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EUROPE INTERCHANGE

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24-25 APRIL: CONFERENCE & EXPO | 22, 23, 26 APRIL: TRAININGS

Submitting Laboratory Data in Multiple Standard Units

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Alexion AstraZeneca Rare Disease



Meet the Speaker

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Alexion AstraZeneca Rare Disease

Éanna Kiely is the co-lead of the Alexion SDTM standards team and member of the ADaM, CRF and Laboratory Standards teams.

He reviews study submission packages for alignment with Alexion internal standards and regulatory requirements.

He is also a volunteer on the CDISC SDTM team including lead of the Lab Units Representation and co-lead of the Protocol Deviations team.

He is an author on CDASHIG 2.0, SDTMIG 3.3 and 3.4 and a trainer in CDASH and SDTM.



Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC or Alexion AstraZeneca Rare Disease.*
- *The author(s) have no real or apparent conflicts of interest to report.*

FDA Study Data Technical Conformance Guide v5.7

- **4.1.1.3 SDTM Domain Specifications LB and LC Domain (Laboratory)**
 - For clinical studies, please submit two separate domains for lab results. The LB domain should contain SI units in LBSTRESU for the SI results in the LBSTRESC and LBSTRESN fields. An additional custom domain called LC structured identically to LB should contain conventional units in --STRESU for the results in conventional units in the --STRESC and --STRESN variables. It is ideal if both conventional and SI units come directly from the lab vendor.

LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESU
SODIUM	Sodium	136	mmol/L	136	mmol/L
GLUC	Glucose	3.9	mmol/L	3.9	mmol/L

<https://academic.oup.com/amamanualofstyle/si-conversion-calculator>

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SODIUM	Sodium	136	mmol/L	136	mmol/L
GLUC	Glucose	3.9	mmol/L	3.9	mmol/L
LCTESTCD	LCTEST	LCORRES	LCORRESU	LCSTRESC	LCSTRESU
SODIUM	Sodium	136	mmol/L	136	mEq/L
GLUC	Glucose	3.9	mmol/L	70.27027	mg/dL

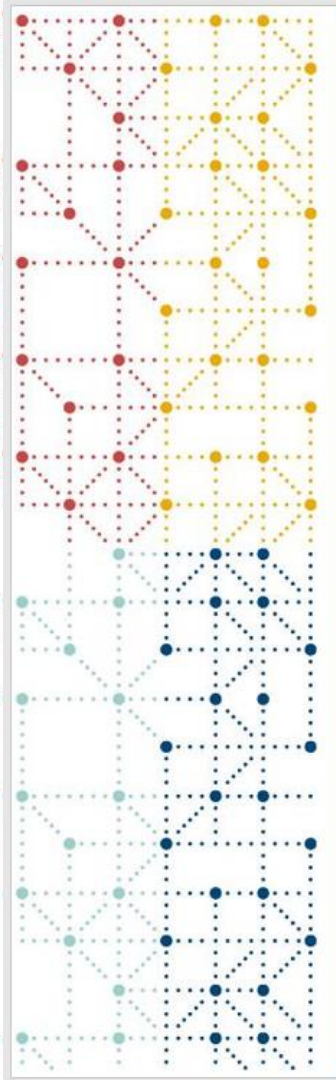
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LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESU
SODIUM	Sodium	136	mmol/L	136	mmol/L
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LCTESTCD	LCTEST	LCORRES	LCORRESU	LCSTRESC	LCSTRESU
SODIUM	Sodium	136	mEq/L	136	mEq/L
GLUC	Glucose	70.27027	mg/dL	70.27027	mg/dL

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**Developing a ...*custom domain called LC*
*structured identically to LB***

LC Domain Label and Definition Proposals

Submission Value	CDISC Synonym(s)	CDISC Definition
DOMAIN		SDTM Domain Abbreviation
LB	Laboratory Test Results	A findings domain that contains laboratory test data such as hematology, clinical chemistry and urinalysis. This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains.
LC	Laboratory Test Results Conventional (37)	A findings domain that contains laboratory test data the same as LB standardized to conventional standard units.
	Laboratory Findings in Conventional Units (41)	
LA	Laboratory Alternative	A findings domain that contains laboratory test data the same as LB standardized to an alternative standard units.
LO	Laboratory Other	A findings domain that contains laboratory test data the same as LB standardized to another standard units.

[SDTM Terminology 2024-03-29](#)

Domain label mentioned in the CDISC Knowledge Base article: [Standardized Lab Units](#)

Discussed between the SDS and Laboratory Team waiting on final agreement before publication

Submitting the LC Upfront or On Request

1. Does the sponsor have to submit the LC domain or only when asked?

- The sponsor is now expected to prospectively submit both the LB and LC domain to the FDA. Not only if requested by an FDA review division.

sdTCG 5.7 (2024-03)

*For clinical studies, **please submit two separate domains** for lab results.*

- In earlier versions of the sdTCG sponsors were informed of the potential for a request for conventional units and requested to discuss with the review division.

sdTCG 4.7 (2021-03)

***FDA may require laboratory data using conventional units** for reviewing submissions and labeling. Sponsors should discuss with the review divisions what laboratory data should utilize conventional units prior to submission.*

What is meant by Identical?

