, GRANULOCYTES	ACD-A/XX/rt	Plasma reduced			
58	Cryopreserved HPC, CORD BLOOD	NS/XX/rt<=150C		NS DMSO		Other additives: Yes
59	Thawed HPC, CORD BLOOD	NS/XX/rtrefg		NS DMSO		Other additives: Yes
60	Thawed Washed HPC, CORD BLOOD	Citrate/XX/rtrefg			3rd party comp: yes	Other additives: Yes
61	CONCURRENT PLASMA, APHERESIS					




## IMPLEMENTATION GUIDE

# Revised Cellular Therapy Terminology

Version 1.0.0  
August 2013

Tracking Number ICCBBA IG-036



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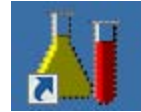


- Inventarisatie benodigde productgegevens, gegenereerd bij afname, bewerking en uitgifte

CELLULAR THERAPY PRODUCT LABELING  
Each label shall include at least the elements detailed in the following table:

Element <sup>3</sup>	Partial label	Label at completion of collection	Label at completion of processing	Label at distribution for administration <sup>2</sup>
Unique numeric or alphanumeric identifier	AF	AF	AF	AF
Proper name of product <sup>1</sup>	AF	AF	AF	AF
Product modifiers <sup>1</sup>	AF		AF	AF
Product attributes (manipulations) <sup>1</sup>			AC	AC
Recipient name and identifier (if applicable)	AF	AT	AT	AT
Identity and address of collection facility or donor registry		AT	AC	AC
Date, time collection ends, and (if applicable) time zone		AT	AC	AC
Approximate volume		AT	AT	AT
Name and volume or concentration of anticoagulant and other additives		AT	AT	AT
Donor identifier and (if applicable) name		AT	AT	AT
Recommended storage temperature range		AT	AT	AT
Biohazard and/or Warning Labels (as applicable, see CM7.4, C7.4, D7.4).		AT	AT	AT
If applicable: Statement "NOT EVALUATED FOR INFECTIOUS SUBSTANCES"				
Statement "WARNING: Advise Patient of Communicable Disease Risks"		AT	AT	AT
Statement "WARNING: Reactive Test Results for [name of disease agent or disease]"		AT	AT	AT
Identity and address of processing and distribution facility(ies)			AC	AC
Statement "Do Not Irradiate"			AT	AT
Expiration Date (if applicable)			AT	AT
Expiration Time (if applicable)			AC	AT
ABO and Rh of donor (if applicable)			AC	AC
RBC compatibility testing results (if applicable)				AC
Statement "Properly Identify Intended Recipient and Product"				AT
Statement indicating that leukoreduction filters should not be used.				AT
Statement "FOR AUTOLOGOUS USE ONLY" (if applicable)		AT	AT	AT
Statement "For Use By Intended Recipient Only" (if for allogeneic recipient)				AT
Statement "For Nonclinical Use Only" (if applicable)				AT
Date of distribution				AC

AF=Affix, AT=Attach or Affix, AC=Accompany, Attach or Affix



N0022 14 000071 S 4

Collected by:  
Hemeferese, C11 – P, K44  
Albinusdreef 2, 2333 ZA LEIDEN (NL)



Reactive testresults for Chagas

Advise patient of Communicable disease



**A pos**

Related donor:  
Testmannetje, x  
LUMCnr: 5395964



Expiration Date/Time:  
(CET)

Intended Recipient:  
**Msc2013** ←  
Date of Birth: –  
Lumcnr: **3318709**



**HPC, APHERESIS**

Approx  
Anticoagulant:

Properly identify intended recipient and product  
Do not use a leucoreduction filter  
Do not irradiate  
For use by intended recipient only

Store at 2–8 °C

Order S-C

S-CST (07/04/2014 13:47) Aanvrager: ?  
Msc2013, 01-01-1913 3318709

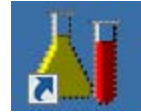
Aanvrag.. Monsters Patient Bijzond. Order Rapport


