

**PROCESSING OF BIOLOGICAL STANDARDS****Requirements for Processing—Acceptance Criteria**

Each new standards project is managed under the auspices of the Reference Materials Quality Manual. Each project is managed by a scientist with relevant specialization with representation of both statisticians, development scientists, production processing, and dispatch staff ensuring that all aspects of the development and production of the standard is adequately addressed. The particular requirements for processing (e.g., batch size, fill volume, and

**TABLE 1** List of Freeze-Dried Candidate International Reference Materials Submitted by NIBSC to WHO and Endorsed in (A) 2006 and (B) 2007, Listing Filling Accuracy (CV) and Residual Moisture Content of Lyophilized Materials

Code	Reference material	CV of fill (%)	Residual moisture content (% wt/wt)	Comments
<b>(A) Lyophilized Materials Submitted to WHO in 2006</b>				
04/176	1st IS <i>Plasmodium falciparum</i> DNA for NAT assay	2.385	ND	Vials filled and dried at external contractor
97/750	2nd IS hepatitis B virus DNA for NAT assays	0.6	ND	Vials filled and dried at external contractor
03/190	1st IS human antibody to human platelet antigen 3a	0.05	0.18 (0.31% wt/wt prior to desiccation)	Further desiccated over phosphorus pentoxide
02/112	Anti-HIV-1 A human reference preparation solvent detergent inactivated. Filled in vials (one of seven panel members)	0.3	0.8 (1.77% wt/wt prior to desiccation)	Further desiccated over phosphorus pentoxide
03/188	Blood grouping anti-A minimum potency reagent	0.08	0.8	
03/164	Blood grouping anti-B minimum potency reagent	0.08	1.2	
03/178	1st IS for serum folate	0.08	0.8	
03/192	1st IS for thyroid-stimulating hormone, recombinant human for bioassay	0.07	3.95	
03/228	2nd IS for protein S in plasma human	0.09	0.06 (FD only sample not taken)	Further desiccated over phosphorus pentoxide
03/242	2nd IS protein C in human plasma	0.06	0.09 (0.41% wt/wt prior to desiccation)	Further desiccated over phosphorus pentoxide
05/162	1st IS for $\alpha$ -1-antitrypsin	0.15	0.66	
03/200	WHO reference reagent for IL-18	0.1	1.94	
01/420	WHO reference reagent for IL-17	0.07	0.39	
82/585	3rd IS for anti-polio antiserum types 1,2,3	0.53	ND	
06/116	2nd IS smallpox vaccine	N/A	1.52	Supplied by commercial vaccine supplier — infectious
94/532	4th IS whole-cell pertussis vaccine	0.26	1.69 (1.45% prior to desiccation)	Further desiccated over phosphorus pentoxide

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