2. Should the LC domain contain all records from the LB domain or only a subset e.g. quantitative results with that require a unit conversion?

- The sponsor should repeat all variables and records from the LB domain in the LC domain making changes in the standard results (LCSTRESC and LCSTRESN), units (LCSTRESU) and standard reference ranges (LBSTNRLO, LBSTNRHI) and reference range indicator (LBNRIND) if impacted.

sdTCG 5.7 (2024-03)

*An additional custom domain called LC **structured identically to LB** should contain conventional units in --STRESU for the results in conventional units in the --STRESC and --STRESN variables*

Copying Records From LB to LC

LBSEQ	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESU
1	SODIUM	Sodium	136	mmol/L	136	mmol/L
2	GLUCOSE	Glucose	3.9	mmol/L	3.9	mmol/L
3	CO2	Carbon Dioxide	25	mEq/L	25	mmol/L
4	CREAT	Creatinine	1.025	mg/dL	90.61	umol/L
5	PH	pH	7.5		7.5	
6	HCG	Choriogonadotropin Beta	-		NEGATIVE	
7	ABO	ABO Blood Group	A		A	
8	TSH	Thyrotropin	2.235	mIU/L	2.235	mIU/L

Copying Records From LB to LC

LBSEQ	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESU
1	SODIUM	Sodium	136	mmol/L	136	mmol/L
2	GLUCOSE	Glucose	3.9	mmol/L	3.9	mmol/L
3	CO2	Carbon Dioxide	25	mEq/L	25	mmol/L
4	CREAT	Creatinine	1.025	mg/dL	90.61	umol/L
5	PH	pH	7.5		7.5	
6	HCG	Choriogonadotropin Beta	-		NEGATIVE	
7	ABO	ABO Blood Group	A		A	
8	TSH	Thyrotropin	2.235	mIU/L	2.235	mIU/L

} SI
 } Conventional
 } Unitless
 } Nominal
 } Same Unit in SI and Conventional

LBSEQ	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESU
1	SODIUM	Sodium	136	mmol/L	136	mmol/L
2	GLUCOSE	Glucose	3.9	mmol/L	3.9	mmol/L
3	CO2	Carbon Dioxide	25	mEq/L	25	mmol/L
4	CREAT	Creatinine	1.025	mg/dL	90.61	umol/L
5	PH	pH	7.5		7.5	
6	HCG	Choriogonadotropin Beta	-		NEGATIVE	
7	ABO	ABO Blood Group	A		A	
8	TSH	Thyrotropin	2.235	mIU/L	2.235	mIU/L

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3	CO2	Carbon Dioxide	25	mEq/L	25	mmol/L
4	CREAT	Creatinine	1.025	mg/dL	90.61	umol/L
5	PH	pH	7.5		7.5	
6	HCG	Choriogonadotropin Beta	-		NEGATIVE	
7	ABO	ABO Blood Group	A		A	
8	TSH	Thyrotropin	2.235	mIU/L	2.235	mIU/L

} SI
 } Conventional
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 } Nominal
 } Same Unit in SI and Conventional

LCSEQ	LCTESTCD	LCTEST	LCORRES	LCORRESU	LCSTRESC	LCSTRESU
1	SODIUM	Sodium	136	mmol/L	136	mEq/L
2	GLUCOSE	Glucose	3.9	mmol/L	70.27027	mg/dL

Only the SI Units?

LBSEQ	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESU
1	SODIUM	Sodium	136	mmol/L	136	mmol/L
2	GLUCOSE	Glucose	3.9	mmol/L	3.9	mmol/L
3	CO2	Carbon Dioxide	25	mEq/L	25	mmol/L
4	CREAT	Creatinine	1.025	mg/dL	90.61	umol/L
5	PH	pH	7.5		7.5	
6	HCG	Choriogonadotropin Beta	-		NEGATIVE	
7	ABO	ABO Blood Group	A		A	
8	TSH	Thyrotropin	2.235	mIU/L	2.235	mIU/L

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LCSEQ	LCTESTCD	LCTEST	LCORRES	LCORRESU	LCSTRESC	LCSTRESU
1	SODIUM	Sodium	136	mmol/L	136	mEq/L
2	GLUCOSE	Glucose	3.9	mmol/L	70.27027	mg/dL
3	CO2	Carbon Dioxide	25	mEq/L	25	mEq/L
4	CREAT	Creatinine	1.025	mg/dL	1.025	mg/dL

Only the quantitative units?



