

Use of LOINC and UCUM in CDISC SDTM and SEND

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Use of LOINC in Healthcare

- Healthcare uses HL7 Standards for exchange
- HL7: Health Level 7
 - Worldwide organization
 - With headquartes in the USA
 - Develops semantic and syntactic standards for healthcare
 - Major groups of standards:
 - HL7-v2: bar delimited exchange format
 - HL7-v3: XML based exchange format



HL7 v2

- Messages between systems
 - Mostly between systems in the same hospital
 - E.g. Lab results from Lab to Hospital Information System
 - Sometimes also between hospitals / other organizations
 - E.g. immunization information



HL7-v2 example Laboratory Result

MSH|^~\&|GHH LAB|ELAB-3|GHH OE|BLDG4|200202150930||ORU^R01|CNTRL-3456|P|2.4<cr>
PID|||555-44-4444||EVERYWOMAN^EVE^E^^^LJJONES|19620320|F|||153 FERNWOOD DR.^ ^STATESVILLE^OH^35292||(206)3345232|(206)752-121|||AC555444444||67-A4335^OH^20030520<cr>
OBR|1|845439^GHH OE|1045813^GHH LAB|15545^GLUCOSE||200202150730|||||||| 555-55-5555^PRIMARY^PATRICIA P^^^MD^^||||||||||||||||444-44-4444^HIPPOCRATES^HOWARD H^^^MD<cr>
OBX|1|SN|1554-5^GLUCOSE^POST 12H CFST:MCNC:PT:SER/PLAS:QN||^182|mg/d]|70_105|H|||F<cr>



Usage of LOINC in healthcare

Used in HL7-v2 messages

MSH|/~\& GHH LAB ELAB-8 GHH OE BLDG4 200202150930 ORU^R01 CNTRL-3456 Pl2.4<cr>
PID || 555-44-4444 || EVERYWOMANAEVEAEAAAL_JONES 19620320 F|| 153 FERNWOOD DR.^ ^STATESVILLE^OH^35292 || (206) 3345232 | (206) 752-121 || || AC555444444 || 67-A4335^OH^20030520<cr>
OBR |1 845439^GHH OE |1045813^GHH LAB 15545^GLUCOSE || 200202150730 || || || || || || || || 555-55-5555^PRIMARY^PATRICIA P^^AMD^A || || || || || || || 444-44-44444 HIPPOCRATES^HOWARD H^^AMD<cr>
OBX |1 SN 1554-5^GLUCOSE^POST 12H CFST:MCNC:PT:SER/PLAS:QN ||^182 |mg/d1 |70_105 || || || F<cr>

- MSH: message header
- GHH LAB: sender
- GHH OE: receiver
- 200202150930: Datetime
- ORU^R01: message type: Observation Result unsollicited



HL7-v2 example Laboratory Result - Details

MSH|^~\&|GHH LAB|ELAB-3|GHH OE|BLDG4|200202150930||ORU^R01|CNTRL-3456|P|2.4<cr>
PTD|||555-44-4444||EVERYWOMAN^EVE^E^^^LIONES|19620320|F|||153 FERNWOOD DR.^ STA_ESVILLE^OH^35292||(206)3345232|(206)752-121|||AC555444444||67-A4335^OH^20030520<cr>
OBR|1|845439^GHH OE|1045813^GHH LAB|15545^GLUCOSE||200202150730|||||||| 555-55-5555^PRIMARY^PATRICIA P^^^MD^^||||||||||||444-44-44444^HIPPOCRATES^HOWARD H^^MD<cr>
OBX|1|SN|1554-5^GLUCOSE^POST 12H CFST:MCNC:PT:SER/PLAS:QN||^182|mg/d1|70_105|H|||F<cr>

- OBR: Observation Request
- 15545^GLUCOSE: "please execute Glucose test with test code 15545"



HL7-v2 example Laboratory Result - Details

MSH|~~\&|GHH LAB|ELAB-3|GHH OE|BLDG4|200202150930||ORU^R01|CNTRL-3456|P|2.4<cr>
PID|||555-44-4444||EVERYWOMAN/EVE^E^^^LJONES|19620320|F|||153 FERNWOOD DR.^ ^STATESVILLE^OH^35292||(206)3345232|(206)752-121|||AC555444444||67-A4335^OH^20030520<cr>
OBR|1|845439^GHH OE|1045813^GHH LAB|15545^GLUCOSE||200202150730|||||||| 55-5555 PRIMARY PATRICLA POMPHINISTIC PT:SER/PLAS:04-44444^HIPPOCRATES^HOWARD H^^^MD<cr>
OBX|1|SN|1554-5^GLUCOSE^POST 12H CFST:MCNC:PT:SER/PLAS:04-7182|mg/d1]70_105|H|||F<cr>

- OBX: Observation Result
- 1554-5^GLUCOSE^POST 12H CFST:MCNC:PT:SER/PLAS:QN
- Meaning:
 - I have executed test with LOINC Code 1554-4 which is a glucose test, 12 hours calory fasting as a mass concentration as a point in time, in serum or plasma as a quantitative test



LOINC is not only lab tests ...

OBR 1 | | ^CDC VAERS-1 (FDA) Report | 20010316 OBX 1 NM 21612-7^Reported Patient Age^LN 05 mo^month^ANSI OBX 1 TS 30947-6^Date form completed^LN 20010316 OBX 2 FT 30948-4 Vaccination adverse events and treatment, if any LN 1 fever of 100 loss of appetite OBX[3]CE[30949-2/Vaccination adverse event outcome/LN[1]E/required emergency room/(OBX 4 CE 30949-2^Vaccination adverse event outcome^LN 1 H^required hospitalization OBX 5 NM 30950-0^Number of days hospitalized due to vaccination adverse event^LN 1 OBX 6 CE 30951-8 Patient recovered LN YAYes HL70239 OBX|7|TS|30952-6^Date of vaccination^LN||20010216| OBX 8 T5 30953-4 Adverse event onset date and time LN 200102180900 OBX 9 FT 30954-2^Relevant diagnostic tests/lab data^LN Electrolytes, CBC, Blood cu OBR 2 30955-9/All vaccines given on date listed in #10/LN OBX 1 CE30955-9&30956-7^Vaccine type^LN 1 08^HepB-Adolescent/pediatric^CVX OBX 2 CE 30955-9&30957-5^Manufacturer^LN 1 MSD^Merck^MVX OBX 3 5T 30955-9&30959-1^Lot number^LN 1 MRK12345 OBX 4 CE 30955-9&30958-3 Route LN 1 IM / Intramuscular / HL70162 OBX 5 CE 30955-9&31034-2^Site^LN 1 LA^Left arm^ HL70163 OBX 6 NM 30955-9&30960-9^Number of previous doses^LN 101I OBX 7 CE CE 30955-9&30956-7^Vaccine type^LN 2 50^DTaP-Hib^CVX OBX 8 CE 30955-9&30957-5^ Manufacturer^LN 2 WAL^Wyeth_Ayerst^MVX OBX 9 ST 30955-9&30959-1^Lot number^LN 2 W46932777 OBX 10 CE 30955-9&30958-34 RouteALN 2 IMAIntramuscularAHL70162



HL7-v2 example Laboratory Result

- 1554-5^{GLUCOSE^{POST} 12H CFST :MCNC:PT:SER/PLAS:QN}
- Test is very granular
- From the LOINC manual:

	Table 7: Example Nature of Challenge					
Туре	Description					
CFst	Calorie fast. No caloric intake (food) for the period specified in the time part of the term, e.g., POST 12H CFst					
Exercise	Exercise undertaken as challenge (can be quantified)					
FFst	Fluid "fast." No fluid intake for the period specified					



HL7-v2 example Laboratory Result

LOINC

LOINC code details:

Number	1554-5
Component	Glucose^post 12H CFst
Property	MCnc
Time Aspect	Pt
System	Ser/Plas
Scale Type	Qn
Class	CHAL
Source	AT
Date Last Changed	20010124
Change Type	MAJ
Status	ACTIVE
Molar Mass	180.2
Class Type	1
Chemical Name Synonyms	CORN SUGAR, D GLUCOPYRANOSE, D GLUCOSE, D GLUCOSE, DEXTROSE, GLU, GRAPE SUGAR,
Units Required	Y
Related Names v2.05	Glu; Gluc; Glucoseur; p 12h fast; Mass concentration; Level; Point in time; Random; SerPl; SerPlas; SerP; Serum; SR; Plasma; Pl; Plsm; Quantitative; QNT; Quant; Quan; PST; After; PC; Fast; Calorie Fast; Fasting; CHEMISTRY.CHALLENGE TESTING; CHEMISTRY.CHALLENGE TESTING; GTT; Glu tol; Glucose tolerance
Short Name	Glucose p 12h fast SerPI-mCnc
Order OBS	Both
Example Units	mg/dL
Long Common Name	Glucose [Mass/volume] in Serum or Plasma12 hours fasting



DOES CDISC USE LOINC ?

Well, somehow ...

