NHS Digital

DAPB4017 Pathology Test and Results Standard Specification

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Data Alliance Partnership Board

Acting on behalf of the Data Alliance Partnership Board (DAPB), which holds delegated authority from the Secretary of State for Health and Social Care, the Data Alliance Partnership Sub Board (DAPSB) has approved a new information standard for publication under section 250 of the Health and Social Care Act 2012.

Assurance that this information standard meets the requirements of the Act and is appropriate for the use specified in the specification document has been provided by the Data Standards Assurance Service (DSAS) and approved by the Data Alliance Partnership Board (DAPB).

This information standard comprises the following documents:

- Specification
- Implementation Guidance

An Information Standards Notice (DAPB4017 Amd 44/2020) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the standard.

The controlled copies of these documents can be found on the NHS Digital website. Any copies held outside of that area, in whatever format (e.g., paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

Date of publication: 17 August 2021

NOTE: From 1 February 2023, Delen - the information sharing and collaboration platform for Terminology and Classifications products - has migrated from https:///hscic.kahootz.com to https://nhsengland.kahootz.com. URLs in this document have been corrected to ensure continuity of access. No other changes have been made.

Glossary of Terms

Term / Abbreviation	What it stands for
UTL	Unified Test List
UCUM	Unified Code for Units of Measure
HL7 FHIR	Health Level Seven Fast Healthcare Interoperability Resources
EDIFACT	Electronic Data Interchange for Administration, Commerce and Transport
NLMC	National Laboratory Medicine Catalogue
PBCL	Pathology Bounded Code List
LIMS	Laboratory Information Management Systems

Contents

1. Introduction

1.1 Related documents

This document should be read alongside:

- DAPB4017 Pathology Test and Results Standard Consultation Report which also includes the background to this standard and
- DAPB4017 Pathology Test and Results Standard Implementation Guidance

1.2 Related Standards and National Products

See Implementation Guidance S3.

- SCCI0034 SNOMED CT the clinical terminology standard to support direct management of care
- EDIFACT ISB 1557 the current clinical message exchange standard for GP-Hospital Communications, including pathology information using variant NHS003
- HL7 Version 2 (V2) and (V3) CDA® (HL7 Clinical Document Architecture); the current message exchange (de-facto) standard across secondary care/middleware including pathology test results from Laboratory Information Management Systems
- HL7 FHIR; the interoperability standard identified to facilitate the exchange of all healthcare information across the NHS in the future
- The Unified Code for Units of Measure (UCUM); the international standard for all units of measure being contemporarily used, including Healthcare
- The NHS Pathology Bounded Code List used within the ISB 1557 EDIFACT for the Pathology domain which, along with the NHS National Laboratory Medicine Catalogue are still released and were utilised to inform this specification.

1.3 Executive Summary

To meet future NHS needs for interoperability and secondary care use within the Pathology domain, three inter-related specifications have been identified based on relevant component parts of international standards, namely:

- Unified Test List (UTL) – a national catalogue of Pathology test requests and results using SNOMED CT
- Units of Measure (UoM) – using The Unified Code for Units of Measure (UCUM), aligned with the UTL and HL7 FHIR
- Message Specification – for interoperable data exchange of Pathology information, using Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR).

The full standard is intended for use by GP, Labs, secondary care and social care (where applicable), used in GP systems, LIMS, Order Comms, pathology middleware, & clinical research.

Together, as an information standard, they enable the electronic communication and exchange of tests, results, quantities, and units used in the Pathology domain across the NHS.

2. Scope

These inter-related specifications are designed to support a generic pathology test request and test report cycle process, but have been developed to exchange:

- high volume haematology and clinical biochemistry (also known as chemical pathology) information, as well as
- pathology domain information currently exchanged via EDIFACT and the PBCL, and
- COVID-19 Pathology test and result information.

Following an agile approach, they will be extended to meet additional user needs for all The Royal College of Pathologist's specialist areas.