LBSEQ	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESU
1	SODIUM	Sodium	136	mmol/L	136	mmol/L
2	GLUCOSE	Glucose	3.9	mmol/L	3.9	mmol/L
3	CO2	Carbon Dioxide	25	mEq/L	25	mmol/L
4	CREAT	Creatinine	1.025	mg/dL	90.61	umol/L
5	PH	pH	7.5		7.5	
6	HCG	Choriogonadotropin Beta	-		NEGATIVE	
7	ABO	ABO Blood Group	A		A	
8	TSH	Thyrotropin	2.235	mIU/L	2.235	mIU/L

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LCSEQ	LCTESTCD	LCTEST	LCORRES	LCORRESU	LCSTRESC	LCSTRESU
1	SODIUM	Sodium	136	mmol/L	136	mEq/L
2	GLUCOSE	Glucose	3.9	mmol/L	70.27027	mg/dL
3	CO2	Carbon Dioxide	25	mEq/L	25	mEq/L
4	CREAT	Creatinine	1.025	mg/dL	1.025	mg/dL
5	PH	pH	7.5		7.5	
6	HCG	Choriogonadotropin Beta	-		NEGATIVE	
7	ABO	ABO Blood Group	A		A	
8	TSH	Thyrotropin	2.235	mIU/L	2.235	mIU/L

All records should be repeated with conversions performed as/if necessary to keep the LB/LCSEQ Key consistent

Should RELEC be used to link LB and LC?

- 3. Since there is a relationship between the LB and LC domains should RELREC be used?
- It is not necessary to use RELREC to show the link between LB and LC since this is a modeled relationship that could be seen as similar to DM (Demographics) and DC (Demographics for Multiple Participations).
- Similarly, the SESEQ domain has a chronological order as opposed to regular --SEQ variables which is an administrative field to show uniqueness per USUBJID.

LC (Laboratory Test Results Conventional) - [SDTMIG 4.1]

Location: [lc.xpt](#)

Variable	Label / Description	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier		Protocol (Source: Sponsor)
DOMAIN	Domain Abbreviation	Domain Abbreviation (LC) <ul style="list-style-type: none">• "LC" = "Laboratory Test Results Conventional"	Assigned (Source: Sponsor)
USUBJID	Unique Subject Identifier		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID
LCSEQ	Sequence Number		Predecessor (Source: Sponsor) Sequential number identifying records within each USUBJID in the domain. That is consistent with the LB domain order.

LBSTRESU/LBORRESU as Sort Keys

- As results are converted to Conventional Units there could be changes in the sort order of certain variables e.g. LBSTRESU/LBORRESU

LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESU	LBPDPUR
1	GLUC	Glucose	URINALYSIS	3.9	mmol/L	3.9	mmol/L	
2	UROBIL	Urobilinogen	URINALYSIS	0.09	mmol/day	0.09	mmol/day	PT24H
3	UROBIL	Urobilinogen	URINALYSIS	1.7	mmol/L	1.70	mmol/L	

LBSEQ Keys: LBCAT, LBTESTCD, LBSTRESU

Submission Value	Synonym(s)	Definition
UNIT	Unit	Terminology codelist used for units within CDISC.
EU	Ehrlich Units; EU/dL	A unit of measure equal to one milligram of urobilinogen per deciliter.

The conventional unit for Urobilinogen are EU (Ehrlich Units)
mmol/L => EU

LBSTRESU/LBORRESU as Sort Keys

- As results are converted to Conventional Units there could be changes in the sort order of certain variables e.g. LBSTRESU/LBORRESU

LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESU	LBDUR
1	GLUC	Glucose	URINALYSIS	3.9	mmol/L	3.9	mmol/L	
2	UROBIL	Urobilinogen	URINALYSIS	0.09	mmol/day	0.09	mmol/day	PT24H
3	UROBIL	Urobilinogen	URINALYSIS	1.7	mmol/L	1.70	mmol/L	

LCSEQ	LCTESTCD	LCTEST	LCCAT	LCORRES	LCORRESU	LCSTRESC	LCSTRESU	LCPDUR
1	GLUC	Glucose	URINALYSIS	3.9	mmol/L	70.27027	mg/dL	
2	UROBIL	Urobilinogen	URINALYSIS	1.7	mmol/L	0.10	EU	
3	UROBIL	Urobilinogen	URINALYSIS	0.09	mmol/day	0.01	mg/day	PT24H

LBSEQ Keys: LBCAT, LBTESTCD, LBSTRESU

Inconsistent LB/LCSEQ

Sub Value	Synonym(s)
UNIT	Unit
EU	Ehrlich Units; EU/dL

LBSTRESU/LBORRESU as Sort Keys

- As results are converted to Conventional Units there could be changes in the sort order of certain variables e.g. LBSTRESU/LBORRESU

LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESU	LBDUR
1	GLUC	Glucose	URINALYSIS	3.9	mmol/L	3.9	mmol/L	
2	UROBIL	Urobilinogen	URINALYSIS	0.09	mmol/day	0.09	mmol/day	PT24H
3	UROBIL	Urobilinogen	URINALYSIS	1.7	mmol/L	1.70	mmol/L	