LOINC Code	Char	Synonym Qualifier of TESTCD	Logical Observation Identifiers Names and Codes (LOINC) code for the topic variable such as a lab test.
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Source: Study Data Tabulation Model v.1.3



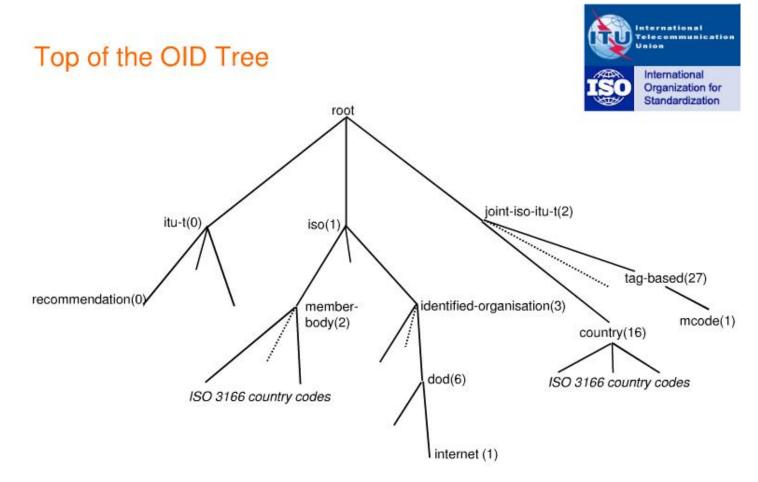
OIDs: object identifiers

- Object identifiers used in healthcare
 - But not only there
- Tree structure
- An organization that has an OID is allowed to assign further OIDs to ...
 - Associated (sub)organizations
 - Documents
 - Persons

•

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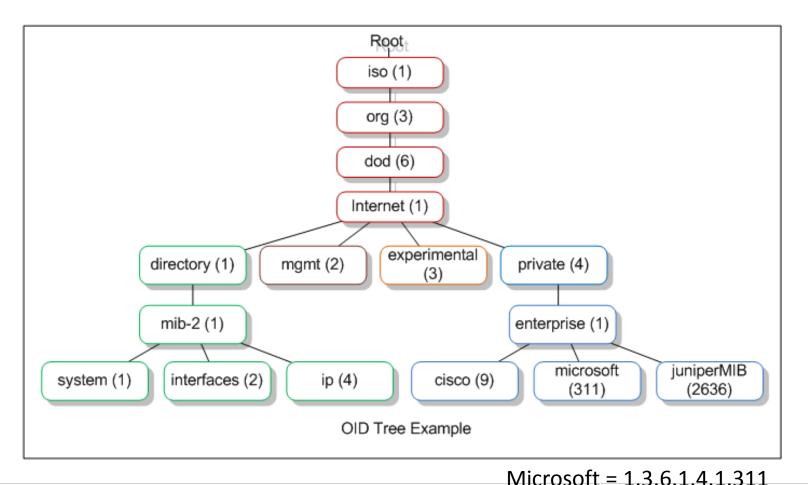
OID tree structure



ITU = International Telecommunication Union (www.itu.int)



OID tree structure





OID ISO country codes and ISO-3166-1

1.2.840 = ISO USA 1.2.40 = ISO Österreich 1.2.276 = ISO Deutschland 1.2.756 = ISO Schweiz

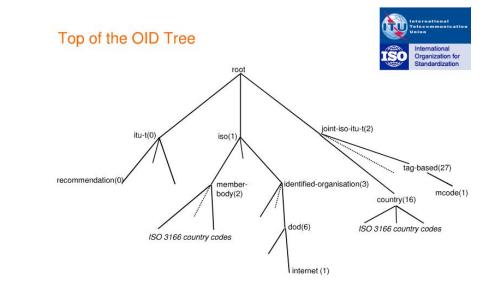
Die Ojekt-Identifikatoren werden als OID abgekürzt. OID sind weltweit eindeutige Kennzeichungen für Objekte und sind in ISO/IEC 9834/1 normiert. Ein Beispiel: Die OID **1.2.756**.5.30.1.104.1.2.1 ist die SoH-Personalnummer, eingesetzt bei der Solothurner Spitäler AG. Sie bedeutet eine eindeutig zuordbare Personalnummer. Die Kombination von OID (= Iden-

	Nigeria	NG	NGA	566
88	Niue	NU	NIU	570
•	Nördliche Marianen	MP	MNP	580
	Norfolkinsel	NF	NFK	574
╡┝═	Norwegen	NO	NOR	578
	Oman	OM	OMN	512
=	Österreich	AT	AUT	040
C	Pakistan	PK	PAK	586
•	Palau	PW	PLW	585
	Panama	PA	PAN	591
	Papua-Neuguinea	PG	PNG	598
	Paraguay	PY	PRY	600
۰	Peru	PE	PER	604
	Philippinen	PH	PHL	608
200 (20	Pitcairninseln	PN	PCN	612



OIDs Germany

- 1.2.276 = ISO Germany
- But! 2.16.840.1.113883.2.6 = HL7 Germany



2.16.840 = USA 2.16.840.1 = US Organization 2.16.840.1.113883 = HL7 USA



HL7 Austria

• OID = 2.16.840.1.113883.2.16

Superior references

- <u>2.16.840.1.113883</u> Health Level Seven, Inc. (HL7)
- <u>2.16.840.1</u> US company arc
- <u>2.16.840</u> USA
- <u>2.16</u> Joint assignments by country
- <u>2</u> ISO/ITU-T jointly assigned OIDs
- Top of OID tree

Subsidiary references (single level)

- 2.16.840.1.113883.2.3 HL7 Australia
- <u>2.16.840.1.113883.2.4</u> HL7 Netherlands Affiliate
- <u>2.16.840.1.113883.2.8</u> HL7 France Affiliate
- <u>2.16.840.1.113883.2.10</u> HL7 ARGENTINA

Organisations can assign OIDs based on their own OID - ELGA Austria (<u>El</u>ektronische <u>G</u>esundheits<u>a</u>kte)

- eHealth-Austria: 1.2.40.0.34
- ELGA CDA Implementierungsleitfaden: 1.2.40.0.34.7.1.1
- ELGA CDA Implementierungsleitfäden Entlassungsbrief (Ärztlich): 1.2.40.0.34.7.2.1



OIDs and Coding Systems

- OID = Maschine-readable and unique
- Each Coding System used in healthcare has an OID
- ICD-10 = 2.16.840.1.113883.6.3
- SNOMED-CT = 2.16.840.1.113883.6.96
- LOINC = 2.16.840.1.113883.6.1



Use of LOINC in EHRs (HL7-CDA)

Domäne	OID	Beispiel Identifikation	Beispiel Syntax HL7 V3
SNOMED-CT	2.16.840.1.113883.6.96	Asthma	<code <br="" code="195967001">codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED CT" displayName="Asthma" /></code>
LOINC	2.16.840.1.113883.6.1	History of present Illness	<code <br="" code="10164-2">codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="Anamnese" /></code>
Laborauftrag im Krankenhaus X	2.16.840.1.113883.2.16.1. 99.3	A-123456	<id <br="" extension=" A-123456">root="2.16.840.1.113883.2.16.1.99.3" /></id>



Use of LOINC in EHRs (HL7-CDA)

<?xml version="1.0" encoding="UTF-8"?>
<?xml-stylesheet type="text/xsl" href="VHITG-CDA-V3.xsl"?>
<?linicalDocument xmlns="urn:hl7-org:v3" xmlns:sciphox="urn::sciphox-org/sciphox"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
</typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
<id extension="60467,36049" root="1.2.276.0.58"/>
</code code="11488-4" codeSystem="2.16.840.1.113883.6.1" displayName="Consultation note"/>
</tibe>

<patientRole>



LOINC Code 11488-4 in codeSystem 2.16.840.1.113883.6.1

| LOINC Number | 11488-4 |
|----------------------|-------------------|
| Component | Consultation note |
| Property | Find |
| Time Aspect | Pt |
| System | {Setting} |
| Scale Type | Doc |
| Method Type | {Provider} |
| Class | DOC.CLINRPT |
| Source | СЈМ |
| Date Last
Changed | 20110829 |



In the same CDA ...

<!-- Laborwerte auf CDA Level 2 -->

<section>

<code code="18723-7" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"/>

<title>24.09.2006: Laborwerte</title>

<text>

<paragraph>Wir berichten kurz zusammenfassend über die Laborergebnisse des obigen Patienten.

| LOINC Number | 18723-7 | |
|--------------|--------------------|--|
| Component | Hematology studies | |
| Property | Cmplx | |
| Time Aspect | - | |
| System | ^Patient | |
| Scale Type | Set | |
| Class | ATTACH.LAB | |

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<code code="24317-2" codeSystem="2.16.840.1.113883.6.1"/> <statusCode code="completed"/> <effectiveTime value="200609241025"/> <component> <observation classCode="OBS" moodCode="EVN"> <code code="789-8" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC" displayName="ERY Erythrozyten"> <originalText> <reference value="#LAB20060924001"/> </originalText> I OINC </code> 789-8 Number <statusCode code="completed"/> <effectiveTime> Erythrocytes Component <center value="200609241025"/> </effectiveTime> Property NCnc <value xsi:type="PQ" value="4.37" unit="10*12/1"/> Time Aspect Pt System Bld Hey! A UCUM Scale Type On Unit! Method Type Automated count HEM/BC Class

In the same CDA ...

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Does CDISC use Object Identifiers? (OIDs)

- The CDISC Organization does not have an OID
- So CDISC coding systems (like CT) do not have an OID either
- So CDISC-CT Code is only valid ... within CDISC
 - And can e.g. not be stored in an EHR ...
- Why?



Use of LOINC in SDTM and SEND

• From the SDTM-IG 3.1.3:

| Ι | BLOINC | LOINC Code | Char | * | Synonym | 1. Dictionary-derived LOINC Code for LBTEST. | Perm |
|---|--------|------------|------|---|-----------|---|------|
| | | | | | Qualifier | 2. The sponsor is expected to provide the dictionary name and | |
| | | | | | | version used to map the terms utilizing the define.xml external | |
| | | | | | | codelist attributes | |

| - 1 | | | | 1 | | | |
|-----|---------|------------|------|---|-----------|---|------|
| | MBLOINC | LOINC Code | Char | * | Synonym | 1. Dictionary-derived LOINC Code for MBTEST. | Perm |
| | | | | | Qualifier | 2. The sponsor is expected to provide the dictionary name and | |
| | | | | | | version used to map the terms utilizing the define.xml external | |
| | | | | | | codelist attributes | |

• Dictionary-derived (!!!)

Permissible



Use of LOINC in SDTM and SEND

- --LOINC should not be used in:
 - EG (ECG Test Results)
 - IE (Inclusion/Exclusion Exceptions)
 - PE (Physical Examination)
 - QS (Questionnaires)
 - SC (Subject Characteristics)
 - DA (Drug Accountability)



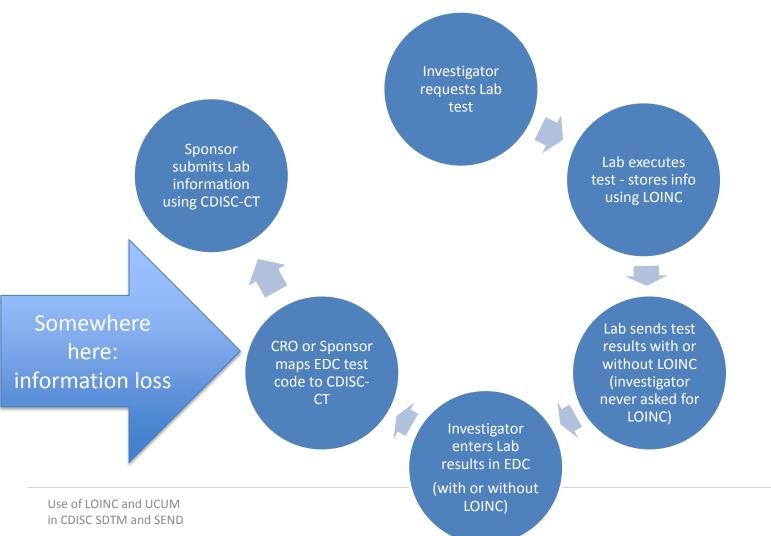
--LOINC is permissible

- Description says:
 "Dictionary-derived LOINC Code for LBTEST"
 - Meaning: "from the value of LBTEST", look for a LOINC code in the dictionary"
 - This is however impossible, as there is a 1:n relationship
 - So sponsors do not use LBLOINC
- However, the LOINC code is in the LIS, HIS or EHR!

