New Biological Reference Materials in 2016

Updated April 2016

Part Number	Part Description/ Intended use
INTERNATIONAL STANDARDS AND REFERENCE PREPARATIONS	
11/234	**Immunoglobulin E(IgE) human serum (3rd International Standard)**
	The measurement of serum IgE aids in the diagnosis and management of atopic allergic disease and hyper-IgE immunodeficiency syndromes. The 3rd International Standard for human serum IgE, 11/234, is intended to standardise assays for serum IgE. It replaces preparation 75/502. Its unitage was assigned relative to 75/502 following an international collaborative study.
15/136	**EBOV RNA NP-VP35-GP in-run control**
	The EBOV RNA NP-VP35-GP in-run control (NIBSC code 15/136) is intended to be used as a control for nucleic acid amplification technique (NAT) assays targeting the Ebola virus NP, VP35 or GP gene. The control should be extracted and amplified alongside unknown samples as part of a continuing quality control programme used to monitor assay performance. 15/136 is supplied to professional users, typically hospital laboratories, public health organisations, assay kit manufacturers and appropriate research organisations.
15/138	**EBOV RNA VP40-L in-run control**
	The EBOV RNA VP40-L in-run control (NIBSC code 15/138) is intended to be used as a control for nucleic acid amplification technique (NAT) assays targeting the Ebola virus VP40 or L gene. The control should be extracted and amplified alongside unknown samples as part of a continuing quality control programme used to monitor assay performance. 15/138 is supplied to professional users, typically hospital laboratories, public health organisations, assay kit manufacturers and appropriate research organisations.

IN VITRO DIAGNOSTIC PRODUCTS	
14/240-002	**British Working Standard for Anti-HCV**
	The British Working Standard for antibodies to Hepatitis C virus (anti-HCV) manufactured by NIBSC have been on the market for approximately 20 years. They serve as the UK Working Standards cited in the Guidelines for Blood Transfusion Services in the United Kingdom, 8th Edition March 2013. www.transfusionguidelines.org.uk The British Working Standard for anti-HCV is intended for use in the field of in vitro diagnostics, in conjunction with diagnostic immunoassay test kits/systems for the detection of anti-HCV, to monitor the performance of these systems. It can be used to monitor the consistency of test performance using statistical process control on a daily basis and over a period of time as a retrospective monitor of batch performance. However, it is for the user to establish suitability of purpose. It is expected that the British Working Standard for anti-HCV will be detected in every series of tests.
OTHER STANDARDS AND REAGENTS	
14/174	**Botulinum Type A Antitoxin, Equine**
	This material is the freeze-dried residue of hyperimmune monovalent horse antiserum to Clostridium botulinum type A toxin. It is intended for calibration of the bioassay for botulinum type A antitoxin. The material may also be suitable to confirm serotype identity of botulinum type A toxin. No cross-neutralization with serotypes B, C, D, E, F or G was confirmed in three laboratories using different test methods (mouse lethality, local flaccid paralysis, or ex vivo mouse phrenic nerve methods) using thousand-fold, or greater, excess of antitoxin, 14/174. This material replaces non WHO reference Botulinum type A antitoxin, equine, coded 59/021, which did show cross-neutralization with type B toxin at high concentrations.