# SDTM-ETL 4.1: Using the LOINC-SDTM-LB Mapping and similar functions

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Last update: **2022-05-28**

## Introduction

Many within the CDISC world consider LOINC coding as a burden, due to the new FDA requirements that for laboratory tests at least, the LOINC code must be delivered in LBLOINC.
However, LOINC coding is not a burden, it is a blessing and a great opportunity.

LOINC is a pre-coordinated coding system for all kinds of tests, so not only for laboratory tests as many think. LOINC is used all over the world, and mandated to be used in laboratory reporting in many countries. So, if you get your lab results from the hospital or an external lab, there is a high probability that the LOINC code can be provided. But of course, one has to ask.

Due to the new FDA requirement, CDISC developed a mapping between the 2000+ most used LOINC codes and the SDTM lab domain. We have considerably extended this mapping to over 9,500 LOINC codes (over 18,000 mappings). These mappings also allows to automatically populate LBTESTCD, LBTEST, LBSPEC, LBLOC, LBMETHOD etc., and that is exactly what we have implemented in SDTM-ETL. This also means that when one has the LOINC code of the lab test (to be delivered by the lab of course), there is no need anymore to spend hours or days to puzzle out the categorization into the SDTM variables. One can simply auto-populate these variables starting from the LOINC code.

Also, the obtained LOINC can be used to fully automatically "standardize" results to either "SI" or "conventional" units. See the tutorial "Performing Unit Conversions in SDTM-ETL".

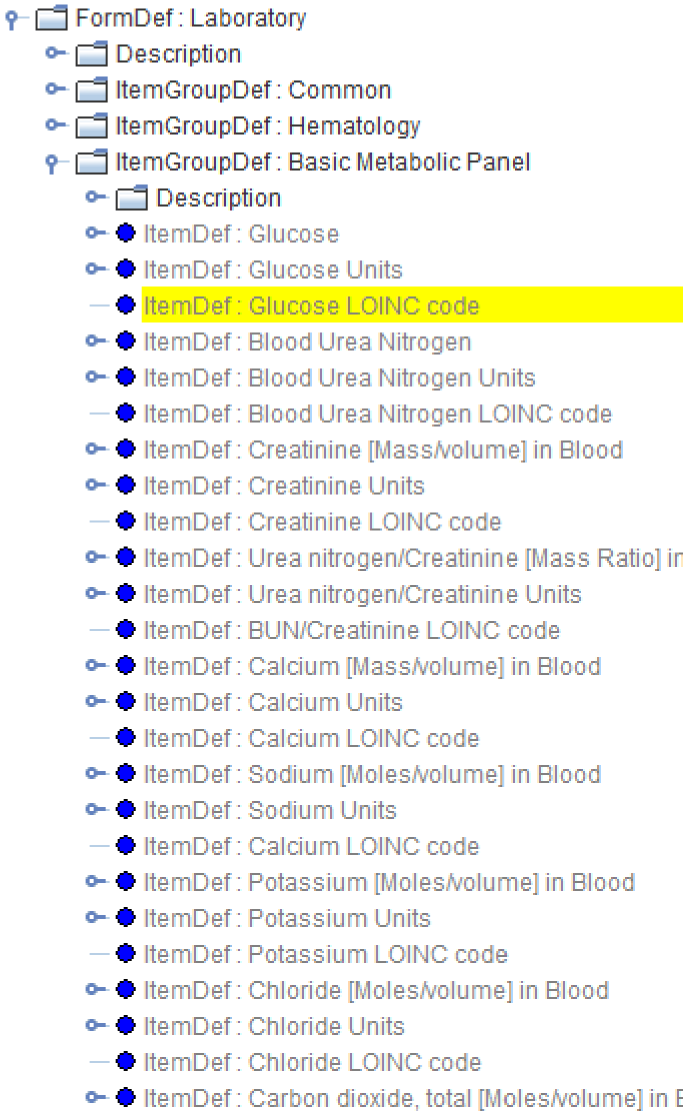
## Getting the LOINC code and populating LBLOINC

If one has the LOINC code of the lab test, it usually is already stored into the EDC system and thus can be exported into the ODM export. Using the normal drag-and-drop procedure, followed by using the wizards, one can then easily generate the mapping for LBLOINC.
In case LBLOINC was not provide it by the template, you can still add it using the menu "Insert – new SDTM Variable". Do also not forget to assign an "external codelist" (named "LOINC" of course) to the properties of the LBLOINC variable.
After that, you can choose to set the structure of the dataset either to the classic "one record per LBTESTCD per … per … per subject", or to "one record per LBLOINC per …". The latter may be a better choice when you have a mixture of quantitative and non-quantitative measurements for the same analyte. A typical example is "glucose in urine", some results being quantitative (a concentration), and other ordinal (+1, +2, …).

## Generating the mappings for LBTESTCD, LBTEST, LBSPEC, LBMETHOD…

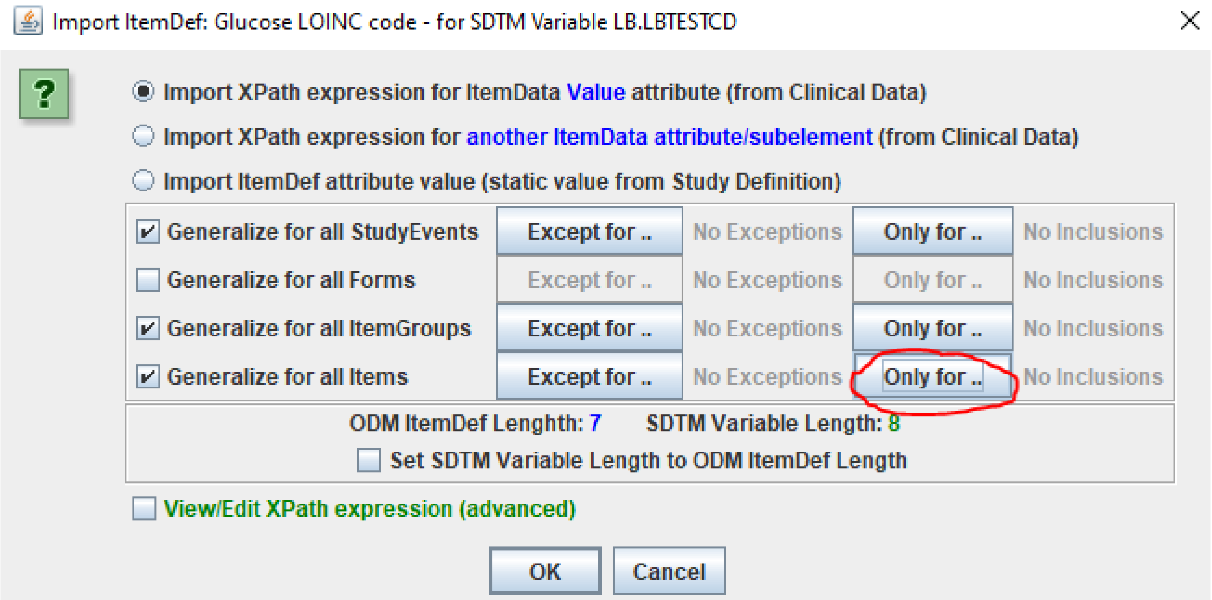
As the variable LBLOINC has been put near the end of the identifiers in LB (a major design errors in our opinion, as the LOINC code is the real identifier of the test, and NOT

LBTESTCD), one cannot simple reuse $LB.LBLOINC in the mappings for LB.LBTESTCD etc. So, one will need to just copy-paste the mapping for LBLOINC into the cells for LBTESTCD, LBTEST etc., or drag-and-drop again from the field in ODM for the LOINC code into the cells for **LBTESTCD**, **LBTEST** etc.. For example:



- FormDef : Laboratory
  - Description
  - ItemGroupDef : Common
  - ItemGroupDef : Hematology
  - ItemGroupDef : Basic Metabolic Panel
    - Description
    - ItemDef : Glucose
    - ItemDef : Glucose Units
    - ItemDef : Glucose LOINC code
    - ItemDef : Blood Urea Nitrogen
    - ItemDef : Blood Urea Nitrogen Units
    - ItemDef : Blood Urea Nitrogen LOINC code
    - ItemDef : Creatinine [Mass/volume] in Blood
    - ItemDef : Creatinine Units
    - ItemDef : Creatinine LOINC code
    - ItemDef : Urea nitrogen/Creatinine [Mass Ratio] in
    - ItemDef : Urea nitrogen/Creatinine Units
    - ItemDef : BUN/Creatinine LOINC code
    - ItemDef : Calcium [Mass/volume] in Blood
    - ItemDef : Calcium Units
    - ItemDef : Calcium LOINC code
    - ItemDef : Sodium [Moles/volume] in Blood
    - ItemDef : Sodium Units
    - ItemDef : Calcium LOINC code
    - ItemDef : Potassium [Moles/volume] in Blood
    - ItemDef : Potassium Units
    - ItemDef : Potassium LOINC code
    - ItemDef : Chloride [Moles/volume] in Blood
    - ItemDef : Chloride Units
    - ItemDef : Chloride LOINC code
    - ItemDef : Carbon dioxide, total [Moles/volume] in

We see that there are several tests in the "Laboratory" form, each having a field for the result, for the unit, and for the LOINC code. When we then do a drag-and-drop of one of them to the LBTESTCD cell, we select that we want to have this for all the visits ("Generalize for all StudyEvents") and for both of the groups ("Generalize for all ItemGroups") "hematology" and "basic metabolic panel":



Import ItemDef: Glucose LOINC code - for SDTM Variable LB.LBTESTCD

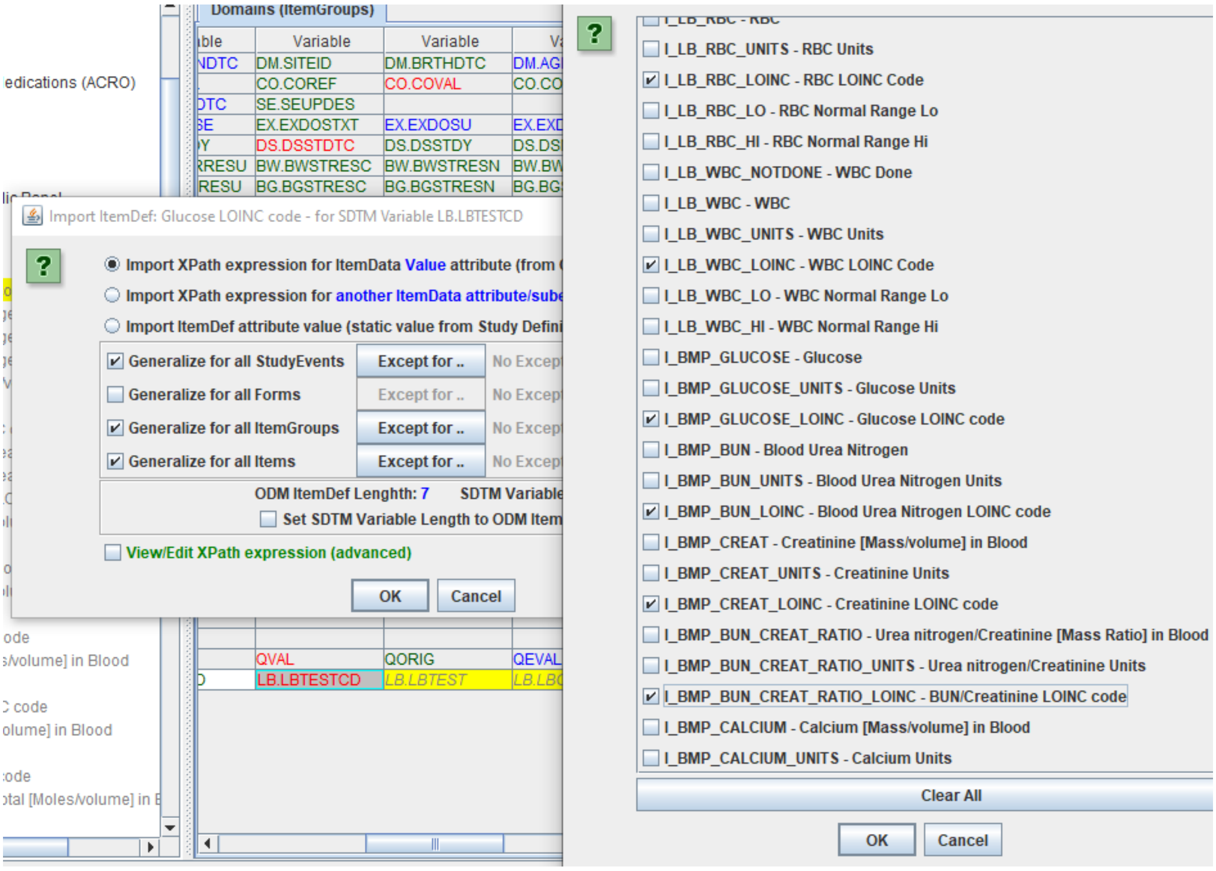
● Import XPath expression for ItemData Value attribute (from Clinical Data)
○ Import XPath expression for another ItemData attribute/subelement (from Clinical Data)
○ Import ItemDef attribute value (static value from Study Definition)

☑ Generalize for all StudyEvents — Except for .. — No Exceptions — Only for .. — No Inclusions
☐ Generalize for all Forms — Except for .. — No Exceptions — Only for .. — No Inclusions
☑ Generalize for all ItemGroups — Except for .. — No Exceptions — Only for .. — No Inclusions
☑ Generalize for all Items — Except for .. — No Exceptions — Only for .. — No Inclusions

ODM ItemDef Length: 7 SDTM Variable Length: 8
☐ Set SDTM Variable Length to ODM ItemDef Length

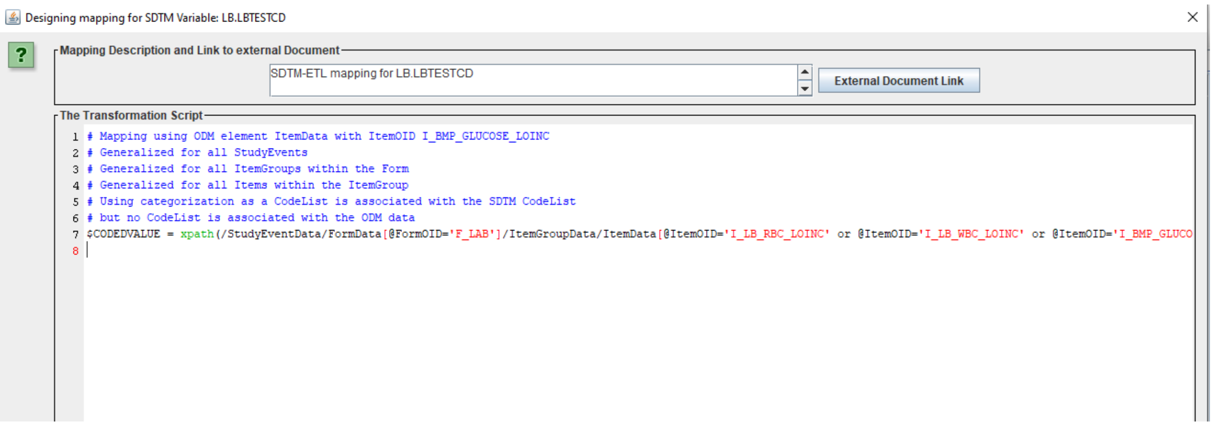
☐ View/Edit XPath expression (advanced)

