

The SNOMED CT Encoded Unified Test List (UTL)

Editorial Principles v1.6

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Revision History

Version	Date	Summary of Changes
0.5	08/11/2019	First draft for review
1.0	25/11/2020	V0.5 formally approved by the PSGB as a live document amended according to need
1.1	26/01/2021	Updates to align with UTL v0.6.0
1.2	17/01/2021	Updates to align with UTL v0.7.0 – Qualitative interpretation UTL pattern for beta review
1.3	17/05/2021	Updates to align with UTL v0.8.0 – Requestable term pattern for beta review, qualitative result pattern for beta review, changes to Human-Readable (HR) release internal structure
1.4	11/08/2021	Updates to align with UTL v0.9.0 – microbiology microscopy, culture and antigenic tests
1.5	05/10/2021	Updates to align with UTL v1.0.0
1.6	10/11/2021	Updates to align with December 2021 Pathology Beta Preview Release, including information on the use of 'Inheres In' and 'Direct Site' attributes in the new section 2.3

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Editorial Principles for the SNOMED CT Encoded Unified Test List (UTL) for the December 2021 Pathology Beta Preview Release

1. Introduction

This document describes the format for clinical terming of clinical laboratory results in the UK based on specific attributes and values that have equivalence across ontologies. It supports a templating approach to content development. It does this in a way that conforms with SNOMED CT editorial principles and maximises interoperability. It will remain a dynamic document, keeping up with the latest developments in international editorial thinking. The guide is framed by the SNOMED CT concept model for observable entities set out by SNOMED International. Guidance for laboratory observables may vary from that for other types of observable such as functional observables.

The guide pertains only to content within the UK Edition of SNOMED CT and is dependent on use and licensing requirements described in the documentation that accompanies releases of that Edition. The formal name 'SNOMED CT®' is abbreviated to 'SNOMED' throughout for readability; laboratory is often shortened to 'lab'.

The guide seeks to represent in SNOMED in a faithful, logical way the laboratory medicine knowledge that is defined by subject domain experts but it is not intended as a specialist guide to laboratory medicine as such.

Feedback on the product, individual representations and on these Editorial Principles is welcomed via email at: pathologyanddiagnostics@nhs.net

1.1. Antecedent laboratory code sets (Read/PBCL)

It is impossible to set out editorial guidance for a developing product without noting the long-standing and continuing daily volume flows of lab results reporting to General Practices in the UK using the Pathology Bounded Code List (PBCL) and EDIFACT messaging. This highly successful and internationally noteworthy product is however based on ageing Read V2 and Read V3 (CTV3) coding that has now been superseded by SNOMED. The UTL is the projected successor to the PBCL alongside the anticipated replacement of the carrier EDIFACT messaging standard by HL7 FHIR profiles. The UTL acknowledges the intellectual work done in the interim National Laboratory Medicine Catalogue (NLMC) to regularise content format and the pathology 'requestable/reportable' (requests/results) model. That work informs the current iteration of laboratory medicine report standards.

1.2. International Reference Standards

SNOMED CT is the recognised NHS standard for clinical data entry in electronic health and care records. The NHS decided in 2017/18 to pursue the development of a lab results PBCL replacement solution within SNOMED CT while recognising the other reference lists that exist with the potential to be mapped to it in the future.

The Nomenclature, Properties and Units (NPU) test lists derived from IUPAC standards and in use in other European countries provides a useful cross-reference, while more general IUPAC metrologic principles are also used to inform the product.

1.3. Ownership

This editorial guidance has been developed by the National Pathology and Diagnostics at NHS Digital. National Pathology and Diagnostics is part of IReS (UK Information Representation Services).

The governance of the product will change over time but as a product in development it is managed by the National Pathology and Diagnostics team. The guidance, in defining a SNOMED product, supplements or extends (without contradicting) the Editorial Guidelines published for the bi-annual UK Edition of SNOMED CT (which in turn supplement those published by SNOMED International). The UK SNOMED CT Editorial Principles are managed by the SNOMED CT Edition (Editorial) Committee.

1.4. Product Status

Following approval of the DAPB4017 [Pathology Test and Results Information Standard](#) by the Data Alliance Partnership Board in August the Unified Test List (UTL) was published as the SNOMED CT UK Pathology Extension as part of the SNOMED CT UK Clinical Edition 32.5.0 on 6th October 2021.

UTL is now formally part of SNOMED CT UK with a status of 'Draft For Trial Use' as defined in the [IReS Terminology Product Development Lifecycle](#) (external PDF). Future Live releases of the UTL will be aligned to the appropriate SNOMED CT UK Clinical Edition.

2. Scope and Structure

2.1. Scoping the Coverage of the Principles

If the value/result/answer to a laboratory test and observation is categorical or numeric, that answer should be represented in a report artefact by a SNOMED observable entity concept with an attached categorical or numeric value along with units of measurement, reference ranges, test preconditions, alerts, patient and sample identifier etc.

It is proposed for this set of editorial principles that the following framework is used to determine scope of SNOMED coding and modelling. This may change over time.

IMPORTANT

The description below of the relationship between requestable and reportable SNOMED codes represents a significant change from the provisional guidance published in earlier releases of UTL. v0.8.0 of UTL is the first release that includes requestable items and has been developed in line with the new design guidance. Users should ensure they are familiar with the updated principles below and understand the implications for their clinical and IT systems environment.

A single lab test with a single result will use a SNOMED procedure code for the request and a SNOMED coded observable entity concept for the reportable result. Requestable procedures will typically be at a higher level of abstraction than reportable results, in current practice requests rarely specify a required *Property* (e.g. molar concentration) or *Method* (e.g. by a specific dye binding method) but *Property* and (if required) *Method* will be included in the result code.