LBSEQ Keys: LBCAT, LBTESTCD, LBSTRESU

Inconsistent LB/LCSEQ

LCSEQ	LCTESTCD	LCTEST	LCCAT	LCORRES	LCORRESU	LCSTRESC	LCSTRESU	LCPDUR
1	GLUC	Glucose	URINALYSIS	3.9	mmol/L	70.27027	mg/dL	
2	UROBIL	Urobilinogen	URINALYSIS	1.7	mmol/L	0.10	EU	
3	UROBIL	Urobilinogen	URINALYSIS	0.09	mmol/day	0.01	mg/day	PT24H

Sub Value	Synonym(s)
UNIT	Unit
EU	Ehrlich Units; EU/dL

LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBSTRESC	LBSTRESU	LBDUR
1	GLUC	Glucose	URINALYSIS	3.9	mmol/L	3.9	mmol/L	
2	UROBIL	Urobilinogen	URINALYSIS	0.09	mmol/day	0.09	mmol/day	PT24H
3	UROBIL	Urobilinogen	URINALYSIS	1.7	mmol/L	1.70	mmol/L	

LBSEQ Keys: LBCAT, LBTESTCD, LBDUR

The order of the LB/LCSEQ is consistent between the 2 domains

LCSEQ	LCTESTCD	LCTEST	LCCAT	LCORRES	LCORRESU	LCSTRESC	LCSTRESU	LCPDUR
1	GLUC	Glucose	URINALYSIS	3.9	mmol/L	70.27027	mg/dL	
2	UROBIL	Urobilinogen	URINALYSIS	0.09	mmol/day	0.01	mg/day	PT24H
3	UROBIL	Urobilinogen	URINALYSIS	1.7	mmol/L	0.10	EU	

Other (Specimen-based) Findings Domains Using SI and Conventional Units?

- 4. The FDA has only requested the use of both SI and Conventional Units in the LB domain. Which other domains could be require a 2 domain approach?

VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESU
HEIGHT	Height	175	cm	175	cm
WEIGHT	Weight	80	kg	80	kg
TEMP	Temperature	37.5	C	37.5	C

Other (Specimen-based) Findings Domains Using SI and Conventional Units?

- 4. The FDA has only requested the use of both SI and Conventional Units in the LB domain. Which other domains could be require a 2 domain approach?
- In Submitting Study Datasets for Vaccines to the Office of Vaccines Research and Review [2.1](#) 2019-12 section **Section 3.1 Reactogenicity Data**
 - All daily temperature measurements are represented in the VS domain. **Standard units should either be Celsius (°C) or Fahrenheit (°F), but not both within a dataset.**
- the guidance is to use either SI or Conventional Units as the standard unit not both. **No second domain has been requested for VS.**

VSTESTCD	VSTEST	VSORRES	VSORRESU	VSSTRESC	VSSTRESU
HEIGHT	Height	175	cm	175	cm
WEIGHT	Weight	80	kg	80	kg
TEMP	Temperature	37.5	C	37.5	C
VCTESTCD	VCTEST	VCORRES	VCORRESU	VCSTRESC	VCSTRESU
HEIGHT	Height	175	cm	68.90	in
WEIGHT	Weight	80	kg	176.37	LB
TEMP	Temperature	37.5	C	99.5	F

Findings	Conversion of Units?
PC, PP	Not expected
IS	PRESENT/ABSENT or TITER
CP	NUMBER FRACTION/ CONCENTRATION
GF	NOMINAL, COUNTS
QRS	ORDINAL, NOMINAL
TR	mm is used by convention

Define-XML 2.1 Predecessor in LC

- Both the FDA and PMDA accept Define-XML 2.1.
- Define-XML 2.1 can show the predecessor of variables in SDTM.
- If the LC domain is copied directly from the LB a number of the variables will be predecessor.

LC (Laboratory Test Results Conventional) - [SDTMIG 4.1]

Location: [lc_xpt](#)

Variable	Label / Description	Controlled Terms or ISO Format	Origin / Source / Method / Comment
STUDYID	Study Identifier		Protocol (Source: Sponsor)
DOMAIN	Domain Abbreviation	Domain Abbreviation (LC) <ul style="list-style-type: none">• "LC" = "Laboratory Test Results Conventional"	Assigned (Source: Sponsor)
USUBJID	Unique Subject Identifier		Derived (Source: Sponsor) Concatenation of STUDYID and SUBJID
LCSEQ	Sequence Number		Predecessor LB.LBSEQ Sequential number identifying records within each USUBJID in the domain. That is consistent with the LB domain order.
LCTESTCD	Lab Test or Examination Short Name	Laboratory Test Code [10 Terms]	Predecessor LB.LBTESTCD
LCTEST	Lab Test or Examination Name	Laboratory Test Name [10 Terms]	Predecessor LB.LBTEST

SDTCG 5.7

It is ideal if both conventional and SI units come directly from the lab vendor

If both standard unit type are received from the laboratory LCORRES is not a predecessor of LBORRES

Updates to the Model: Rows vs Columns

- The Laboratory Units Representation (LUR) Team formed in 2018 with members from the SDS and Lab team to model SI and Conventional Units in SDTM.
- CDISC Global Governance Group reviewed 9 options in 2020. With options 2 preferred options the 2 domain approach that is now in the sdTCG and option 7.

