JCTLM
Accurate results for patient care

Database Newsletter

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This Special Report gives the results of the gap analysis carried out on the JCTLM Database by Dr Graham Jones (ILAC representative on the JCTLM Executive Committee) in March 2017. The JCTLM database comprises lists of higher-order reference materials, measurement methods and services that have been reviewed against appropriate metrological criteria and judged to be compliant with applicable ISO standards.

The JCTLM database – Gap analysis March 2017, G. Jones

Gap analysis

The JCTLM database now includes listings for a wide range of reference materials (RM), both pure preparations and matrix-matched materials, reference measurement procedures (RMP) and reference measurement services (RMS). It is hoped that relevant organizations will continue to make developments for future additions to the database, to support traceability in clinical laboratories. A gap analysis of the current database has been performed to assist in identifying missing components of the calibration hierarchies of clinical measurands. There are of course many measurands which have no listing in the database and developments are needed for all of these. Of those measurands with current listings, these may be complete or partial. The database is analysed below to address these listings. The JCTLM wishes to work with stakeholders to 'reduce the gap'.

Complete listings

For most measurands a complete listing includes a pure RM, a matrix-matched RM, an RMP and a RMS. The 26 measurands listed below currently meet this criteria. Note that for the serum enzymes, the reference measurement procedure is considered the top of the calibration hierarchy and a pure material is not required for a listing to be considered complete. Inclusion in this list of course does not preclude development and submission of additional entries in any category, as a widely-available supply of RMs, RMPs and RMSs can facilitate wider adoption of laboratory traceability. Note that for the purposes of this summary no distinction is drawn between serum and plasma. Inclusion of a measurand on this list can be considered a successful provision of higher-order references for traceabililty.

Measurand	RM (pure material)	RM (matrix matched)	RMP	RMS
17 beta estradiol in serum/plasma	1	3	4	1
Alanine Amino Transferase (ALT) in serum/plasma			1	10
Alkaline Phosphatase (ALP) in serum/plasma			1	7
Alpha-Amylase in serum/plasma	1		1	7
Aspartate Amino Transferase (AST) in serum/plasma	1		1	9
Calcium in serum/plasma	2	4	8	3
Chloride in serum/plasma	2	3	5	1
Cholesterol in serum/plasma	3	4	8	7
Cortisol in serum/plasma	2	4	5	4
Creatine Kinase (CK) in serum/plasma	1		1	7
Creatinine in serum/plasma	5	12	7	5
Digoxin in serum/plasma	1	2	2	1
Gamma glutamic acid (GGT) in serum/plasma	1		1	7
HbA1c in serum/plasma	1	1	3	4
HDL Cholesterol in serum/plasma	3	1	1	1
Lactate Dehydrogenase (LDH) in serum/plasma			1	7
LDL Cholesterol in serum/plasma	3	1	1	1
Lithium in serum/plasma	2	3	4	3
Magnesium in serum/plasma	3	3	6	3

Measurand	RM (pure material)	RM (matrix matched)	RMP	RMS
Potassium in serum/plasma	3	4	6	4
Progesterone in serum/plasma	1	2	3	2
Sodium in serum/plasma	3	4	6	4
Testosterone in serum/plasma	1	2	4	4
Triglycerides/total glycerides in serum/plasma	1	4	6	2
Urea in serum/plasma	3	2	3	4
Uric acid in serum/plasma	3	3	4	4

Table 1. JCTLM database measurands with complete listings. The numbers indicate the number of entries for each of the components

Partial listings

Partial or incomplete listings are missing at least one of the components. The list below shows the tests with two or more components in the database and the number of entries where they are present.

Measurand	RM (pure material)	RM (matrix matched)	RMP	RMS
17-hydroxyprogesterone in serum/plasma			1	1
19-norandrosterone in urine	1		1	
25-hydroxyvitamin D2 in serum/plasma			3	1
25-hydroxyvitamin D3 in serum/plasma			3	1
5-methyltetrahydrofolic acid		1	3	
albumin in serum/plasma	1	1	1	
aldosterone in serum/plasma			2	1
arsenic in urine		1	1	
bilirubin in serum/plasma			2	1
cadmium in serum/plasma		2	1	
cadmium in urine		2	1	
cadmium in whole blood		5	1	
cobalt in urine		2	1	
copper in serum/plasma		1	1	
C-peptide in serum/plasma	1		2	
C-reactive protein (CRP) in serum/plasma	1	1	1	
creatinine in urine	1		1	1
digitoxin in serum/plasma			2	2
estriol (non conjugated) in serum/plasma			1	1
free thyroxine in serum	1		1	1
glucose in urine	1		1	1
homocysteine in serum/plasma		1	3	
immunoglobulin A in serum/plasma		1	1	
immunoglobulin G in serum/plasma		1	1	
immunoglobulin M in serum/plasma		1	1	
lead in urine		2	1	
lead in whole blood		5	1	

