Integrating the Healthcare Enterprise

IHE Anatomic Pathology (PAT)

Technical Framework
Volume 1

Revision 2.0

Trial Implementation
July 23, 2010

Developed under the sponsorship of ADICAP, SEIS, SEAP, SFP

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1 Introduction

Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established messaging standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework, organizes educational sessions, exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is to support the use of existing standards, e.g HL7, ASTM, DICOM, ISO, IETF, OASIS, CLSI and others as appropriate, rather than to define new standards. IHE profiles further constrain configuration choices where necessary in these standards to ensure that they can be used in their respective domains in an integrated manner between different actors. When clarifications or extensions to existing standards are necessary, IHE refers recommendations to the relevant standards bodies.

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA) and the American College of Cardiology (ACC).IHE Canada has also been formed. IHE Europe (IHE-EU) is supported by a large coalition of organizations including the European Association of Radiology (EAR) and European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and Electro medical Industries (COCIR), the Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), the Société Francaise de Radiologie (SFR), Deutsche Röntgengesellschaft (DRG), the Euro-PACS Association, Società Italiana di Radiologia Medica (SIRM) and the European Institute for Health Records (EuroRec), the Association pour le Développement de l'Informatique en Cytologie et Anatomie Pathologiques (ADICAP), the Spanish Health Informatics Society (SEIS), the Spanish Society of Pathology (SEAP) and the Société Française de Pathologie (SFP). In Japan IHE-J is sponsored by the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and Welfare; and MEDIS-DC; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Japan Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan Association of Medical Informatics (JAMI). The list presented here is not closed and other organizations representing healthcare professionals are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

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1.1 Overview of the Anatomic Pathology Technical Framework

This document, the Anatomic ¨Pathology Technical Framework (IHE PAT TF) is produced with the help of these organizations:

- ADICAP (Association pour le Développement de l'Informatique en Cytologie et Anatomie Pathologique)
- SEIS (Spanish Health Informatics Society)
- SEAP (Spanish Society of Pathology)
- SFP (French Society of Pathology)

The document defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. It is expanded annually, after a period of public review, and maintained regularly through the identification and correction of errata.

The current version, rev. 2.0 for Trial Implementation, specifies the IHE transactions defined and specified as of July 2010. The latest version of the document is always available via the Internet at:

http://www.ihe.net/Technical_Framework/index.cfm#pathology

The IHE Pathology Technical Framework identifies a subset of the functional components of the healthcare enterprise, called IHE actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth.

The present volume (PAT TF-1) provides a high-level view of IHE functionality, showing the transactions organized into functional units called integration profiles that highlight their capacity to address specific IT Infrastructure requirements.

Volume 2 of the Anatomic Pathology Technical Framework (PAT TF-2) provides detailed technical descriptions of each IHE transaction used in the Anatomic Pathology Profiles. These two volumes are consistent and can be used in conjunction with the Profiles of other IHE domains.

The other domains within the IHE initiative also produce Technical Frameworks within their respective areas that together form the IHE Technical Framework. Currently, the following IHE Technical Framework(s) are available:

- IHE Anatomic Pathology Technical Framework
- IHE Cardiology Technical Framework
- IHE Eye Care Technical Framework
- IHE IT Infrastructure Technical Framework
- IHE Laboratory Technical Framework
- IHE Patient Care Coordination Technical Framework
- IHE Patient Care Devices Technical Framework
- IHE Quality, Research and Public Health Technical Framework

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- IHE Radiology Technical Framework

Where applicable, references are made to other technical frameworks.

1.2 Overview of Volume 1

The remainder of Section 1 further describes the general nature, purpose and function of the IHE Anatomic Pathology Technical Framework and introduces the concept of IHE Integration Profiles that make up the Technical Framework.

Section 2 and the subsequent sections of this volume provide detailed documentation on each profile, including the problem it is intended to address and the IHE actors and transactions it comprises.

The aim is to extend the IHE initiative to pathology laboratories, their information, automation and imaging systems and equipment. This document, the **Pathology Technical Framework** identifies the workflow, the IHE **actors** (i.e. functional components, application roles), and shows the **transactions** between them. This description is organized into functional units called **integration profiles** that highlight their capacity to address specific clinical needs. It also chooses the appropriate messages of established standards to cover this domain, and defines their implementation.

