CLINICAL

Reference Materials
Catalogue 2024

LGC

NML
UK NATIONAL MEASUREMENT LABORATORY
FOR CHEMICAL AND BIO-MEASUREMENT
HOSTED AT LGC

Clinical

Blood & Serum Materials

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ERM-DA111	Human blood - sirolimus
ERM-DA200	Frozen human serum - digoxin, high level
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Clinical Purity Materials

ERM-AC021	Sirolimus
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Forensic Ethanol Materials

LGC5409	Aqueous ethanol - 20 mg/100 mL
ERM-AC510	Aqueous ethanol - 50 mg/100 mL
ERM-AC511	Aqueous ethanol - 67 mg/100 mL
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LGC5402	Aqueous ethanol - 107 mg/100 mL
LGC5403	Aqueous ethanol - 200 mg/100 mL

Clinical

Blood and Serum Materials

Human blood - tacrolimus
ERM-DA110

Batch: a
Unit size: 1 mL

The material was prepared by Analytical Services International (London, UK) by spiking blank pooled human blood with a standard solution of tacrolimus to give a nominal concentration of 8 µg/kg tacrolimus in blood.

This material is intended for use in the calibration of instruments, the validation of new methods, and monitoring the performance of methods commonly used in clinical laboratories to determine the tacrolimus content of human blood samples. It can also be used in the training and evaluation of staff.

Certified value:	
Tacrolimus	7.41 ± 0.25 µg/kg

Additional material information:	
Tacrolimus	7.82 ± 0.25 µg/L

UKAS REFERENCE MATERIALS
4005

Human blood - sirolimus
ERM-DA111

Batch: a
Unit size: 1 mL

The material was prepared by Analytical Services International (London, UK) by spiking blank pooled human blood with an acetonitrile solution of ERM-AC021a (pure sirolimus) to achieve a nominal sirolimus concentration of approximately 10 µg/L.

The intended use of this material is for the calibration of instruments, the validation of new methods, and monitoring the performance of methods used in clinical laboratories to determine the sirolimus content of human blood samples. It can also be used in the training and evaluation of staff.

Certified value:	
Sirolimus	9.24 ± 0.52 µg/kg

Additional material information:	
Sirolimus	9.73 ± 0.55 µg/L

UKAS REFERENCE MATERIALS
4005

Frozen human serum - digoxin, high level
ERM-DA200

Batch: a
Unit size: 1 mL

Human serum from donors was supplied by Scipac (Sittingbourne, UK), and prepared by Cardiff Bioanalytical Services Ltd. The serum had been filtered to remove particulates below 0.2 µm. Digoxin in methanol was added to give a final target concentration near the upper decision level in serum digoxin monitoring (2.0 µg/L). The material was subjected to one freeze-thaw cycle, and filtered through a 0.2 µm Pall filter to remove oxalates.

This material is intended for use in the validation of new methods, and monitoring the performance of methods, commonly used in clinical laboratories to determine the digoxin content of human serum samples. It can also be used in the training and evaluation of staff. The material is clinically relevant since it closely matches the upper decision level for digoxin monitoring.

Certified value:	
Digoxin	2.08 ± 0.15 µg/kg

Additional material information:	
Digoxin	2.74 ± 0.19 nmol/L
Digoxin	2.14 ± 0.15 µg/L

UKAS REFERENCE MATERIALS
4005

Frozen human serum - digoxin, low level
ERM-DA201

Batch: a
Unit size: 1 mL

Human serum from donors was supplied by Scipac (Sittingbourne, UK), and prepared by Cardiff Bioanalytical Services Ltd. The serum had been filtered to remove particulates below 0.2 µm. Digoxin in methanol was added to give a final target concentration near the lower decision level in serum digoxin monitoring (0.8 µg/L). The material was subjected to one freeze-thaw cycle, and filtered through a 0.2 µm Pall filter to remove oxalates.

This material is intended for use in the validation of new methods, and monitoring the performance of methods commonly used in clinical laboratories to determine the digoxin content of human serum samples. It can also be used in the training and evaluation of staff. The material is clinically relevant since it closely matches the lower decision level for digoxin monitoring.