LUMC nr.:

Geboortedatum:  Geslacht:  Leeftijd:  Stu

Naam echtgenoot:


Naam:





**N0022 14 000071 S 4**

Collected by:  
Hemeferese, C11 – P, K44  
Albinusdreef 2, 2333 ZA LEIDEN (NL)




**HPC, APHERESIS**

Approx  
Anticoagulant:


Properly identify intended recipient and product  
Do not use a leucoreduction filter  
Do not irradiate  
For use by intended recipient only

**Store at 2–8 °C**




**Reactive testresults for Chagas**

**Advise patient of Communicable disease**



**A pos**

Related donor:  
Testmannetje, x  
LUMCnr: 5395964



Expiration Date/Time:  
(CET)

Intended Recipient:  
Msc2013  
Date of Birth: –  
Lumcnr: 3318709

**Formulier**

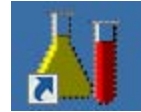
ormulier: S-CST Patient    Urgentie: N    Toepassen

Afname:  Beenm...  DLI  PBSC  Granulo...  UCB  Afrondi...  Na Ont...

Aanvraaggegevens     Bldgrp elders bepaald    \* Order sluiten en opslaan  
\* Etiketten printen

**Selecteer een keuze of resultaatcode**

Code	Naam - Beschrijving	Actie
anti-HBc	Reactive testresults for anti-HBc	
anti-HTLV	Reactive testresults for anti-HTLV	
HIV	Reactive testresults for HIV ag/ab combo	
Chagas	Reactive testresults for Chagas	
WNV	Reactive testresults for WNV	
TPHA + anti-HCV	Reactive testresults for TPHA + anti-HCV	
TPHA + anti-HBc	Reactive testresults for TPHA + anti-HBc	
TPHA + anti-HTLV	Reactive testresults for TPHA + anti-HTLV	
TPHA + HIV	Reactive testresults for TPHA + HIV ag/ab	
TPHA + Chagas	Reactive testresults for TPHA + Chagas	



N0022 14 000071 S 4

Collected by:  
Hemeferese, C11 – P, K44  
Albinusdreef 2, 2333 ZA LEIDEN (NL)



Reactive testresults for Chagas

Advise patient of Communicable disease



**A pos**

Related donor:  
Testmannetje, x  
LUMCnr: 5395964



Expiration Date/Time:  
(CET)

Intended Recipient:  
Msc2013  
Date of Birth: –  
Lumcnr: 3318709



HPC, APHERESIS

Approx  
Anticoagulant:

Properly identify intended recipient and product  
Do not use a leucoreduction filter  
Do not irradiate  
For use by Intended recipient only

Store at 2–8 °C

Relaties van Msc2013, 01-01-1913 3318709

Relatie

Hoofdpagina Site attr.

Gerelateerd met: Msc2013, 01-01-1913 3318709 stamcelontvanger

is: Testmannetje, x.X.X.X. 12-12-1912 (V) 5395964 stamcelonor

als: Stamcelonor  Genetische relatie

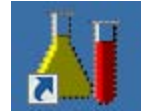
Relaties van Msc2013, 01-01-1913 3318709

Relatie

Hoofdpagina Site attr.

Verwant/Onverwant: Verwant





N0022 14 000071 S 4

Collected by:  
Hemeferese, C11 – P, K44  
Albinusdreef 2, 2333 ZA LEIDEN (NL)



Reactive testresults for Chagas

Advise patient of Communicable disease



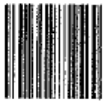
**A pos**

Related donor:  
Testmannetje, x  
LUMCnr: 5395964



Expiration Date/Time:  
(CET)

Intended Recipient:  
Msc2013  
Date of Birth: –  
Lumcnr: 3318709



HPC, APHERESIS

Approx  
Anticoagulant:

Properly identify intended recipient and product  
Do not use a leucoreduction filter  
Do not irradiate  
For use by intended recipient only

