

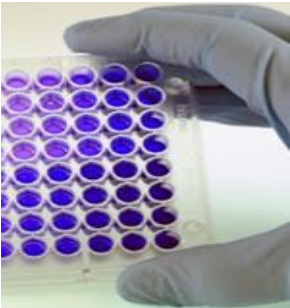


Medicines & Healthcare products
Regulatory Agency



Role of Reference Material for Emerging viruses outbreak preparedness

Giada Mattiuzzo



Biological Standardization – a bit of history...

- 1890's First Biological: Diphtheria antitoxin
No reliably produced. Lot to lot variation as biological activity differed from physical property
- Paul Ehrlich: STANDARD ANTITOXIN PREPARATION – calibrated in Units and used to calibrate future batches
- Henry Dale applied concept to insulin and other biologics (1920s) and on International level – appearance of International Units (IUs) as measure of strength or activity of a product

WHO International Standards

- WHO International Standards are the highest order of reference material for the CALIBRATION of assays worldwide, which will ensure HARMONISATION and therefore COMPARABILITY of the results across a range of assays measuring biological activity
- WHO Expert Committee on Biological Standardization

Uses of a Reference Material

- Effective and reliable diagnostic tools (e.g. HCV RNA test)
- Interpreting vaccine/treatment clinical trial data
- Establishing protective antibody levels (e.g. protective anti-HBs titer >10 IU/L)
- Sero-prevalence

Anyone for coffee?

In which country is coffee more expensive?



19.95 francs

2.7 euro



125 pesetas

1.5 euro



1200 lire

1.3 euro



5.70 marks

2.5 euro

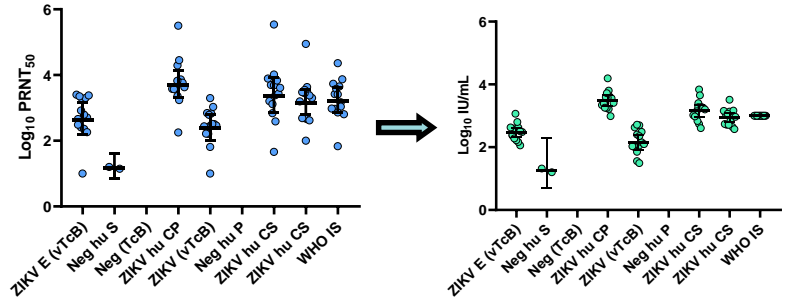
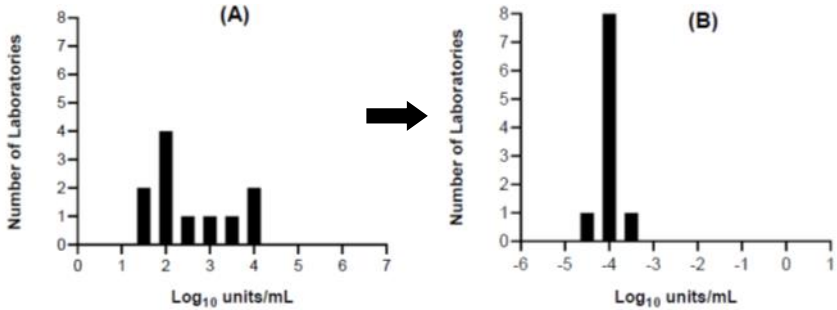


Standards for an outbreak scenario: Ebola/Zika examples

15/220	Anti-EBOV plasma, human (WHO Reference Reagent) International Reference Reagent
15/262	1st International Standard for Ebola virus (EBOV) antibodies Sierra Leone Convalescent Plasma Pool International Standard
16/344	WHO Anti-EBOV Convalescent Plasma (International Reference Panel) International Reference Preparation

15/222	EBOV RNA NP-VP35-GP (WHO Reference Reagent) International Reference Reagent
15/224	EBOV RNA VP40-L (WHO Reference Reagent) International Reference Reagent

Product Number	16/352
Product Description	Anti-Asian Lineage Zika Virus Antibody (human) (1st international standard)
Type of Standard	International Standard



Priority pathogens: WHO R&D Blueprint list

1st WHO International Standard for anti-virus antibodies

Lassa Virus	*recruiting for CS
MERS-CoV	*CS in progress
Nipah virus	sourcing material
Rift Valley Fever virus	***sourcing material
Marburg virus	in pipeline
Sudan virus	in pipeline
CCHF	***recruiting for CS
Dengue	recruiting for CS

1st WHO International Standard for virus RNA

**recruiting for CS
in pipeline
in pipeline
sourcing material
in pipeline
in pipeline
in pipeline
established by CBER 2016

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