The name *Test Set* has been adopted as a general term describing a single requestable code that will initiate multiple component or sub-tests in the Laboratory, and thus produce multiple results. The term Test Set encompasses request types that are called panel, profile, battery etc., plus screen or dynamic function test requests. Test Set requests will use a SNOMED procedure code. The results for a Test Set will comprise multiple SNOMED coded observable entity concepts, one for each result in the panel. Alternatively, a narrative or free

text report, possibly including SNOMED clinical findings codes may be sent as a single result of the test but that is out of scope for these principles defining observable entities as lab test result components.

2.2. The Structure of SNOMED Descriptions

2.2.1 Reportable Concepts

The guidance describes the detail of standardised term/description forms for Fully Specified Names (FSN), Preferred Terms (PT) and synonymous terms. The aim is to have terms from which the related model attribute/value pairs can be deduced, such that is possible to both build terms from SNOMED code expressions and to build the expressions from the terms in a consistent and machine and human readable form. The terms should conform to the concept model and thereby they will conform to the attribute and qualifier value constraints of the model.

The triad of **Property-OF-Thing-IN-Specimen** with the complementing addition of **Method** form the core of proposed UK modelling of reportable concepts at present. These are a subset of the full range of possible attributes that can be defined. Further testing is needed of utility, of auto-classification outcomes and of alignment with planned SNOMED International observables model expansion; other attributes may be introduced where appropriate (for example, 'Relative To' for ratios of one substance to another). The Property/Thing/Specimen triad relate to SNOMED mostly as follows:

Thing (substance, entity or process):	246093002 Component (attribute)
Property:	370130000 Property (attribute)
Specimen:	704319004 Inheres in (attribute) 704327008 Direct site (attribute)
Technique (or method or assay used):	246501002 Technique (attribute)

Example:

Sodium	molar concentration	[IN] serum
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Property: molar concentration

Component (thing/substance): sodium

Inheres in (substance): serum

Direct Site (specimen): serum

In SNOMED the focus of the concept is the property being measured. Hence the FSN word ordering of 'Property', 'Component', 'Inheres In/Direct Site'. However, laboratory specialists would usually describe the thing being measured first when listing tests and this might be expected catalogue behaviour. This latter form is reflected in the Preferred Term that users normally see in systems.

Note that this core set of parts of the term does not preclude the defining or inheritance of other permitted attribute/value pairs in the observables model as it develops. While 'Fully Defined' content within the model is

the long term aim it is anticipated that significant volumes of 'Primitive' (i.e. not fully defined) concepts will remain for some time yet.

2.2.2 Requestable Concepts

The decision has been made in the UK to model requestable items as concepts of type *Procedure*. This makes it possible to differentiate codes intended for request items from those intended report items directly from of the SNOMED type hierarchy.

The distinction between procedure (requestable) and observable entity (reportable) concepts has little impact on the descriptive terms created for requestable items. Of more significance is the specificity of the terms designed for requesting.

UTL reportable terms are quite specific, more so than their historic equivalents in PBCL, in order to reduce ambiguity in results, e.g. where different test methods may produce results that are not safely comparable, and to allow for more effective validation of the UoM reported against the measure Property of the test.

However, in current practice requests rarely specify a required *Property* or *Method* and our user research has indicated that the flexibility that this affords (e.g. to select an analyser workflow based on capacity, if the lab has analysers that produce results for the same basic test in distinct UoM) is important to labs and accepted by clinicians.

Therefore, UTL requestable terms are defined at a higher level of abstraction. The *Property* element will generally be omitted. As for reportables, the *Method* is optional and will only be include if the test method makes a material difference to the reported result and the method is frequently specified by the requesting clinician.

The general model (e.g. for Blood Sciences) is therefore-

Thing (substance, entity or process):	246093002 Component (attribute)
Specimen:	116686009 Has specimen (attribute)
Technique (optional, if specified by requesters):	260686004 Method (attribute)

Examples:

Sodium	level	[IN] serum
Sodium measurement, serum (procedure)		<i>(Fully Specified Name)</i>
Serum sodium level		<i>(Preferred Term)</i>

Property: (not specified, will be defined by the procedure or test method selected by the laboratory)

Component (thing/substance): sodium

Has specimen (specimen): serum

2.3. Use of 'Inheres In' & 'Direct Site' attributes

Up to and including the first Live release of UTL content, specimen information for each concept has been contained within a single column entitled 'Specimen'. Since 'Specimen' does not directly correspond to a single SNOMED attribute, this column was always intended to be a placeholder until the appropriate SNOMED attribute(s) to use in its place were determined.

Following modelling analysis performed by NHS Digital's terminologists and consultation with SNOMED International, in the December 2021 Pathology Beta Preview Release the original single 'Specimen' column has now been replaced by two columns, one entitled 'Inheres In' and another entitled 'Direct Site'. The 'Inheres In' column corresponds to the SNOMED attribute 704319004 |Inheres in (attribute)| and the 'Direct Site' column corresponds to the SNOMED attribute 704327008 |Direct site (attribute)|, in line with the [SNOMED International attribute set for observable entity concepts](#).

Inheres In is used to represent the component of which the measurement property refers to i.e. the thing (being measured) in which the quality (property) exists.

Direct Site is used to represent the site from which the component comes from, or the entity on which the observation is directly made.

To use a crude example using the fictional term *length of fingernail on fingertip*, in this case the **Property is length** which **Inheres In the fingernail** and is observed from the **Direct Site of the fingertip**.

An example from the UTL is 1491000237105 |Mean corpuscular volume of erythrocytes in blood (observable entity). In this case the **Property is entitic volume**, which **Inheres In the erythrocytes**, and is observed in the **Direct Site of the blood specimen**. For this concept, the Inheres In value is 703062004 | Population of all erythrocytes in portion of fluid (body structure) | and the Direct Site value is 119297000 | Blood specimen (specimen)|.