And by clicking "Only for", then select all the LOINC Code" items



☐ I_LB_RBC - RBC
☐ I_LB_RBC_UNITS - RBC Units
☑ I_LB_RBC_LOINC - RBC LOINC Code
☐ I_LB_RBC_LO - RBC Normal Range Lo
☐ I_LB_RBC_HI - RBC Normal Range Hi
☐ I_LB_WBC_NOTDONE - WBC Done
☐ I_LB_WBC - WBC
☐ I_LB_WBC_UNITS - WBC Units
☑ I_LB_WBC_LOINC - WBC LOINC Code
☐ I_LB_WBC_LO - WBC Normal Range Lo
☐ I_LB_WBC_HI - WBC Normal Range Hi
☐ I_BMP_GLUCOSE - Glucose
☐ I_BMP_GLUCOSE_UNITS - Glucose Units
☑ I_BMP_GLUCOSE_LOINC - Glucose LOINC code
☐ I_BMP_BUN - Blood Urea Nitrogen
☐ I_BMP_BUN_UNITS - Blood Urea Nitrogen Units
☑ I_BMP_BUN_LOINC - Blood Urea Nitrogen LOINC code
☐ I_BMP_CREAT - Creatinine [Mass/volume] in Blood
☐ I_BMP_CREAT_UNITS - Creatinine Units
☑ I_BMP_CREAT_LOINC - Creatinine LOINC code
☐ I_BMP_BUN_CREAT_RATIO - Urea nitrogen/Creatinine [Mass Ratio] in Blood
☐ I_BMP_BUN_CREAT_RATIO_UNITS - Urea nitrogen/Creatinine Units
☑ I_BMP_BUN_CREAT_RATIO_LOINC - BUN/Creatinine LOINC code
☐ I_BMP_CALCIUM - Calcium [Mass/volume] in Blood
☐ I_BMP_CALCIUM_UNITS - Calcium Units

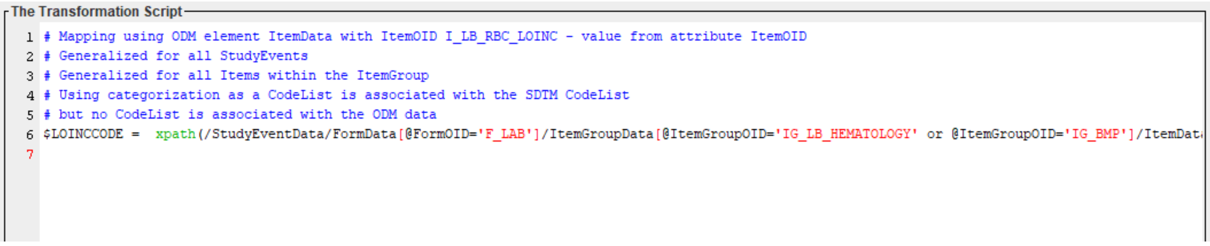
leading to the following mapping script:



SDTM-ETL mapping for LB.LBTESTCD

```
# Mapping using ODM element ItemData with ItemOID I_BMP_GLUCOSE_LOINC
# Generalized for all StudyEvents
# Generalized for all ItemGroups within the Form
# Generalized for all Items within the ItemGroup
# Using categorization as a CodeList is associated with the SDTM CodeList
# but no CodeList is associated with the ODM data
$CODEDVALUE = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/ItemGroupData/ItemData[@ItemOID='I_LB_RBC_LOINC' or @ItemOID='I_LB_WBC_LOINC' or @ItemOID='I_BMP_GLUCO
```

In total, selecting 11 items from the "Laboratory" form. We can now replace "$CODEDVALUE" by e.g. "$LOINCCODE" as that is more clear for what we want to do.



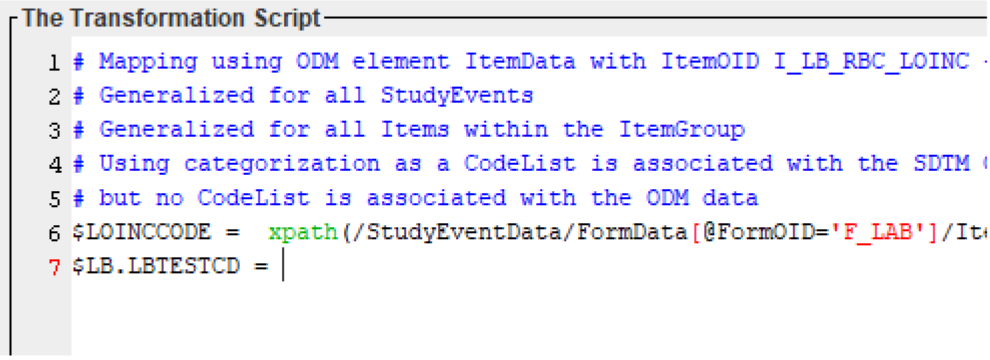
```
# Mapping using ODM element ItemData with ItemOID I_LB_RBC_LOINC - value from attribute ItemOID
# Generalized for all StudyEvents
# Generalized for all Items within the ItemGroup
# Using categorization as a CodeList is associated with the SDTM CodeList
# but no CodeList is associated with the ODM data
$LOINCCODE =  xpath(/StudyEventData/FormData[@FormOID='F_LAB']/ItemGroupData[@ItemGroupOID='IG_LB_HEMATOLOGY' or @ItemGroupOID='IG_BMP']/ItemDat
```

We now do exactly the same (or copy-paste the code) for the cells with LBLOINC, LBTEST, LBMETHOD, LBSPEC, LBMETHOD, as these are the SDTM variables we want to populate automatically starting from the LOINC code.

Let us now go back to the cell for LBTESTCD.

We can now use one of the new functions of SDTM-ETL that will use a RESTful web service[1] to use the mapping between the most popular LOINC coded and SDTM-LB published by CDISC.

We just type the first part of the equation for retrieving the value of LBTESTCD from LBLOINC:



```
# Mapping using ODM element ItemData with ItemOID I_LB_RBC_LOINC
# Generalized for all StudyEvents
# Generalized for all Items within the ItemGroup
# Using categorization as a CodeList is associated with the SDTM
# but no CodeList is associated with the ODM data
$LOINCCODE =  xpath(/StudyEventData/FormData[@FormOID='F_LAB']/It
$LB.LBTESTCD = 
```

In the panel with functions, then look for the button "RESTful WS" (RESTful Web Services). You will find it near the bottom:

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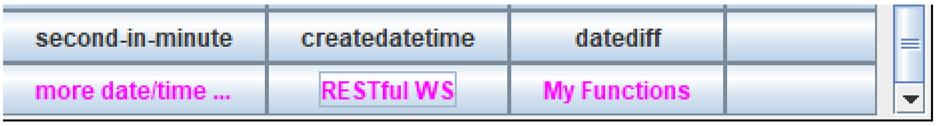
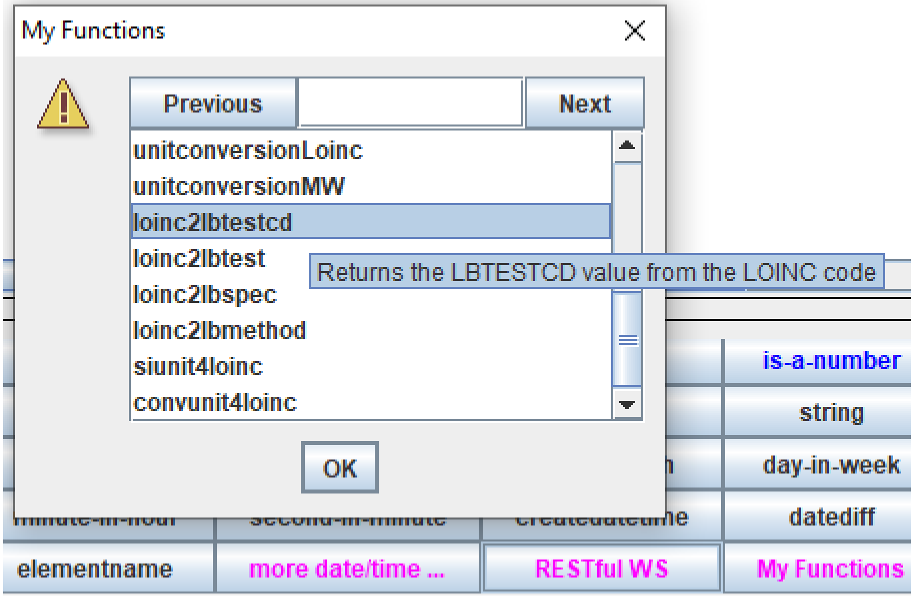
[1] The description of this RESTful web service can be found at: http://xml4pharmaserver.com/WebServices/LOINC2CDISC_webservices.html