LIS = Laboratory Information System - HIS = hospital information system



LBLOINC in SDTM - possible process





CDISC decided to develop its own CT for Laboratory tests

• LBTESTCD

| Lab Test or Examination
Short Name | Char | (LBTESTCD) |
|---------------------------------------|------|------------|
| | | |

| | 10 |
|-------|---|
| Topic | Short name of the measurement, test, or examination described in |
| | LBTEST. It can be used as a column name when converting a dataset from |
| | a vertical to a horizontal format. The value in LBTESTCD cannot be |
| | longer than 8 characters, nor can it start with a number (e.g."1TEST"). |
| | LBTESTCD cannot contain characters other than letters, numbers, or |
| | underscores. Examples: ALT, LDH. |
| | |



CDISC-CT for Lab tests

- Latest version: 2013-07-08
 - 975 test codes
- LOINC
 - > 70000 test codes
- CDISC-CT cannot be mapped well to LOINC
 - We tried ...
 - Granularity is completely different



CDISC-CT versus LOINC for Lab tests An example

| | lb.xpt | | | | | | | | | |
|-----|---------|--------|-------------|-------|----------|----------------------|----------------|--------------|----------|----------|
| Row | STUDYID | DOMAIN | USUBJID | LBSEQ | LBTESTCD | LBTEST | LBCAT | LBSCAT | LBORRES | LBORRESU |
| 1 | ABC | LB | ABC-001-001 | 1 | ALB | Albumin | CHEMISTRY | | 30 | g/L |
| 2 | ABC | LB | ABC-001-001 | 2 | ALP | Alkaline Phosphatase | CHEMISTRY | | 398 | IU/L |
| 3 | ABC | LB | ABC-001-001 | 3 | ALP | Alkaline Phosphatase | CHEMISTRY | | 350 | IU/L |
| 4 | ABC | LB | ABC-001-001 | 4 | ALP | Alkaline Phosphatase | CHEMISTRY | | | |
| 5 | ABC | LB | ABC-001-001 | 5 | WBC | Leukocytes | HEMATOLO
GY | | 5.9 | 10^9/L |
| б | ABC | LB | ABC-001-001 | 6 | LYMLE | Lymphocytes | HEMATOLO
GY | DIFFERENTIAL | 6.7 | % |
| 7 | ABC | LB | ABC-001-001 | 7 | NEUT | Neutrophils | HEMATOLO
GY | DIFFERENTIAL | 5.1 | 10^9/L |
| 8 | ABC | LB | ABC-001-001 | 8 | PH | pH | URINALYSIS | | 7.5 | |
| 9 | ABC | LB | ABC-001-001 | 9 | ALB | Albumin | CHEMISTRY | | | |
| 10 | ABC | LB | ABC-001-001 | 10 | CHOL | Cholesterol | CHEMISTRY | | 229 | mg/dL |
| 11 | ABC | LB | ABC-001-001 | 11 | WBC | Leukocytes | HEMATOLO
GY | | 5.9 | 10^9/L |
| 12 | ABC | LB | ABC-001-001 | 12 | PROT | Protein | URINALYSIS | | MODERATE | |

Source: CDISC SDTM-IG 3.1.3



CDISC-CT versus LOINC for Lab tests

| CDISC CT Code
(LBTESTCD) | CDISC CT Name
(LBTEST) | Nr. of LOINC Codes |
|-----------------------------|---------------------------|--------------------|
| ALB | Albumin | 51 (++) |
| ALP | Alkaline Phosphatase | 12 (++) |
| WBC | Leukocytes | 81 (++) |
| LYMLE | Lymphocytes | 24 (++) |
| NEUT | Neutrophils | 33 (++) |
| РН | рН | 3 |
| CHOL | Cholesterol | 21 (++) |
| PROT | Protein | 36 (++) |

++ : Exclusing similar tests, e.g. excluding "Cholesterol crystals".

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CDISC-CT versus LOINC Example GLUC (Glucose)

- LBTESTCD = GLUC
- 68 LOINC Codes

| | 5,6493 | 6300-8 | Glucose | MCnc | Pt | Amnio fld | Qn | |
|--|--------|---------|---------|------|-----|--------------|----|----------------------|
| | 5,6493 | 2339-0 | Glucose | MCnc | Pt | Bld | Qn | |
| | 5,6493 | 2341-6 | Glucose | MCnc | Pt | Bld | Qn | Test strip manual |
| | 5,6493 | 2340-8 | Glucose | MCnc | Pt | Bld | Qn | Test strip.automated |
| | 5,6493 | 15074-8 | Glucose | SCnc | Pt | Bld | Qn | |
| | 5,6493 | 72516-8 | Glucose | SCnc | Pt | Bld | Qn | Test strip.automated |
| | 5,6493 | 41651-1 | Glucose | MCnc | Pt | BIdA | Qn | |
| | 5,6493 | 39481-7 | Glucose | SCnc | Pt | BIdA | Qn | |
| | 5,6493 | 32016-8 | Glucose | MCnc | Pt | BIdC | Qn | |
| | 5,6493 | 41653-7 | Glucose | MCnc | Pt | BIdC | Qn | Glucometer |
| | 5,6493 | 51596-5 | Glucose | SCnc | Pt | BIdC | Qn | |
| | 5,6493 | 14743-9 | Glucose | SCnc | Pt | BIdC | Qn | Glucometer |
| | 5,6493 | 47995-6 | Glucose | SCnc | Pt | BldCo | Qn | |
| | 5,6493 | 41652-9 | Glucose | MCnc | Pt | BldV | Qn | |
| | 5,6493 | 39480-9 | Glucose | SCnc | Pt | BldV | Qn | |
| | 5,6493 | 2344-0 | Glucose | MCnc | Pt | Body fld | Qn | |
| | 5,6493 | 14745-4 | Glucose | SCnc | Pt | Body fld | Qn | |
| | 5,6493 | 40366-7 | Glucose | SRat | 24H | Body fld | Qn | |
| | 5,6493 | 2342-4 | Glucose | MCnc | Pt | CSF | Qn | |
| | 5,6493 | 14744-7 | Glucose | SCnc | Pt | CSF | Qn | |
| | 5,6493 | 2343-2 | Glucose | MCnc | Pt | Dial fld | Qn | |
| | 5,6493 | 45297-9 | Glucose | SCnc | 24H | Dial fld | Qn | |
| | 5,6493 | 15075-5 | Glucose | SCnc | Pt | Dial fld | Qn | |
| | 5,6493 | 12629-2 | Glucose | MCnc | 24H | Dial fld prt | Qn | |
| | 5,6493 | 12628-4 | Glucose | MCnc | Pt | Dial fld prt | Qn | |

Use of LOINC and UCUM in CDISC SDTM and SEND



OK, but we have LBCAT, LBMETHOD ...

 LBCAT, LBSCAT, LBMETHOD, LBSPEC do not have controlled terminology!

| | LBTESTCD | LBCAT | LBSPEC | LBMETHOD | LBLOINC |
|-----------|----------|-----------|----------------|------------|---------|
| Sponsor 1 | GLUC | CHEMISTRY | BLD | QUANT | 2339-0 |
| Sponsor 2 | GLUC | CHEM | WHOLE
BLOOD | ENZYMATIC | 15074-8 |
| Sponsor 3 | GLUC | CHEMI | BLOOD | HEXOKINASE | 2339-0 |

Where these the same test?



Use of LOINC by the FDA

- Even if there is consistency in LBCAT, LBMETHOD, ... within a study or even a submission, how can FDA reviewers compare different submissions?
- If LBLOINC was made "expected" instead of "permissible" they could.



Arguments heard against using LOINC in FDA submissions

- Preclinical is not well covered by LOINC
 - => make separate LBTESTCD-CT for SEND
- Not each combination of 5 variables has a test code
 - => see following slides
- LOINC does not always make a distinction between Serum and Plasma
 - => Does CDISC?



Once upon a time ... CDISC tried ...

- 2005 Document by LOINC: "Common LOINC codes used in clinical research"
 - <u>http://loinc.org/discussion-</u> <u>documents/CDISCcommonLOINCtests20050214.pdf</u>
- Never updated afterwoods
- No mapping with CDISC-CT



Common LOINC codes used in clinical research

LOINC[®] Codes for Common CDISC tests

The following table is a subset of the LOINC[®] database terms that have been identified by 3 central laboratories as the most frequently used terms in clinical trials. This is a small representation of the LOINC[®] codes and it is recommended that you use the RELMA[®] mapping tool to search the database.

Please visit the LOINC[®] web site (<u>www.loinc.org</u>) for more information about LOINC[®] and to download the complete set of LOINC[®] codes and the RELMA[®] mapping tool.

