Change request

Lab Result

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Dataset release	2022.1	Consulted expert	-

1 Change request input / rationale

The *Lab Result* concept is under review since additional metadata regarding lab tests are to be added (see documentation for new *Lab Test* concept). Further, there has been a request to improve the description of the *Lab Result* concept and to improve the representation of normal ranges. The present change request document reflects all changes proposed to the *Lab Result* concept.

2 Comparison to other standards/data models

Comparisons to other standards and data models are described in the documentation of the new concepts *Lab Test* and *Reference Range*.

3 Change content

3.1 Currently released concept

Concept name	Description	Type	Standard	Meaning binding SNOMED CT	Meaning binding LOINC	Additional information
Lab Result	laboratory analysis transmitted			118246004 |Laboratory test finding (navigational concept)|		
unstructured lab result	comments up to full report	string				
lab test	code of the lab test	Code	LOINC	15220000 |Laboratory test (procedure)|		use for standard laboratory tests (not for microbiology or pathology)
biosample	any material sample taken from a biological entity for testing, diagnostic, propagation, treatment or research purposes	Biosample				
analysis datetime	datetime the analysis takes place	temporal			45353-0 Date of analysis of unspecified specimen	
value	result of the laboratory test	string				
unit	unit of the result	Unit				
normal range	normal range for population	string		260395002 |Normal range (qualifier value)|	19146-0 Reference lab test results	

3.2 Proposed new concept

Contextualized concept name	Description	Type	Standard	Meaning binding SNOMED CT	Meaning binding LOINC	Additional information
Lab Result	transmitted laboratory analysis results for a specific biosample analyzed			118246004 |Laboratory test finding (navigational concept)|		
quantitative result	value and unit of the quantitative laboratory test result	Quantity				
qualitative result	qualitative laboratory test results, e.g. positive, negative	string				
qualitative result code	code, name, coding system and version of the qualitative test result	Code				
comment	comment or remark to the laboratory test result	string				
lab test	lab test information including information elements provided by LOINC, instrument and test kit	Lab Test				use for standard laboratory tests (not for microbiology or pathology)
biosample	any material sample taken from a biological entity for testing, diagnostic, propagation, treatment or research purposes	Biosample				
report datetime	datetime the lab reported the laboratory test result	temporal				
normal range	normal range for population	Reference Range		260395002 |Normal range (qualifier value)|		

4 Pros and cons

4.1 Advantages

- Quantitative test results can be represented as numeric values instead of free text (string)
- Comparators, such as >= or < are available via the Quantity concept and facilitate representing non-exact quantitative results
- Changing from analysis datetime to report datetime allows more accurate description of the acutal data delivered by the data providers
- Normal ranges represented with type Reference Range allow distinction between lower limit of normal (LLN) and upper limit of normal (ULN) and thus facilitate deriving if a certain quantitative result is lower than the LLN or higher than the ULN

4.2 Disadvantages

- None.

5 Discussion

Different types of results and their types
There is a need to represent quantitative test results, qualitative test results and comments separately. Qualitative test results should have a coded value set. However, it is not clear yet which is the appropriate semantic stancard for that. Therefore, there are two composedOfs “qualitative result” and “qualitative result code” giving the opportunity to deliver the result either as a code (e.g. SNOMED CT 10828004 |Positive (qualifier value)| or as a string (positive). It is planned to publish a value set once it has been assessed which is the appropriate semantic standard and which values need to be coverd.

Change from analysis datetime to report datetime
Not all data providers are able to deliver the analysis datetime, some data providers only have the validation datetime (datetime at which the sample was validated after being analysed by the laboratory) available. There are other time stamps that are available but the overview of all possibilities and a detailed assessment of what is needed for research has not yet been performed. With regard to data analysis in relation to other events during the patient journey in the healtcare system, such as treatment start datetimes the important date information is the date the clinical team has been aware of the laboratory test result. Therefore, the analysis datetime has been changed to the report datetime.