

5th September 2017

DECLARATION

We, **Randox Laboratories of 55 Diamond Road, Crumlin, County Antrim, United Kingdom** are an established and recognized manufacturer of *in vitro* diagnostics devices. The majority of products manufactured by Randox Laboratories Ltd are CE marked in accordance with the *In Vitro* Diagnostic Device Directive 98/79/EC

RIQAS products are provided as part of the Randox International Quality Assurance Scheme for external quality assurance program for lawful sales and distribution in the UK and throughout the world.

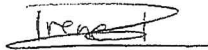
All products are manufactured under a Quality Management System, which is registered to ISO 13485.

We certify that RIQAS products detailed below meet the safety requirements for Proficiency Testing set out under UK and EU legislation and are accredited in accordance with the recognized International guide ISO/IEC 17043:2010 – Conformity Assessment.

Product Name	Catalogue Number
RIQAS Therapeutic drugs	RQ9111
RIQAS General Clinical Chemistry 10 parameters	RQ9112
RIQAS General Clinical Chemistry 17 parameters	RQ9112/S
RIQAS General Clinical Chemistry 51 parameters	RQ9113
RIQAS Specific Proteins 26 parameters (3ml samples)	RQ9114
RIQAS Human Urine	RQ9115
RIQAS Haematology	RQ9118
RIQAS Immunoassay 4 parameters	RQ9125/a
RIQAS Immunoassay 13 parameters	RQ9125/b
RIQAS Immunoassay 49 parameters	RQ9125/c
RIQAS Lipid 3 parameters	RQ9126/a
RIQAS Lipid 7 parameters	RQ9126/b
RIQAS Cardiac 2 parameters	RQ9127/a
RIQAS Cardiac 7 parameters	RQ9127/b
RIQAS Monthly General Clinical Chemistry	RQ9128
RIQAS Glycated Haemoglobin (HbA1c)	RQ9129
RIQAS Monthly Immunoassay	RQ9130
RIQAS Blood Gas	RQ9134
RIQAS Blood Gas (samples only)	RQ9134/a
RIQAS Coagulation 5 parameters	RQ9135/a
RIQAS Coagulation 16 parameters	RQ9135/b
RIQAS Liquid Cardiac	RQ9136
RIQAS Maternal Screening	RQ9137
RIQAS Urinalysis	RQ9138

RIQAS Urine Toxicology	RQ9139
RIQAS Monthly Haematology	RQ9140
RIQAS Immunoassay Speciality I	RQ9141
RIQAS Immunoassay Speciality 2	RQ9142
RIQAS Serology (HIV/Hepatitis)	RQ9151
RIQAS Serology (ToRCH)	RQ9152
RIQAS Serology (EBV)	RQ9153
RIQAS Serology (Syphilis)	RQ9154
RIQAS Immunosuppressant	RQ9159
RIQAS Specific Proteins 26 parameters (2ml samples)	RQ9160
RIQAS Specific Proteins 26 parameters (1ml samples)	RQ9161
RIQAS ESR	RQ9163
RIQAS Ammonia/Ethanol	RQ9164
RIQAS BNP	RQ9165
RIQAS Cerebrospinal Fluid (CSF)	RQ9168
RIQAS Trace elements in serum	RQ9170
RIQAS Trace elements in urine	RQ9171
RIQAS Trace elements in blood	RQ9172
RIQAS Sweat testing	RQ9173
RIQAS Anti-TSH Receptor	RQ9174
RIQAS CYFRA 21-1	RQ9175

For and on behalf of Randox Laboratories Ltd.



Irene Perea Carro
Product Registration Officer