Explanation of fields:

Unique LOINC[®] code is a numeric code with a mod 10-check digit. The fully specified LOINC[®] name consists of 6 fields:

- 1. Component (analyte) being measured
- 2. Property observe red (e.g. mass concentration, volume, number fraction)
- 3. Timing of the measurement (point in time or collected over 24 hours)
- System (specimen)
- 5. Scale of measurement (quantitative, ordinal, nominal)
- 6. Method (where applicable)

REMARK: The CDISC-CT Code is not mentioned

The LOINC[®] short name is an abbreviation of the fully specified LOINC[®] name consisting of less than 30 characters. The short names are unique, but are subject to change as better algorithms for generating them are developed. It is recommended that the short name be included along with the LOINC[®] code as the 2^{nd} part of the HL7 CE data type in H17 messages.

| LOINC [®] | Fully Specified LOINC [®] Name | | | | | LOINC [®] short name |
|--------------------|---|----------|----------------|--------|--------------|-------------------------------|
| code | Component | Property | Time
Aspect | System | Scale Method | |
| ALLERG | Y | | | | | |
| 25638-8 | EOSINOPHIL CATIONIC PROTEIN | MCNC | PT | SER | QN | ECP-mCnc |
| CELLMA | RKERS | | | | | |
| 27011-6 | CELLS.CD14 | NCNC | PT | BLD | QN | CD14 Cells # Bld |
| 8111-7 | CELLS.CD14/100 CELLS | NFR. | PT | BLD | QN | CD14 Cells % Bld |
| 20402-4 | CELLS.CD16+CD56+ | NCNC | PT | BLD | QN | CD16+CD56+ Cells # Bld |
| 18267-5 | CELLS.CD16+CD56+/100 CELLS | NFR | PT | BLD | QN | CD16+CD56+ Cells % Bld |
| 8116-6 | CELLS.CD19 | NCNC | PT | BLD | QN | CD19 Cells # Bld |
| 8117-4 | CELLS.CD19/100 CELLS | NFR | PT | BLD | QN | CD19 Cells % Bld |
| 8122-4 | CELLS.CD3 | NCNC | PT | BLD | QN | CD3 Cells # Bld |
| 8124-0 | CELLS.CD3/100 CELLS | NFR | PT | BLD | ON | CD3 Cells % Bld |