Option 6: Additional Variable to Indicate Unit Type – Rows

Variable Name	Variable Label
LBSTRSUT	Standard Unit Type

LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESU	LBSTRSUT
SODIUM	Sodium	136	mmol/L	136	mmol/L	SI
GLUC	Glucose	3.9	mmol/L	3.9	mmol/L	SI
SODIUM	Sodium	136	mmol/L	136	mEq/L	CONVENTIONAL
GLUC	Glucose	3.9	mmol/L	70.2702703	mg/dL	CONVENTIONAL

Option 7: Add Variables for SI and US Conventional Units similar to LBSTRESC/N – Columns

LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSIRESC	LBSIRESU	LBCVRESC	LBCVRESU
SODIUM	Sodium	136	mmol/L	136	mmol/L	136	mEq/L
GLUC	Glucose	3.9	mmol/L	3.9	mmol/L	70.27027	mg/dL

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LBSTRSUT	Standard Unit Type

LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESU	LBSTRSUT
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GLUC	Glucose	3.9	mmol/L	3.9	mmol/L	SI
SODIUM	Sodium	136	mmol/L	136	mEq/L	CONVENTIONAL
GLUC	Glucose	3.9	mmol/L	70.2702703	mg/dL	CONVENTIONAL

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LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSIRESC	LBSIRESU	LBCVRESC	LBCVRESU
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SODIUM	Sodium	136	mmol/L	136	mmol/L	SI
GLUC	Glucose	3.9	mmol/L	3.9	mmol/L	SI
SODIUM	Sodium	136	mmol/L	136	mEq/L	CONVENTIONAL
GLUC	Glucose	3.9	mmol/L	70.2702703	mg/dL	CONVENTIONAL

Variable Name	Variable Label
LBSTRSUT	Standard Unit Type

LB **ST** RESU: **ST** = **Standard**
 LB **SI** RESU: **SI** = **SI**
 LB **CV** RESU: **CV** = **Conventional**

Option 7: Add Variables for SI and US Conventional Units similar to LBSTRESC/N – Columns

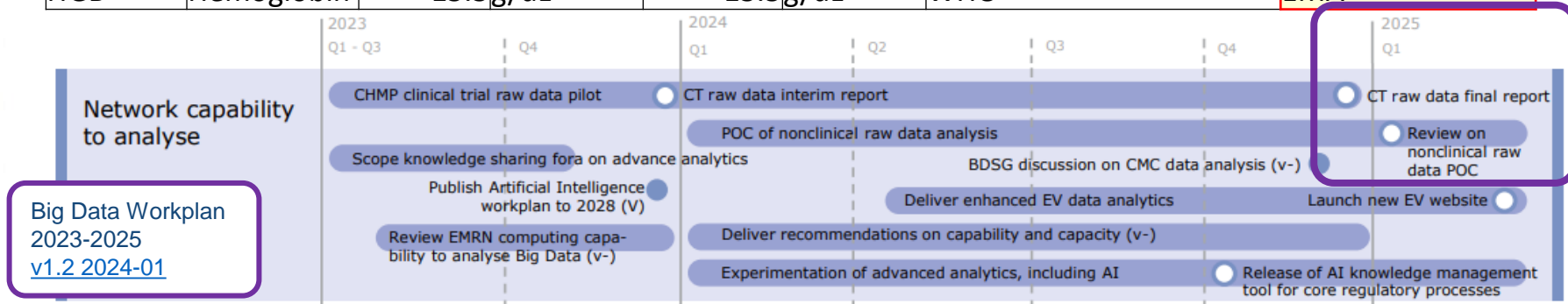
LBTESTCD	LBTEST	LBORRES	LBORRESU	LB SI RESC	LB SI RESU	LB CV RESC	LB CV RESU
SODIUM	Sodium	136	mmol/L	136	mmol/L	136	mEq/L
GLUC	Glucose	3.9	mmol/L	3.9	mmol/L	70.27027	mg/dL

Variable	Variable Label
LB SI RESU	Character Result/Finding in SI Format
LB SI RESU	SI Units
LB CV RESC	Character Result/Finding in Conv Format
LB CV RESU	Conventional Units

Option 6 Rows: Under Review

- A question on standard lab units has been sent to the EMA [Raw Data Pilot](#) team.
- If different National Competent Authorities (NCAs) will require different standard units option 6 more rows could be recommended.
 - Technical approach e.g. the UCUM code system have been mentioned to support conversions
- Other regulators e.g. NMPA should be contacted for their input.

LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESU	LBSTRSUT	Regulator(s)
HGB	Hemoglobin	15.5	g/dL	15.5	g/dL	US CONVENTIONAL	FDA
HGB	Hemoglobin	15.5	g/dL	9.62	mmol/L	SI	FDA, PMDA, EMA?
HGB	Hemoglobin	15.5	g/dL	155.0	g/L	GERMAN CONVENTIONAL	BfArM?
HGB	Hemoglobin	15.5	g/dL	15.5	g/dL	WHO	EMA



Option 7: Columns – Potential Doubling/Tripling of New Variables

#	Variable	Label
1	LBSIRESC	Character Result/Finding in SI Format
2	LBSIRESN	Numeric Result/Finding in SI Units
3	LBSIRESU	SI Units
4	LBSINRLO	Reference Range Lower Limit-SI Units
5	LBSINRHI	Reference Range Upper Limit-SI Units
6	LBSINRC	Reference Range for Char Rslt-SI Units
7	LBSIREFC	Reference Result in SI Format
8	LBSILLOQ	Lower Limit of Quantitation SI
9	LBSIULOQ	Upper Limit of Quantitation SI
10	LBCVRESC	Character Result/Finding in Convl Format
11	LBCVRESN	Numeric Result/Finding in Convl Units
12	LBCVRESU	Conventional Units
13	LBCVNRLO	Reference Range Lower Limit-Convl Units
14	LBCVNRHI	Reference Range Upper Limit-Convl Units
15	LBCVNRRC	Reference Range for Char Rslt-Cnvl Units
16	LBCVREFC	Reference Result in Conventional Format
17	LBCVLLOQ	Lower Limit of Quantitation Conventional
18	LBCVULOQ	Upper Limit of Quantitation Conventional

Results

Reference Ranges

Limits of Quantitation

- In draft SDTMIG [4.0](#) there are 62 LB variables. 18 additional variables would be 29% increase.
- In draft SDTM [2.1](#) there are 68 Findings variables 31 of which are not in the LB. None impact Standard variables.
- Would LBSTRESC/N/U (Unspecified Standard Unit Type) be deprecated or kept for use by the sponsor for Sponsor Standard Units?
- Variable duplication between LB and LC would be reduced e.g.
 - Identifiers, Timing, Non-Standard Unit Qualifiers.
- This approach is more in line with the CDISC LAB Model ([v1.0.1 2004-04-14](#))

CDISC LAB Model (v1.0.1 2004-04-14) - BaseDataFields

FIELD NAME	REQD	SAS VARIABLE
Base Test Level		
Lab Test ID	Yes	LBTESTCD
Lab Test Name	No	LBTEST
Base Result Level		
Reported Text Result	Cond.	RPTRESC
Reported Numeric Result	Cond.	RPTRESN
Reported Reference Range Low	No	RPTNRLO
Reported Reference Range High	No	RPTNRHI
Reported Units	No	RPTU
Conventional Level		
Conventional Text Result	No	CNVRESC
Conventional Numeric Result	Cond.	CNVRESN
Conventional Reference Range Low	No	CNVNRLO
Conventional Reference Range High	No	CNVNRHI
Conventional Units	No	CNVU
SI Level		
SI Text Result	No	SIRESC
SI Numeric Result	Cond.	SIRESN
SI Reference Range Low	No	SINRLO
SI Reference Range High	No	SINRHI
SI Units	No	SIU

- The CDISC LAB Model was created to support the transfer of data from Laboratories.
- Lab1-0-1-BaseDataFields allows the results to be reported simultaneously for:
 - Reported
 - Similar to LBORRES but not based on the UNIT Codelist i.e. SDTMIG 3.4 LB Assumption 7.
 - Conventional
 - SI

CDISC LAB Model (v1.0.1 2004-04-14) - ReferenceRanges

- Lab1-0-1-ReferenceRanges could support with the new FDA request from the sdTCG 5.7
 - *Identify all reference ranges used for specific populations in the SDRG and ADRG.*
- With details including: Sex, Race, Age

FIELD NAME	Subject Characteristics	Subject Sex	Subject Race	Subject Age Lower Limit	Subject Age Upper Limit	Subject Age Units	Medical Condition
REQD FIELD?	Subject Characteristics	No	No	Yes	Yes	Yes	No
SAS VARIABLE NAME	Subject Characteristics	SEX	RACE	AGELO	AGEHI	AGEU	MEDCND
		Male					
		Female					