1.3 Audience

The intended audience of this document is:

- Technical staff of vendors participating in the IHE initiative
- IT departments of healthcare institutions
- Experts involved in standards development
- Anyone interested in the technical aspects of integrating healthcare information systems.

1.4 Relationship to Standards

The IHE Technical Framework identifies functional components of a distributed healthcare environment (referred to as IHE actors), solely from the point of view of their interactions in the healthcare enterprise. At its current level of development, it defines a coordinated set of transactions based on ASTM, DICOM, HL7, IETF, ISO, OASIS and W3C standards. As the scope of the IHE initiative expands, transactions based on other standards may be included as required.

In some cases, IHE recommends selection of specific options supported by these standards; however, IHE does not introduce technical choices that contradict conformance to these standards. If errors in or extensions to existing standards are identified, IHE's policy is to report them to the appropriate standards bodies for resolution within their conformance and standards evolution strategy.

IHE is therefore an implementation framework, not a standard. Conformance claims for products must still be made in direct reference to specific standards. In addition, vendors who have implemented IHE integration capabilities in their products may publish IHE Integration Statements to communicate their products' capabilities. Vendors publishing IHE Integration Statements accept full responsibility for their content. By comparing the IHE Integration

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Statements from different products, a user familiar with the IHE concepts of actors and integration profiles can determine the level of integration between them.

Two specific Pathology working groups dedicated to anatomic pathology have been recently created within DICOM and HL7. Moreover, in Europe, Technical Committee CEN/TC 251 dealing with “Health informatics also addresses some issues related to anatomic pathology. At last, SNOMED CT is a de facto international terminology standard now maintained by the International Health Terminology Standards Development Organization (IHTSDO).

1.4.1 DICOM WG26

The group will be responsible for formulating components of the DICOM standard that relate to imaging for Pathology.

Some pathology-related image formats do not as yet have applicable DICOM Information Object Definitions. Examples include whole slide images (WSI), high-order multispectral images, flow cytometry, electron microscopy.

1.4.2 HL7 Pathology Special Interest Group

The group will achieve a complementary effort, focusing on the "orders and observations" aspects of the pathology workflow

HL7 Pathology Special Interest Group international mailing list: pathology@lists.hl7.org

1.4.3 International Health Terminology Standards Development Organisation (IHTSDO)

This group is integrated with internal staff from SNOMED International and external collaborators. They define new terms and establish relationships between accepted terms. There is a need to define the best way to integrate SNOMED Clinical Terms in anatomic pathology information systems (SNOMED CT value sets), and how to exchange information with other clinical departments and other institutions, using a common terminology.

1.4.4 CEN TC 251

The document TC 251 Work Item 130.(Health informatics — Service request and report messages), prepared under mandate M/255 given by the European Commission and the European Free Trade Association, has been prepared by Technical Committee CEN/TC 251 “Health informatics”, and has replaced the previous standards ENV 1613 (Medical informatics - Messages for exchange of laboratory information)., ENV 12538 (Medical informatics - Referral and discharge messages), and ENV 12539 (Medical informatics - Request and report messages for medical service departments). The scope of the messages specified by this European standard comprises healthcare service requests and reports related to investigations carried out by healthcare service providers on subjects of care. They cover electronic information exchange between computer systems used by healthcare parties requesting the services of healthcare service providers.

Typical use cases are available by CEN TC251 in prEN 14720-1:2003 (Health informatics — Service request and report messages — Part 1: Basic services including referral and discharge, TC 251 WI 130.1.1:2003 – E. See: http://www.centc251.org/):

- Service to be performed on specimens supplied by the requester
- Services that require scheduling prior to the receipt of the sample collected by the requester (frozen sections, renal biopsy)

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- Services performed on samples collected by the service provider (fine needle aspiration)
- Services in which the subject of care is examined by the service provider
- Services involving evaluation of an existing sample or study product (second opinion)
- Modification of an existing request following any of the above scenarios (additional investigations or revised clinical information)
- Cancellation of an existing request following any of the above scenarios

Scheduling: See section B.2.3 Services that require scheduling prior to the receipt of the sample collected by the requester in CEN TC-251 WI 130 Part 1 (examples: frozen section and renal biopsy).