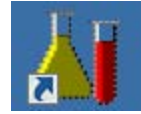
Store at 2–8 °C

**Monster variabelen**

Monster S=N002214000072002, materiaal, afname op 07/04/201  
Object Testmannetje, x.X.X.X. 12-12-1912 (V) 5395964

Naam	Keuze	Info
herkomst:	?	?
	?	
	BM	
	CPA	
	DLI	
	Granulocytes	
	<b>PBSC</b>	
	TC-study	

OK



N0022 14 000071 S 4

Collected by:  
Hemeferese, C11 – P, K44  
Albinusdreef 2, 2333 ZA LEIDEN (NL)



Reactive testresults for Chagas

Advise patient of Communicable disease



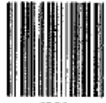
**A pos**

Related donor:  
Testmannetje, x  
LUMCnr: 5395964



Expiration Date/Time:  
(CET)

Intended Recipient:  
Msc2013  
Date of Birth: –  
Lumcnr: 3318709



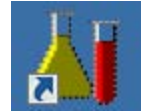
HPC, APHERESIS

Approx  
Anticoagulant:

Properly identify intended recipient and product  
Do not use a leucoreduction filter  
Do not irradiate  
For use by intended recipient only

Store at 2–8 °C

Etiket tijdens afname  
voltooid



N0022 14 000071 84

Collected by:  
Hemafereze, C11 – P, K44  
Albinusdreef 2, 2933 ZA LEIDEN (NL)

Collection End Date/Time:  
07 – 04 – 2014 14:33 (CET)



HPC, APHERESIS

Approx 311 mL  
Anticoagulant: ACDA 31 ml

Properly identify intended recipient and product  
Do not use a leucoreduction filter  
Do not irradiate  
For use by intended recipient only

Store at 2 – 8 °C



Reactive testresults for Chagas

Advise patient of Communicable disease



**A pos**

Related donor:  
Testmannetje, x  
LUMCnr: 5395964

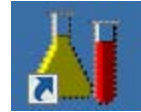



Expiration Date/Time:  
09 – 04 – 2014 14:33 (CET)

Intended Recipient:  
Msc2013  
Date of Birth: –  
Lumc nr: 3318709

Orders op interne id begin

Object	Aanv
Msc2013, 01-01-1913 3318709	Nete
<b>Afnametijd wijzigen</b>	
Nieuwe afnametijd:	07/04/14 14:33 Nu
OK Annuleren	






**N0022 14 000071 S4**

Collected by:  
Hemafereze, C11 – P, K44  
Albinusdreef 2, 2333 ZA LEIDEN (NL)

Collection End Date/Time:  
**07 – 04 – 2014 14:33 (CET)**




**HPC, APHERESIS**

Approx 311 mL  
Anticoagulant: ACDA 31 ml


Properly identify intended recipient and product  
Do not use a leucoreduction filter  
Do not irradiate  
For use by intended recipient only

**Store at 2 – 8 °C**




**Reactive testresults for Chagas**

**Advise patient of Communicable disease**



**A pos**

Related donor:  
Testmannetje, x  
LUMCnr: 5395964



Expiration Date/Time:  
**09 – 04 – 2014 14:33 (CET)**

Intended Recipient:  
**Msc2013**  
Date of Birth: –  
Lumcnr:**3318709**

**Formulier**

Formulier: S-CST Patient    Urgentie: N    Toep

Afname    Beenm..    DLI    PBSC    Granulo..    UCB

**Aanvraaggegevens**     Bldgrp elders bepaald    \* On  
\* Eti

Gegevens 1ste afname  
 Gegevens 2de afname

**Geef de waarde voor Volume 1ste afgenomen product (mL)**

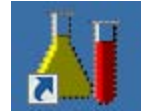
Waarde: 311

OK    Annuleren

**Geef de waarde voor Soort en volume antistolling 1ste afname**

Waarde: ACDA 31 ml

OK    Annuleren



N0022 14 000071 S4

Collected by:  
Hemafereze, C11 – P, K44  
Albinusdreef 2, 2333 ZA LEIDEN (NL)

