## 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). |
| **14/148** | **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. |
| **14/300** | **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. |
| **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.<br>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.<br>The antiserum reagent was prepared in sheep using the purified HA of A/California/7/09-like virus. |

| | |
|---|---|
| **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. |
| **14/312** | **Influenza Virus Infectious B/Phuket/3073/2013** |
| | Reagent 14/312 is prepared from B/Phuket/3073/2013 which was processed for freeze drying in 250 µl volumes as described by Campbel, PJ, Journal of Biological Standardisation, 1974, 2, 249-267. The known passage history of B/Phuket/3073/2013 is attached. |
| **14/306** | **Influenza Virus Infectious NYMC X-243 40180 E13** |
| | Reagent 14/306 is prepared from NYMC X-243 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 NYMC X-243 is attached |

| | |
|---|---|
| **15/154** | **Influenza Virus Infectious NIB-93** |
| | Reagent 15/154 is prepared from NIB-93 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 NIB-93 is attached |
| **15/158** | **Influenza Virus Infectious NYMC X-263** |
| | Reagent 15/158 is prepared from NYMC X-263 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 NYMC X-263 is attached |
| **14/200** | **Influenza Antigen A/Puerto Rico/8/34 (HINI)** |
| | Influenza antigen reagent 14/200 is prepared for single radial diffusion assay of A/Puerto Rico/8/34 antigens using an appropriate NIBSC antiserum reagent. |
| **15/184** | **Influenza Virus Infectious NYMC X-263B** |
| | Reagent 15/184 is prepared from NYMC X-263B 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 NYMC X-263B is attached |
| **15/188** | **Influenza Virus Infectious NYMC X-263A** |
| | Reagent 15/188 is prepared from NYMC X-263A 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 NYMC X-263A is attached |
| **14/314** | **Influenza Virus Infectious NIB-88** |
| | Reagent 14/314 is prepared from NIB-88 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 NIB-88 is attached |
| **15/192** | **Influenza Virus Infectious A/Hong Kong/4801/2014** |
| | Reagent 15/192 is prepared from A/Hong Kong/4801/2014 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 A/Hong Kong/4801/2014 is attached |

| | |
|---|---|
| **15/196** | **Influenza Virus Infectious NYMC X-261** |
| | Reagent 15/196 is prepared from NYMC X-261 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 NYMC X-261 is attached |
| **15/212** | **Influenza Virus Infectious NYMC BX-53C** |
| | Reagent 15/212 is prepared from NYMC BX-53C 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 NYMC BX-53C is attached |
| **15/230** | **Influenza Antigen A/Hong Kong/4801/2014 (NYMCX-263B)** |
| | Influenza antigen reagent 15/230 is prepared for single radial diffusion assay of A/Hong Kong/4801/2014 egg derived antigens using an appropriate NIBSC antiserum reagent. |
| **15/234** | **Influenza Virus Infectious B/Texas/2/2013 41340 E7** |
| | Reagent 15/234 is prepared from B/Texas/2/2013 which was processed for freeze drying in 250 µl volumes as described by Campbel, PJ, Journal of Biological Standardisation, 1974, 2, 249-267. The known passage history of B/Texas/2/2013 is attached. |
| **15/236** | **Influenza Anti-A/Hong Kong/4801/2014 Like HA serum** |
| | Influenza antiserum reagent 15/236 is prepared for single radial diffusion assay of A/Hong Kong/4801/2014-like antigens using an appropriate NIBSC antigen reagent. The antiserum reagent was prepared in sheep using the purified HA of A/Hong Kong/4801/2014-like viruses. |
| **15/238** | **Influenza Antigen A/New Caledonia/71/2014 (NYMCX-257A)(Egg derived antigen)** |
| | Influenza antigen reagent 15/238 is prepared for single radial diffusion assay of A/New Caledonia/71/2014 egg 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.<br>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. |