1.4.5 Harmonization

It is important that the parallel efforts of IHE-pathology initiative and standardization bodies (DICOM WG 26 and Pathology Special Interest Group being formed for HL7, IHTSDO, and CEN CT 251 – be harmonized, , each one with its own purpose and organizational context.

Clearly there will be overlap in defining the information model for specimens, in standardizing reports including quantitative measurements and assessments made with reference to images, etc.

Information model for specimens and templates for structured reports should be established in common across both HL7 and DICOM standards.

HL7-DICOM interoperation in anatomic pathology will be addressed in a HL7-DICOM joint working group (HL7 Pathology SIG / DICOM WG26) defining clauses for harmonization of standards.

1.5 Relationship to Real-world Architectures

The IHE actors and transactions described in the IHE Technical Framework are abstractions of the real-world healthcare information system environment. While some of the transactions are traditionally performed by specific product categories (e.g. HIS, Clinical Data Repository, Radiology Information Systems, Clinical Information Systems or Cardiology Information Systems), the IHE Technical Framework intentionally avoids associating functions or actors with such product categories. For each actor, the IHE Technical Framework defines only those functions associated with integrating information systems. The IHE definition of an actor should therefore not be taken as the complete definition of any product that might implement it, nor should the framework itself be taken to comprehensively describe the architecture of a healthcare information system.

The reason for defining actors and transactions is to provide a basis for defining the interactions among functional components of the healthcare information system environment. In situations where a single physical product implements multiple functions, only the interfaces between the product and external functions in the environment are considered to be significant by the IHE initiative. Therefore, the IHE initiative takes no position as to the relative merits of an integrated environment based on a single, all-encompassing information system versus one based on multiple systems that together achieve the same end. IHE demonstrations emphasize the integration of multiple vendors' systems based on the IHE Technical Framework.

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1.6 Conventions

This document has adopted the following conventions for representing the framework concepts and specifying how the standards upon which the IHE Technical Framework is based should be applied.

1.6.1 IHE Actor and Transaction Diagrams and Tables

Each integration profile is a representation of a real-world capability that is supported by a set of actors that interact through transactions. Actors are information systems or components of information systems that produce, manage, or act on categories of information required by operational activities in the enterprise. Transactions are interactions between actors that communicate the required information through standards-based messages.

The diagrams and tables of actors and transactions in subsequent sections indicate which transactions each actor in a given profile must support.

The transactions shown on the diagrams are identified both by their name and the transaction number as defined in PAT TF-2. The transaction numbers are shown on the diagrams as bracketed numbers.

In some cases, a profile is dependent on a prerequisite profile in order to function properly and be useful. For example, Anatomic Pathology Workflow (APW) profile depends on Patient Administration Management (PAM) and Consistent Time (CT) profiles. These dependencies can be found by locating the desired profile in Table 1.17-1 to determine which profile(s) are listed as prerequisites. An actor must implement all required transactions in the prerequisite profiles in addition to those in the desired profile.

1.6.2 Process Flow Diagrams

The descriptions of integration profiles that follow include process flow diagrams that illustrate how the profile functions as a sequence of transactions between relevant actors.

These diagrams are intended to provide an overview so the transactions can be seen in the context of an institution's workflow. Certain transactions and activities not defined in detail by IHE are shown in these diagrams in *italics* to provide additional context on where the relevant IHE transactions fit into the broader scheme of healthcare information systems.

These diagrams are not intended to present the only possible scenario. Often other actor groupings are possible, and transactions from other profiles may be interspersed.

In some cases the sequence of transactions may be flexible. Where this is the case there will generally be a note pointing out the possibility of variations. Transactions are shown as arrows oriented according to the flow of the primary information handled by the transaction and not necessarily the initiator.

1.6.3 Technical Framework Cross-references

When references are made to another section within a Technical Framework volume, a section number is used by itself. When references are made to other volumes or to a Technical Framework in another domain, the following format is used:

<domain designator> TF-<volume number>: <section number>, where

<domain designator> is a short designator for the IHE domain (ITI = IT Infrastructure, RAD = Radiology, PAT = Anatomic Pathology)

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<volume number> is the applicable volume within the given Technical Framework (e.g., 1, 2, 3), and

<section number> is the applicable section number.

For example: ITI TF-1: 3.1 refers to Section 3.1 in volume 1 of the IHE IT Infrastructure Technical Framework, RAD TF-3: 4.33 refers to Section 4.33 in volume 3 of the IHE Radiology Technical Framework. PAT TF-1:2.5 refers to section 2.5 in volume I of the IHE Anatomic Pathology Technical Framework.