Another example is 1107861000000100 |Substance concentration of sodium in plasma (observable entity) |. In this case the **Property is substance concentration**, which **Inheres In the plasma substance**, and is observed in the **Direct Site of the plasma specimen**. For this concept, the Inheres In value is 50863008 |Plasma (substance)| and the Direct Site value is 119361006 |Plasma specimen (specimen)|. It's important to note here that the Property of substance concentration inheres in the plasma rather than the sodium, as it is reported as a characteristic of the plasma itself (i.e. the relative amount of sodium present in the plasma).

For the majority of concepts in the UTL the Inheres In and Direct Site values will be similar but from different hierarchies, as in the example above where we have an Inheres In value of 50863008 |Plasma (substance)| and a Direct Site value of 119361006 |Plasma specimen (specimen)|. Where this is true, the guidance from SNOMED International is that only the Inheres In value is populated within the concept model, and the Direct Site value is not retained. However, for those concepts modelled within the UTL we have chosen to populate values for both attributes in order to allow for greater flexibility when populating specimen information in the FHIR message profiles accompanying the UTL.

2.4. Units of Measurement (UoMs)

The general property types that determine (and indeed validate in use) the range of allowed units of measurement are a part of the terming and modelling project for the UTL. **The specific UoM assigned to each result is not included in the description in the UTL member concept.** UoMs are applied in the FHIR result message in a separate field alongside the actual result text and with the reference range and alerts where applicable. The range of valid UoMs are determined from the Property Type attribute. Reference ranges are also not part of the SNOMED model described.

2.5. Test Preconditions

2.5.1 Fasting, random, timed specimens etc.

While there is clearly a need to capture such information, *where* it is captured is yet to be decided. The important point in this is that the essential nature of the test and its result are no different in these further qualified terms. A 'serum glucose' is exactly the same as a 'fasting serum glucose'. Until the mechanism for displaying and retaining this information is determined no items of this form have been included. However, it remains possible that the solution is within SNOMED. For example, the 'fasting' information could be assigned to the sample as a 'serum sample taken from fasted patient'.

2.6. Clinical Domain and Sub-domain Coverage

This guidance currently mainly covers the broad domain of 'blood sciences' (blood but also other body fluids), including:

- Clinical chemical pathology/biochemistry
- Endocrinology
- Haematology
- Immunology
- Some areas of microbiology/virology (e.g. some antibody and antigen reporting)

Domains for subsequent stages of work are:

- Andrology
- Transfusion
- Nucleic acid amplification tests for organisms
- Molecular biology for genetic mutations/Genomics

Some of the above categories may only have minimal content to start with but are expected to expand rapidly over time as UTL development continues.

3. Content Patterns

3.1. 'Amounts and Counts' - The Concept of 'Quantity' In Laboratory Results Categorisation

In ontology, 'quantity' is a basic class of fundamental 'things' along with quality, substance, change and relation. Quantity is further divided by multitude and magnitude.

- Magnitude covers that which is continuous and divisible only into smaller divisibles (such as mass and energy). Such measurements of quantity can be fundamental direct measurements or relational combinations built from these.
- Multitude includes (among other collectives) the notion of number (of indivisible entities - such as cells or organisms).

From this, ontologically or metrologically, but then also by empirical confirmation from laboratory results lists in use, test result observables can be categorised (in common across systematic representational standards) as either scalar magnitudes or multitudes and most commonly of the types (or of variations of the types):

Molar/mass concentration (moles/volume and mass/volume)

or

Entity counts per unit volume (number/volume)

...where ‘substance’ and ‘entity’ are fundamental things and ‘mass/volume or number/volume’ are fundamental properties of things. The common incidence of measurements involving a “per volume” aspect is because of the preponderance of lab procedures that involve processing of substances in liquids, either naturally occurring body fluids like blood or urine, extracts of these fluids e.g. plasma, or solvents used in more complex procedures.

Most of these thing/property pairs can be further specified in the laboratory by the *in vitro* environment in which they are measured, more specifically a specimen/sample. These three attributes form the core heuristic triad that go towards defining laboratory observables in SNOMED and, not surprisingly given the fundamentals, in other reference terminologies. This triad can then be further defined through the SNOMED concept model by several other attributes described below but the triad remains the core of the representation.

The development of UTL aims to take a pragmatic path taking adequate account of both current clinical and laboratory practice and theory, with due regard to international scientific nomenclature and conventions. The result will develop iteratively with practitioner review at each stage to ensure the product remains grounded and usable.

3.2. Other Result Property Types

Substance/mass concentration and entity counts are not the only types of results, but just the most common types in clinical laboratory practice. Below is an overview of types of results, many of which are refinements of the basic types described above. [*Note: this is an evolving characterisation*].