Test Level	Performing Laboratory ID	Performing Laboratory Name	Lab Test ID	Lab Test Name	Reference Range Level	Units System	Units	Reference Low	Reference High
Test Level	Yes	No	Yes	No	Reference Range Level	No	Cond.	No	No
Test Level	PLBNUM	PLBNAM	LBTESTCD	LBTEST	Reference Range Level	UNITSYS	UNIT	NORMLO	NORMHI
	7248	Cavan General Hospital Department of Clinical & Laboratory Sciences	SODIUM	Sodium		SI	mmol/L	133	146
	4093	Mount Sinai	SODIUM	Sodium		C	mEq/L	135	145
	7248	Cavan General Hospital Department of Clinical & Laboratory Sciences	IRON	Iron		SI	umol/L	11	31
	7248	Cavan General Hospital Department of Clinical & Laboratory Sciences	IRON	Iron		SI	umol/L	9	30

What Units Should be Used for SI and Conventional

5. Which units should be reported in SI and Conventional and is there a list of units to be followed?

- Multiple lists of SI and Conventional units exist some contain conversions.
- There can be differences in SI and Conventional Units
- There does not appear to be a single compressive list of standard units with associated conversions that is maintained.

Units List / Database	Comment
AMA Manual of Style 11th Edition Units of measure converter	Enzymatic Activity is in Katal
labcorp SI Unit Conversion Table	Enzymatic Activity is in Enzymatic Units
MSD Normal Laboratory Values	Minor inconsistencies between units
LOINC, NPU terminology	Contains multiple units available for use but does not propose a single standard unit. Does not contain conversions.
Properties and units in the clinical laboratory sciences. Part X. Properties and units in general clinical chemistry (IUPAC-IFCC Technical Report 1999)	

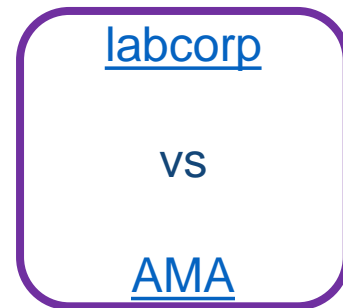
What is unit for Enzymatic Activity? kat, IU, Enzyme U

SI Unit Conversion Table

Analyte	Conventional Units	Conventional to SI (multiply by)	SI Units	SI to Conventional (multiply by)
Acid phosphatase	units/L	NA	units/L	NA

Table 2: Selected laboratory tests and conversion factors^a

Analyte	Specimen	Conventional unit	Conversion factor	SI unit
Acid phosphatase	Serum	<input type="text"/> U/L	16.667	<input type="text"/> nkat/L



What is unit for Enzymatic Activity? kat, IU, Enzyme U

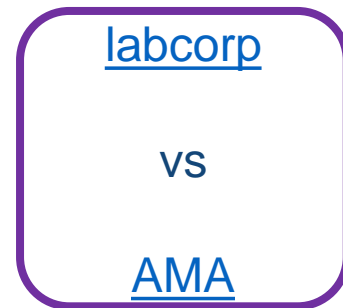
- The Silver Book and the NPU Format for Clinical Laboratory Science Reports Regarding Properties, Units, and Symbols ([2017-04-25](#))
 - *The term “katal” and symbol “kat” for the ‘SI coherent derived unit for catalytic activity’ have been recognized by IUPAC, IFCC, International Union of Biochemistry and Molecular Biology (IUBMB), World Health Organization (WHO), and General Conference on Weights and Measures (CGPM) [3]. IUPAC & IFCC [9] recommended that the enzyme unit, international unit U be progressively replaced by submultiples of the katal, where 1 U = 1 $\mu\text{mol}\cdot\text{min}^{-1} \approx 16.67 \text{ nkat}$;*

SI Unit Conversion Table

Analyte	Conventional Units	Conventional to SI (multiply by)	SI Units	SI to Conventional (multiply by)
Acid phosphatase	units/L	NA	units/L	NA

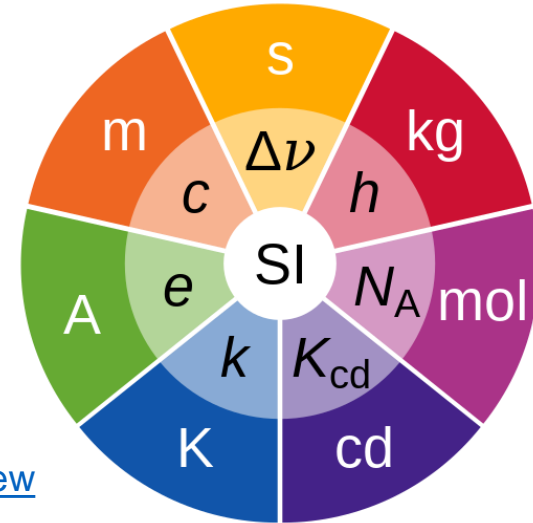
Table 2: Selected laboratory tests and conversion factors^a

Analyte	Specimen	Conventional unit	Conversion factor	SI unit
Acid phosphatase	Serum	<input type="text"/> U/L	16.667	<input type="text"/> nkat/L