Certified value:	
Digoxin	0.845 ± 0.050 µg/kg

Additional material information:	
Digoxin	1.110 ± 0.065 nmol/L
Digoxin	0.868 ± 0.051 µg/L

UKAS REFERENCE MATERIALS
4005

Frozen human serum
ERM-DA250

Batch: a
Unit size: 1 mL

Human blood serum from donors at the University Hospital of Wales was prepared as two separate pools, one at high concentration of electrolytes and creatinine and one at low, using the method for the preparation of General Chemistry EQA (External Quality Assessment) samples for the Wales External Quality Assessment Scheme (WEQAS). The pools were screened to ensure they were negative for HIV and Hepatitis, then mixed to obtain the required range of concentrations and sterile filtered to 0.2 µm.

UKAS REFERENCE MATERIALS
4005

This material is intended for use in the validation and ongoing monitoring of methods of analysis for the determination of creatinine and electrolytes in human blood samples.

Certified values:			
Creatinine	39.0 ± 2 mg/kg	Magnesium	47 ± 3 mg/kg
Calcium	123 ± 5 mg/kg	Potassium	277 ± 14 mg/kg
Lithium	6.6 ± 0.4 mg/kg	Sodium	3370 ± 160 mg/kg

Frozen human serum
ERM-DA251

Batch: a
Unit size: 1 mL

Human blood serum from donors at the University Hospital of Wales was prepared as two separate pools, one at high concentration of electrolytes and creatinine and one at low, using the method for the preparation of General Chemistry EQA (External Quality Assessment) samples for the Wales External Quality Assessment Scheme (WEQAS). The pools were screened to ensure they were negative for HIV and Hepatitis, then mixed to obtain the required range of concentrations and sterile filtered to 0.2 µm.

UKAS REFERENCE MATERIALS
4005

This material is intended for use in the validation and ongoing monitoring of methods of analysis for the determination of creatinine and electrolytes in human blood samples.

Certified values:			
Creatinine	22 ± 2 mg/kg	Magnesium	19 ± 2 mg/kg
Calcium	71 ± 3 mg/kg	Potassium	136 ± 7 mg/kg
Lithium	4.5 ± 0.3 mg/kg	Sodium	2740 ± 80 mg/kg

Frozen human serum
ERM-DA252

Batch: a
Unit size: 1 mL

Human blood serum from donors at the University Hospital of Wales was prepared as two separate pools, one at high concentration of electrolytes and creatinine and one at low, using the method for the preparation of General Chemistry EQA (External Quality Assessment) samples for the Wales External Quality Assessment Scheme (WEQAS). The pools were screened to ensure they were negative for HIV and Hepatitis, then mixed to obtain the required range of concentrations and sterile filtered to 0.2 µm.

UKAS REFERENCE MATERIALS
4005

This material is intended for use in the validation and ongoing monitoring of methods of analysis for the determination of creatinine in human blood samples.

Certified value:	
Creatinine	3.1 ± 0.5 mg/kg

Additional material information:			
Calcium	58 mg/kg	Potassium	67 mg/kg
Lithium	1.3 mg/kg	Sodium	2400 mg/kg
Magnesium	8.1 mg/kg		

Frozen human serum
ERM-DA253

Batch: a
Unit size: 1 mL

Human blood serum from donors at the University Hospital of Wales was prepared as two separate pools, one at high concentration of electrolytes and creatinine and one at low, using the method for the preparation of General Chemistry EQA (External Quality Assessment) samples for the Wales External Quality Assessment Scheme (WEQAS). The pools were screened to ensure they were negative for HIV and Hepatitis, then mixed to obtain the required range of concentrations and sterile filtered to 0.2 µm.

UKAS REFERENCE MATERIALS
4005

This material is intended for use in the validation and ongoing monitoring of methods of analysis for the determination of creatinine in human blood samples.