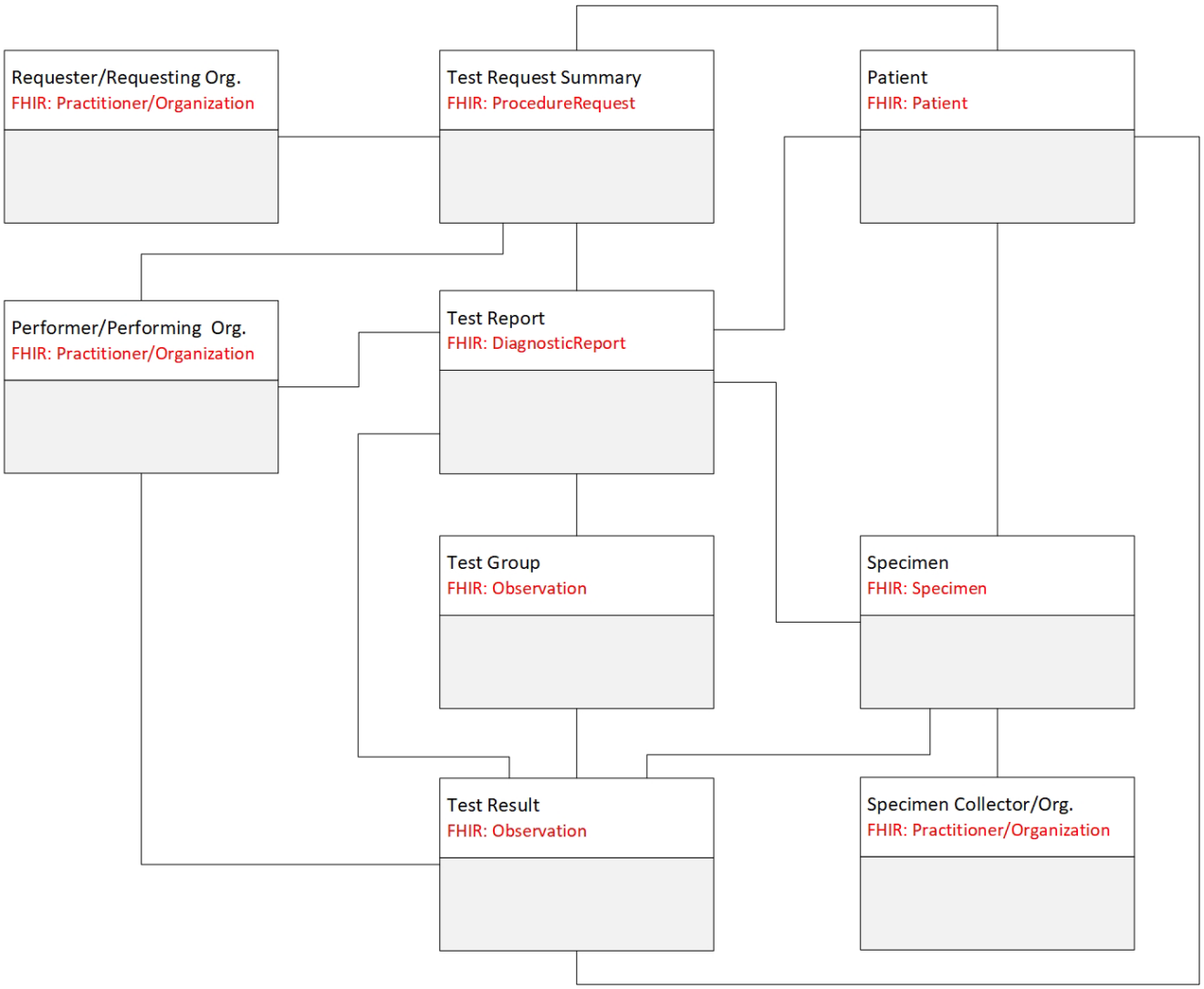
2.1 Clinical Scenarios

Based on the User Centred Design (see Consultation Report) the following key clinical scenarios were defined and used to inform development of the specifications:

- Single Test Request, Single Test Result
- Single Test Profile Request, Multiple Test Results
- Two Test Requests, Two Test Results
- Multiple Test Requests, Multiple Samples
- Split Test Request, Different Sample Types.

2.2 Information Model

The high-level relationship between the business entities in the Information Model and corresponding FHIR profiles is illustrated in the following diagram:



2.3 Message Specification

Each of the (above information model) business entities map to the component HL7 FHIR profiles as follows:

- **Test Request Summary** of information relating to the requested test(s) and maps to the Procedure Request FHIR profile
- **Test Report** is the overall findings and clinical interpretation of one or more test results and maps to the Diagnostic Report FHIR profile
- **Specimen** details the specimen(s) provided for testing and maps to the Specimen FHIR profile
- **Test Group** is used to define a group of related tests, for example, Full Blood Count. Test groups are often referred to as batteries, panels, or profiles and map to the Observation FHIR profile

- **Test Result** of information relating to a single test result maps to the Observation FHIR profile
- The business entities representing the **Requester / Requesting Organisation**, **Performer / Performing Organisation** and **Specimen Collector / Specimen Collecting Organisation** map to the Practitioner and Organization FHIR profiles respectively
- The **Patient** business entity maps to the Patient FHIR profile.

A list of all the versions of FHIR (Fast Healthcare Interoperability Resources) specifications are available at FHIR Specification (hl7.org).

Full details and guidance for the pathology specifications with examples are published in the developer.nhs.uk library.