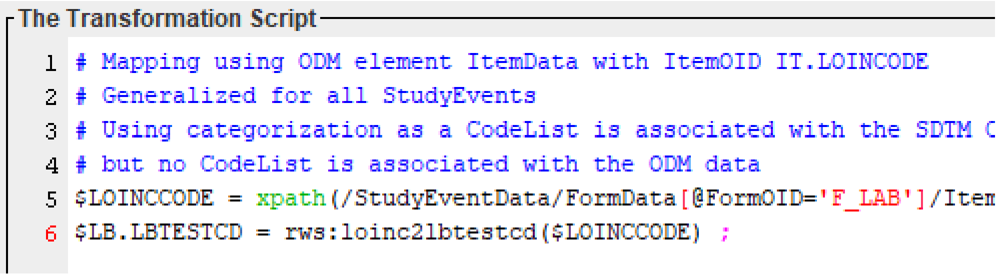


then click the button and then look for the function "loinc2lbtestcd":



Returns the LBTESTCD value from the LOINC code

It takes just one parameter, which is the LOINC code.
Clicking the entry "loinc2lbtestcd" will then add it to the mapping code. One then only needs to add the variable $LOINCCODE as the argument, e.g.:



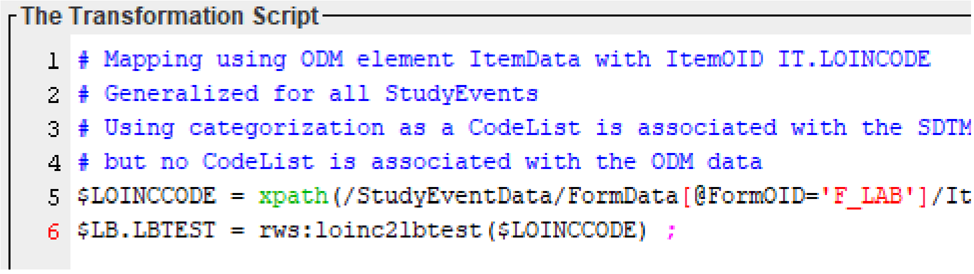
```
# Mapping using ODM element ItemData with ItemOID IT.LOINCCODE
# Generalized for all StudyEvents
# Using categorization as a CodeList is associated with the SDTM C
# but no CodeList is associated with the ODM data
$LOINCCODE = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/Item
$LB.LBTESTCD = rws:loinc2lbtestcd($LOINCCODE) ;
```

Very similar functions also exist for generating the mappings for LBTEST, LBSPEC and LBMETHOD starting from the LOINC code. These are:

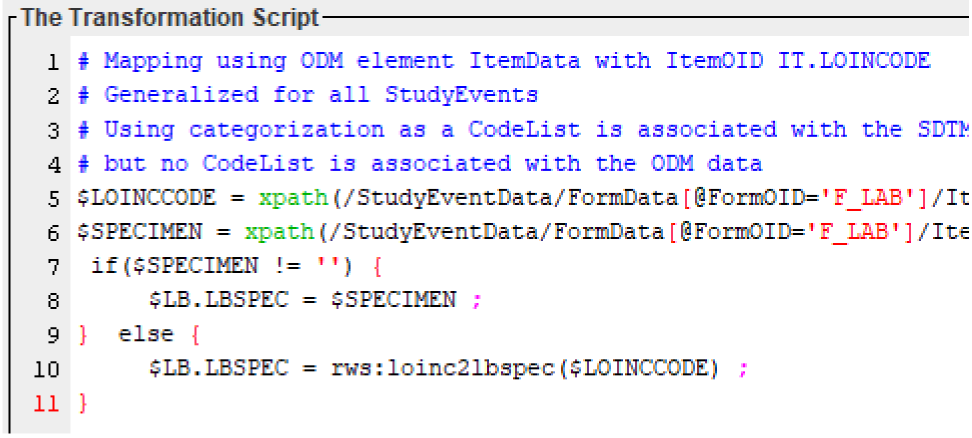
- loinc2lbtest(string loinccode)
- loinc2lbspec(string loinccode)
- loinc2lbmethod(string loinccode)

It is advised to use the methods "loinc2lbspec" and "loinc2lbmethod" only when no explicit value for the specimen and/or analysis method is provided in the source data.

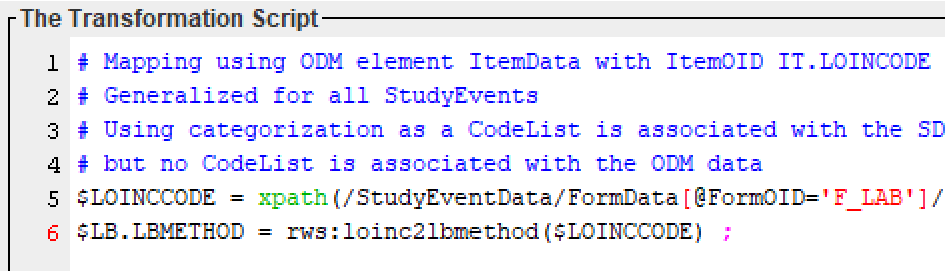
So, in our mapping scripts, we will then e.g. have:



```
# Mapping using ODM element ItemData with ItemOID IT.LOINCODE
# Generalized for all StudyEvents
# Using categorization as a CodeList is associated with the SDTM
# but no CodeList is associated with the ODM data
$LOINCCODE = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/It
$LB.LBTEST = rws:loinc2lbtest($LOINCCODE) ;
```

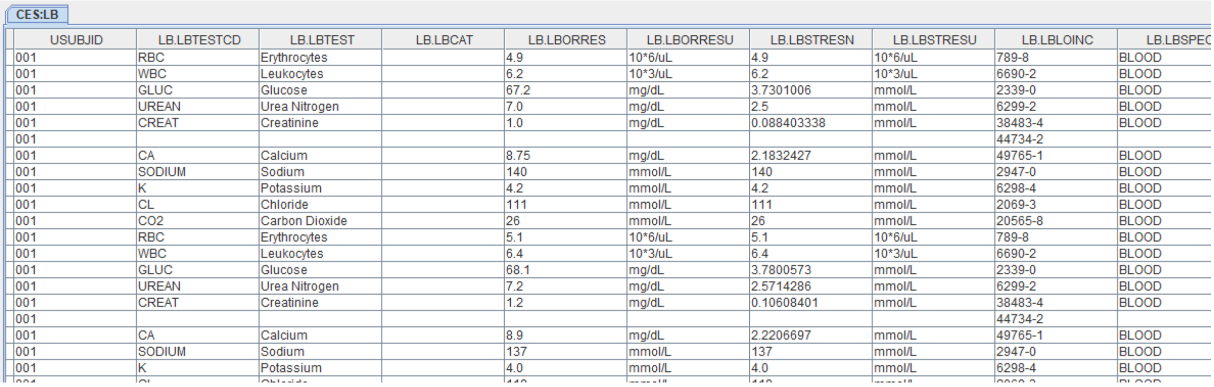


```
# Mapping using ODM element ItemData with ItemOID IT.LOINCODE
# Generalized for all StudyEvents
# Using categorization as a CodeList is associated with the SDTM
# but no CodeList is associated with the ODM data
$LOINCCODE = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/It
$SPECIMEN = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/Ite
 if($SPECIMEN != '') {
     $LB.LBSPEC = $SPECIMEN ;
}  else {
     $LB.LBSPEC = rws:loinc2lbspec($LOINCCODE) ;
}
```



```
# Mapping using ODM element ItemData with ItemOID IT.LOINCODE
# Generalized for all StudyEvents
# Using categorization as a CodeList is associated with the SD
# but no CodeList is associated with the ODM data
$LOINCCODE = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/
$LB.LBMETHOD = rws:loinc2lbmethod($LOINCCODE) ;
```