When references are made to Transaction numbers in the Technical Framework, the following format is used:

[<domain designator><transaction number>], where

<transaction number> is the transaction number within the specified domain.

For example [PAT-1] refers to Transaction 1 from the IHE PAT Technical Framework.

1.7 Scope introduced in the current year

The IHE Technical Framework is updated annually to reflect new profiles, corrections and new transactions (refer to PAT TF-2) used in those profiles.

This document refers to 2009-2010 cycle of the IHE PAT Infrastructure initiative. It is the second release of this technical framework, and will be the basis for the 2011 Connectathon process and associated exhibition process.

This release 2 of IHE PAT TF-1 results from the integration of the following Change Proposals to the APW profile:

- CP18-PAT-APW (Antonio Gonzalez): Adding transaction PAT-6 “Modality Procedure Status Notification”.

1.8 Security

IHE transactions of the Anatomic Pathology domain, often contain information that must be protected in conformance with privacy laws and regulations. The first profile of this domain, Anatomic Pathology Workflow (APW) will be tested at the connectathon standalone, without any further security constraints for this Year 1 cycle. The intent of the domain technical committee is to raise the security requirements on all profiles of the Anatomic Pathology domain, as of Year 2. The Year 2 cycle will bring the requirements to leverage the ITI ATNA Integration Profile.

1.9 Comments

ADICAP, GMSIH, SEIS, SEAP, SFP welcome comments on this document and the IHE initiative. They should be directed to co-chairs:

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INSERM U872 eq 20,	Hospital General de Ciudad Real	Deparment of Pathology, Charite
15 rue de l’école de médecine	Avda Tomelloso s/n	Chariteplatz 1
75006 – PARIS. FRANCE	13005 - Ciudad Real. SPAIN	10117, Berlin. GERMANY
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Comments may also be addressed to the IHE Pathology international mailing list:

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ihe-anatomic-pathology-committee@googlegroups.com

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1.11 IHE Technical Framework Development and Maintenance Process

The IHE PAT Technical Framework is continuously maintained and expanded on an annual basis by the IHE Anatomic Pathology Technical Committee. The development and maintenance process of the Framework follows a number of principles to ensure stability of the specification so that both vendors and users may use it reliably in specifying, developing and acquiring systems with IHE integration capabilities.

The first of these principles is that any extensions, clarifications and corrections to the Technical Framework must maintain backward compatibility with previous versions of the framework in order to maintain interoperability with systems that have implemented IHE Actors and Integration Profiles defined there.

The IHE PAT Technical Framework is developed and re-published annually following a three-step process:

1. The Anatomic Pathology Technical Committee develops supplements to the current stable version of the Technical Framework to support new functionality identified by the IHE Strategic and Planning Committees and issues them for public comment.
2. The Committee addresses all comments received during the public comment period and publishes an updated version of the Technical Framework for "Trial Implementation." This version contains both the stable body of the Technical Framework from the preceding cycle and the newly developed supplements. It is the version of the Technical Framework used by vendors in developing trial implementation software for the annual Connectathon.
3. The Committee regularly considers change proposals to the Trial Implementation version of the Technical Framework, including those from implementers who participate in the Connectathon. After resolution of all change proposals received within 60 days of the Connectathon, the Technical Framework version is published as "Final Text".

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1.12 Glossary

This glossary introduces all the acronyms, abbreviations and specific terms used in this Anatomic Pathology Technical Framework.

