Change request

Lab Test

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Project	General importance	**Contact person**	DCC
Dataset release	2024.1	**Consulted expert**	

1 Change request input / rationale

The concept Lab Test in its current form is limited to LOINC-encoded laboratory tests, i.e. primarily tests from clinical chemistry, haematology etc. It falls short to cover tests of other areas of interest, e.g., microbiology or sequencing.

In addition, Lab Test is until now reused in the Lab Result which mixes many information elements that can be better represented in different concepts.

In general, the lab concepts do not follow the guiding principles defined in SPHN where concepts are defined from a process to a result. The Lab Test should be adapted to include the result and not the result including the lab test. The rationale is that a lab test performed in the context of a specific lab test event will hold one or multiple results. This enables the extensibility of a test where other elements come into play (e.g. tested substance effect on a sample) for which we would get one result for each tested element.

The reorganisation of concepts for representing Lab-related events enable a cleaner representation and connectivity of the different elements: The new concept ‘Lab Test Event holds metadata about a test event (analysis datetime, sample, report datetime and order number). The Lab Test is reused in the Lab Test Event concept: each Lab Test Event can have a series of lab tests being performed, on the same sample. The Lab Test holds the result of the test performed.

The ‘Lab Result’ was previously holding the Reference Range information but since this concept is becoming generic, the reference range can’t belong to this concept. There are additional information that needs to be taken into account when defining a reference range for a lab test. This is tackled in a new concept document: Reference Determination.

Proposed changes:

1. broaden the scope of standard for the composedOf code: add SNOMED CT in addition to LOINC to overcome the restriction to (clinical) laboratory tests
2. add ‘result’ as a composedOf of Lab Test for a knowledge-oriented representation of the data
3. add lab test as a composedOf of Lab Test Event

2 Comparison to other standards/data models

2.1 UMLS Semantic Network

The UMLS-term “Laboratory Procedure” (Version 2023AA; Unique Identifier: T059; Tree Number: B1.3.1.1) corresponds closest to “Lab Test”. It is defined as “A procedure, method, or technique used to determine the composition, quantity, or concentration of a specimen, and which is carried out in a clinical laboratory. Included here are procedures which measure the times and rates of reactions.”.

3 Change content

3.1 Currently released concept

Concept or concept compositions or inherited	General concept name	General description	Contextualized concept name	Contextualized description	Type	Standard	Value set or subset	Meaning binding
concept	Lab Test	lab test information including information elements provided by LOINC, instrument and test kit	Lab Test	lab test information including information elements provided by LOINC, instrument and test kit				SNOMED CT: 15220000 |Laboratory test (procedure)|
composedOf	code	code, name, coding system and version describing the concept	code	code, name, coding system and version of the lab test	Code	LOINC		
composedOf	instrument	instrument used for the concept	instrument	instrument used to assess medical laboratory samples	Lab Analyzer			
composedOf	test kit	test kit used for the concept	test kit	test kit used to assess medical laboratory samples	Lab Analyzer			

3.2 Proposed new concept

Concept or concept compositions or inherited	General concept name	General description	Contextualized concept name	Contextualized description	Type	Standard	Value set or subset	Meaning binding	Cardinality for composed Of
concept	Lab Test	scientific laboratory test performed to analyze a sample with a given equipment and leading to specific results	Lab Test	scientific laboratory test performed to analyze a sample with a given equipment and leading to specific results				SNOMED CT: 15220000 |Laboratory test (procedure)|	
composedOf	code	coded information specifying the concept	lab test code	coded information specifying the lab test performed	Code	LOINC, SNOMED CT			1:1
composedOf	instrument	instrument used for the concept	lab test instrument	instrument used to assess medical laboratory samples	Lab Analyzer				0:1
composedOf	test kit	test kit used for the concept	lab test test kit	test kit used to assess medical laboratory samples	Lab Analyzer				0:1
composedOf	result	evaluation outcome associated to the concept	lab test result	transmitted laboratory analysis results for an analyzed sample in a specific lab test	Result				1:n

General concept name	cardinality for concept to Administrative Case	cardinality for concept to Data Provider	cardinality for Subject Pseudo Identifier	cardinality for Source System
Lab Test				

4 Pros and cons

4.1 Advantages

Multiple lab tests done on a single sample in the context of a Lab Test Event are bundled together. Each test gets its own result.
The lab concepts follow a natural representation of the process followed in a laboratory setting: for a given sample, a lab test event or protocol is put in place with a list of tests to be performed, each test leading to a result.

4.2 Disadvantages

The structure changes, we now go from the process (Lab Test Event) to the result (Lab Test which holds the Result).

5 Impact on SPHN Dataset

Following the process-oriented view, the Lab Test will now hold the Result and not the other way around.
The Lab Test is reused in the new concept Lab Test Event. The Lab Result is now deprecated.
The Reference Determination concept will connect and hold information about Reference Value and/or Reference Range that applies in specific contexts.

6 Discussion

It is difficult to envision all the different tests to be dealt with, but the concept now allows an easy extension of the scope if required in the future. It is possible to add metadata that are specific to a test, such as substances tested, genetic resistances, done on a sample without having the need to instantiate for each test a lab test event. The lab test logically holds the metadata describing the test and its specific characteristics.

7 Example

Lab Test:
code: LOINC:2951-2 |Sodium [Moles/volume] in Serum or Plasma|
instrument: 04015630930845 |cobas 8000 c 702 Module|
test kit: 08430215011546 |Sodium Electrode|

result:
quantity:
value: 135.0
unit: mmol/L
code: -
string value: -

Lab Test:
code: LOINC:26449-9 |Eosinophils [#/volume] in Blood|
instrument: 04987562424221 |Automated Hematology Analyzer XN series XN-20|
test kit: -
result:
quantity:
value: 0.07
unit: 10*3/uL
code: -
string value: -

Lab Test:
code: 104178000 |Bacterial culture (procedure)|
instrument: -
test kit: -
result:
quantity:
value: 10000
unit: {germs}/mL
code: -