Certified value:	
Creatinine	50 ± 2 mg/kg

Additional material information:			
Calcium	96 mg/kg	Potassium	238 mg/kg
Lithium	8.4 mg/kg	Sodium	3260 mg/kg
Magnesium	35 mg/kg		

Frozen human serum – testosterone, high level ERM-DA345

Batch: a
Unit size: 0.8 mL

Time expired human blood serum from donors to the National Blood Transfusion Service, Bristol was prepared at the University Hospital in Wales using their standard method for the General Chemistry EQA (External Quality Assessment) samples for the WEQAS scheme.
Female blood serum was used and testosterone in methanol added to bring the concentration within the normal range for male human serum. The material was screened to ensure it was negative for HIV and Hepatitis B and C, then mixed and sterile filtered to 0.2 µm. Gentamicin was added as a preservative.

This material is intended for use in the validation and ongoing monitoring of methods of analysis for the determination of testosterone in human blood samples.

Certified value:	
Testosterone	5.39 ± 0.16 µg/kg

UKAS REFERENCE MATERIALS
4005

Frozen human serum – testosterone, low level ERM-DA346

Batch: a
Unit size: 0.8 mL

Time expired human blood serum from donors to the National Blood Transfusion Service, Bristol was prepared at the University Hospital in Wales using their standard method for the General Chemistry EQA (External Quality Assessment) samples for the WEQAS scheme.
Female blood serum was used with a concentration within the normal range for female human serum. The material was screened to ensure it was negative for HIV and Hepatitis B and C, then mixed and sterile filtered to 0.2 µm. Gentamicin was added as a preservative.

This material is intended for use in the validation and ongoing monitoring of methods of analysis for the determination of testosterone in human blood samples.

Certified value:	
Testosterone	0.25 ± 0.04 µg/kg

UKAS REFERENCE MATERIALS
4005

Frozen human serum – elements and selenomethionine
LGC8211

Batch: 001
Unit size: 1.1 mL

Human serum from a single donor was prepared from blood obtained at the Royal Surrey County Hospital (Guildford, UK). Five donations were taken, with a minimum of 13 weeks between each donation. The blood was allowed to clot at rom temperature, centrifuged, and the serum pipetted into an acid washed container which was then stored frozen at (-80 +40/-10) °C. Each batch of serum collected was added directly into the same bottle. The 'clean' serum was mixed thoroughly and then dispensed.

4005

This material is intended for use in the calibration of instruments and the validation and performance monitoring of methods used for the determination of calcium, copper, iron, magnesium, potassium, selenium, zinc and selenomethionine in human serum samples. It can also be used in the training and evaluation of staff.

Certified values:			
Copper	1130 ± 33 µg/kg	Selenomethionine	25.0 ± 1.6 µg/kg
Zinc	658 ± 33 µg/kg	Calcium	87.0 ± 2.2 mg/kg
Iron	496 ± 22 µg/kg	Magnesium	20.28 ± 0.58 mg/kg
Selenium	64.1 ± 3.0 µg/kg	Potassium	142.0 ± 3.7 mg/kg

Additional material data:			
Copper	18.18 ± 0.53 µmol/L	Selenomethionine	0.1304 ± 0.0086 µmol/L
Zinc	10.30 ± 0.52 µmol/L	Calcium	2.220 ± 0.071 mmol/L
Iron	9.08 ± 0.43 µmol/L	Magnesium	0.853 ± 0.031 mmol/L
Selenium	0.830 ± 0.038 µmol/L	Potassium	3.71 ± 0.13 mmol/L

Blood – hip replacement wear metals – Cr and Co
LGC8276

Batch: 001
Unit size: 1.8 mL

The material was prepared by the UK's Trace Elements External Quality Assessment Scheme (TEQAS), (Guildford, UK) by adding the elements of interest to equine blood containing EDTA at a concentration of 1 mg/mL.

4005

This material is intended for use in the calibration of instruments and the validation of new methods commonly used in clinical laboratories to determine the metal content of human blood samples. It can also be used for monitoring the performance of methods and in the training and evaluation of staff.

Certified values:	
Chromium	6.69 ± 0.28 µg/kg
Cobalt	6.78 ± 0.20 µg/kg

Indicative values:	
Molybdenum	9 µg/kg
Nickel	5 µg/kg
Titanium	10 µg/kg

Clinical Purity Materials

Sirolimus
ERM-AC021

Batch: a
Unit size: 0.1 g

This material was produced from a batch of sirolimus in powder form kindly donated by Pfizer, Inc (New York, USA). The purity was assessed by combining data from HPLC-UV, Karl Fischer and TGA.