Accession Number	The unique identifier assigned by the LIS of an Anatomic Pathology laboratory to an imaging Study. As expressed in DICOM Supplement 122: The concept of "accession" in Anatomic Pathology has been determined to be sufficiently equivalent to an "accession" in Radiology so that the existing Accession Number at the Study level may be reused for the same purpose and with essentially the existing definition. For Anatomic Pathology, like in Radiology, the Accession Number may correspond to the Order Filler Number, as specified in HL7 v2.x.
APW	Anatomic Pathology Workflow
ATNA	Audit Trail and Node Authentication
LIS	Laboratory Information System. This TF refers to a LIS having the capability of fulfilling anatomic pathology analysis.
Modality Worklist	A mechanism defined to support the imaging workflow, by which the LIS provides the attributes of the imaging subject to modalities. In radiology, the imaging subject is the patient; in anatomic pathology, the imaging subject is a specimen derived from the patient. The Modality Worklist provides patient, order (study) and specimen identification and description to be included in the acquired images. Therefore the LIS needs to provide the attributes of the Specimen Module for each specimen being imaged. Therefore, the attributes of the Specimen Module have been defined in a 'Macro' construct, and added to the Scheduled Procedure Step Module of Modality Worklist. Conceptually, then, the Procedure Step is scheduled for the imaging of one or more specimen containers. While the use of the specimen attributes is optional according to the Standard for any Modality Worklist implementation, the APW profile requires their use for effective interoperability.
OF	Abbreviation for Order Filler Actor.
OP	Abbreviation for Order Placer Actor.
Order	A request to perform examination of a specimen or a set of specimens taken from a patient. The Order is the focal object of the transactions between Order Filler and Order Placer or Order Result Tracker. An Order may be standalone or belong to an Order Group. The anatomic pathology laboratory may reorganize the orders placed by a clinical unit, especially in cases where an order was received attached to a set of specimens, which will have to be analyzed separately by different pathologists. For this reason the Order Filler may replace, merge, or split orders received from the Order Placer. This process is accomplished through messages of transactions PAT-1 and PAT-2 initiated by the Order Filler.

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Order Group	A laboratory request, that is a set of orders placed together by a ward and/or a physician to one or more laboratories for a patient, to be performed on one or more specimens collected from this patient. Any message exchanged between Order Filler and Order Placer or Order Result Tracker, is carrying zero or one Order Group.
ORT	Abbreviation for Order Result Tracker Actor.
Procedure Step	For each Requested Procedure (see this entry), the basic or special techniques involved in the processing of the corresponding specimen(s) may require different devices (automatons, image acquisition modality, etc). Each Requested Procedure may contain one or more Procedure Steps. A Procedure Step is the smallest unit of work in the workflow that is scheduled (work to do) and/or performed (work done) by a person or a machine (automaton, image acquisition modality, etc) on an object (specimen, tissue sample, tissue section, etc)
Requested Procedure	In anatomic Pathology, a "Requested Procedure" or imaging "Study" is identified by its unique Accession Number (see this entry in the glossary). A Requested Procedure is attached to an Order. As expressed in DICOM Supplement 122: The concept of "accession" in Anatomic Pathology has been determined to be sufficiently equivalent to an "accession" in Radiology so that the existing Accession Number at the Study level may be reused for the same purpose and with essentially the existing definition. A Requested Procedure may involve more than one acquisition modality (e.g. gross imaging, microscopic imaging) and/or more than one specimen, in which cases the Study will include more than one Series.
Series	A subset of an imaging Study (see this entry) acquired from a single specimen by a single acquisition modality. Whenever an image is acquired from a new specimen or involves a new acquisition modality a new Series is created. A new series is also created when an image is acquired for an existing study after the original order has been fulfilled.
Tissue microarray	Tissue microarrays (TMA) consist of paraffin blocks in which up to 1000 separate tissue cores coming from different donor blocks, different parts and different patients, are assembled in array fashion to allow simultaneous processing and histological analysis. TMA slides created from TMA blocks include tissue items (spots) coming from the different tissue items (cores) in TMA blocks. Each Specimen (spot) may be localized in the TMA slide, for example, by X-Y coordinates, or by a textual column-row identifier for the spot (e.g., "E3" for fifth column, third row). If the TMA slide is imaged as a whole, e.g., at low resolution as an index, it must be given a "pseudo-patient" identifier (since it does not relate to a single patient). Images created for each spot should be assigned to the real patients.
TMA	Tissue Micro Array (see this entry)
WSI	Whole Slide Image

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1.13 Hierarchy of units of work in anatomic pathology

The following figure shows the hierarchy between units of work focused on by the Anatomic Pathology Technical Framework. Refer to the above glossary for definition of each unit.

Each nested unit of work is repeatable within the nesting unit.