When we then execute the mappings on the clinical data, we get:



| USUBJID | LB.LBTESTCD | LB.LBTEST | LB.LBCAT | LB.LBORRES | LB.LBORRESU | LB.LBSTRESN | LB.LBSTRESU | LB.LBLOINC | LB.LBSPEC |
|---|---|---|---|---|---|---|---|---|---|
| 001 | RBC | Erythrocytes | | 4.9 | 10*6/uL | 4.9 | 10*6/uL | 789-8 | BLOOD |
| 001 | WBC | Leukocytes | | 6.2 | 10*3/uL | 6.2 | 10*3/uL | 6690-2 | BLOOD |
| 001 | GLUC | Glucose | | 67.2 | mg/dL | 3.7301006 | mmol/L | 2339-0 | BLOOD |
| 001 | UREAN | Urea Nitrogen | | 7.0 | mg/dL | 2.5 | mmol/L | 6299-2 | BLOOD |
| 001 | CREAT | Creatinine | | 1.0 | mg/dL | 0.088403338 | mmol/L | 38483-4 | BLOOD |
| 001 | | | | | | | | 44734-2 | |
| 001 | CA | Calcium | | 8.75 | mg/dL | 2.1832427 | mmol/L | 49765-1 | BLOOD |
| 001 | SODIUM | Sodium | | 140 | mmol/L | 140 | mmol/L | 2947-0 | BLOOD |
| 001 | K | Potassium | | 4.2 | mmol/L | 4.2 | mmol/L | 6298-4 | BLOOD |
| 001 | CL | Chloride | | 111 | mmol/L | 111 | mmol/L | 2069-3 | BLOOD |
| 001 | CO2 | Carbon Dioxide | | 26 | mmol/L | 26 | mmol/L | 20565-8 | BLOOD |
| 001 | RBC | Erythrocytes | | 5.1 | 10*6/uL | 5.1 | 10*6/uL | 789-8 | BLOOD |
| 001 | WBC | Leukocytes | | 6.4 | 10*3/uL | 6.4 | 10*3/uL | 6690-2 | BLOOD |
| 001 | GLUC | Glucose | | 68.1 | mg/dL | 3.7800573 | mmol/L | 2339-0 | BLOOD |
| 001 | UREAN | Urea Nitrogen | | 7.2 | mg/dL | 2.5714286 | mmol/L | 6299-2 | BLOOD |
| 001 | CREAT | Creatinine | | 1.2 | mg/dL | 0.10608401 | mmol/L | 38483-4 | BLOOD |
| 001 | | | | | | | | 44734-2 | |
| 001 | CA | Calcium | | 8.9 | mg/dL | 2.2206697 | mmol/L | 49765-1 | BLOOD |
| 001 | SODIUM | Sodium | | 137 | mmol/L | 137 | mmol/L | 2947-0 | BLOOD |
| 001 | K | Potassium | | 4.0 | mmol/L | 4.0 | mmol/L | 6298-4 | BLOOD |

We see that all the values for LBTESTCD, LBTEST, LBSPEC and LBMETHOD (the latter not visible here) have automatically been populated, except for … LOINC code 44734-2. The reason for this is that this LOINC code is NOT in the list of the 2000+ most popular test codes for which CDISC has published a mapping. This is also the reason that we decided to extend the mapping with several thousands of LOINC codes ourselves[2].

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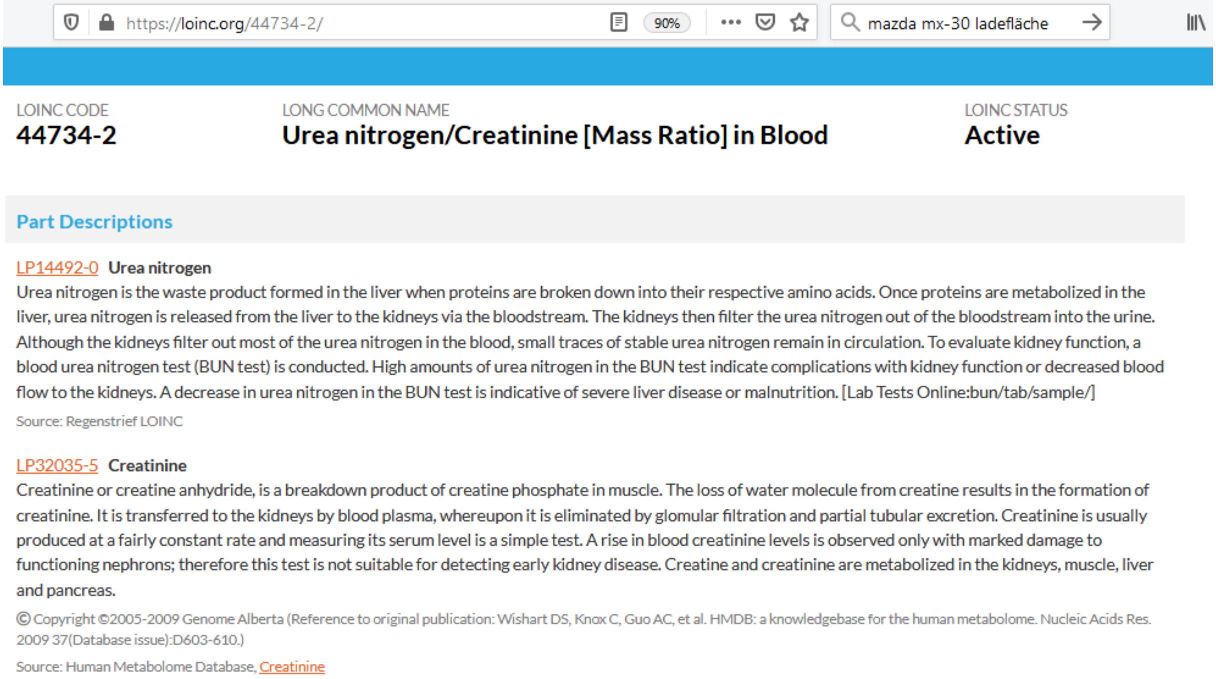
[2] Although we have already mappings for over 9,500 LOINC codes, we are still extending this. All additional mappings will also incorporated into the RESTful web service. You can follow out progress at: http://xml4pharmaserver.com/WebServices/LOINC2CDISC_webservices.html

In case no mapping for a LOINC code can be obtained from the RESTful web service (such as here for LOINC code 44734-2[3]), and the conversion cannot be fully automated, we need to do a little bit of manual work. First, we look up on the LOINC website what the LOINC code 44734-2 means. We find:



LOINC CODE
**44734-2**

LONG COMMON NAME
**Urea nitrogen/Creatinine [Mass Ratio] in Blood**

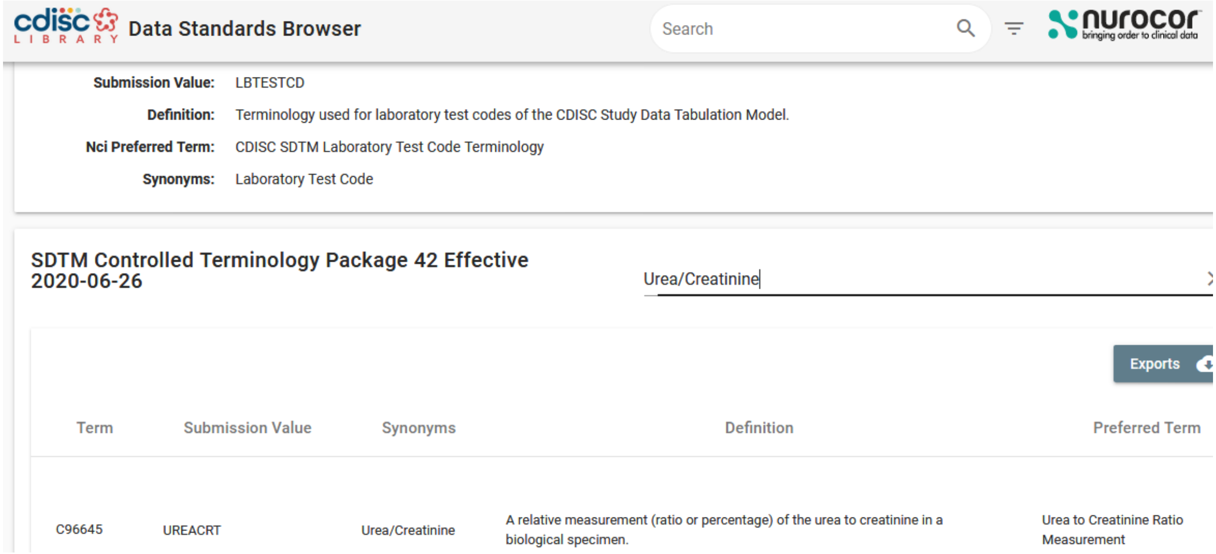
LOINC STATUS
**Active**

**Part Descriptions**

LP14492-0 **Urea nitrogen**
Urea nitrogen is the waste product formed in the liver when proteins are broken down into their respective amino acids. Once proteins are metabolized in the liver, urea nitrogen is released from the liver to the kidneys via the bloodstream. The kidneys then filter the urea nitrogen out of the bloodstream into the urine. Although the kidneys filter out most of the urea nitrogen in the blood, small traces of stable urea nitrogen remain in circulation. To evaluate kidney function, a blood urea nitrogen test (BUN test) is conducted. High amounts of urea nitrogen in the BUN test indicate complications with kidney function or decreased blood flow to the kidneys. A decrease in urea nitrogen in the BUN test is indicative of severe liver disease or malnutrition. [Lab Tests Online:bun/tab/sample/]
Source: Regenstrief LOINC

LP32035-5 **Creatinine**
Creatinine or creatine anhydride, is a breakdown product of creatine phosphate in muscle. The loss of water molecule from creatine results in the formation of creatinine. It is transferred to the kidneys by blood plasma, whereupon it is eliminated by glomular filtration and partial tubular excretion. Creatinine is usually produced at a fairly constant rate and measuring its serum level is a simple test. A rise in blood creatinine levels is observed only with marked damage to functioning nephrons; therefore this test is not suitable for detecting early kidney disease. Creatine and creatinine are metabolized in the kidneys, muscle, liver and pancreas.
© Copyright ©2005-2009 Genome Alberta (Reference to original publication: Wishart DS, Knox C, Guo AC, et al. HMDB: a knowledgebase for the human metabolome. Nucleic Acids Res. 2009 37(Database issue):D603-610.)
Source: Human Metabolome Database, Creatinine

Ok, this looks to be a pretty easy one.
We then look up whether there is an entry for this in the CDISC Controlled Terminology. There are several ways to do it (e.g. by searching in the CDISC-CT Excel worksheet), but using the CDISC Library browser is of course more elegant:



**Submission Value:** LBTESTCD
**Definition:** Terminology used for laboratory test codes of the CDISC Study Data Tabulation Model.
**Nci Preferred Term:** CDISC SDTM Laboratory Test Code Terminology
**Synonyms:** Laboratory Test Code

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Urea/Creatinine

| Term | Submission Value | Synonyms | Definition | Preferred Term |
|---|---|---|---|---|
| C96645 | UREACRT | Urea/Creatinine | A relative measurement (ratio or percentage) of the urea to creatinine in a biological specimen. | Urea to Creatinine Ratio Measurement |

Finding that the LBTESTCD for this is "UREACRT". Similarly, we find that the corresponding LBTEST is "Urea/Creatinine".

We can now incorporate this information in our mapping script (here e.g. for LBTESTCD) using an if-statement:

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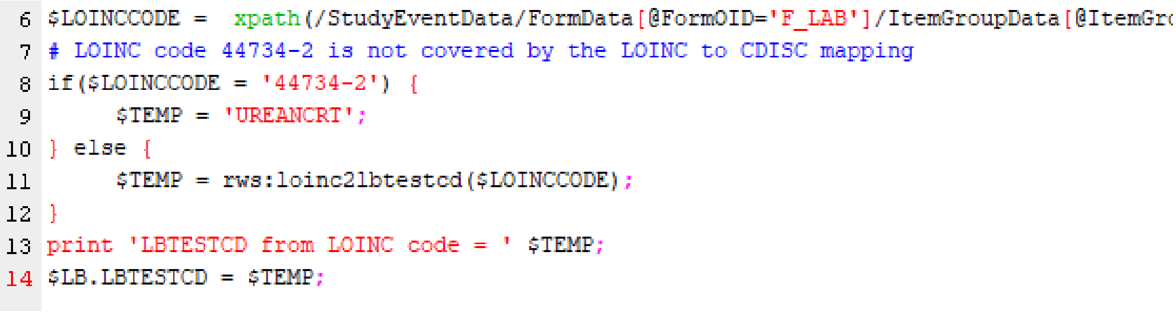
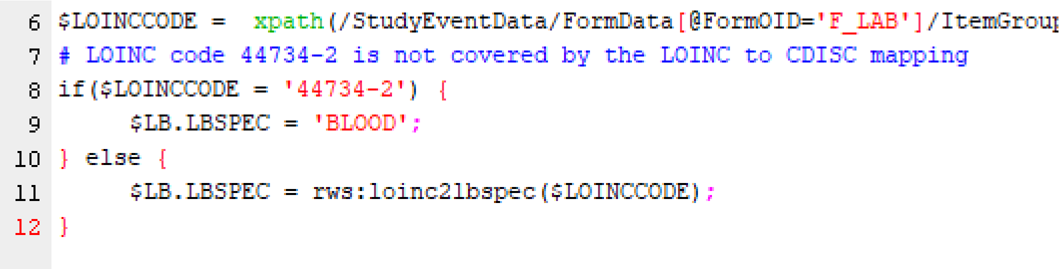
3 The code 44734-2, with its mappings, has in the mean time being added to the RESTful web service.



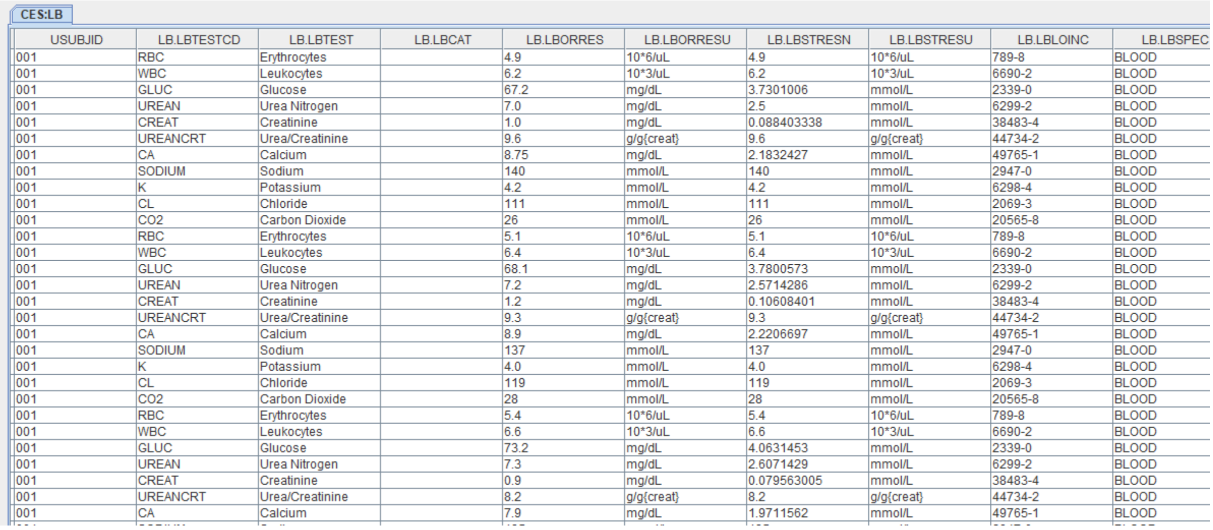
```
$LOINCCODE =  xpath(/StudyEventData/FormData[@FormOID='F_LAB']/ItemGroupData[@ItemGr
# LOINC code 44734-2 is not covered by the LOINC to CDISC mapping
if($LOINCCODE = '44734-2') {
     $TEMP = 'UREANCRT';
} else {
     $TEMP = rws:loinc2lbtestcd($LOINCCODE);
}
print 'LBTESTCD from LOINC code = ' $TEMP;
$LB.LBTESTCD = $TEMP;
```