History of SI Units

- **Système international d'unités (SI)** (International System of Units) is system of measurement that provides base units and has broad adoption and support internationally.
- SI was introduced to the European Union in 1971
 - [Council Directive 71/354/EEC of 18 October 1971](#)
 - Updated [Commission Directive \(EU\) 2019/1258 of 23 July 2019](#)
- In 1975 the US adopted a voluntary conversion to the metric system included SI Units
 - [US Metric Conversion Act of 1975](#)
- The PMDA requires SI units for regulatory submissions
 - [Notification on Handling of Submission of Electronic Study Data for New Drug Applications \(2022-04-01\) Page 12, Section 4 \(2\) d](#)
- International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and International Union of Pure and Applied Chemistry (IUPAC) work to develop conventions for the use of units in laboratory data e.g.
 - The Silver Book and the NPU Format for Clinical Laboratory Science Reports Regarding Properties, Units, and Symbols ([2017-04-25](#))



Further SI Conventions

- **PMDA FAQs on Electronic Study Data Submission ([2024-04-08](#))**
 - Q4-23: ...Please indicate the SI units that the PMDA considers acceptable, and any other points that should be considered when storing data in SI units.
 - A: Currently, the PMDA considers the use of SI units, non-SI units that are accepted for use with SI units, and SI prefixes listed in published BIPM (Bureau International des Poids et Mesures) brochure as acceptable use of the SI units. **Prefixes should be used to keep numbers in the range of 0.1–1000.**
- **The Silver Book and the NPU Format for Clinical Laboratory Science Reports Regarding Properties, Units, and Symbols ([2017-04-25](#))**
- **Prefixes for Multiples and Submultiples of Units**
 - *the Commission on Clinical Chemistry of IUPAC and IFCC recommended a preference in the clinical laboratory for decimal factors with **decimal prefixes in steps of a factor 1000** [1]. This selection of a decimal prefix often permits numerical results to be reported with a numerical value in the **recommended interval between 0.1 and 999**.*

Conventional Units: Increments and decrements do not follow a defined structure e.g. mg/dL, ug/mL, ng/mL, pg/mL, ug/dL, mg/L, ug/L, g/dL

Unit	n*	Term
mmol/L	10 ³	milli
umol/L	10 ⁶	micro
nmol/L	10 ⁹	nano
pmol/L	10 ¹²	pico

* n is the decimal exponent of the factor.

Maintaining Sponsors Standards Laboratory Units and Conversions

- As new tests are encountered that do not have a defined SI or Conventional Unit discuss with internal laboratory and clinical experts to define an appropriate unit.
- If the molecular mass and structure of the analyte, enzyme is known it can support in the creation of Molar Concentrations as discussed in the IFCC and IUPAC [Silver Book](#).

LBCF (Conversion Factor)

LBMWS (Molecular Mass Status)

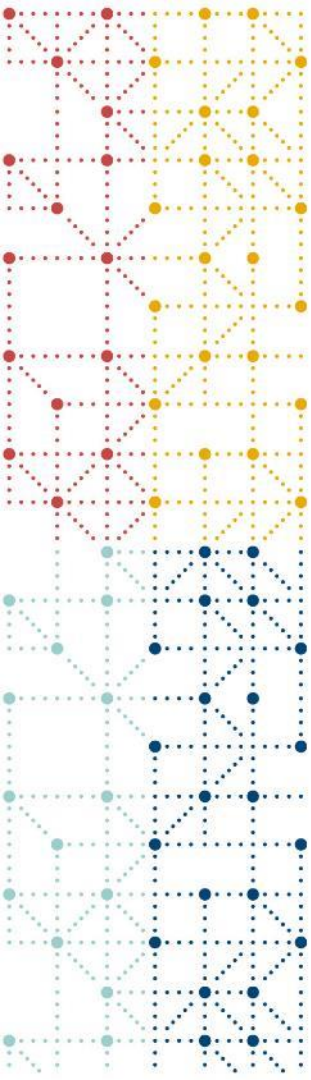
LBSTRSUS (Standard Unit Source)

LBRES	LBCRESU	LBCF	LBSEQ	LBTESTCD	LBTEST	LBORRES	LBORRESU	LBSTRESC	LBSTRESU
44	mg/mL	0.1	1	ALB	Albumin	44	g/L	44	g/L

LCRES	LCCRESU	LCCF	LCSEQ	LCTESTCD	LCTEST	LCORRES	LCORRESU	LCSTRESC	LCSTRESU
4.4	mg/mL	0.1	1	ALB	Albumin	4.4	g/dL	4.4	g/dL

LBSEQ	LBMMS	LBSTRSUS
1	MULTIPLE	AMA Manual of Style 11 th Edition Units of measure converter

LCSEQ	LCMMS	LCSTRSUS
1	MULTIPLE	AMA Manual of Style 11 th Edition Units of measure converter



Thank You!
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cdisc