



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
BUREAU OF FOOD AND DRUGS
Filinvest Corporate City, Alabang, Muntinlupa City

October 5, 2001

BUREAU CIRCULAR
No. 12 s. 2001

**SUBJECT : ADDENDUM TO BUREAU CIRCULAR NO. 6-A s.
2001 DATED JUNE 11, 2001**

As an addendum to Bureau Circular No.6-A s. 2001 dated June 11, 2001 re: Revised Minimum required samples for laboratory Analysis, in accordance to M.C.20 s. 1994, hereunder is the additional list of the minimum required samples for laboratory analysis to be incorporated in B.C. No.6-A s. 2001.

**1. GOVERNMENT DELIVERIES/COLLECTED SAMPLES/ PRODUCT
REGISTRATION**

1.4 Bacterial Endotoxin Test (LAL Method)


SAMPLE TYPE	AMOUNT REQUIRED
Parenterals:	
1. Injectable vials and ampules 0.5 - 100ml	5 vials / ampules
2. Large Volume / Infusions (250ml, 500ml, 1000ml)	2 bottles / bags

2. MEDICAL DEVICES

2.3 Bacterial Endotoxin Test (LAL Method)

SAMPLE TYPE	AMOUNT REQUIRED
Transfusion / Infusion	2 pcs.
Assemblies	2 pcs.
Syringes	20 pcs.
Cannula / Needles	20 pcs.
Long Tubular Catheter	2 pcs.
Catheter Sets & Introduces Cannula	2 pcs.
Scalp Vein Set	20 pcs.
Surgical Blades	2 pcs.
Short IV Catheter	2 pcs.
Medium & Wide Bore Catheter,	2 pcs.
Probes, Urological Stents & Drainage	
Dialysis Fluid Lines	2 pcs.
Closure Caps	2 pcs.
Blood Collection Bags	2 pcs.

This Supplemental Bureau Circular by way of Addendum takes effect immediately.


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