New Biological Reference Materials in 2015

Updated January 2016

Part Number	Part Description/ Intended use
INTERNATIONAL STANDARDS AND REFERENCE PREPARATIONS	
13/172	**Lupus Anticoagulant (1st International Reference Panel)**
	The 1st International Reference Plasma Panel for Lupus Anticoagulant, 13/172, is a set of three freeze-dried human plasmas: Lupus Anticoagulant (LA) negative plasma (12/148), a moderate LA positive plasma (12/150) and a strong LA positive plasma (12/152).The intended use of this set of reference materials is for validation of lupus anticoagulant assay methods whenever clinical laboratories have the need to set up new methods or change in instruments and operators or for trouble shooting.
14/266	**Diphtheria Antitoxin Equine (DI) 1st International Standard**
	This antitoxin preparation is suitable for use as the reference diphtheria antitoxin in toxin neutralisation tests in vivo and in vitro, but is primarily intended for calibration of secondary standards. For measurement of diphtheria antitoxin in human serum, customers should use the International Standard for Diphtheria Antitoxin Human (NIBSC code 10/262).
13/132	**Antibodies, Human, to Toxoplasma gondii (4th International Standard)**
	13/132, the 4th International Standard (IS) for Antibodies, Human, to Toxoplasma Gondii is suitable for use in Enzyme Linked Fluorescence Assays and Enzyme Linked Immuno Sorbent Assays for Ig, IgA, IgM, IgG and IgG avidity, and for agglutination assays, Immuno Fluorescence Assays and Immunoblot assays to detect IgG and IgM. 13/132 reacted strongly positive for Ig, IgA, IgG and IgM in all these assays
13/146	**C-Peptide, Human (1st International Standard).**
	The 1st International Standard for human C-peptide, 13/146, is intended for the calibration of immunoassays for human C-peptide.
13/204	**TNF Rec II- FC Fusion protein (1st International Standard)**
	13/204 can serve to control the performance of biological assays for etanercept and to support the establishment of in-house bioassay standards.

13/212	**Diphtheria Toxoid for use in Flocculation Test (3rd International Standard)**
	The 3rd International Standard for Diphtheria Toxoid for use in Flocculation Test (13/212) intended to be used for standardization of flocculation assay to determine the Lf content of diphtheria toxoid.
13/246	**Meningococcal serogroup A polysaccharide (1st WHO International Standard).**
	The freeze-dried preparation of Neisseria meningitidis serogroup A capsular polysaccharide (MenA), is intended for use as a standard for quantification of MenA in final fills and bulks of MenA vaccines (including Phosphorus and HPAEC-PAD assays).
14/114	**JC Virus (JCV) DNA (1st International Standard)**
	The 1st WHO International Standard for JC virus (JCV), is intended for the standardisation of nucleic amplification technique-based assays for JCV. It should be used primarily for the calibration of secondary and/or in-house working standards. The material has been evaluated in a worldwide collaborative study involving 23 laboratories using a range of JCV NAT-based assays
14/148	**Human Coagulation Factor IX Concentrate (5th International Standard).**
	The 5th International Standard for Blood Coagulation Factor IX, Concentrate Human is intended for the calibration of factor IX functional activity in therapeutic concentrates.
14/150	**Hepatitis C virus (HCV) For nucleic acid amplification techniques (5th International standard 2015)**
	The 5th WHO International Standard for hepatitis C virus (HCV), NIBSC code 14/150, is intended to be used for the calibration of HCV secondary standards. The standard comprises genotype 1a HCV antibody-negative, HCV RNA-positive plasma, diluted in pooled human plasma.

