

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

 コスモ・バイオ株式会社 COSMO BIO CO., LTD.	KOJ Human Serum (pool) 100ML
	Cat. 12181201
	Lot. BJ7001A

## 血清データシート

2016/5/25

①	品名	正常ヒト血清・プール		
②	ロット番号	BJ7001A		
③	容量	100mL		
④	使用ロット	N122340 -M	N122342 -F	N122359 -F
		R291941 -M	R291942 -M	R291944 -M
		R291958 -M	R291959 -M	R292010 -F
		R292016 -M	R292029 -M	R292030 -F
		R292033 -F	R292038 -M	R292047 -M
		R292058 -F	R292063 -F	R292072 -F
		R292083 -F	R292110 -F	
⑤	プール日	2016/5/25		
⑥	性別	<input checked="" type="checkbox"/> 男性 - M <input checked="" type="checkbox"/> 女性 - F		
⑦	ウイルス試験	HBsAg	-	Nonreactive
		HBV DNA	-	Nonreactive
		HIV-1/2 Antibody	-	Nonreactive
		HIV-1 RNA	-	Nonreactive
		HCV Antibody	-	Nonreactive
		HCV RNA	-	Nonreactive
		Syphilis Serology	-	Nonreactive

以上の製品であることを証明致します。



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FDA Registration Number 1072765  
AN ISO 9001-2008 Registered Company, ANAB Accredited  
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## CERTIFICATE OF ANALYSIS

Date: 4-1-16 Packing List No. D-70860

This is to certify that the HUMAN SERUM  
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 HBV DNA by FDA Licensed NAT test
3.  Reactive  Nonreactive for HIV-1/2 Antibody by FDA Licensed test
4.  Reactive  Nonreactive for HIV-1 RNA by FDA Licensed NAT test
5.  Reactive  Nonreactive for HCV Antibody by FDA Licensed test
6.  Reactive  Nonreactive for HCV RNA by FDA Licensed NAT test
7.  Reactive  Nonreactive for Syphilis Serology by FDA approved test
8. Not tested for anti-HTLV-I/II or anti-HBc.

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