and similar for LBSPEC:



```
$LOINCCODE =  xpath(/StudyEventData/FormData[@FormOID='F_LAB']/ItemGrou
# LOINC code 44734-2 is not covered by the LOINC to CDISC mapping
if($LOINCCODE = '44734-2') {
     $LB.LBSPEC = 'BLOOD';
} else {
     $LB.LBSPEC = rws:loinc2lbspec($LOINCCODE);
}
```

Then executing the mappings again on the clinical data leads to:



| USUBJID | LB.LBTESTCD | LB.LBTEST | LB.LBCAT | LB.LBORRES | LB.LBORRESU | LB.LBSTRESN | LB.LBSTRESU | LB.LBLOINC | LB.LBSPEC |
|---|---|---|---|---|---|---|---|---|---|
| 001 | RBC | Erythrocytes |  | 4.9 | 10*6/uL | 4.9 | 10*6/uL | 789-8 | BLOOD |
| 001 | WBC | Leukocytes |  | 6.2 | 10*3/uL | 6.2 | 10*3/uL | 6690-2 | BLOOD |
| 001 | GLUC | Glucose |  | 67.2 | mg/dL | 3.7301006 | mmol/L | 2339-0 | BLOOD |
| 001 | UREAN | Urea Nitrogen |  | 7.0 | mg/dL | 2.5 | mmol/L | 6299-2 | BLOOD |
| 001 | CREAT | Creatinine |  | 1.0 | mg/dL | 0.088403338 | mmol/L | 38483-4 | BLOOD |
| 001 | UREANCRT | Urea/Creatinine |  | 9.6 | g/g{creat} | 9.6 | g/g{creat} | 44734-2 | BLOOD |
| 001 | CA | Calcium |  | 8.75 | mg/dL | 2.1832427 | mmol/L | 49765-1 | BLOOD |
| 001 | SODIUM | Sodium |  | 140 | mmol/L | 140 | mmol/L | 2947-0 | BLOOD |
| 001 | K | Potassium |  | 4.2 | mmol/L | 4.2 | mmol/L | 6298-4 | BLOOD |
| 001 | CL | Chloride |  | 111 | mmol/L | 111 | mmol/L | 2069-3 | BLOOD |
| 001 | CO2 | Carbon Dioxide |  | 26 | mmol/L | 26 | mmol/L | 20565-8 | BLOOD |
| 001 | RBC | Erythrocytes |  | 5.1 | 10*6/uL | 5.1 | 10*6/uL | 789-8 | BLOOD |
| 001 | WBC | Leukocytes |  | 6.4 | 10*3/uL | 6.4 | 10*3/uL | 6690-2 | BLOOD |
| 001 | GLUC | Glucose |  | 68.1 | mg/dL | 3.7800573 | mmol/L | 2339-0 | BLOOD |
| 001 | UREAN | Urea Nitrogen |  | 7.2 | mg/dL | 2.5714286 | mmol/L | 6299-2 | BLOOD |
| 001 | CREAT | Creatinine |  | 1.2 | mg/dL | 0.10608401 | mmol/L | 38483-4 | BLOOD |
| 001 | UREANCRT | Urea/Creatinine |  | 9.3 | g/g{creat} | 9.3 | g/g{creat} | 44734-2 | BLOOD |
| 001 | CA | Calcium |  | 8.9 | mg/dL | 2.2206697 | mmol/L | 49765-1 | BLOOD |
| 001 | SODIUM | Sodium |  | 137 | mmol/L | 137 | mmol/L | 2947-0 | BLOOD |
| 001 | K | Potassium |  | 4.0 | mmol/L | 4.0 | mmol/L | 6298-4 | BLOOD |
| 001 | CL | Chloride |  | 119 | mmol/L | 119 | mmol/L | 2069-3 | BLOOD |
| 001 | CO2 | Carbon Dioxide |  | 28 | mmol/L | 28 | mmol/L | 20565-8 | BLOOD |
| 001 | RBC | Erythrocytes |  | 5.4 | 10*6/uL | 5.4 | 10*6/uL | 789-8 | BLOOD |
| 001 | WBC | Leukocytes |  | 6.6 | 10*3/uL | 6.6 | 10*3/uL | 6690-2 | BLOOD |
| 001 | GLUC | Glucose |  | 73.2 | mg/dL | 4.0631453 | mmol/L | 2339-0 | BLOOD |
| 001 | UREAN | Urea Nitrogen |  | 7.3 | mg/dL | 2.6071429 | mmol/L | 6299-2 | BLOOD |
| 001 | CREAT | Creatinine |  | 0.9 | mg/dL | 0.079563005 | mmol/L | 38483-4 | BLOOD |
| 001 | UREANCRT | Urea/Creatinine |  | 8.2 | g/g{creat} | 8.2 | g/g{creat} | 44734-2 | BLOOD |
| 001 | CA | Calcium |  | 7.9 | mg/dL | 1.9711562 | mmol/L | 49765-1 | BLOOD |

Imagine that we did not have the LOINC code, and needed to puzzle out about suitable values of LBTESTCD, LBTEST, LBSPEC, LBMETHOD, … ourselves …! That is what I mean that LOINC is a blessing rather than a burden!

In the above screenshot with results, we also see that (surprise, surprise, …) all values have been standardized to SI units in LBSTRESN/LBSTRESU. How this was fully automated is explained in the tutorial "Performing Unit Conversions in SDTM-ETL".

## Generic mapping functions

One can also use the function "loinc2sdtmlb" that is taking two arguments:

***loinc2sdtmlb***(string loinccode, string sdtmvarname) where the second argument is the SDTM variable name (which can also be a Non-Standard variable, but then need to be prefixed by "SUPPLB.").

For example:

$LB.LBTESTCD = loinc2sdtmlb('1751-7', 'LBTESTCD');

which is equivalent to using the function rws:loinc2lbtestcd('1751-7').