Property	<p>The term Property has been adopted in some areas of metrology as a generalisation of Quantity. Whereas Quantity is by definition composed of a numeric magnitude and a scale unit (Unit of Measure), Property encompasses measurements or comparative judgements that are not on a numeric scale. These non-numeric results are referred to as “semi-quantitative” in materials produced by the programme to date.</p> <p>Note that this definition of the term Property does not necessarily coincide precisely with the use of that term in SNOMED definition of clinical usage. This overlap and potential confusion between terms in clinical ontology vs. metrology (and also sometimes vs. usage in software development) is a challenge that is difficult to solve in a general way.</p>
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Quantity	<p>Direct scalar measurement expressed as a combination of a numeric magnitude/multitude and a scale unit. For countable entities the scale unit is the value “1” (unity) which by convention is implied by the absence of an explicit scale unit, thus the unit “1” is omitted in most situations.</p> <p>Quantity is often described as a mathematical identity involving the multiplication of the magnitude with the scale unit, of the form-</p> $Q \equiv \{Q\} [Q]$ <p>where {Q} is a numerical value and [Q] is a unit, however this identity only holds for measurements of a specific scale type: - a <i>Ratio</i> scale. While ratio scales are the most common type in most environments they are not universal and incorrect assumptions about the scale type applicable to a measurement can lead to serious errors, e.g. in unit conversions.</p>
Amount	<p>Although often used in a general synonym of Quantity the term Amount has been used in metrology as a qualification constraining a Quantity to positive values (and zero) only. As many real-world measurements cannot realistically have negative values this constraint could be useful to support automated sanity checking of results.</p>
Ratio	<p>A generalised division of one measurement by another. Measured ratios are very common in laboratory practice (e.g. <i>mmol/L</i>). Any ratio can generally be expressed in many forms that are mathematically equivalent (e.g. <i>mmol/L</i> vs. <i>μmol/mL</i>). Whether the original specification of the ratio must be preserved unchanged during transmission and processing in some or all cases is an open question that needs to be addressed.</p>
Fraction or Dimensionless Ratio	<p>A division of one measurement by another of the same dimension. The <i>Dimension</i> of a measurement is the symbolic representation of the <i>Property</i> reduced (where possible) to an equivalent minimised set of base concepts, for example the property Length is conventionally given the symbolic dimension L while Volume has the dimension L³.</p> <p>Symbols are more convenient for mathematical manipulation, including dimensional analysis.</p> <p>A consequence of the rules of mathematics applied to metrology (metrology calculus) is that in a measurement of dimension D divided by a measurement of the same dimension (or a multiple) the dimensions of numerator and denominator cancel, leaving the result with a dimensionality or unit scale of “1” (unity) plus, possibly, a scale factor. As the unit scale of 1 can be omitted by convention, and as (any dimension) raised to the power of zero $\equiv 1$, these values are often referred to as “dimensionless”.</p> <p>Thus <i>ug/g</i> (a <i>mass fraction</i>) $\equiv 10^{-6}$. Given that, for example <i>uL/L</i> (a <i>volume fraction</i>) $\equiv 10^{-6}$ dimensionless ratios raise some specific issues around transmission and conversion of measured results that need to be considered.</p>

Fractional Proportion	<p>A measure of one component in a mixture of components. Measurements of this type occur when a single component (e.g. Carbon Dioxide) is measured in a mixture of two or more components (e.g. exhaled air) and the component of interest (numerator) and the whole (denominator) are measurements of the same dimension.</p> <p>This a <i>Fractional Proportion</i> is a <i>Fraction</i> (aka <i>Dimensionless Ratio</i>) but with the additional constraints that result cannot be less than zero or more than one. A mixture cannot contain less than none (<0%) of the component of interest, or be composed of more than 100% of that component.</p>
Percentage	<p>A scaled dimensionless ratio, possibly a scaled Fractional Proportion. While in software and IT is common to treat % values as simply any other number multiplied by 100 for display (i.e. the value measured in “hundredths”), percentages in Chemistry-related disciplines including clinical BioChemistry are most commonly used to represent an amount of a component in a mixture. I.e. these are Fractional Proportions and constrained to $0\% \leq value \leq 100\%$. Adoption of the more constrained meaning could have value in automated processing of test results.</p> <p>The recommendation that SI units are used only in scaled multiples of 10^3 (e.g. mm, metres, km etc.) calls the use of percentages into some question as they represent a multiple of 10^2, however the use of <i>percent</i> is deeply embedded in current lab practice and likely to be difficult to change.</p>
Count	<p>‘Absolute’ count of entities: Rare in laboratory practice although common in other medical areas (e.g. Pharmacy and prescribing). Counts per unit volume or some other divisor such as area are more common.</p>
Count per (dividing unit)	<p>Count of entities per unit: Counts per unit volume (e.g. millions of red blood cells per Litre of whole blood) or some other divisor (e.g. per square millimetre, per high power microscope field of view) are very common in pathology.</p>
Semi-Quantitative result	<p>A result categorisation or interpretation reported as a result: For some laboratory tests, while the procedure may produce a numeric value the result is reported to the requesting clinician only as one of a limited number of outcomes described in text. These text descriptions often use terms that are common in result <i>interpretations</i>, but conventionally are reported as the <i>value</i> of the test result.</p> <p>These results are often selected from a set that represents a small range of values (possibly only two) such as-</p> <ul style="list-style-type: none"> • Not Detected Intermediate Detected • Negative Positive • Not Sensitive Sensitive <p>But the picture can be complicated by reported results that potentially represent something other than a valid value such as Indeterminate or Equivocal.</p>

Time	Relative/elapsed time (from zero not clock time) - mainly clotting times
Rate	Quantity measured against (divided by) time
Output/Excretion	Quantity specifically in 24 hours and often in urine (note: may be modelled as a simple mass/molar defined in SNOMED 'Process duration (attribute)': '/day')
Titre	Becoming less frequently used? Determining a clear definition of Titre/Titration as regards the distinction between the measurement method or procedure, a possible proxy indication (e.g. colour change), and the actual property being measured has proven challenging.
Activity	Catalytic (enzyme) and other substance activity are generally measured by comparison to standards (the value that forms the basis of the unit scale) that are arbitrary in nature and do not have a defined relationship to other scales or dimensions.
Calculation	Result arrived at by formula from quantitations e.g. eGFR, AKI warning stage, clearance
Type, subtype, group, class, grade, phenotype, identity etc.	Classification/category
Narrative text	Text report on an examination, study, dynamic function test, composite test interpretation, conclusion etc

The two common subdivisions above, with smaller numbers of the patterns in the above table, comprise much of UK laboratory result content analysed so far for UTL inclusion.