Common LOINC codes used in clinical research

| 14879-1PHOSPHATESCNCPTSER/PLASONPhosphate 2H-014881-7PHOSPHATESKAT24HURONPhosphate 2H-012979-7PHOSPHATESCNC24HURONPhosphate 2H-02775.5PHOSPHATESCNC24HURONPhosphate 2H-02775.6PHOSPHATEMCNCPTDIAFONPhosphate 2H-02777.1PHOSPHATEMCNCPTDIAFONPhosphate 8H-02778.9PHOSPHATEMCNCPTURONPhosphate 8H-02779.7PHOSPHATEMCNCPTURONPhosphate 4H-02174.6-7PTASSIUMSCNCPTURONPhosphate 4H-02823.3POTASSIUMSCNCPTSER/PLASONPhosphate 4H-02824.4PTASSIUMSCNCPTSER/PLASONPhosphate 4H-0283.9PTASSIUMSCNCPTSER/PLASONPhosphate 4H-0284.3PROGESTERONESCNCPTSER/PLASONPhosphate 4H-0284.4PROGESTERONESCNCPTSER/PLASONPhosphate 4H-0284.5PROTENMCNCPTSER/PLASONPhosphate 4H-0284.4PROTENMCNCPTSER/PLASONPhosphate 4H-0284.5PROTENMCNCPTSER/PLASONPhosphate 4H-0284.5PROTENMCNCPTSER/PLASONPhotsenH | LOINC [®] | I | LOINC [®] short name |
|---|-----------------------|--------------|-------------------------------|
| 2756-5 PH SCNC PT UR QN PHOsPhaTE 14379-1 PHOSPHATE SCNC PT UR QN Phosphate Ur-Gc. 14879-1 PHOSPHATE SCNC PT UR QN Phosphate Ur-Gc. 14879-1 PHOSPHATE SCNC PT SERPLAS QN Phosphate 2H U 1487-7 PHOSPHATE MCNC 2H UR QN Phosphate 2H U 21973-9 PHOSPHATE MCNC 2H UR QN Phosphate 2H U 2977-7 PHOSPHATE MCNC PT DLAF QN Phosphate SerPLAS 2777-7 PHOSPHATE MCNC PT UR QN Phosphate SerPLAS 2233-3 POTASSIUM SCNC PT UR QN Phosphate SerPLAS 223-4 POTASSIUM SCNC PT UR QN Phosphate SerPLAS 233-3 POTASSIUM SCNC PT UR QN Phosphate SerPLAS 243-5 POTASSIUM SCNC PT UR QN Phosphate SerPLAS 243-6 POTASSIUM SCNC PT UR QN Phosphate SerPLAS 253-7 POTASSIUM | code Component | Scale Method | |
| 2756-5PHCNCPTURQNPH Ury-Che1353-2PHOSPHATESCNCPTURQNPH Ury-Che14879-1PHOSPHATESCNCPTSER/PLASQNPhotphate Ury-Che14879-1PHOSPHATESCNCPTSER/PLASQNPhotphate 2H U14879-1PHOSPHATESCNC2HURQNPhotphate 2H U14879-1PHOSPHATESCNC2HURQNPhotphate 2H U14879-1PHOSPHATESCNC2HURQNPhotphate 2H U14979-1PHOSPHATESCNC2HURQNPhotphate 2H U1497-5PHOSPHATEMCNCPTDIAFQNPhotphate Strift2777-1PHOSPHATEMCNCPTURQNPhotphate Strift2778-7PHOSPHATEMCNCPTURQNPhotphate Strift2717-7PHOSPHATEMCNCPTSER/PLASQNPhotphate Strift2813-3POTASSIUMSCNCPTURQNPhotpstate Strift2823-4POTASSIUMSCNCPTURQNPhotpstate Strift-GC2839-9PROGESTERONESCNCPTSER/PLASQNProgets Strift-AC2841-3PROTEINMCNCPTSER/PLASQNProgets Strift-AC2852-1POTASSIUMSCNCPTSER/PLASQNProgets Strift-AC2853-9PROGESTERONEMCNCPTSER/PLASQN< | 2753-2 PH | ON | pH SerPl-sCnc |
| 14879-1PHOSPHATESCNCPTSER/PLASQNPhosphate 2H:U14881-7PHOSPHATESKAT24HURQNPhosphate 24H U21458-5PHOSPHATESCNC24HURQNPhosphate 24H U25973-9PHOSPHATESCNC24HURQNPhosphate 24H U2775.5PHOSPHATEMCNCPTDIAFQNPhosphate 24H U2775.4PHOSPHATEMCNCPTDIAFQNPhosphate 24H U2778.9PHOSPHATEMCNCPTSER/PLASQNPhosphate 24H U2778.9PHOSPHATEMCNCPTURQNPhosphate 24H U2778.9PHOSPHATEMCNCPTURQNPhosphate 24H U2718.7POTASSIUMSCNCPTURQNPhosphate 24H U21476.7POTASSIUMSCNCPTURQNPhosphate 24H U2813.3POTASSIUMSCNCPTSER/PLASQNPhosphate 24H U2814.4PROGESTERONESCNCPTSER/PLASQNPhosphate 24H U2842.3PROGESTERONESCNCPTSER/PLASQNPhosphate 24H U2842.4PROGESTERONEMCNCPTSER/PLASQNPhosphate 24H U2842.5PROTEINMCNCPTSER/PLASQNPhosphate 24H U2843.4PROTEINMCNCPTSER/PLASQNPhosphate 24H U2845.2PROTEINMCNCPTSER/PLA | 2756-5 PH | QN | pH Ur-sCne |
| 14679-1PHOSPHATESCNCPTSER/PLASQNPhosphate 2H:U1481-7PHOSPHATESAT24HURQNPhosphate 2H:U21435-5PHOSPHATESCNC24HURQNPhosphate 2H:U25973-9PHOSPHATESCNC24HURQNPhosphate 2H:U2775.5PHOSPHATEMCNCPTDIAFQNPhosphate 2H:U2775.4PHOSPHATEMCNCPTSER/PLASQNPhosphate 2H:U2775.7PHOSPHATEMCNCPTSER/PLASQNPhosphate 2H:U2778.9PHOSPHATEMCNCPTSER/PLASQNPhosphate 2H:U2778.9PHOSPHATEMCNCPTSER/PLASQNPhosphate 2H:U2778.9PHOSPHATEMCNCPTSER/PLASQNPhosphate 2H:U278.9POTASSIUMSCNCPTURQNPhosphate 2H:U281.3POTASSIUMSCNCPTSER/PLASQNPotassium U-sc282.9POTASSIUMSCNCPTSER/PLASQNPotassium U-sc284.4PROGESTERONESCNCPTSER/PLASQNPotassium U-sc284.5PROTEINMCNCPTSER/PLASQNPotassium U-sc284.2.5PROTEINMCNCPTSER/PLASQNPotassium U-sc284.2.5PROTEINMCNCPTSER/PLASQNPotassium U-sc284.2.5PROTEINMCNCPTSER/PLAS< | 13539-2 PHOSPHATE | QN | Phosphate Ur-sCnc |
| 14881-7PHOSPHATESRAT24HURQNPhosphate 24H U21435-5PHOSPHATEMCNC24HURQNPhosphate 24H U25973-9PHOSPHATEMCNCPTDJAFQNPhosphate Diafe2775-5PHOSPHATEMCNCPTDJAFQNPhosphate Diafe2777-1PHOSPHATEMCNCPTDJAFQNPhosphate SerPl-42778-9PHOSPHATEMCNCPTURQNPhosphate 24H U2779-7PHOSPHATEMCNCPTURQNPotosinus 24H U21375-7PHOSPHATEMRAT24H URQNPotosinus 24H U21376-7POTASSIUMSCNCPTSERPLASQNPotosinus 24H U2832-2POTASSIUMSCNCPTSERPLASQNPotosinus 24H U2838-2POTASSIUMSCNCPTSERPLASQNPotosinus 24H U2839-9PROGESTERONESCNCPTSERPLASQNPotosinus 24H U2842-3PROGESTERONEMCNCPTSERPLASQNProjest SerPl-aC2842-3PROTEINMCNCPTSERPLASQNPotosinus 24H U-nC2842-3PROTEINMCNCPTSERPLASQNPotosinus 24H U-nC2842-3PROTEINMCNCPTSERPLASQNPotosinus 24H U-nC2842-3PROTEINMCNCPTSERPLASQNPotosinus 24H U-nC2842-3PROTEINMCNCPTSERPLAS | 14879-1 PHOSPHATE | QN I | Phosphate SerPl-sCnc |
| 21458-5PHOSPHATEMCNC24HURQNPhosphate 24H U25973-9PHOSPHATEMCNCPTDIAFQNPhosphate 24H U2775-5PHOSPHATEMCNCPTDIAFQNPhosphate BarPl-42777-1PHOSPHATEMCNCPTSER/PLASQNPhosphate BarPl-42778-7PHOSPHATEMCNCPTURQNPhosphate U-IN2779-7PHOSPHATEMCNCPTURQNPhosphate U-IN21476-7POTASSIUMSCNC24HURQNPhosphate U-IN2823-3POTASSIUMSCNCPTSER/PLASQNPhospinate U-IN2823-4POTASSIUMSCNCPTURQNPhospinate U-IN2829-0POTASSIUMSCNCPTSER/PLASQNPhospinate SePI-GC2839-8PROGESTERONEMCNCPTSER/PLASQNPhospinate SePI-GC2842-3PROLACTINMCNCPTSER/PLASQNPhospinate SePI-GC2842-5PROTEINMCNCPTSER/PLASQNPhot SePI-GC2854-6PROTEINMCNCPTSER/PLASQNPhot SePI-GC2854-7PROTEINMCNCPTSER/PLASQNPhot SePI-GC2854-8PROTEINMCNCPTSER/PLASQNPhot SePI-GC2854-3PROTEINMCNCPTVRQNPhot SePI-GC2854-4PROTEINMCNCPTVRQN <t< td=""><td>14881-7 PHOSPHATE</td><td>QN I</td><td>Phosphate 24H Ur-sRate</td></t<> | 14881-7 PHOSPHATE | QN I | Phosphate 24H Ur-sRate |
| 25973-9PHOSPHATESCNC24HURQNPhosphate 24H U2775-5PHOSPHATEMCNCPTDIAFQNPhosphate Diaf2777-1PHOSPHATEMCNCPTURQNPhosphate SerPl-42778-7PHOSPHATEMCNCPTURQNPhosphate 24H U2176-7POTASSUMSCNC24HURQNPotasium 24H U2823-3POTASSUMSCNCPTURQNPotasium 24H U2828-2POTASSUMSCNCPTURQNPotasium 24H U2828-2POTASSUMSCNCPTURQNPotasium 24H U14890-8PROGESTERONESCNCPTSENPLASQNPotasium 24H U2839-9PROGESTERONESCNCPTSENPLASQNProget SePL-SC2843-3PROLACTNMCNCPTSENPLASQNProget SePL-SC2847-4PROTEINMCNCPTSENPLASQNProget SePL-SC2857-1PROTEINMCNCPTSENPLASQNProf SePL-MC2857-2PROTEINMCNCPTSENPLASQNProf SePL-MC2859-3PROTEINMCNCPTSENPLASQNProf SePL-MC2859-4PROTEINMCNCPTSENPLASQNProf SePL-MC2859-5PROTEINMCNCPTSENPLASQNProf SePL-MC2859-6PROTEINMCNCPTURQNProf SePL-MC2 | 21458-5 PHOSPHATE | QN | Phosphate 24H Ur-mCnc |
| 2777-1PHOSPHATEMCNCPTSER/PLASQNPhosphate BarPla2778-9PHOSPHATEMCNCPTURQNPhosphate U-ac2779-7PHOSPHATEMRAT24HURQNPhosphate U-ac21476-7POTASSIUMSCNC24HURQNPotassium SarPla2823-3POTASSIUMSCNCPTSER/PLASQNPotassium SarPla2828-2POTASSIUMSCNCPTURQNPotassium SarPla2829-0POTASSIUMSCNCPTURQNPotassium SarPla2839-3PROGESTERONESCNCPTSER/PLASQNPotget SarPlaC2842-3PROLACTNMCNCPTSER/PLASQNPoget SarPlaC2857-1PROSTATE SPECIFIC AGMCNCPTSER/PLASQNProfest SarPl-MCR2852-2PROTEINMCNCPTSER/PLASQNProf SarPl-MCR2885-2PROTEINMCNCPTSER/PLASQNProf SarPl-MCR2885-2PROTEINMCNCPTSER/PLASQNProf SarPl-MCR2885-2PROTEINMCNCPTSER/PLASQNProf SarPl-MCR2889-4PROTEINMCNCPTSER/PLASQNProf SarPl-MCR2889-5PROTEINMCNCPTSER/PLASQNProf SarPl-MCR2889-6PROTEIN/CREATININESCNCPTURQNProf SarPl-MCR2889-7PYRIDINOLINE/CREATININESCNC< | 25973-9 PHOSPHATE | QN I | Phosphate 24H Ur-sCnc |
