

Written By: Dr. J. G. Reeve	Form 21-06a	Rev. No. 12
Approved By: Mr G. Gower	Effective Date: 14 th January 2011	Page 1 of 3

EC Declaration of Conformity

In accordance with Directive 98/79/EC

We, Genesis Diagnostics Ltd. of Eden Research Park, Henry Crabb Road, Littleport, Ely, Cambridgeshire, UK declare that:

Product names:

Rheumatoid Factor-IgA Control Serum, Rheumatoid Factor-IgG Control Serum, Rheumatoid Factor-IgM Control Serum, Proteinase-3 (PR3) Abs Control Serum, Myeloperoxidase (MPO) Abs Control Serum, dsDNA Abs Control Serum, SSA/SSB Abs Control Serum, Jo-1Abs Control Serum, Centromere B Abs Control Serum, TPO/Tg Abs Control Serum, Cardiolipin IgG/IgM Control Serum , B2-GP-1 IgG Control Serum, Prothrombin IgG Control Serum, LKM-1/LC-1 IgG Control Serum, Gliadin IgG/IgA Control Serum, Intrinsic Factor/GPC Antibodies Control Serum, GAD Abs Control Serum, GBM Abs Control Serum, Scl 70 Abs Control Serum, Sm/Sm RNP Abs Control Serum, Acetylcholine Receptor Abs Control Serum, Transglutaminase IgA Antibodies Control Serum, U1-Sm RNP Control Serum, Citrullinated Peptide antibodies Control Serum, Hp-G Screen ELISA Kit, Hp-G Screen ELISA Kit (10 pack), MPO Antibodies ELISA Kit, PR3 Antibodies ELISA Kit, GBM Antibodies ELISA Kit, GBM Antibodies ELISA Kit (48 well), Rheumatoid Factor Screen ELISA Kit, *Ps. aeruginosa* IgG ELISA Kit, *H. pylori* IgA ELISA Kit, Total IgE ELISA Kit, dsDNA Antibodies ELISA Kit, ssDNA Antibodies ELISA Kit, Food IgG ELISA Kit, Food IgG ELISA Kit (10 Pack), Food IgG (Mediterranean) ELISA Kit, Food IgG (Mediterranean) ELISA Kit (10 Pack), 40 Food IgG ELISA Kit (4 tests), 40 Food IgG ELISA Kit (10 pack), Gliadin IgG ELISA Kit, Gliadin IgA ELISA Kit, *Ps. aeruginosa* IgA ELISA Kit, *Candida* IgA ELISA Kit, *Candida* IgM ELISA Kit, *Candida* IgG ELISA Kit, Rheumatoid Factor IgM ELISA Kit, Rheumatoid Factor IgA ELISA Kit, Cardiolipin IgA ELISA Kit, Cardiolipin IgG ELISA Kit,

Product names continued:


Cardiolipin IgM ELISA Kit, Total Anti-Cardiolipin Screen ELISA Kit, Aspergillus IgG ELISA Kit, β 2 GP-IgA ELISA Kit, β 2 GP-IgG ELISA Kit, β 2 GP-IgM ELISA Kit, CagA IgG ELISA Kit, Intrinsic Factor IgG ELISA Kit, GPC Antibodies ELISA Kit, Rheumatoid Factor IgG ELISA Kit, β -Lactoglobulin IgA ELISA Kit, β -Lactoglobulin IgG ELISA Kit, Ovalbumin IgA ELISA Kit, Ovalbumin IgG ELISA Kit, Casein IgA ELISA Kit, Casein IgG ELISA Kit, Soya IgA ELISA Kit, Soya IgG ELISA Kit, Thyroglobulin IgG ELISA Kit, TPO IgG ELISA Kit, α -lactalbumin IgA ELISA Kit, α -lactalbumin IgG ELISA Kit, ENA-6 Screen ELISA Kit, Jo-1 Antibodies ELISA Kit, SSA/Ro Antibodies ELISA Kit, Sm Antibodies ELISA Kit, RNP/Sm Antibodies ELISA Kit, Scl-70 Antibodies ELISA Kit, SSB/La Antibodies ELISA Kit, Transglutaminase IgA ELISA KIT, Transglutaminase IgA (recombinant) ELISA KIT, Transglutaminase IgA (recombinant) ELISA KIT (10 pack), Transglutaminase IgG (recombinant) ELISA Kit, ANA Ease ELISA Kit, Prothrombin (Factor II) IgG ELISA Kit, Gliadin IgG/IgA Combined ELISA Kit, ASCA IgG ELISA Kit, ASCA IgA ELISA Kit, HSV-1 IgG ELISA Kit, HSV-2 ELISA Kit, HSV-1/-2IgM ELISA Kit, Tg-AGT ELISA Kit, Centromere B IgG ELISA Kit, LKM-1 IgG ELISA Kit, LC1 IgG ELISA Kit, 5 Food IgG ELISA Kit, Citrullinated Protein IgG ELISA Kit, Glia-check G ELISA Kit, Glia-check A ELISA Kit, Gliadin IgG ELISA Kit, Gliadin IgA ELISA Kit, Tissue Transglutaminase IgA (recombinant) ELISA Kit, Tissue Transglutaminase (recombinant) IgG ELISA Kit, *H. pylori* IgM ELISA Kit, U1-RNP IgG ELISA Kit, Intrinsic Factor IgG ELISA Kit, High Avidity dsDNA IgG ELISA, Genarrayt™ Microarray 200+ food IgG 64 pt, Genarrayt™ Microarray 200+ food IgG 4 pt, Genarrayt™ Microarray 200+ food IgG 20 pt, Genarrayt™ Microarray 200+ food IgG 16 pt; Genarrayt™ Microarray 200+ food IgG 16 pt.

Product numbers: GDA01A, GDA01G, GDA01M, GDA02, GDA03, GDA04, GDA05, GDA06, GDA07, GDA08, GDA09, GDA10, GDA11, GDA12, GDA14, GDA15, GDA16, GDA17, GDA18, GDA19, GDA20, GDA21, GDA22, GDA23, GD01, GD01/10, GD02, GD03, GD04, GD04A, GD06, GD07, GD08, GD09, GD10, GD12, GD14, GD14/10, GD14M, GD14M/10, GD15, GD15/10, GD16, GD17, GD18, GD19, GD20, GD22, GD23, GD24, GD25, GD26, GD27, GD28, GD29, GD30, GD31, GD32, GD33, GD35, GD36, GD37, GD38, GD39, GD40, GD41, GD42, GD43, GD44, GD45, GD48, GD49, GD50, GD51, GD60, GD61, GD62, GD63, GD64, GD65, GD66, GD70, GD71, GD71/10, GD72, GD74, GD76, GD77, GD78, GD79, GD86, GD87, GD88, GD101, GD104, GD107, GD108, GD109, GD110, GD111, GD112, GD113, GD114, GD116, GD117, GD124, GD125, GD126, GD128, GD201, GD201-1, GD201-1/20, GD201-4, GD201Z.

in accordance with the Directive 98/79/EC 'The In Vitro Diagnostic Medical Devices Directive' have been designed and manufactured to the following specifications:

BS EN ISO 9001:2008	Quality systems – Model for quality assurance in design/development, production, installation and servicing
BS EN ISO 13485: 2003	Quality Systems – Medical Devices – Particular requirements for the application of ISO 9001
BE EN ISO 14971:2009	Medical Devices – Application of risk management to medical devices
BS EN 375:2001	Information supplied by the manufacturer with in vitro diagnostic reagents for professional use
BS EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
BS EN 13640:2002	Stability testing of in vitro diagnostic reagents

I hereby declare that the devices named above have been designed to comply with the relevant sections of the above referenced specifications. The devices comply with all essential requirements of the Directive.

Signed by: 
Name: Geoff Gower
Position: Managing Director
Place: Genesis Diagnostics Ltd
Date: 14th January 2011