Supporting information and a detailed logical data model can be found from NHS Digital's collaboration website.

The Message specification payload includes the Units of Measure and UTL value sets for test requests and results as follows.

2.4 Units of Measure Specification

Measured values in Pathology will be communicated with a Unit of Measure (UoM) described in UCUM.

The Unified Code for Units of Measure (UCUM) is a code system intended to include all units of measures used in international science, engineering, and business, facilitating the unambiguous electronic communication of quantities together with their units.

The Unified Code for Units of Measure was inspired by and based upon ISO 2955-1983, ANSI X3.50-1986, and HL7 extensions. UCUM is based on the ISO 80000-1:2009 Quantities and Units standards series that specify the use of System International (SI) units in publications.

More details can be found here:

- The Unified Code for Units of Measure (UCUM) full specification includes all units of measures being contemporarily used in international science, engineering, and business
- The Commonly Used UCUM Codes – Data (hl7.de) is the subset of commonly used Healthcare units also permissible in HL7 FHIR
- Units described in the NHS Data Model and Dictionary.

For additional information please refer to NHS Digital's Units of Measure (Kahootz page) and/or the documents referenced in S1.1 Related Documents (above).

Where a specific test result only has one permissible unit, this will also be incorporated in the UTL/SNOMED CT model.

2.5 Test and Results Specification

The Pathology Unified Test List (UTL) is a constrained set of SNOMED coded terms designed to operate either directly in an electronic patient record, in a FHIR message relating to that patient by carrying a test result, or as a central reference list to support the interoperability of information exchanged with clinical pathology laboratories and their Laboratory Information Systems (LIMS).

The UTL is designed to be the standard reference terminology for all requesting and reporting of laboratory tests in the UK and will be extended iteratively until development of all The Royal College of Pathologists' specialist areas are complete.

- Product Overview of the UTL as a list of SNOMED coded laboratory test result terms published by NHS Digital
- UTL/SNOMED Editorial Principles where different/in addition to the SNOMED CT Editorial Principles below
- Release Format specification schema guide describes the human (for review) and machine-readable release formats of the UTL
- Human Readable release and further information is available at: Unified Test List
- Machine Readable releases are available (registration required) from NHS Digital's Technology Reference data Update Distribution Releases · TRUD (digital.nhs.uk).

This assumes a basic familiarity with SNOMED CT at the level of distinguishing the hierarchies of procedures, findings and observable entities, and the modelled requirements embodied in SNOMED representations, but for further reading on the wider terminology you can refer initially to the UK SNOMED CT website. There is also background documentation including a SNOMED CT starter guide (PDF) on the SNOMED International website:

- Machine Readable SNOMED CT Release format (RF2)
- SNOMED CT Editorial Principles
- For further information please refer SNOMED CT - NHS Digital and /or The SNOMED CT Implementation sharing platform (Delen)
- Further SNOMED CT International documentation is also available including a SNOMED CT starter guide on the SNOMED International web site, if required.

3. Maintenance

Whilst The Royal College of Pathologists' specialist areas are being iteratively developed, there will be a short period of a "Devops" Practice that combines software development (Dev) and IT operations (Ops).

DevOps is complementary with Agile software development including Government Digital Services (GDS).

Additional, Discovery, alpha, beta, and transition to Operations/Live service will continue to be commissioned by NHSX until all The Royal College of Pathologists' specialist area user needs are met, whereupon the operational services will maintain and change as required.

4. Governance

Pathology Informatics National User Group (PINUG)

The purpose of the PINUG is to ensure:

- Feedback on the Unified Test List (UTL), Units of Measure (UoM), Information Model and Pathology FHIR profiles are provided and relevant business activity across the reporting period is discussed.
- The Pathology product backlog are prioritised and assessed from a user impact and business value perspective to support NHS Digital Pathology Product Owner decision making.
- Identify suitable candidates to support user research and user story elaboration from a user perspective.

Pathology Standards Governance Board (PSGB)

The purpose of the Pathology Standards Governance Board (PSGB) is to ensure a high quality UTL containing SNOMED CT concepts and processes for maintaining them to ensure they are clinically safe, accepted and effective for the user community.

The PSGB oversees the clinical and technical assurance of the UTL releases and the associated UoM.

- Approve the UTL releases, including new test requests and results and retiring inactivated codes.
- Provide recommendations to IReS on UTL related products and service developments.
- Facilitate the expansion of the UTL, as required for the pathology disciplines, in consultation with stakeholders.
- Promote uptake and use within the user community.
- Provide leadership in acceptance and integration of the UTL deployment in the NHS aligned with the mandatory requirements identified by NHS England and NHS Improvement’s National Pathology Optimisation and Delivery board.

4.1. Contacts

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