| 2777-1PHOSPHATEMCNCPTSER/PLASQNPhosphate BarPla2778-9PHOSPHATEMCNCPTURQNPhosphate U-ac2779-7PHOSPHATEMRAT24HURQNPhosphate U-ac21476-7POTASSIUMSCNC24HURQNPotassium SarPla2823-3POTASSIUMSCNCPTSER/PLASQNPotassium SarPla2828-2POTASSIUMSCNCPTURQNPotassium SarPla2829-0POTASSIUMSCNCPTURQNPotassium 24H14890-8PROGESTERONESCNCPTURQNPotassium 24H2842-3PROLACTNSCNCPTURQNPotassium 24H2842-3PROLACTNMCNCPTSER/PLASQNPotget SerPl-aC2857-1PROSTATE SPECIFIC AGMCNCPTSER/PLASQNProfest SerPl-aC2885-2PROTEINMCNCPTSER/PLASQNProf SerPl-aCa2885-2PROTEINMCNCPTSER/PLASQNProf SerPl-aCa2889-4PROTEINMCNCPTSER/PLASQNProf SerPl-aCa2889-4PROTEINMCNCPTSER/PLASQNProf SerPl-aCa2889-5PROTEIN/CREATININESCNCPTURQNProf SerPl-aCa289-6PROTEIN/CREATININESCNCPTURQNProf 24H UGA2967-70PYRIDNOLINE/CREATININESCNCPT | 2775-5 PHOSPHATE | QN | Phosphate Diaf-mCnc |
| 2778-9PHOSPHATEMCNCPTURQNPhosphate U-mCR2779-7PHOSPHATEMRAT24HURQNPhosphate 24H UL21476-7POTASSIUMSCNC24HURQNPotassium 24H UL2823-3POTASSUMSCNCPTSER/PLASQNPotassium SerPL-2828-2POTASSUMSCNCPTURQNPotassium 24H UL14890-8PROGESTERONESCNCPTSER/PLASQNPotassium 24H UL2843-3PROACESTERONESCNCPTSER/PLASQNProget SerPL-GC2843-3PROACTINMCNCPTSER/PLASQNProget SerPL-GC2843-3PROACTINMCNCPTSER/PLASQNProget SerPL-GC2844-3PROTENMCNCPTSER/PLASQNProget SerPL-GC2845-2PROTENMCNCPTSER/PLASQNProf 24H Ur-mCn2885-2PROTENMCNCPTSER/PLASQNProf 24H Ur-mCn2885-4PROTENMCRTOPTURQNProf 24H Ur-mCn289-4PROTENMCRTOPTURQNProf 24H Ur-mCn289-5PROTENNMCRTOPTURQNProf 24H Ur-mCn2512-8SODIUMSCNCPTSER/PLASQNPT04 Ur-mCn2512-8SODIUMSCNCPTSER/PLASQNSodium 24H Ur-SC2953-3SODIUMSCNCPTSER/PLASQN< | 2777-1 PHOSPHATE | QN | Phosphate SerPl-mCnc |
| 2779-7PHOSPHATEMRAT24HURQNPhosphate 24H U21476-7POTASSIUMSCNC24HURQNPotassium 24H U2823-3POTASSIUMSCNCPTSER/PLASQNPotassium 24H U2828-2POTASSIUMSCNCPTURQNPotassium U-sGC2828-3POTASSIUMSRAT24HURQNPotassium U-sGC2829-0POTASSIUMSRAT24HURQNPotassium U-sGC2839-9PROGESTERONESCNCPTSER/PLASQNProget SePI-SC2842-3PROLACTINMCNCPTSER/PLASQNProject SePI-SC2857-1PROSTATE SPECIFIC AGMCNCPTSER/PLASQNProf 24H U-mCR2857-2PROTEINMCNCPTSER/PLASQNProf 24H U-mCR2889-4PROTEINMCNCPTSER/PLASQNProf 24H U-mCR2889-4PROTEINMCRTOPTURQNProf 24H U-mCR2890-2PROTEIN/CREATININESCNCPTURQNProf 24H U-mCR25172-8SODIUMSCNCPTSERQNSHBG Ser-Crec21123-1SODIUMSCNCPTSERSodium 24H U-SSodium 24H U-S2951-2SODIUMSCNCPTURQNSodium 24H U-S2951-3SODIUMSCNCPTSERSodium 24H U-SSodium 24H U-S2953-3SODIUMSCNCPTSER/PLA | 2778-9 PHOSPHATE | QN I | Phosphate Ur-mCnc |
| 21476-7POTASSIUMSCNC24HURQNPotassium 24H U2823-3POTASSIUMSCNCPTSER/PLASQNPotassium SerPl-a2828-2POTASSIUMSCNCPTURQNPotassium U-sCr2829-0POTASSIUMSRAT24HURQNPotassium U-sCr14890-8PROGESTERONESCNCPTSER/PLASQNProgest SerPl-SCR2839-9PROGESTERONEMCNCPTSER/PLASQNProgest SerPl-SCR2842-3PROLACTINMCNCPTSER/PLASQNProject SerPl-SCR2857-1PROTEINMCNCPTSER/PLASQNProject 24H Ur-mCR2852-2PROTEINMCNCPTSER/PLASQNProject 44H Ur-mCR2852-2PROTEINMCNCPTSER/PLASQNProject 44H Ur-mCR289-4PROTEINMRAT24HURQNProject 44H Ur-mCR289-2PROTEIN/CREATININEMCNCPTSER/PLASQNProject 44H Ur-mCR289-3PYRIDINOLINE/CREATININESCNC24HURQNProject 44H Ur-sCR2197-6PYRIDINOLINE/CREATININESCNCPTSERQNSodium Ur-sCR2192-8PYRIDINOLINE/CREATININESCNCPTSER/PLASQNSodium Sel-sCR2192-12SODIUMSCNCPTSER/PLASQNSodium Ur-sCR2951-2SODIUMSCNCPTSER/PLASQNSodium Ur-sCR< | 2779-7 PHOSPHATE | QN | Phosphate 24H Ur-mRate |
| 2828-2POTASSIUMSCNCPTURQNPotassium Us-SCN2829-0POTASSIUMSRAT24HURQNPotassium 24H UL14890-8PROGESTERONESCNCPTSER/PLASQNProget SerPL-SCR2839-9PROGESTERONEMCNCPTSER/PLASQNProget SerPL-SCR2842-3PROLACTINMCNCPTSER/PLASQNProlectin SerPL-MC2842-5PROTEINMCNCPTSER/PLASQNProlectin SerPL-MC2855-2PROTEINMCNC24HURQNProt 24H Ur-mCa2889-4PROTEINMCNCPTSER/PLASQNProt 24H Ur-mCa2890-2PROTEINMCNCPTURQNProt 24H Ur-mCa25129-8PYRIDINOLINE/CREATININESCNC24HURQNProt 24H Ur-sCa21525-1SODIUMSCNCPTURQNPYD 24H Ur-sCa21525-1SODIUMSCNCPTURQNPYD/creat Ur-sRt25129-8PYRIDINOLINE/CREATININESCNCPTSERQNSodium 24H Ur-21525-1SODIUMSCNCPTSERQNSodium 24H Ur-SCA2951-2SODIUMSCNCPTSER/PLASQNSodium 24H Ur-SCA2951-3SODIUMSCNCPTVRQNSodium 24H Ur-SCA2951-3SODIUMSCNCPTVRQNSodium 24H Ur-SCA2951-3SODIUMSCNCPT | 21476-7 POTASSIUM | QN 1 | Potassium 24H Ur-sCnc |
| 2828-2POTASSIUMSCNCPTURQNPotassium Us-SCN2829-0POTASSIUMSRAT24HURQNPotassium 24H UL14890-8PROGESTERONESCNCPTSER/PLASQNProget SerPL-SCR2839-9PROGESTERONEMCNCPTSER/PLASQNProget SerPL-SCR2842-3PROLACTINMCNCPTSER/PLASQNProlectin SerPL-MC2842-5PROTEINMCNCPTSER/PLASQNProlectin SerPL-MC2855-2PROTEINMCNC24HURQNProt 24H Ur-mCa2889-4PROTEINMCNCPTSER/PLASQNProt 24H Ur-mCa2890-2PROTEINMCNCPTURQNProt 24H Ur-mCa25129-8PYRIDINOLINE/CREATININESCNC24HURQNProt 24H Ur-sCa21525-1SODIUMSCNCPTURQNPYD 24H Ur-sCa21525-1SODIUMSCNCPTURQNPYD/creat Ur-sRt25129-8PYRIDINOLINE/CREATININESCNCPTSERQNSodium 24H Ur-21525-1SODIUMSCNCPTSERQNSodium 24H Ur-SCA2951-2SODIUMSCNCPTSER/PLASQNSodium 24H Ur-SCA2951-3SODIUMSCNCPTVRQNSodium 24H Ur-SCA2951-3SODIUMSCNCPTVRQNSodium 24H Ur-SCA2951-3SODIUMSCNCPT | 2823-3 POTASSIUM | ON I | Potassium SerPl-sCnc |
| 2829-0POTASSIUMSRAT24HURQNPotassium 24H UL14890-8PROGESTERONESCNCPTSER/PLASQNProget SerPL-mC2839-9PROGESTERONEMCNCPTSER/PLASQNProget SerPL-mC2842-3PROLACTINMCNCPTSER/PLASQNProlactin SerPL-mC2842-5PROTEINMCNCPTSER/PLASQNProlactin SerPL-mC21482-5PROTEINMCNCPTSER/PLASQNProt SerPL-mCnc2885-2PROTEINMCNCPTSER/PLASQNProt SerPL-mCnc2889-4PROTEIN/CREATININEMCNCPTSER/PLASQNProt SerPL-mCnc289-4PROTEIN/CREATININEMCRTOPTURQNProt SerPL-mCnc289-5PROTIEN/CREATININESCNC24HURQNProt 24H Ur-sCn2517-6PYRIDINOLINE/CREATININESCNCPTSERQNSHBG Ser-sCnc2152-1SODIUMSCNCPTSER/PLASQNSHBG Ser-sCnc2951-2SODIUMSCNCPTSER/PLASQNSodium Ur-sCnc2951-2SODIUMSCNCPTURQNSodium Ur-sCnc2951-3SODIUMSCNCPTURQNSodium Ur-sCnc2951-4SODIUMSRAT24HURQNSodium Ur-sCnc2951-5SODIUMSRAT24HURQNSodium Ur-sCnc2951-6SODIUMSRAT24 | | ON I | Potassium Ur-sCnc |
| 14890-8PROGESTERONESCNCPTSER/PLASQNProgest SerPl-sCn2839-9PROGESTERONEMCNCPTSER/PLASQNProgest SerPl-sCn2842-3PROLACTINMCNCPTSER/PLASQNProgest SerPl-mCnc2857-1PROSTATE SPECIFIC AGMCNCPTSER/PLASQNProt 24H Un-mCn2858-2PROTEINMCNCPTSER/PLASQNProt 24H Un-mCn2859-4PROTEINMCNCPTSER/PLASQNProt 24H Un-mCn2890-2PROTEINMRAT24HURQNProt 24H Un-mCn2900-2PROTEIN/CREATININEMCRTOPTURQNProt/creat Un-mKn2907-0PYRDINOLINE/CREATININESCNC24HURQNPYD 24H Un-sCn2917-5SEX HORMONE BINDING GLOBULINSCNCPTSERQNSodium 24H Un-sCn2951-2SODIUMSCNCPTSER/PLASQNSodium 24H Un-sCn2951-2SODIUMSCNCPTSER/PLASQNSodium 24H Un-sCn2951-2SODIUMSCNCPTVIRQNSodium 24H Un-sCn2951-3SODIUMSCNCPTVIRQNSodium 24H Un-sCn2951-1SODIUM URATE CRYSTALSACNCPTCALCORDINFRARED2963-7SOMATOTROPINMCNCPTSER/PLASQNSodium 24H Un-sCn2963-7SOMATOTROPINMCNCPTSER/PLASQNSodium 24H Un-sCn< | | ON | Potassium 24H Ur-sRate |
| 2839-9PROGESTERONEMCNCPTSER/PLASQNProgest SerPl-mC2842-3PROLACTINMCNCPTSER/PLASQNProlactin SerPl-mC2857-1PROTEINMCNCPTSER/PLASQNPSA SerPl-mC2852PROTEINMCNC24HURQNProt 24H Ur-mCn2855-2PROTEINMCNCPTSER/PLASQNProt 5erPl-mC2890-2PROTEINMCNCPTSER/PLASQNProt 5erPl-mCnc2890-2PROTEIN/CREATININEMCRTOPTURQNProt 24H Ur-mR25977-0PYRIDINOLINE/CREATININESCNC24HURQNProt/creat Ur-mR25975-5SEX HORMONE BINDING GLOBULINSCNCPTVRQNSodium 24H Ur-sCn13967-5SEX HORMONE BINDING GLOBULINSCNCPTSER/PLASQNSodium 24H Ur-sCn2512-1SODIUMSCNCPTSER/PLASQNSodium 24H Ur-sCn2512-1SODIUMSCNCPTVIRQNSodium 24H Ur-sCn2512-2SODIUMSCNCPTVIRQNSodium 24H Ur-sCn2512-3SODIUMSCNCPTVIRQNSodium 24H Ur-sCn2512-4SODIUMSCNCPTVIRQNSodium 24H Ur-sCn2512-5SODIUMSCNCPTVIRQNSodium 24H Ur-sCn2512-6SODIUMSCNCPTVIRQNSodium 24H Ur-sCn2512-7SODIUM< | | QN | Progest SerPl-sCnc |