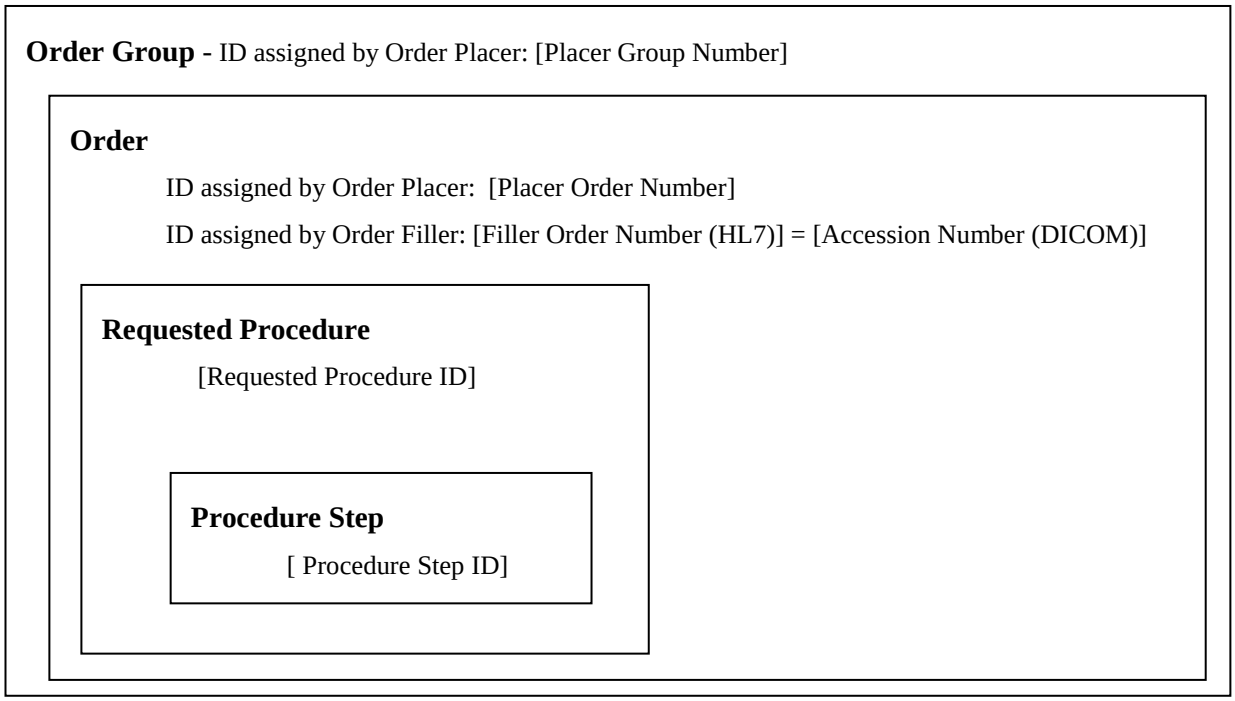

Figure 1.13-1: Hierarchy of Units of Work in Anatomic Pathology

1.14 Open Issues regarding Volume 1

1.14.1 Scheduling imaging Requested Procedures

In future cycles we should request the capability of the LIS to provide the hanging protocol attached to a Requested Procedure.

1.14.2 Future units of work for automation

Work Order: A Work Order is a type of examination (e.g. histo-pathological examination, molecular examination, clinical autopsy) to be performed in fulfillment of an Order, on one or more of the specimens attached to this Order. A Work Order belongs to zero or one Order Group.

Work Order Step: A Work Order Step is an atomic operation belonging to a Work Order, to be performed on one specimen by a single type of device (e.g. immune-histo-chemistry automaton, staining automaton, image acquisition modality). Some Work Order Steps are dedicated to image acquisition ; these particular Work Order Steps are called “Requested Procedure” (see this entry in the glossary).

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1.14.3 Need of extensions to RAD-14 and RAD-18 Transactions from RAD TF

There is a need of specific extensions to Query Image (RAD-14) and Retrieve Image (RAD-18) transactions in order to use specimen-related querying and response keys (e.g specimen ID, container ID, specimen type, etc). These functionalities are needed in order to adapt Image Display to the specific querying/browsing processes within anatomic pathology series and studies.

1.15 Scope of the Anatomic Pathology Technical Framework

The Anatomic Pathology Technical Framework aims at the integration of the anatomic pathology laboratory department in the healthcare enterprise. The diagnostic process requires tight consultation and close cooperation between different healthcare providers: pathologists and technicians, surgeons, oncologists, clinicians, radiologists, etc. The ultimate goal is a comprehensive digital pathology record for the patient, of which images are a significant part.

