

ここに記載の情報はロット毎に異なりますので、ご注意ください。

コスモ・バイオ株式会社



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COSMO BIO CO., LTD.

KOJ Human Plasma (pool, heparin)

100mL

Cat. 12250210

Lot. BJ+' +&5

血漿データシート

2016/7/8

①	品名	正常ヒト血漿・プール		
②	ロット番号	BJ7372A		
③	容量	100mL		
④	使用ロット	R297595 -F	R297597 -F	R297598 -F
		R297604 -F	R297608 -F	R297646 -M
		R297647 -M	R297656 -M	R297826 -M
		R297831 -M		
⑤	プール日	2016/7/8		
⑥	抗凝固剤	ヘパリンナトリウム		
⑦	性別	■ 男性 - M		■ 女性 - F
⑧	ウイルス試験	HBsAg	-	Nonreactive
		HBc Antibody	-	Nonreactive
		HBV DNA	-	Nonreactive
		HIV-1/2 Antibody	-	Nonreactive
		HIV-1 RNA	-	Nonreactive
		HCV Antibody	-	Nonreactive
		HCV RNA	-	Nonreactive
		West Nile RNA	-	Nonreactive
		Chagas (T.Cruzi)	-	Nonreactive
		Syphilis Serology	-	Nonreactive

以上の製品であることを証明致します。



807 Poplar Avenue
Memphis, TN 38105

FDA Registration Number 1072765
AN ISO 9001-2008 Registered Company, ANAB Accredited
Phone (901) 526-0293 Fax (901) 529-0531
Email: tbsadmin@tennesseeblood services.com

CERTIFICATE OF ANALYSIS

Date: 7/1/16 Packing List No. 71616

This is to certify that the UNITS OF HUMAN PLASMA IN NA HEPARIN
listed on the above packing list was collected, processed and tested in accordance with appropriate
FDA regulations and guidelines at a FDA registered facility and meets the specifications listed below:

1. Reactive Nonreactive for HBsAg by FDA Licensed test
2. Reactive Nonreactive for HBc Antibody by FDA Licensed test
3. Reactive Nonreactive for HBV DNA by FDA Licensed NAT test
4. Reactive Nonreactive for HIV-1/2 Antibody by FDA Licensed test
5. Reactive Nonreactive for HIV-1 RNA by FDA Licensed NAT test
6. Reactive Nonreactive for HCV Antibody by FDA Licensed test
7. Reactive Nonreactive for HCV RNA by FDA Licensed NAT test
8. Reactive Nonreactive for West Nile RNA by FDA Licensed NAT Test
9. Reactive Nonreactive for *Chagas (T.Cruzi) by FDA Licensed test
10. Reactive Nonreactive for Syphilis Serology by FDA Licened Test
11. Not tested for anti-HTLV-I/II

* Units have been currently or previously tested as negative/nonreactive for Chagas.

NOTE: "Use only for the manufacture of unlicensed, non-injectable diagnostic products not
subject to license by the FDA under Section 351 of the Public Health Service Act."

Approved By: _____

TBSP800 Attachment 12
Revision: PC11-14
Approved: 9/20/11
Effective: 9/22/11

Tennessee Blood Services
 807 Poplar Avenue
 Memphis, Tennessee 38105
 Phone: (901) 526-0293 Fax: (901) 529-0531

Ship Date: 7/1/2016 Via: FEDEX
 P.O.# BJ7372 P.L.# 71616

Total Units: 10 Volume: 2.835 Liters

PRODUCT:		HUMAN PLASMA IN NA HEPARIN						
	Bleed Number	Bleed Date	RS	Age	Volume	ABO		
1	R297595	6/23/2016	BF	34	275	B+		
2	R297597	6/23/2016	BF	27	290	B+		
3	R297598	6/23/2016	BF	19	290	O+		
4	R297604	6/23/2016	BF	56	280	O+		
5	R297608	6/23/2016	BF	51	290	O+		
6	R297646	6/24/2016	BM	22	280	B+		
7	R297647	6/24/2016	BM	57	285	A+		
8	R297656	6/24/2016	WM	28	265	O+		
9	R297826	6/28/2016	BM	38	290	B=		
10	R297831	6/28/2016	BM	27	290	B+		

REVIEWED BY

AC/BJ

Signature

AC