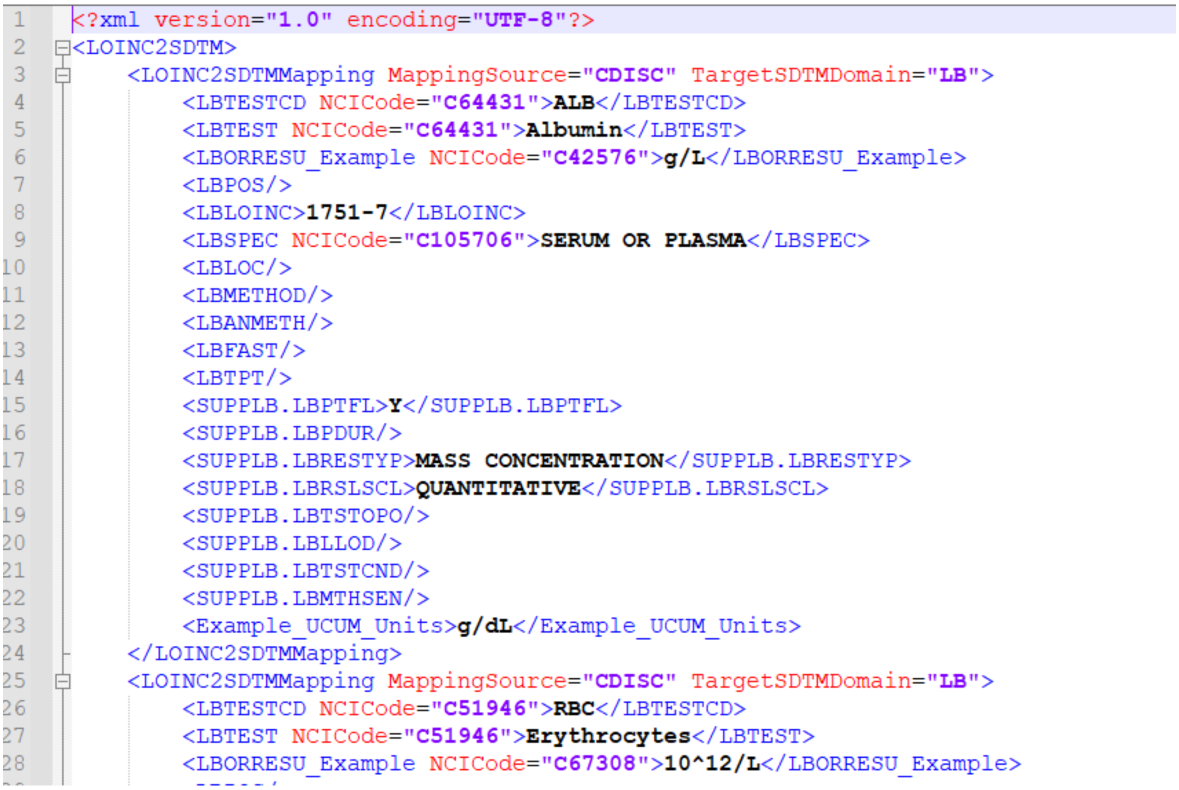
The extra advantage of the current function "loinc2sdtmlb" is that it can also be used for the new "standard non-standard" variables (NSVs) such as "SUPPLB.LBRSSCL" (result scale).

The second argument is always the SDTM variable name for which the value need to be retrieved for. It also contains a number of "Supplemental Qualifier" variables. Here is a more complete list.

| | | | | | |
|---|---|---|---|---|---|
| LBTESTCD (test code) | LBTEST (test name) | LBSPEC (location) | LBMETHOD (method) | LBTPT (time point) | LBANMETH (analysis method) |
| LBPOS (position) | LBLOC (location) | LBFAST (fasting status) | SUPPLB. LBRESTYP (result type) | SUPPLB. LBRSSCL (result scale) | SUPPLB. LBTSTOPO (test operational objective) |
| SUPPLB. LBLLOD (lower limit of detection) | SUPPLB. LBTSTCND (test condition) | SUPPLB. MTHSEN (method sensitivity) | SUPPLB. LBPTFL (point in time flag) | SUPPLB. LBPDUR (planned duration) | |

## Re-using existing mappings from an XML file ("caching")

Although the RESTful web service is fast, when there are thousands of lab data points, the generation of LBTESTCD, LBTEST, LBSPEC etc. using the above mentioned functions may still take considerable time.
In the folder "CDISC_CT" you will therefore find an XML file named "LOINC2SDTM_cached.xml" containing a few sample mappings. For example:



```
<?xml version="1.0" encoding="UTF-8"?>
<LOINC2SDTM>
    <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">
        <LBTESTCD NCICode="C64431">ALB</LBTESTCD>
        <LBTEST NCICode="C64431">Albumin</LBTEST>
        <LBORRESU_Example NCICode="C42576">g/L</LBORRESU_Example>
        <LBPOS/>
        <LBLOINC>1751-7</LBLOINC>
        <LBSPEC NCICode="C105706">SERUM OR PLASMA</LBSPEC>
        <LBLOC/>
        <LBMETHOD/>
        <LBANMETH/>
        <LBFAST/>
        <LBTPT/>
        <SUPPLB.LBPTFL>Y</SUPPLB.LBPTFL>
        <SUPPLB.LBPDUR/>
        <SUPPLB.LBRESTYP>MASS CONCENTRATION</SUPPLB.LBRESTYP>
        <SUPPLB.LBRSLSCL>QUANTITATIVE</SUPPLB.LBRSLSCL>
        <SUPPLB.LBTSTOPO/>
        <SUPPLB.LBLLOD/>
        <SUPPLB.LBTSTCND/>
        <SUPPLB.LBMTHSEN/>
        <Example_UCUM_Units>g/dL</Example_UCUM_Units>
    </LOINC2SDTMMapping>
    <LOINC2SDTMMapping MappingSource="CDISC" TargetSDTMDomain="LB">
        <LBTESTCD NCICode="C51946">RBC</LBTESTCD>
        <LBTEST NCICode="C51946">Erythrocytes</LBTEST>
        <LBORRESU_Example NCICode="C67308">10^12/L</LBORRESU_Example>
```

If there are LOINC codes for which you have many data points, you may add their mappings here as XML. The easiest way to do so is by copy-paste by using the RESTful web service "LOINC to CDISC-SDTM-LB Extended Mapping" described at: [http://xml4pharmaserver.com/WebServices/LOINC2CDISC_webservices.html#loinc2lb_extended](http://xml4pharmaserver.com/WebServices/LOINC2CDISC_webservices.html#loinc2lb_extended), and copying the obtained XML (starting from the LOINC2SDTMMapping tag) to the contents of the file "LOINC2SDTM_cached.xml".

The "generic" function "loinc2sdtmlb" will then first try to pick up the requested information from the file "LOINC2SDTM_cached.xml" and only use the RESTful web service when it cannot find the information in the XML file.

You are of course free to extend the file "LOINC2SDTM_cached.xml" with other mappings, including your own mappings when necessary.

Also, if you find a LOINC code that you need and that is not covered by the RESTful web service, please let us know and we will develop the mapping and add it.

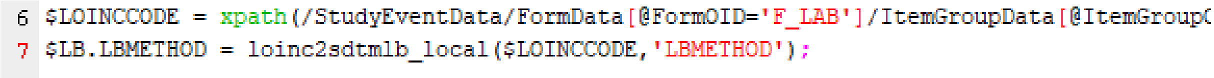
## Creating the mapping without using a RESTful web service using the CDISC CSV file

In the ultimate case that one cannot use the RESTful web service, there is a second function. It is using the CSV file, named "LOINC_to_LB_Mapping_Document_FINAL.csv" that was published by CDISC and can be found in the folder "CDISC-CT".
Using this function works nicely as well, but has two disadvantages:

- it is considerably slower, as the whole file needs to be parsed at each function call (the RESTful web service is 5-10 times faster, as the underlying database is indexed)
- the mappings are limited to those published by CDISC, which is far from sufficient (only 2000+ LOINC codes).

The function is named "loinc2sdtmlb_local" and has the same two arguments as the function "loinc2sdtmlb". The results are the same as for the "loinc2sdtmlb" are identical, except for that the "extended mappings" (developed by us) are of course not covered.

For example, for LBMETHOD:



```
$LOINCCODE = xpath(/StudyEventData/FormData[@FormOID='F_LAB']/ItemGroupData[@ItemGroup
$LB.LBMETHOD = loinc2sdtmlb_local($LOINCCODE,'LBMETHOD');
```

## Further work

We have also developed mappings for LOINC codes for COVID-19 tests to MB (Microbiology). A RESTful web service is also available for these mappings (see http://xml4pharmaserver.com/WebServices/LOINC2CDISC_webservices.html#loinccorona2mb) but we have not added a function for this mapping yet to SDTM-ETL. The same applies for a mapping using VSLOINC (LOINC code for vital signs) and the SDTM-VS variables. Other mappings that are still in the mapping phase are for EG (ECG Test Results) and QS (Questionnaires). More may follow.