| 2442-3PROLACTINMCNCPTSER/PLASQNProlactin SerPl-m2857-1PROSTATE SPECIFIC AGMCNCPTSER/PLASQNPSA SerPl-mCnc21482-5PROTEINMCNC24HURQNProt 24H Un-mCn2855-2PROTEINMCNCPTSER/PLASQNProt 24H Un-mCn2885-2PROTEINMCNCPTSER/PLASQNProt 24H Un-mCn289-4PROTEIN/CREATININEMCRT24HURQNProt 24H Un-mCn289-7PYRIDINOLINEMCRTOPTURQNPYD 24H Un-sCn25977-0PYRIDINOLINE/CREATININESCNC24HURQNPYD 24H Un-sCn13967-5SEX MOMONE BINDING GLOBULINSCNCPTSERQNSHBG Sen-chc2551-1SODIUMSCNCPTSER/PLASQNSodium 24H Un-sCn2951-2SODIUMSCNCPTSER/PLASQNSodium 24H Un-sCn2951-3SODIUMSCNCPTVRQNSodium 24H Un-sCn2951-1SODIUMSCNCPTVRQNSodium 24H Un-sCn2951-2SODIUMSCNCPTVRQNSodium SerPl-sCn2951-3SODIUMSCNCPTVRQNSodium 24H Un-sCn2951-1SODIUMSCNCPTVRQNSodium 24H Un-sCn2951-2SODIUMSCNCPTVRQNSodium 24H Un-sCn2951-3SODIUMSCNCPT <td>2839-9 PROGESTER</td> <td></td> <td>Progest SerPl-mCnc</td> | 2839-9 PROGESTER | | Progest SerPl-mCnc |
| 2857-1PROSTATE SPECIFIC AGMCNCPTSER/PLASQNPSA SerPl-mCnc21482-5PROTEINMCNC24HURQNProt 24H Ur-mCnc285-2PROTEINMCNCPTSER/PLASQNProt 24H Ur-mCnc2889-4PROTEINMRAT24HURQNProt 24H Ur-mCnc2890-2PROTEIN/CREATININEMCRTOPTURQNProt/24H Ur-sCn25129-8PYRIDINOLINE/CREATININESCNC24HURQNPYD/creat Ur-sRn31967-5SEX HORMONE BINDING GLOBULINSCNCPTSERQNSHBG Ser-sCnc21525-1SODIUMSCNCPTSERQNSodium 24H Ur-sCn2951-2SODIUMSCNCPTURQNSodium 24H Ur-sCn2955-3SODIUMSCNCPTURQNSodium 24H Ur-sCn2956-1SODIUMSCNCPTURQNSodium 24H Ur-sCn2956-1SODIUM URATE CRYSTALSACNCPTCALCORDINFRARED
SPECTROSCOPYNa Urate Cry Cala2963-7SOMATOTROPINMCNCPTSER/PLASQNGH SerPI-mCnc | | | Prolactin SerPl-mCnc |
| 21482-5PROTEINMCNC24HURQNProt 24H Ur-mCn2885-2PROTEINMCNCPTSER/PLASQNProt SerPl-mCnc2889-4PROTEINMRAT24HURQNProt 24H Ur-mCn2890-2PROTEIN/CREATININEMCRTOPTURQNProt/creat Ur-mRn25977-0PYRIDINOLINE/CREATININESCNC24HURQNPYD 24H Ur-sCn25129-8PYRIDINOLINE/CREATININESCNC24HURQNSHBG Ser-Cnc13967-5SEX HORMONE BINDING GLOBULINSCNCPTSERQNSHBG Ser-Cnc21525-1SODIUMSCNCPTSERQNSodium 24H Ur-sCn2951-2SODIUMSCNCPTURQNSodium 24H Ur-sCn2956-1SODIUMSCNCPTURQNSodium 24H Ur-sCn2956-1SODIUM URATE CRYSTALSACNCPTCALCORDINFRARED
SPECTROSCOPYNa Urate Cry Cala2963-7SOMATOTROPINMCNCPTSER/PLASQNGH SerPl-mCnc | | ON | |
| 2885-2PROTEINMCNCPTSER/PLASQNProt SerPl-mCnc2889-4PROTEINMRAT24HURQNProt 24H UL-mRa2890-2PROTEIN/CREATININEMCRTOPTURQNProt 24H UL-mRa25977-0PYRIDINOLINESCNC24HURQNPYD 24H UL-sCn25129-8PYRIDINOLINE/CREATININESCNCPTURQNPYD/creat UL-sRa13967-5SEX MONONE BINDING GLOBULINSCNCPTURQNSodium 24H UL-sCn2152-1SODIUMSCNC24HURQNSodium 24H UL-sCn2951-2SODIUMSCNCPTSER/PLASQNSodium 24H UL-sCn2951-1SODIUMSCNCPTURQNSodium 24H UL-sCn2951-2SODIUMSCNCPTURQNSodium 24H UL-sCn2951-3SODIUMSCNCPTURQNSodium 24H UL-sCn2951-4SODIUMSCNCPTURQNSodium 24H UL-sCn2951-5SODIUMSCNCPTURQNSodium 24H UL-sCn2951-61SODIUMSRAT24HURQNSodium 24H UL-sCn2963-7SOMATOTROPINMCNCPTSER/PLASQNNa Urate Cry Cals2963-7SOMATOTROPINMCNCPTSER/PLASQNGH SerPl-mCnc | | ON | Prot 24H Ur-mCnc |
| 2889-4PROTEINMRAT24HURQNProt 24H Ur-mRa2890-2PROTEIN/CREATININEMCRTOPTURQNProt/creat Ur-mRa2597-0PYRIDINOLINESCNC24HURQNPYD 24H Ur-sCn25129-8PYRIDINOLINE/CREATININESCRTOPTURQNPYD 24H Ur-sCn13967-5SEX HORMONE BINDING GLOBULINSCNCPTSERQNSHBG Ser-sCnc2152-1SODIUMSCNCPTSERQNSodium 24H Ur-sCn2951-2SODIUMSCNCPTURQNSodium 24H Ur-sCn2955-3SODIUMSCNCPTURQNSodium 24H Ur-sCn2956-1SODIUMSCNCPTURQNSodium 24H Ur-sCn2957-8SODIUM URATE CRYSTALSACNCPTCALCORDINFRARED
SPECTROSCOPYNa Urate Cry Cale2963-7SOMATOTROPINMCNCPTSER/PLASQNGH SerPI-mCnc | 2885-2 PROTEIN | ON I | Prot SerPl-mCnc |
| 2890-2 PROTEIN/CREATININE MCRTO PT UR QN Prot/creat UT-mR 2597-0 PYRIDINOLINE SCNC 24H UR QN PYD 24H UT-sCn 25129-8 PYRIDINOLINE/CREATININE SCRTO PT UR QN PYD/creat UT-sR 13967-5 SEX HORMONE BINDING GLOBULIN SCNC PT SER QN SHBG Ser-sCnc 21525-1 SODIUM SCNC PT SER QN Sodium 24H Ur-sCnc 2951-2 SODIUM SCNC PT SER/PLAS QN Sodium 24H Ur-sCnc 2955-3 SODIUM SCNC PT UR QN Sodium 24H Ur-sCnc 2956-1 SODIUM SCNC PT UR QN Sodium Ur-sCnc 2956-1 SODIUM URATE CRYSTALS ACNC PT CALC ORD INFRARED 2963-7 SOMATOTROPIN MCNC PT SER/PLAS QN Sodium 24H Ur-sC | 2889-4 PROTEIN | | Prot 24H Ur-mRate |
| 25977-0 PYRIDINOLINE SCNC 24H UR QN PYD 24H Ur-sCn 25129-8 PYRIDINOLINE/CREATININE SCRTO PT UR QN PYD/creat Ur-sCn 13967-5 SEX HORMONE BINDING GLOBULIN SCNC PT SER QN SHBG Ser-Scne 21525-1 SODIUM SCNC PT SER/LAS QN Sodium 24H Ur-s 2951-2 SODIUM SCNC PT SER/LAS QN Sodium 24H Ur-s 2951-3 SODIUM SCNC PT UR QN Sodium 24H Ur-s 2955-1 SODIUM SCNC PT UR QN Sodium 0r-sCne 2956-1 SODIUM SRAT 24H UR QN Sodium 24H Ur-s 16257-8 SODIUM URATE CRYSTALS ACNC PT CALC ORD INFRARED Na Urate Cry Cale 2963-7 SOMATOTROPIN MCNC PT SER/PLAS QN GH SerPI-mCne | | ON | Prot/creat Ur-mRto |
| 25129-8 PYRIDINOLINE/CREATININE SCRTO PT UR QN PYD/creat Ur-sRt 13967-5 SEX HORMONE BINDING GLOBULIN SCNC PT SUR QN SHBG Ser-sCnc 2152-1 SODIUM SCNC 24H UR QN Sodium 24H Ur-s 2951-2 SODIUM SCNC PT SER/PLAS QN Sodium 24H Ur-s 2955-3 SODIUM SCNC PT UR QN Sodium 24H Ur-s 2956-1 SODIUM SCNC PT UR QN Sodium 24H Ur-s 16257-8 SODIUM SRAT 24H UR QN Sodium 24H Ur-s 2963-7 SODIUM URATE CRYSTALS ACNC PT CALC ORD INFRARED
SPECTROSCOPY Na Urate Cry Cale 2963-7 SOMATOTROPIN MCNC PT SER/PLAS QN GH SerPI-mCnc | | ON | PYD 24H Ur-sCne |
| 13967-5 SEX HORMONE BINDING GLOBULIN SCNC PT SER QN SHBG Ser-sCnc 21525-1 SODIUM SCNC 24H UR QN Sodium 24H Ur-s 2951-2 SODIUM SCNC PT SER/PLAS QN Sodium 24H Ur-s 2955-3 SODIUM SCNC PT UR QN Sodium Ur-sCnc 2956-1 SODIUM SRAT 24H UR QN Sodium 24H Ur-s 16257-8 SODIUM URATE CRYSTALS ACNC PT CALC ORD INFRARED
SPECTROSCOPY Na Urate Cry Cale 2963-7 SOMATOTROPIN MCNC PT SER/PLAS QN GH SerPI-mCnc | | ON | PYD/creat Ur-sRto |
| 21525-1 SODIUM SCNC 24H UR QN Sodium 24H Ur-5 2951-2 SODIUM SCNC PT SER/PLAS QN Sodium SerPl-5C 2955-3 SODIUM SCNC PT UR QN Sodium Ur-5CE 2956-1 SODIUM SRAT 24H UR QN Sodium Ur-5CE 16257-8 SODIUM URATE CRYSTALS ACNC PT CALC ORD INFRARED Na Urate Cry Cale 2963-7 SOMATOTROPIN MCNC PT SER/PLAS QN GH SerPI-mCnc | 13967-5 SEX HORMO | ON | SHBG Ser-sCnc |
| 2951-2 SODIUM SCNC PT SER/PLAS QN Sodium SerPl-sCn 2955-3 SODIUM SCNC PT UR QN Sodium Ur-sCnc 2956-1 SODIUM SRAT 24H UR QN Sodium 24H Ur-si 16257-8 SODIUM URATE CRYSTALS ACNC PT CALC ORD INFRARED Na Urate Cry Cale 2963-7 SOMATOTROPIN MCNC PT SER/PLAS QN GH SerPl-mCnc | 21525-1 SODIUM | ON | Sodium 24H Ur-sCne |
| 2955-3 SODIUM SCNC PT UR QN Sodium Ur-sCnc 2956-1 SODIUM SRAT 24H UR QN Sodium 24H Ur-s 16257-8 SODIUM URATE CRYSTALS ACNC PT CALC ORD INFRARED
SPECTROSCOPY Na Urate Cry Calc 2963-7 SOMATOTROPIN MCNC PT SER/PLAS QN GH SerPI-mCnc | | ON | Sodium SerPl-sCnc |
| 2956-1 SODIUM SRAT 24H UR QN Sodium 24H Ur-si 16257-8 SODIUM URATE CRYSTALS ACNC PT CALC ORD INFRARED Na Urate Cry Calc 2963-7 SOMATOTROPIN MCNC PT SER/PLAS QN GH SerPI-mCnc | | | |
| 16257-8 SODIUM URATE CRYSTALS ACNC PT CALC ORD INFRARED
SPECTROSCOPY Na Urate Cry Cale 2963-7 SOMATOTROPIN MCNC PT SER/PLAS QN GH SerPI-mCnc | | | Sodium 24H Ur-sRate |
| 2963-7 SOMATOTROPIN MCNC PT SER/PLAS QN GH SerPI-mCnc | | | Na Urate Cry Calc Ql IR |
| | | | |
| | | | |
| | | | Sp Gr Ur Qn |
| | | | Testost SerPl-sCnc |
| | | QN | Testost SerPl-mCnc |
| | | QN | Testost Free SerPl-sCnc |
| 2991-8 TESTOSTERONE.FREE MCNC PT SER/PLAS QN Testost Free SerP. | | QN | Testost Free SerPl-mCnc |
| | | QN | TXB2 24H Ur-mRate |
| 3016-3 THYROTROPIN ACNC PT SER/PLAS QN TSH Ser/Pl-aCnc | | | |
| 14921-1 THYROXINE SCNC PT SER/PLAS QN T4 SerPI-sCnc | | | |
| | | | T4BG SerPl-sCnc |
| | | | T4BG SerPl-mCnc |
| 32215-6 THYROXINE FREE INDEX ACNC PT SER/PLAS QN FTI SerPI-aCnc | | | FTI SerPl-aCnc |
| | | | Free T4 SerPl-sCnc |
| | | | Free T4 SerPl-mCnc |
| | | QN | Transferrin SerPl-sCnc |
| Lies of LOINC a 3034-6 TRANSFERRIN MCNC PT SER/PLAS QN Transferrin SerP- | | QN | Transferrin SerPl-mCnc |
| Use of LOINC a 30248-9 TRANSFERRIN RECEPTOR SOLUBLE MCNC PT SERVELAS QN STRF SerPI-mCnc | - C 30248-9 TRANSFERF | QN | sTfR SerPl-mCnc |
| | | QN J | Lipase SerPl-cCnc |
| 14927-8 TRIGLYCERIDE SCNC PT SER/PLAS QN Trigl SerPI-sCnc | 14927-8 TRIGLYCER | | Trigl SerPl-sCnc |
| | 2571-8 TRIGLYCER | | Trigl SerPl-mCnc |