From the categories above, inputs to the UTL can be parsed to support the standardisation of terming and modelling. However, some test names/results are condensed forms, eponymous or termed from historic usage and, from which, inferences on modelling cannot be easily drawn directly. As usage over time means these are well established and defined, no attempt is being made at this stage to expand them in a long form encyclopaedic manner, for example:

- APTT - Activated Partial Thromboplastin Time
- INR – International Normalised Ratio
- Coombes Test

However, some of these may be defined more fully on a case basis. Semantic constructions not fitting with the above patterns and specifically, those not bearing a direct single result, are dealt with in later sections. These are usually terms standing for evaluation procedure such as screening test results, study conclusions, function test results and profiles/batteries/panels.

3.3. Content Patterns - Worked Examples

3.3.1 Reportable

3.3.1.1 Substance (molar) concentration and mass concentration

The following pattern can be repeated for any component reported with a mass or molar concentration unit of measurement.

Property Attribute | Value Pair

370130000 | Property (attribute) | 118539007 | Mass concentration (property) (qualifier value)
370130000 | Property (attribute) | 118556004 | Substance concentration (property) (qualifier value)

Example: Oxalate

- FSN: Mass concentration of oxalate in plasma
- UK PT: Oxalate mass concentration in plasma
- FSN: Mass concentration of oxalate in serum
- PT: Oxalate mass concentration in serum
- FSN: Substance concentration of oxalate in plasma
- UK PT: Oxalate molar concentration in plasma
- FSN: Substance concentration of oxalate in serum
- UK PT: Oxalate molar concentration in serum

Notes

Mass concentration denotes mass/volume UoMs such as 'mg/L'.

Substance concentration denotes moles/volume UoMs such as 'mmol/L' and is conventionally written as molar concentration by UK labs.

The word 'specimen' is usually redundant and left out.

The FSN currently uses the current international terming order convention '*property of thing in specimen*' although this can sometimes produce incongruous terms.

The PT places the thing first for ordering/indexation based on this being the key element from a clinical utility perspective.

'Molar concentration' is more familiar usage to UK labs while 'substance concentration' is used more internationally.

3.3.1.2 Quantitations reported both as concentrations and as interpreted qualitative results based on cut-off/threshold value.

Either or both a quantitation concept and a 'presence' concept are provided unless the quantitative result is not reported.

Example: Adalimumab antibodies

Quantitation:

- FSN: Mass concentration of adalimumab antibody in serum
- PT: Adalimumab antibody mass concentration in serum

Qualitative result based on quantitative cut-off value:

- FSN: Qualitative result of adalimumab antibody in serum
- PT: Adalimumab antibody in serum qualitative result

Example: Hepatitis C virus core antigens

Quantitation:

- FSN: Arbitrary concentration of Hepatitis C virus core Ag in serum (observable entity)
- PT: HCV core Ag (hepatitis C virus core antigen) arbitrary concentration in serum

Qualitative result based on quantitative cut-off value:

- FSN: Qualitative result of Hepatitis C virus core Ag test in serum (observable entity)
- PT: HCV core Ag (hepatitis C virus core antigen) test in serum qualitative result

Alternatively, a titre or antibody index cut off could be used. Users are free to use any conventional qualitative forms (positive/negative, detected/not detected) but the detection report describes where the presence or otherwise is asserted based on a cut-off value or threshold.

3.3.1.3 Arbitrary concentration

Where a substance concentration is reported using International Units (IU) or Units (U) then the NPU convention based on IUPAC Silver Book is applied of describing the property as 'arbitrary concentration'. (*ref*). This does not mean the units are arbitrary in the lay sense but that they rely on a designated externally maintained reference as the unit to be measured rather than a mathematic unit. The following pattern can be repeated for any component reported with a Units (U) or International Units (IU) unit of measurement.

Property Attribute | Value Pair

370130000 | Property (attribute) | 118569000 | Arbitrary concentration (property) (qualifier value)

TSH (thyroid stimulating hormone)

- FSN: Arbitrary concentration of TSH (thyroid stimulating hormone) in serum
- PT: TSH (thyroid stimulating hormone) arbitrary concentration in serum

Autoantibody: Antinuclear Antibody (ANA)

- FSN: Arbitrary concentration of antinuclear antibody in serum
- PT: Antinuclear antibody arbitrary concentration in serum

Allergen: IgE Antibody to Peanut

- FSN: Arbitrary concentration of Arachis hypogaea specific immunoglobulin E in serum
- PT: Peanut specific IgE arbitrary concentration in serum

Allergen: IgE Antibody to Peanut Allergen Component

- FSN: Arbitrary concentration of recombinant Ara h 2 peanut specific immunoglobulin E antibody in serum
- PT: rAra h 2 peanut specific IgE arbitrary concentration in serum

Notes and questions

Could we miss out 'antibody' from terms that already describe an immunoglobulin?

Note that IgE is an approved UK abbreviation and does not require expansion.

Autoantibodies and anti-x antibodies. The policy will follow emerging quality assurance body consensus on descriptions on the use of 'auto-' and 'anti-' prefixes.

'Autoantibody' will not be used, just antibody.

The 'anti-' prefix on substances or organisms will not be supported in terms except in the very few cases of strongest usage. This removes unpredictable variation and makes cataloguing, parsing and searching more reliable.

Specific IgE antibodies: The units used are kU_A/L 'kilounits (A = 'of antibody'?) per litre' (often written without subscript: kUA/L). The property applied is therefore 'arbitrary concentration'.