This material is intended for use in the calibration of instruments, quality control and the validation of methods to determine the immunosuppressant drug sirolimus. It can also be used in the training and evaluation of staff.

4005

Certified value:	
Purity	98.89 ± 0.64 % mass

Tacrolimus
ERM-AC022

Batch: a
Unit size: 0.1 g

This material was produced from a batch of tacrolimus monohydrate in powder form kindly donated by Sandoz International GmbH. The purity was assessed by combining data from HPLC-UV, Karl Fischer and TGA.

This material is intended for use in the calibration of instruments, quality control and the validation of methods to determine the immunosuppressant drug tacrolimus. It can also be used in the training and evaluation of staff.

4005

Certified value:	
Purity	97.65 ± 0.68 % mass

Digoxin
ERM-AC200

Batch: a
Unit size: 0.5 g

A batch of digoxin was obtained from a commercial supplier of reagents. The purity was assessed by combining data from HPLC-UV, Karl Fischer, ICP-OES, ICP-MS and GC/MS.

This material is intended for use in the validation, calibration and monitoring of methods to determine digoxin content, including methods commonly used in clinical laboratories for digoxin in human blood samples. It can be used in the training and evaluation of staff.

4005

Certified value:	
Purity	98.0 ± 0.5 % mass

Forensic Ethanol Materials

Aqueous ethanol – 20 mg/100 mL LGC5409

Batch: 004
Unit size: 50 mL

This material, produced by LGC is a solution of ethanol in water at a nominal concentration of 20 mg/100 mL.

This material is primarily intended for use as a reference material for the calibration and validation of methods for the determination of ethanol in biological fluids.

Certified value:	
Ethanol content	19.9 ± 0.6 mg/100 mL

4005

0423

Aqueous ethanol - 50 mg/100 mL ERM-AC510

Batch: a
Unit size: 25 mL

This material, produced by LGC is a solution of ethanol in water at a nominal concentration of 50 mg/100 mL.

This material is primarily intended for use as a reference material for the calibration and validation of methods for the determination of ethanol in biological fluids.

Certified value:	
Ethanol content	49.6 ± 0.6 mg/100 mL

4005

0423

Aqueous ethanol - 67 mg/100 mL ERM-AC511

Batch: a
Unit size: 25 mL

This material, produced by LGC is a solution of ethanol in water at a nominal concentration of 67 mg/100 mL.

This material is primarily intended for use as a reference material for the calibration and validation of methods for the determination of ethanol in biological fluids.

Certified value:	
Ethanol content	66.9 ± 0.6 mg/100 mL

4005

0423

Aqueous ethanol - 80 mg/100 mL LGC5401

Batch: 039
Unit size: 25 mL

This material, produced by LGC, is a solution of ethanol in water at a nominal concentration of 80 mg/100 mL.

This material is primarily intended for use as a reference material for the calibration and validation of methods for the determination of ethanol in biological fluids.

Certified value:	
Ethanol content	80.1 ± 0.6 mg/100 mL

4005

0423

Aqueous ethanol - 107 mg/100 mL LGC5402

Batch: 026
Unit size: 25 mL

This material, produced by LGC, is a solution of ethanol in water at a nominal concentration of 107 mg/100 mL.

This material is primarily intended for use as a reference material for the calibration and validation of methods for the determination of ethanol in biological fluids.

Certified value:	
Ethanol content	106.9 ± 0.6 mg/100 mL

UKAS REFERENCE MATERIALS 4005

UKAS CALIBRATION 0423

Aqueous ethanol – 200 mg/100 mL LGC5403

Batch: 024
Unit size: 25 mL

This material, produced by LGC, is a solution of ethanol in water at a nominal concentration of 200 mg/100 mL.

This material is primarily intended for use as a reference material for the calibration and validation of methods for the determination of ethanol in biological fluids.

Certified value:	
Ethanol content	199.8 ± 0.7 mg/100 mL

UKAS REFERENCE MATERIALS 4005

UKAS CALIBRATION 0423

www.lgcgroup.com/nml
measurement@lgcgroup.com
+44 (0)20 8943 7393 • LGC Queens Road,
Teddington, Middlesex, TW11 0LY, UK