Measurand	RM (pure material)	RM (matrix matched)	RMP	RMS
mercury in urine		2	1	
mercury in whole blood		2	1	
phenobarbital in serum/plasma		1	1	
phenytoin in serum/plasma		1	1	
theophylline in serum/plasma	1		2	2
total T3 in serum/plasma	1		2	2
total thyroxine (T4) in serum/plasma	1		4	4
transferrin in serum/plasma		1	1	
transthyretin in serum/plasma		1	1	
urea in urine	1	1	1	
uric acid in urine	1		1	1
zinc in serum/plasma		1	1	

Table 2. JCTLM database measurands with incomplete listing. The numbers indicate the number of entries for the components.

Single Entries

There are a large number of measurands for which there is a listing in only one of the categories. These are shown in the lists below for those with only a pure material or calibration solution, those with a matrix matched material and those with only an RMP. There are no measurands with only an entry for RMS as it is a requirement for the procedure to be listed on the JCTLM database. Note that the lists do not include all entries in the database as some may be better described as reagents or standards which are distinct from the analyte itself. Some examples of this are thromboplastin and bovine serum albumin.

Pure RM only (includes calibration solutions) (n=63)

in calibration solution
alanine
albumin
arginine
aspartic acid
BCR-ABL b3a2 transcript
cystine
ethanol
glutamic acid
glycine
histidine
human cardiac troponin I (cTnI)
isoleucine
leucine
lysine
methionine
phenylalanine
proline
threonine
total C-peptide
tyrosine
valine

in high-purity material
4-hydroxy- 3-methoxymandelic acid
acid phosphatase (prostatic) (PAP)
alphafoetoprotein
amphetamine
apolipoprotein A1 (apo A I)
captopril
cocaine
cortisol
epitestosterone
fructose
galactose
glycine
heroin
lactose
L-alanine
L-aspartic acid
L-cystine
L-glutamic acid
L-histidine
L-isoleucine
L-leucine
L-lysine
L-methionine
L-phenylalanine
L-proline
L-serine
L-threonine
L-tyrosine
L-valine
MDA
MDMA
methamphetamine
metronidazole
morphine
prostate specific antigen
sirolimus
sodium diclofenac
sucrose
triolein
tripalmitin
tyroglobulin (human)
xylose

Matrix matched reference materials only (n=60)

Blood plasma reference materials
anti-c antibodies
anti-D antibodies
cadmium
HIV molecular marker

Blood serum reference materials
alpha1 acid glycoprotein (AAG)
alpha1 antitrypsin (AAT)
alpha2 macroglobulin (A2M)
alpha-tocopherol
anti-myeloperoxidase immunoglobulin G
ascorbic acid
beta-2-microglobulin
carbamazepine
carbohydrate deficient transferrin
complement 3c (C3c)
complement 4 (C4)
cystatin C
ethosuximide
gamma-tocopherol
haptoglobin (HPT)
HLA specific allo-antibodies
primidone
selenium
tacrolimus
total beta-carotene
total beta-cryptoxanthin
total lutein
total retinolm
total zeaxanthin
transferrin
transthyretin
valproic acid

Urine reference materials
antimony
arsenic acid
arsenocholine
arsenous acid
barium
benzoylecgonine
beryllium
cesium
chromium
codeine
copper
dimethylarsinic acid
iodine
manganese
molybdenum
monomethylarsonic acid
morphine
nickel
nitrate
perchlorate
phencyclidine
platinum
selenium
thallium
THC-9-COOH
thorium
trimethylarsine oxide
uranium
vanadium

Reference measurement procedure only (n=17)
(24R),25-dihydroxyvitamin D3 in blood serum
acetaminophen in blood serum
amyloid beta 1-42 in CSF
copper in whole blood
estrone in blood plasma
folic acid in blood serum
free glycerol in blood serum
gentamicin in blood serum/plasma
glycoprotein in blood serum
hemoglobin in whole blood
lamotrigine in blood serum
norandrosterone in urine
ortho-phosphate in blood serum
theophylline in blood serum
thrombocyte in whole blood
topiramate in blood serum
vancomycin in blood serum