We acknowledge that 'arbitrary' can get read in its lay sense rather than the purist metrological sense in which it is strictly true. Nevertheless, it is the standard. For end users could we shorten arbitrary concentration in some way? Perhaps 'units concentration'?

3.3.1.4 Entity count

Although counts have a formal property of 'number/volume' etc this is not expressed directly in terms (although examples are found in SNOMED, including use of American hash '#' for number); instead, the word 'count' is used as a matter of clinical usage.

Example: Neutrophils

Absolute count

- FSN: Count of neutrophils in blood
- PT: Neutrophil count in blood

Relative count

- FSN: Relative count of neutrophils in blood expressed as a percentage (*overworked even if correct?*)

OR

- FSN: Percent count of neutrophils in blood
- PT: Neutrophil percent count in blood
- FSN: Per thousand erythrocytes count of schistocytes in blood by light microscopy
- PT: Schistocytes per thousand erythrocytes count in blood by light microscopy

Per thousand is strictly 'per mille' as percent but this seems to not be common usage.

3.3.1.4 Cluster Of Differentiation (CD)

Note:

CD is an approved SNOMED UK abbreviation in the pathology domain (only) and does not require expansion.

Worked example: CD11a

This is shorthand for 'T lymphocyte positive for CD11a antigen'.

- FSN Count of T lymphocytes positive for CD11a antigen in blood
- PT: CD11a+ count in blood

- FSN Count of T lymphocytes positive for CD11a antigen in blood expressed as a percentage
- PT: CD11a+ percent count in blood

Notes:

Pre-existing content of long standing may not follow this FSN format nor include 'blood'. However, leucocytes may be counted in other fluids so 'blood' is required here by default.

The specimen is usually blood or bone marrow.

Absolute count means a number per microlitre e.g. $10.0 \times 10^9/L$ and not simply '10,000 cells'. If 'count' is not qualified it is by default an absolute count but 'absolute' is missed out.

Percent count is a count relative to another count. It takes a result of a count and expresses the relative number of cells as a percentage of a higher population level total. Percent, while operating as a UoM in the result is actually only a way of expressing the fraction result but still intrinsic to the description so it is treated as a special case property. This also applies to fractional amounts expressed as a percentage (percent fraction).

3.3.1.5 Qualitative test result pattern

The representation of qualitative **Presence** terms with associated values of positive/negative/equivocal/etc for a given test result was flagged as a clinical risk by stakeholders and end user experts. Specifically, a risk of default positive interpretation by the clinical recipient if the value on the right is overlooked.

For example, **Presence of HIV 1 RNA by NAAT = negative (value)**

In response to this potential risk, the UTL SNOMED CT representation was integrated into the user research activities in order to ascertain the end user workflow and cognitive process, relative to the current laboratory reporting mechanism and HL7 FHIR design. The examples below summarise the output.

The updated representation spans all laboratory specialities reporting the outputs of analysers in this format (positive/negative; seen/not seen; isolated/not isolated; detected/not detected etc).

Fully Specified Name – **Qualitative result** of **substance/entity** in **specimen technique** (observable entity)

Preferred Term – **Substance/entity** in **specimen technique qualitative result**

Microbiology/virology nucleic acid amplification (no specimen):

- FSN - **Qualitative result** of **Adenovirus ribonucleic acid** nucleic acid amplification (observable entity)
- PT – **Adenovirus RNA** nucleic acid amplification **qualitative result**

Andrology antibody:

- FSN – **Qualitative result** of **sperm antibody** in **sperm** immunobead immunoglobulin A (observable entity)
- PT – **Sperm antibody** in **sperm** immunobead immunoglobulin A **qualitative result**

Microbiology culture (no specimen):

- FSN – **Qualitative result** of **bacillus anthracis** culture (observable entity)
- PT – **Bacillus anthracis** culture **qualitative result**

Microbiology antigenic test:

- FSN – **Qualitative result** of **Clostridium difficile antigen** test in **serum** (observable entity)
- PT – **Clostridium difficile antigen** test in **serum** **qualitative result**

3.3.1.6 Microbiology Microscopy

A Gram-stain microscopy reportable is included in UTL release v0.9.0, with a view to considering the use of related 'findings' terms subject to design approval. As findings would be a new domain in the UTL, further work needs to be undertaken to as to how these are incorporated and how they complement the FHIR message specification.

3.3.2 Requests

3.3.2.1 Panels and groups

Terminology for panels and group test request codes are mostly existing content in the UK SNOMED CT Clinical Extension and follow a heterogeneous design according to the preferred description of the test in practice.

Examples:

54610007 | Kidney panel (procedure) |

Preferred Term - Kidney panel

Synonym - Renal profile

26604007 | Complete blood count (procedure) |

Preferred Term - Full blood count

252325003 | Circulating immune complexes assay (procedure) |

Preferred Term - Circulating immune complexes assay

These concepts are logically modelled in SNOMED CT in accordance with their level of specificity using the attributes in Section 2.2.2

3.3.2.2 Screening test requests

Terminology for screening test request codes are mostly existing content in the UK SNOMED CT Clinical Extension and follow the pattern:

Substance/entity/clinical indication screening

Examples:

171191008 | Cystic fibrosis screening (procedure) |

171122006 | Hepatitis B screening (procedure) |

The screening logical model is well established in SNOMED CT and introduces two further attributes:

363702006 | Has focus (attribute) | - to represent the focus substance/entity/clinical indication

363703001 | Has intent (attribute) | - to represent screening procedure intent

Example:

Cystic fibrosis screening (procedure) ☆

SCTID: 171191008

171191008 | Cystic fibrosis screening (procedure) |

Cystic fibrosis screening
Cystic fibrosis screening (procedure)

Method → Evaluation - action
Has focus → Cystic fibrosis
Has intent → Screening - procedure intent

3.3.2.2 Single test requests

Terminology for single test request codes are mostly existing content in the UK SNOMED CT Clinical Extension and follow the patterns:

Substance/entity level/measurement

Substance/entity specimen level/measurement

Example:

390955003 | Plasma albumin level (procedure) |

Plasma albumin level (procedure) ☆

SCTID: 390955003

390955003 | Plasma albumin level (procedure) |

Plasma albumin level (procedure)
Plasma albumin level

Has specimen → Plasma specimen
Component → Albumin
Method → Measurement - action

3.4. Other Worked examples (reportable)

3.4.1 Enzymes

Enzymes are usually reported by catalytic activity (but sometimes as concentrations) and are constructed as with 'substances' above but with some more specific parameters.