Collection End Date/Time:  
07 – 04 – 2014 14:33 (CET)



HPC, APHERESIS

Approx 311 mL  
Anticoagulant: ACDA 31 ml

Properly identify intended recipient and product  
Do not use a leucoreduction filter  
Do not irradiate  
For use by intended recipient only

Store at 2 – 8 °C



Reactive testresults for Chagas

Advise patient of Communicable disease



**A pos**

Related donor:  
Testmannetje, X  
LUMCnr: 5395964



Expiration Date/Time:  
09 – 04 – 2014 14:33 (CET)

Intended Recipient:  
Msc2013  
Date of Birth: –  
Lumcnr:3318709

Planning... (S-990407-0001/S-CST)

S-990407-0001/S-CST (07/04/2014 14:33) Aanvrager: Netelenbos T (Interne specialist)  
Msc2013, 01-01-1913 3318709, Bet. ov.: Regulier1

Aanvraag.. Monsters Patient Bijzond. Order Rapport Verreken.. Extra Site attr.

Aanvraag (11): ? ? 14:33 07/04/14 N

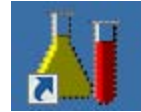
Monster (1): ?

**Houdbaarheid product 1**

Kies juiste periode in uren voor de houdbaarheid van product 1:

Uren
4
6
8
24
48
onbeperkt

OK



**N0022 14 000071 S4**

Collected by:  
Hemafereze, C11 – P, K44  
Albinusdreef 2, 2333 ZA LEIDEN (NL)

Collection End Date/Time:  
**07 – 04 – 2014 14:33 (CET)**



**HPC, APHERESIS**

Approx 311 mL  
Anticoagulant: ACDA 31 ml

Properly identify intended recipient and product  
Do not use a leucoreduction filter  
Do not irradiate  
For use by intended recipient only

**Store at 2 – 8 °C**



Reactive testresults for Chagas

Advise patient of Communicable disease



**A pos**

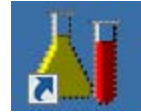
Related donor:  
Testmannetje, x  
LUMCnr: 5395964



Expiration Date/Time:  
**09 – 04 – 2014 14:33 (CET)**

Intended Recipient:  
**Msc2013**  
Date of Birth: –  
**Lumcnr:3318709**

**Etiket na afname  
voltooid**



NL108470N00221400007101 S1694 – a00120140407



N0022 14 000071 4

Collected by:  
LUMC, Centrum voor Stamceltherapie  
Albinusdreef 2, 2333 ZA Leiden (NL)

Collection End date/time:  
07-04-2014 14:33 (CET)

Properly identify intended recipient and product  
Do not use a leucoreduction filter  
For use by intended recipient only  
Do not irradiate



HPC  
APHERESIS CD34 enriched

Approx 311 mL  
Anticoagulantia: ACDA  
Other additives: None

Store at 1 – 10 C



\*15000

A pos



Reactive testresults for Chagas  
Advise patient of communicable disease risk!

Related donor:  
Testmannetje, x  
LUMCnr: 5395964



Expiration Date/Time:  
07-04-14 20:50

Intended Recipient:  
Mso2013  
Date of Birth: 01/01/1913  
Lumcnr: 3318709

Distributed by: Lab. voor Stamceltransplantatie L3 – 24  
LUMC, Centrum voor Stamceltransplantatie  
Albinusdreef 2, 2333 ZA Leiden (NL)

TNC: 0.39 x10<sup>9</sup>/L

Order S-990407-0001/S-CST

S-990407-0001/S-CST (07/04/2014 14:33) Aanvrager: Netelenbos T (Interne spe  
Mso2013, 01-01-1913 3318709, Bet. ov.: Regulier1

