New Biological Reference Materials in 2015

Updated July 2015

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**
	The International Standard (dried horse serum) was prepared and characterised by the Statens Serum Institut (SSI), Copenhagen, Denmark (see enclosed package insert from SSI for details [1]). With effect from 1st July 1997, the National Institute for Biological Standards and Control (NIBSC), Potters Bar, UK is the custodian and distributor of this material. This standard preparation is distributed as a dilution of the dried horse serum prepared at NIBSC in 66% glycerol in normal saline. A liquid fill is prepared from the original dried material approximately every 2 years. The current preparation coded 14/266 was prepared and filled on 21 January 2015 and replaces the previous preparation coded 12/302. 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) [2].
INFLUENZA REAGENTS	
14/250	**Influenza Antigen. A/Anhui/1/2013 (H7N9) NIBRG-268**
	Influenza antigen reagent 14/250 is prepared for single radial diffusion assay of A/Anhui/1/2013 antigens using an appropriate NIBSC antiserum reagent.

14/254	**Influenza Antigen A/Switzerland/9715293/2013(NIB-88) Egg derived**
	Influenza antigen reagent 14/254 is prepared for single radial diffusion assay of A/Switzerland/9715293/2013 (NIB88) egg derived antigens using an appropriate NIBSC antiserum reagent.
14/272	**Influenza Anti-A/Switzerland/9715293/2013 like HA serum**
	Influenza antiserum reagent 14/272 is prepared for single radial diffusion assay of A/Switzerland/9715293/2013-like antigens using an appropriate NIBSC antigen reagent. The antiserum reagent was prepared in sheep 620, 621, 622 and 623 using the purified HA of A/Switzerland/9715293/2013-like viruses. The HA antigens were extracted from purified virus by treatment with bromelain and purified by sedimentation on sucrose gradients (Brand, CN and Skehel, JJ, Nature, New Biology, 1972, 238, 145-147.
14/274	**Influenza Antigen B/Brisbane/9/2014 (Egg Derived)**
	Influenza antigen reagent 14/274 is prepared for single radial diffusion assay of B/Brisbane/9/2014 egg derived antigens using an appropriate NIBSC antiserum reagent.
14/308	**Influenza Virus Infectious IVR-178 40200 E7**
	Reagent 14/ 308 is prepared from IVR-178 which was processed for freeze drying in 250µl volumes as described by Campbell, PJ, Journal of Biological Standardisation, 1974, 2,249-267. The known passage history of IVR-178 is attached
14/310	**Influenza Anti-A/California/7/2009-Like HA Serum**

	Influenza antiserum reagent 14/310 is prepared for single radial diffusion assay of A/California/7/09-like antigens using an appropriate NIBSC antigen reagent. The antiserum reagent was prepared in sheep 606 and 610 using the purified HA of A/California/7/09-like virus. The HA antigens were extracted from purified virus by treatment with bromelain and purified by sedimentation on sucrose gradients (Brand, CN and Skehel, JJ, Nature, New Biology, 1972, 238, 145-147.
14/320	**Influenza Virus Infectious B/Utah/9/2014**
	Reagent 14/320 is prepared from B/Utah/9/2014, which was processed for freeze drying in 250 µl volumes as described by Campbell, PJ, Journal of Biological Standardisation, 1974, 2, 249-267. The known passage history of B/Utah/9/2014 is attached.
14/322	**Influenza Virus Infectious NIB-91**
	Reagent 14/322 is prepared from NIB-91 which was processed for freeze drying in 250µl volumes as described by Campbell, PJ, Journal of Biological Standardisation, 1974, 2,249-267.
15/100	**Influenza Antigen B/Utah/9/2014 (Cell Derived)**
	Influenza antigen reagent 15/100 is prepared for single radial diffusion assay of B/Utah/9/2014 cell derived antigens using an appropriate NIBSC antiserum reagent.
15/104	**Influenza Antigen A/South Australia/55/2014 Cell derived**
	Influenza antigen reagent 15/104 is prepared for single radial diffusion assay of A/South Australia/55/2014 cell derived antigens using an appropriate NIBSC antiserum reagent.
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.
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.
13/242	**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.