An alterntive for the LB domain

- For usage in case the source data comes from a HIS, LIS or EHR
- Recently proposed to CDISC
 - But with little prospect of being accepted
- Based on usage of LOINC and UCUM instead of CDISC-CT

HIS = Hospital Information System



The alternative proposal

- Make LBLOINC expected
- Remove current LBCAT, LBSCAT, LBSPEC, LBMETHOD
- Add (LOINC) LBPROP (property measured), LBTIMEAS (time aspect), LBSYSTEM (system), LBSCALE (scale), LBCLASS (class), LBMETHOD (method, when applicable)



The alternative proposal

| Sponsor | LBLOINC | LBCOMP | LBPROP | LBTIMEAS | LBSYSTEM | LBSCALE | LBCLASS |
|-----------|---------|---------|--------|----------|----------|---------|---------|
| Sponsor 1 | 2339-0 | Glucose | MCnc | Pt | Bld | Qn | CHEM |
| Sponsor 2 | 15074-8 | Glucose | SCnc | Pt | Bld | Qn | CHEM |
| Sponsor 3 | 2339-0 | Glucose | MCnc | Pt | Bld | Qn | CHEM |

| | LBLOINC | LBCOMP | LBPROP | LBTIMEAS | LBSYSTEM | LBSCALE | LBCLASS |
|---|---------|---------------|--------|----------|----------|---------|---------|
| | 11217-7 | Hexaporphyrin | MRat | 24H | Urine | Qn | CHEM |
| | 30529-9 | Hexaporphyrin | ACnc | Pt | Urine | Ord | CHEM |
| Valid LOINC
combination
without LOINC | | Hexaporphyrin | MRat | 12H | Urine | Qn | CHEM |
| code | 50856-4 | Hexaporphyrin | SRat | 24H | Urine | Qn | CHEM |

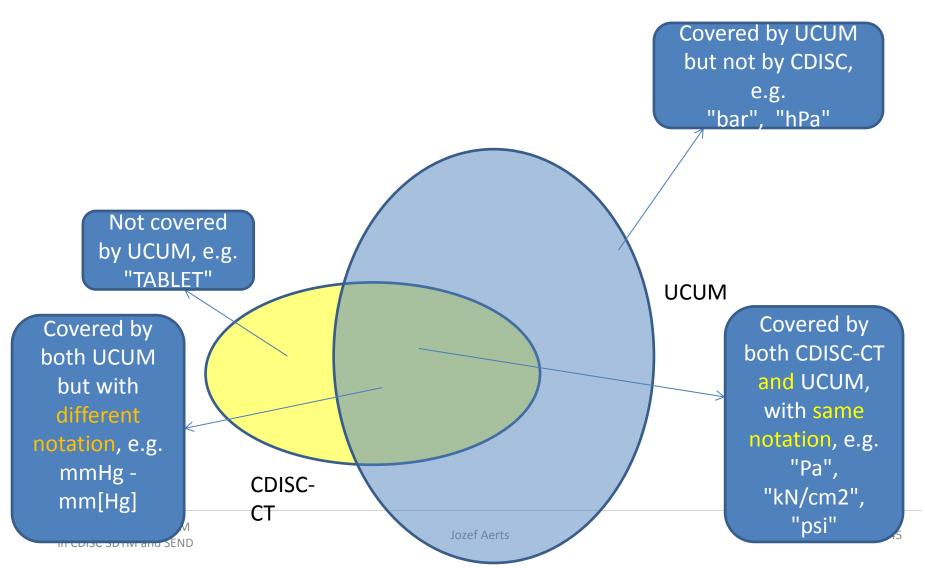


Use of UCUM in CDISC

- CDISC has own CT [UNIT]
- Is a list, not a system
- Latest version (July 2013) contains 516 "units"
- The list grows and grows ...

FH JOANNEUM University of Applied Sciences

CDISC claims to use a subset of UCUM





Some differences

| Property | CDISC | UCUM | |
|------------------|---|--------------|--|
| (blood) pressure | mmHg | mm[Hg] | |
| pressure | cm H2O | cm[H2O] | |
| count | 10^9/I | 10*9/I | |
| cell count | cells/uL | {cells}/ul | |
| energy | Joule | J | |
| time | Years | а | |
| non-SI length | ft | [ft_i] | |
| non-SI length | IN | [in_i] | |
| Code | CDISC meaning | UCUM meaning | |
| bar | Dosing unit
(e.g. bar of
chocolate) | pressure | |



CDISC [UNIT] list is problematic

- CDISC-CT contains:
 - ug/g/day,
 - ug/g/h
 - ug/g/min
 - ug/g Creatinine
- But not
 - ug/g



CDISC-CT [UNIT] mixes up object and unit

- Object = what is measured
 - E.g "cells", "creatinine"
- Unit = "ug/g"
- CDISC-CT: "ug/g Creatinine"
- UCUM:
 - {cre} ug/g
 - or ug/g



CDISC-CT [UNIT] dosing "units"

 Dosing units: ampule, tablet, bar, bottle, capsule, can, cylinder

| Unit | AMPULE | Ampule Dosing Unit | A dosing measurement based on the ampule unit.(NCI) |
|------|-----------|--------------------------|--|
| Unit | BAG | Bag Dosing Unit | A dosing measurement based on the bag unit.(NCI) |
| Unit | BAR | Bar Dosing Unit | A dosing measurement based on the bar unit.(NCI) |
| Unit | BOLUS | Bolus Dosing Unit | A dosing measurement based on the bolus unit.(NCI) |
| Unit | BOTTLE | Bottle Dosing Unit | A dosing measurement based on the bottle unit.(NCI) |
| Unit | BOX | Box Dosing Unit | A dosing measurement based on the box unit.(NCI) |
| Unit | CAN | Can Dosing Unit | A dosing measurement based on the can unit.(NCI) |
| Unit | CAPSULE | Capsule Dosing Unit; cap | A dosing measurement based on the capsule unit.(NCI) |
| Unit | CARTRIDGE | Cartridge Dosing Unit | A dosing measurement based on the cartridge unit.(NCI) |
| Unit | COAT | Coat Dosing Unit | A dosing measurement based on the coat unit.(NCI) |
| Unit | CONTAINER | Container Dosing Unit | A dosing measurement based on the container unit.(NCI) |
| | | | |
| Unit | CYLINDER | Cylinder Dosing Unit | A dosing measurement based on the cylinder unit.(NCI) |
| Unit | DISK | Disk Dosing Unit | A dosing measurement based on the disk unit.(NCI) |
| Unit | DRUM | Drum Dosing Unit | A dosing measurement based on the drum unit.(NCI) |



CDISC-CT [UNIT] dosing "units"

- Is a "dosing unit" a "unit"?
- Suggestion to make this a separate codelist has been turned down



Why CDISC does not want to accept/support UCUM

- Investigators are unfamiliar with UCUM notation (e.g. "mm[Hg]" versus "mmHg")
- SEND "units" are not covered by UCUM
- Some "special" units used in clinical research are not covered by UCUM
- Investigators, sponsors, reviewers would need to learn UCUM
- Not invented at CDISC ...

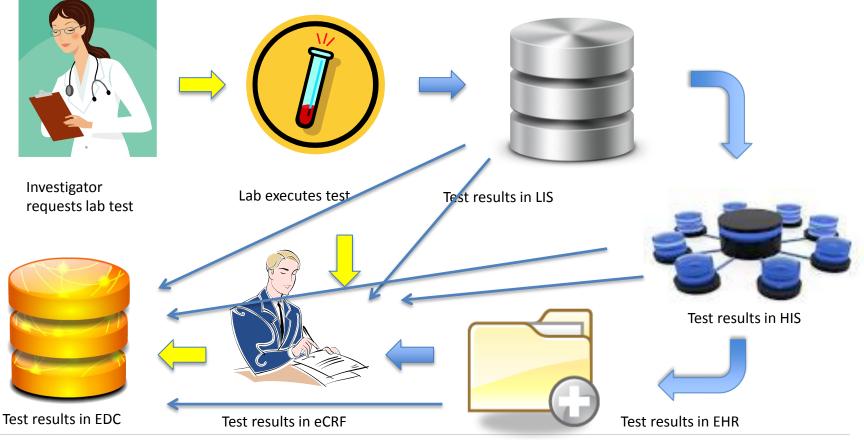


LOINC and UCUM for CDISC submissions - proposals

- Allow different "flavor" of LB domain (e.g. "LBLOINC" for cases where the laboratory information comes from LIS, HIS or EHR)
- For these cases, allow UCUM units to be used (documented in define.xml -"ExternalCodeList")



LOINC and UCUM for CDISC submissions - why we need this





The end?

• I don't think so ...



The long and winding road to interoperability ...

Use of LOINC and UCUM in CDISC SDTM and SEND

Jozef Aerts