14/156	**Meningococcal group X polysaccharide (1st WHO International Standard)**
	The freeze-dried preparation of Neisseria meningitidis serogroup X capsular polysaccharide (MenX), provided by Finlay Istitute, Cuba was prepared in ampoules (2014) at the Centre for Biological Reference Materials (CBRM, NIBSC). A collaborative study was carried out on this material by 11 laboratories in 2014/2015 to determine the MenX content in SI units based on the quantitative nuclear magnetic resonance assay, and to evaluate its suitability for use as a standard for quantification of MenX in final fills and bulks of MenX vaccines (including Phosphorus and HPAEC-PAD assays).
14/212	**BK Virus (BKV)(1st International Standard)**
	The 1st WHO International Standard for BK virus (BKV) is intended for the standardisation of nucleic amplification technique-based assays for BKV. It should be used primarily for the calibration of secondary and/or in-house working standards. The material has been evaluated in a worldwide collaborative study involving 33 laboratories using a range of BKV NAT-based assays,
14/300	**High titre anti-A and anti-B in serum (WHO Reference Reagent).**
	This reference material is intended to help overcome inter-laboratory variability in anti-A and anti-B titrations.
15/220	**Anti-EBOV plasma, human (WHO Reference Reagent)**
	The WHO Reference Reagent for anti-EBOV plasma, human has been established by the WHO Expert Committee on Biological Standardisation (ECBS) for use in neutralisation, pseudotype neutralisation and enzyme immunoassays for antibodies against Ebola virus. 15/220 was assessed in a WHO international collaborative study and is also known as EBOV Ab Sample Code 79.
15/222	**EBOV RNA NP-VP35-GP (WHO Reference Reagent)**
	The EBOV RNA NP-VP35-GP WHO Reference Reagent is intended to be used for the calibration of secondary references for nucleic acid amplification technique (NAT)-based assays targeting the Ebola virus NP, VP35, or GP gene. 15/222 is supplied to professional users, typically hospital laboratories, public health organisations, assay kit manufacturers and appropriate research organisations.

15/224	**EBOV RNA VP40-L (WHO Reference Reagent)**
	The EBOV RNA VP40-L WHO Reference Reagent is intended to be used for the calibration of secondary references for nucleic acid amplification technique (NAT)-based assays targeting the Ebola virus VP40 or L gene. 15/224 is supplied to professional users, typically hospital laboratories, public health organisations, assay kit manufacturers and appropriate research organisations.
15/240	**Erythropoietin Antibody Reference Panel A (1st International Standard)**
	The Reference Panel of human monoclonal antibodies against human erythropoietin (EPO) is intended to facilitate in selection of an assay capable of detecting all EPO antibodies, for evaluating the performance of antibody assays and for assay validation. The antibodies have been grouped into: Panel A, Panel B and a Negative control Panel A coded 15/240 contains: 12/272 IgG2 (Low affinity, non-neutralizing) 12/268 IgG2 (Moderate affinity, weakly neutralizing) 12/274 IgM (Low affinity, non-neutralizing) 12/264 IgG4 (High affinity, neutralizing) 13/158 IgG1 (High affinity, strongly neutralizing)
15/242	**Erythropoietin Antibody Reference Panel B(1st International Standard)**
	The Reference Panel of human monoclonal antibodies against human erythropoietin (EPO) is intended to facilitate in selection of an assay capable of detecting all EPO antibodies, for evaluating the performance of antibody assays and for assay validation. The antibodies have been grouped into: Panel A, Panel B and a Negative control Panel B coded 15/242 contains 12/266 IgG1 (Low affinity, weakly neutralizing) 12/260 IgG2 (High affinity, strongly neutralizing) 13/150 IgG4 (High affinity, strongly neutralizing) 12/270 IgM (Moderate affinity, weakly neutralizing)
13/122	**Erythropoietin Antibody Reference Panel Negative Control Antibody (1st WHO Reference Panel)**
	IgG1 Negative control antibody for use with either of the EPO antibody reference panels described above.