**Formulier**

Aanvrag. Formulier: S-CST Patient Urgentie: N Toe

Aanvraag Afname | Beenm.. | DLI | PBSC | Granulo.. | UCB

Monste

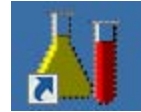
Onbewerkt	PRP
Manueel conc.	
Tcel depletie	
Conc. + Tcel depl.	
<input checked="" type="checkbox"/> CD34 isolatie	
CD34 iso. + Tcel addback	

Tr	Mner
R	S-CD
R	S-CD
R	S-MN
R	S-MN
R	S-CD
R	S-CD

Geef de waarde voor Productsoort

Selecteer een keuze of resultaatcode

Code	Naam
S1712	PBSC manueel conc. Dooi + was
S1694-a	PBSC CD34 sel
S1694-b	PBSC CD34 sel. + T-cel
S1685	PBSC CD34 sel. Cryo



NL108470N00221400007101 S1694 – a00120140407



N0022 14 000071 4

Collected by:  
LUMC, Centrum voor Stamceltherapie  
Albinusdreef 2, 2333 ZA Leiden (NL)

Collection End date/time:  
07-04-2014 14:33 (CET)

Properly identify intended recipient and product  
Do not use a leucoreduction filter  
For use by intended recipient only  
Do not irradiate



S1694-a

HPC  
APHERESIS CD34 enriched

Approx 311 mL  
Anticoagulantia: ACDA  
Other additives: None

Store at 1 – 10 C



\*45000

A pos



Reactive testresults for Chagas  
Advise patient of communicable disease risk

Related donor:  
Testmannetje, x  
LUMCnr: 5395964



2014041672050

Expiration Date/Time:  
07-04-14 20:50

Intended Recipient:  
Msc2013  
Date of Birth: 01/01/1913  
Lumcnr: 3318709

Distributed by: Lab. voor Stamceltransplantatie L3-24  
LUMC, Centrum voor Stamceltransplantatie  
Albinusdreef 2, 2333 ZA Leiden (NL)

TNC: 0.39 x10<sup>9</sup>/L

Order S-990

S-990407-0001/S-CST (07/04/2014 14:33) Aanvrager: Nete  
Msc2013, 01-01-1913 3318709, Bet. ov.: Regulier1

Formulier: S-CST Patient Urgentie: N

Afname | Beenm.. | DLI | FBSC | Granulo.. | U

Eindtijd procedure \* Order sluiten en opslaan

productsoort

Rapportage Ezis

Opslaginformatie

? Kies juiste periode in uren voor de houdbaarheid

1

2

4

6

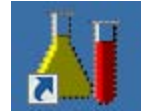
8

24

OK







NL108470N00221400007101 S1694 – a00120140407



N0022 14 000071

Collected by:  
LUMC, Centrum voor Stamceltherapie  
Albinusdreef 2, 2333 ZA Leiden (NL)

Collection End date/time:  
07-04-2014 14:33 (CET)

Properly identify intended recipient and product  
Do not use a leucoreduction filter  
For use by intended recipient only  
Do not irradiate



S1694-a

**HPC**  
**APHERESIS CD34 enriched**

Approx 311 mL  
Anticoagulantia: ACDA  
Other additives: None

Store at 1 – 10 C



\*15000

**A pos**



Reactive testresults for Chagas  
Advise patient of communicable disease risk

Related donor:  
Testmannetje, x  
LUMCnr: 5395964



201404072050

Expiration Date/Time:  
07-04-14 20:50

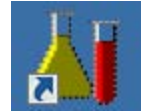
Intended Recipient:  
Msc2013  
Date of Birth: 01/01/1913  
Lumcnr: 3318709

Distributed by: Lab. voor Stamceltransplantatie L3-24  
LUMC, Centrum voor Stamceltransplantatie  
Albinusdreef 2, 2333 ZA Leiden (NL)