Example: Amylase

246093002 | Component (attribute) | <<90668006 | Enzyme (substance)

370130000 | Property (attribute) | 118523000 | Catalytic activity (property)

- FSN: Catalytic activity of amylase in serum
- PT: Amylase enzyme activity in serum

Notes

Enzymes can be measured quantitatively but more commonly are reported by catalytic activity. This is expressed as arbitrary concentration. *Is there a case for activity/mass or activity/volume?*

'Enzyme activity' is approved UK terming for enzymes in UTL, rather than 'catalytic activity' or just 'activity'.

3.4.2 Excretion/Output (in urine in 24 hours)

Example: Aetiocholanone, 24h, urine

- FSN: Mass of aetiocholanone in urine in 24 hours
- PT: Aetiocholanone mass in 24 hr urine

Notes

24-hour output/excretion is described with the 24-hour period ascribed to the specimen (24-hour urine) ...add mass/24h, moles/24h property? There is emerging discussion on possibly saying mass/moles and use 'Process duration' attribute for time period.

Output term needed?

Excretion term needed?

3.4.3 Concentration ratios

Ratios here are not pure dimensionless ratios but relative concentrations, often of an amount per amount of creatinine. The numerator and denominator of the ratio will therefore need specific substance concentration result codes as a prerequisite.

3.4.2.1 Ratio of two components in one fluid

Albumin/creatinine in urine, mg/mol or mg/mol creatinine

- FSN: Mass ratio of albumin to creatinine in urine
- PT Albumin/creatinine mass ratio in urine

3.4.2.2 Ratio of a single component in two fluids

Glutamine CSF/plasma, mol/mol

- FSN: Substance concentration ratio of glutamine in cerebrospinal fluid and glutamine in plasma
- PT Glutamine molar ratio in CSF/plasma

3.4.2.3 Ratio of two components in 24h urine specimen

Calcium/creatinine, urine, 24h, mol/mol

- FSN: Substance concentration ratio of calcium to creatinine in 24-hour urine
- PT Calcium/creatinine molar ratio in 24h urine

Notes

Ratios can be mass/mass, moles/moles. The albumin example is a mixed mg/mol ratio(?). Is one converted to align units? How is enzyme to non-enzyme managed?

Ratios in 24 hours are described with the 24-hour period ascribed to the urine specimen (24-hour urine). See output/excretion above.

3.4.4 Antimicrobial susceptibility

Attribute: 704320005 | Towards (attribute) |

This attribute is used to define disposition SNOMED CT observable entity concepts in relation to a substance or entity. In the SNOMED CT PaLM extension, this attribute has been used to define microbiology microorganism susceptibility reporting concepts with the following property:

Property: 118588007 | Susceptibility (property) (qualifier value) |

SNOMED CT description pattern example:

- FSN: Susceptibility of organism to ampicillin (observable entity)
- PT: Organism susceptibility to ampicillin

Where **organism** is post-coordinated and captured as a SNOMED CT (organism) concept and associated with the susceptibility SNOMED CT (observable entity) code in the information model and messaging specification. This design decision is to prevent an unmanageable quantity of precoordinated SNOMED CT concepts with combinations of organism and antimicrobial substance.

3.5. Further Definition Of Concepts By Assay/Technique/Method Used

Attribute/Value Pair:

246501002 | Technique (attribute)

<<272394005 | Technique (qualifier value)

Although often unstated where assumed or irrelevant, this often has utility in:

- Determining the UoM and thus the property of the UTL member
- Distinguishing between result reference ranges for different assays
- Informing clinical decisions by degree of reliability and significance
- Consistent graphing and trending results over time
- Secondary use in monitoring assay usage over time
- Assisting in short term in migration between an obsolete assay and the latest approved one (but the code itself is then obsolescent).

For these reasons, this attribute is considered definitive in UK UTL terming and classification, alongside the core attribute triad. New concepts may need to be added to allow fuller definition to be attained. Immunovirology etc content work is under way and the wide range of techniques/methods available will certainly expand as the test method is needed by microbiologists and immunologists.

3.6. Relative To

This attribute is used to define the second substance or entity in a ratio report or any result where the value is relative to another value.

4. Molecular Biology - Nucleic Acid Amplification

The procedure codes used historically to record DNA/RNA ‘observable’ reports have generally been termed as ‘[Organism] nucleic acid detection test’. These two different uses have become jumbled. Ontologically this is a detection assay, a test not a test result in SNOMED. SNOMED content in this domain is currently under development and provisionally has been constructed in the following format, subject to editorial approval:

- FSN: Presence of human herpesvirus 6 deoxyribonucleic acid in serum by nucleic acid amplification (observable entity)
- PT: Human herpesvirus 6 DNA Presence in serum by nucleic acid amplification

Notes

Additional words after ‘amplification’ (e.g. test, method) seem to be redundant.

Content will be further extended merely by replacing ‘nucleic acid amplification’ with the specific method e.g. ‘by RT-PCR’.