03/178	**Vitamin B12, Serum Folate and holoTC (International standard)**
	This International Standard for Vitamin B12 has undergone another international collaborative study to assign a holoTC value. Twelve laboratories in 8 countries participated.
09/172	**Blood coagulation Factors II, VII, IX, X Plasma (4th International Standard 2010)**
	The 4th International Standard for Blood Coagulation Factors II, VII, IX, X, Plasma was established in 2010 and is intended for use as a primary reference standard for calibration of factors II, VII, IX and X functional activity in plasma samples.
IN VITRO DIAGNOSTIC PRODUCTS	
14/B655-01	**QCRVZVQC1-Anti VZV: Quality Control Serum: Sample 1**
	This product is CE marked for use as an IVD in Europe. In all other territories it is the sole responsibility of the Recipient to ascertain whether it can be used as an IVD. Anti-VZV QC1 is intended for use in the internal laboratory quality control of immunoassays that detect antibodies to the varicella zoster virus. The anti-VZV QC1 should be included in each run as part of a continuing quality control programme to monitor the performance of the assay. Data obtained with the anti-VZV QC1 can be used to construct quality control charts that can be visually monitored each time the assay is run, to check for consistency of performance of the assay. Examples of how these charts are constructed and used have been described elsewhere. Anti-VZV QC1 is NOT INTENDED TO BE USED TO COMPARE THE SENSITIVITY OF PARTICULAR ASSAYS.
14/198-001	**HBV,HCV,HIV Multiplex**
	This product is CE marked for use as an IVD in Europe. In all other territories it is the sole responsibility of the Recipient to ascertain whether it can be used as an IVD. The Triplex Reagent is designed as a low positive control material to assure the sensitivity of PCR assays for HBV, HCV and HIV and contains a low concentration of each of these analytes in normal human plasma. This reagent contains a dilution of HBV, HCV and HIV in normal human plasma and as such should be considered infectious. The product may be positive for the presence of antibodies to HBsAg, HCV and HIV. The product must not diluted and must only be used once.

OTHER STANDARDS AND REAGENTS	
13/218	**Polio Anti Sabin type 1 (inactivated) Serum**
	This antiserum is intended to be used for ELISA or neutralisation assays for the evaluation of type 1 poliovirus.
13/220	**Polio Anti Sabin type 2 (inactivated) serum**
	This antiserum is intended to be used for ELISA or neutralisation assays for the evaluation of type 2 poliovirus.
13/222	**Polio Anti Sabin type 3 (inactivated) serum**
	This antiserum is intended to be used for ELISA or neutralisation assays for the evaluation of type 3 poliovirus.
13/242	**FEIBA Concentrate 2nd NIBSC Working Reference Standard**
	The 2nd NIBSC Working Standard for FEIBA Concentrate, consists of ampoules coded 13/242 and was established by National Institute for Biological Standards and Control (NIBSC) in December 2014. Each ampoule contains aliquots of freeze-dried concentrate of plasma derived human activated prothrombin complex concentrate (FEIBA). This standard is primarily intended to be used for measurement of FEIBA potency in FEIBA therapeutic concentrates.
14/160	**High titre anti-A in IVIG working reference reagent**
	The passive transfer of anti-A and/or anti-B in IVIG can cause adverse reactions in recipients, including haemolysis. Therefore, there are regulatory requirements in place to control levels of these haemagglutinins. Common WHO-Ph. Eur.-FDA reference preparations are available to improve international harmonisation of the testing of IVIG products, and define the pharmacopoeial limit where this applies. Preparation 14/160 is an IVIG preparation with high titre haemolytic anti-A. Testing by 4 laboratories has shown that the anti-A titre of 14/160 is above that of the Limit Preparation 07/310, which defines the Ph. Eur. and FDA limits (titre of 64 from 5% IVIG for both anti-A and anti-B). Preparation 14/160 was found to have an anti-A titre of 128-256 and an anti-B titre of 32-64 (from 5% IVIG) at NIBSC. It is intended for use in haemolysis assays and as an out-of-specification control for anti-A in haemagglutination titrations.