TNC: 0.39 x10<sup>9</sup>/L



Resultaten van order S-990407-0001		
1) Monsternr: S=N002214000071004 Msc2013, Gebdat: 01/01/1913 Aanvrager: P18466	VolumePBSCS TNC PBSCS	311 0.39



NL108470N00221400007101 S1694 – a00120140407



N0022 14 000071  4

Collected by:  
LUMC, Centrum voor Stamceltherapie  
Albinusdreef 2, 2333 ZA Leiden (NL)

Collection End date/time:  
07-04-2014 14:33 (GET)

Properly identify intended recipient and product  
Do not use a leucoreduction filter  
For use by intended recipient only  
Do not irradiate



HPC  
APHERESIS CD34 enriched

Approx 311 mL  
Anticoagulantia: ACDA  
Other additives: None

Store at 1 – 10 C ←



A pos

\*15000



Reactive testresults for Chagas  
Advise patient of communicable disease risk!

Related donor:  
Testmannetje, x  
LUMCnr: 5395964



Expiration Date/Time:  
07-04-14 20:50

Intended Recipient:  
Mso2013  
Date of Birth: 01/01/1913  
Lumcnr: 3318709

Distributed by: Lab. voor Stamceltransplantatie L3 – 24  
LUMC, Centrum voor Stamceltransplantatie  
Albinusdreef 2, 2333 ZA Leiden (NL)

TNC: 0.39 x10<sup>9</sup>/L

**Formulier**

Formulier: S-CST Patient    Urgentie: N    Toepass

Afname    Beenm.    DLI    PBSC    Granulo.    UCB    Af

Eindtijd procedure \* Order sluiten en opslaan     Geg

productsoort     Geg

Rapportage Ezis     Geg

Opslaginformatie     Geg

Extra informatie     Geg

**Geef de waarde voor Opslaginformatie**


Waarde:

OK    Annuleren



NL108470N00221400007101 S1694 – a00120140407



N0022 14 000071 

Collected by:  
LUMC, Centrum voor Stamceltherapie  
Albinusdreef 2, 2333 ZA Leiden (NL)

Collection End date/time:  
07-04-2014 14:33 (CET)

Properly identify intended recipient and product  
Do not use a leucoreduction filter  
For use by intended recipient only  
Do not irradiate



S1694-a

**HPC**  
**APHERESIS CD34 enriched**

Approx 311 mL  
Anticoagulantia: ACDA  
Other additives: None

Store at 1 – 10 C



\*15000

**A pos**



Reactive testresults for Chagas  
Advise patient of communicable disease risk

Related donor:  
Testmannetje, x  
LUMCnr: 5395964



201404072050

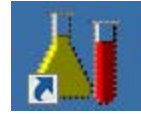
Expiration Date/Time:  
07-04-14 20:50

Intended Recipient:  
Mso2013  
Date of Birth: 01/01/1913  
Lumcnr: 3318709

Distributed by: Lab. voor Stamceltransplantatie L3-24  
LUMC, Centrum voor Stamceltransplantatie  
Albinusdreef 2, 2333 ZA Leiden (NL)

TNC: 0.39 x10<sup>9</sup>/L

Single European Code  
automatisch gegenereerd



NL108470N00221400007101 S1694 – a00120140407



N0022 14 000071 

Collected by:  
LUMC, Centrum voor Stamceltherapie  
Albinusdreef 2, 2333 ZA Leiden (NL)

Collection End date/time:  
07–04–2014 14:33 (CET)

Properly identify intended recipient and product  
Do not use a leucoreduction filter  
For use by intended recipient only  
Do not irradiate



S1694-a

**HPC**  
**APHERESIS CD34 enriched**

Approx 311 mL  
Anticoagulantia: ACDA  
Other additives: None

Store at 1 – 10 C



\*15000

**A pos**



Reactive testresults for Chagas  
Advise patient of communicable disease risk!