Recording organism species/strains not specified in the coded term could be done using a separate ‘type/identity’ code or a text field but this has not been worked through yet. By this design, the SNOMED CT concept would not pre-coordinate the specimen as follows:

- FSN: Number concentration of human herpesvirus 6 deoxyribonucleic acid by nucleic acid amplification (observable entity)
- PT: Human herpesvirus 6 DNA number concentration by nucleic acid amplification

5. Batteries/Profiles/Panels, Screens and Dynamic Function Tests etc.

These coded items do not take a single value but head up a string of single results or an interpretation in text/narrative form (or both). The expectation at this stage is that headings (requests) will be represented by the existing procedure codes which could be handled as a separate set or merged with the UTL set. Where the report is a single result a UTL item can be used here but there may be a case for additional concept additions ending in ‘...interpretation’ on to a test name to support these results. There is a specific field in the developing FHIR message profile for result interpretation. Policy to be developed.

6. Generating Regular SNOMED-Conformant Descriptions From User Requirements

6.1 Thing/Property/System Triad + Technique + Relative To

The data model developer can concatenate elements of terms directly from the parts or derive them from within a template structure via inheritance of term format and modelling. The template could be that used in SNOMED authoring or an independently maintained one aligned with the SNOMED concept model. *Ref SI Templating Guide.*

The heuristic for templating takes the components described above: the thing to be measured, the property of the thing being measured (derived from the report UoM or asserted from research or inherited from

supertypes) and the specimen in which the thing is being measured, but also supplemented by the method/technique we are using to take the measurement.

All the above, as also described, are SNOMED coded and, with access to SNOMED, can be held as lists for concatenation in terms/descriptions in formal SNOMED CT syntax (or in derived intermediate terming standards, mappable to SNOMED because containing the same basic pattern of information). They can also be expanded and improved over time using machine learning and algorithmic refinement.

6.2 Summary of Heuristic Term Formations

Properties:

1. Amount
2. Ratio
3. Fraction
4. Fractional Proportion
5. Count
6. Count per unit
7. Qualitative interpretation (with values e.g. Presence/Absence)
8. Time
9. Rate
10. Output/Excretion
11. Titre
12. Activity
13. Calculation
14. Type, subtype, group, class, grade, phenotype, identity etc.
15. Narrative text

Appendix 1: Links to Online Resources

Resource	Link
UK Editorial Principles (NHS Digital)	Not currently available
SNOMED International Editorial Principles: Observable Entity hierarchy:	https://confluence.ihtsdotools.org/display/DOCEG/SNOMED+CT+Editorial+Guide https://confluence.ihtsdotools.org/display/DOCEG/2.4.5+Observable+Entity
TRUD is NHS Digital's SNOMED CT and Derivative Product Download Site. It can be accessed here:	https://isd.digital.nhs.uk/trud3/user/guest/group/0/home
HL7 FHIR	https://www.hl7.org/fhir/overview.html
NHS Digital UTL page	https://hscic.kahootz.com/connect.ti/PathologyandDiagnostics/view?objectID=13047024

Appendix 2: Core Attributes and Values Sets

1. Concentrations

Component

246093002 | Component (attribute): <<105590001 | Substance (substance)

Property

370130000 | Property (attribute)

118539007 | Mass concentration (property) (qualifier value)

118556004 | Substance concentration (property) (qualifier value)

118569000 | Arbitrary concentration (property) (qualifier value)

Specimen

704327008 | Direct site (attribute) |

704319004 | Inheres in (attribute)

<<309051001 | Body fluid sample (specimen)

e.g.

122575003 | Urine specimen

119361006 | Plasma specimen

119364003 | Serum specimen

258580003 | Whole blood sample

119297000 | Blood specimen

258450006 | Cerebrospinal fluid sample

441620008 | Oral fluid specimen

119339001 | Stool specimen

The default at this point is 309051001 | Body fluid sample (specimen)

Other options for specimen are available.

2. Entity counts

Component

246093002 | Component (attribute) <<410607006 | Organism (organism)

<<123037004 | Body structure (body structure)

Property

370130000 | Property (attribute)

...Number fraction

Specimen

704327008 | Direct site (attribute) |

704319004 | Inheres in (attribute)

<<309051001 | Body fluid sample (specimen)

e.g.

122575003 | Urine specimen

119361006 | Plasma specimen

119364003 | Serum specimen

258580003 | Whole blood sample

119297000 | Blood specimen

258450006 | Cerebrospinal fluid sample

441620008 | Oral fluid specimen (forensic use)

119339001 | Stool specimen

Blood spot

The default at this point is 309051001 | Body fluid sample (specimen)

3. Test Method/Technique

246501002 | Technique (attribute)

<<272394005 | Technique (qualifier value)

4. Other Attributes

Quantitative/Qualitative.

This attribute is somewhat redundant to 'property/UoM'? 90% of tests will be quantitative so of questionable value.

Relative to

This is useful to describe second component in relative results like ratios and percentages. It is therefore definitive in SNOMED but the availability to implementers as a useable component has not yet been established.

704325000 | Relative to (attribute) |

<<105590001 | Substance (substance)

<<410607006 | Organism (organism)

<<123037004 | Body structure (body structure)

Appendix 3: Domain-Specific Abbreviation Conventions

The following are approved abbreviations not requiring expansion in UK SNOMED descriptions *in the laboratory medicine domain* (from UK Edition Editorial Principles 2017):

IgA - Immunoglobulin A

IgE – Immunoglobulin E

IgG - Immunoglobulin G

IgM - Immunoglobulin M

CD – Cluster of differentiation

HLA – Human leucocyte antigen

Draft under consideration: CSF, DNA, RNA

* Examples only. Not definitive or exhaustive.

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