Related donor:  
Testmannetje, x  
LUMCnr: 5395964



201404072050

Expiration Date/Time:  
07–04–14 20:50

Intended Recipient:  
Mso2013  
Date of Birth: 01/01/1913  
Lumcnr: 3318709

Distributed by: Lab. voor Stamceltransplantatie L3 – 24  
LUMC, Centrum voor Stamceltransplantatie  
Albinusdreef 2, 2333 ZA Leiden (NL)

TNC: 0.39 x10<sup>9</sup>/L

Eindetiket na  
bewerking voor uitgifte  
voltooid

- Validatie voor collectie afgerond.
  - Hemaferese ingewerkt.
- Validatie voor “processing” in gang.
  - Inwerken tijdens testen.
- Nieuwe codering opgenomen in interne auditplanning.

## Conclusie

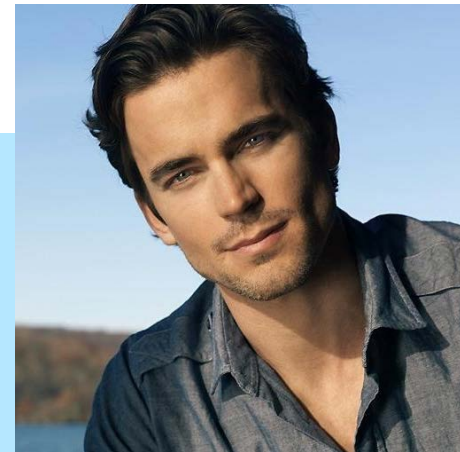
- GLIMS is een geschikt software programma voor codering.
- Voor CST en de ICT was het project complex, door verschillende productsoorten, bewerkingen en oorsprong (autoloog, verwant, onverwant).
- ICT proces en celtherapie proces moest onderling begrepen worden, om project goed te laten slagen.



- SEC makkelijk te genereren door inrichting voor ISBT 128 codering




*En zeg nou zelf!*



Productnr: 5.395.964/14/48/5001 HPC, Aferese, CD34 verrijkt

07-03-2014



**Hematopoïetische voorlopercellen, Aferese**

Collectiedatum 07-mrt-2014    Bewerksdatum 07-mrt-2014  
 Eindtijd 14:13    Tijd 14:46

Bloedgroep donor: AB neg

Antistolling: 31 ml ACD-A

Volume produkt: 311 ml

WBC: 0,39 x10e9

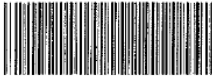
Niet gebruiken na 20,46 uur

Bewaartemperatuur 2°C tot 8°C


*Produkt alleen geschikt voor: toediening bij deze patiënt / autologe toediening;  
 identificeer nauwkeurig de bedoelde ontvanger en produkt  
 Produkt niet bestralen en geen leukocytenfilter <200µm gebruiken*

LUMC, Centrum voor Stamceltransplantatie, Albinusdreef 2, 2333 ZA Leiden, NL  
 Laboratorium voor Stamceltransplantatie - E3-41 tel 3138    Versie 3


NL108470N00221400007101 S1694 – a00120140407



N0022 14 000071 94



A pos




Collected by:  
 LUMC, Centrum voor Stamceltherapie  
 Albinusdreef 2, 2333 ZA Leiden (NL)

Collection End date/time:  
 07-04-2014 14:33 (GET)

Properly identify intended recipient and product  
 Do not use a leucoreduction filter  
 For use by intended recipient only  
 Do not irradiate

Reactive testresults for Chagas  
 Advise patient of communicable disease risk!

Related donor:  
 Testmannelje, x  
 LUMCnr: 5395964



201404072050

Expiration Date/Time:  
 07-04-14 20:50

Intended Recipient:  
 Mso2013  
 Date of Birth: 01/01/1913  
 Lumcnr: 3318709

Distributed by: Lab. voor Stamceltransplantatie L3-24  
 LUMC, Centrum voor Stamceltransplantatie  
 Albinusdreef 2, 2333 ZA Leiden (NL)

Store at 1 – 10 C

TNC: 0.39 x10<sup>9</sup>/L