The primary focus will be digital formats for clinical patient management, but digital imaging for research applications may also be addressed as appropriate (dealing with Tissue Micro Arrays (one slide for hundreds of patients) with a link to patient information or dealing with animal experimentation, etc).

The aim is to progressively cover all specialties of anatomic pathology: surgical pathology, clinical autopsy, cytopathology, biopsies and all special techniques (gross examination, frozen section, immunohistochemistry (including TMAs), molecular pathology, flow cytometry, special microscopy techniques (confocal laser scanning, multispectral microscopy), etc.

The diagnostic process in anatomic pathology (figure 1.15-1) differs from that in the clinical laboratory since it relies on image interpretation. It also differs from that in radiology since it is specimen-driven and when digital imaging is performed many types of imaging equipments (gross imaging, microscopic still imaging, whole slide imaging, multispectral imaging, etc) may be involved for a single examination. Moreover, images of the same study may be related to different specimen (parts and/or slides) from one or even different patients (e.g. Tissue Micro Array). Finally, slides are always available to acquire more images, if needed. In radiology, the diagnostic process is patient-driven, an examination (study) usually involves a single image acquisition modality and all images of the study are related to one and only one patient.

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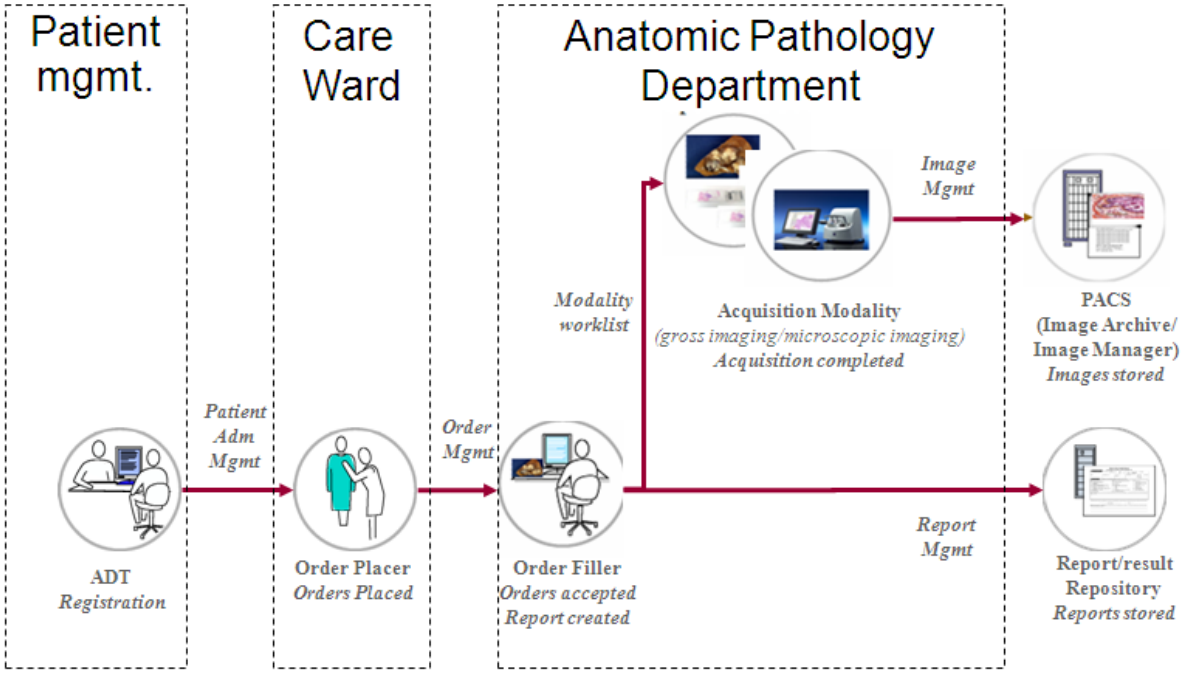

Figure 1.15-1: Overview of Anatomic Pathology Workflow

1.16 Anatomic Pathology Integration Profiles

Integration profiles describe real-world scenarios or specific sets of capabilities of integrated
570 systems. An Integration Profile applies to a specified set of actors and for each actor specifies the transactions necessary to support those capabilities.

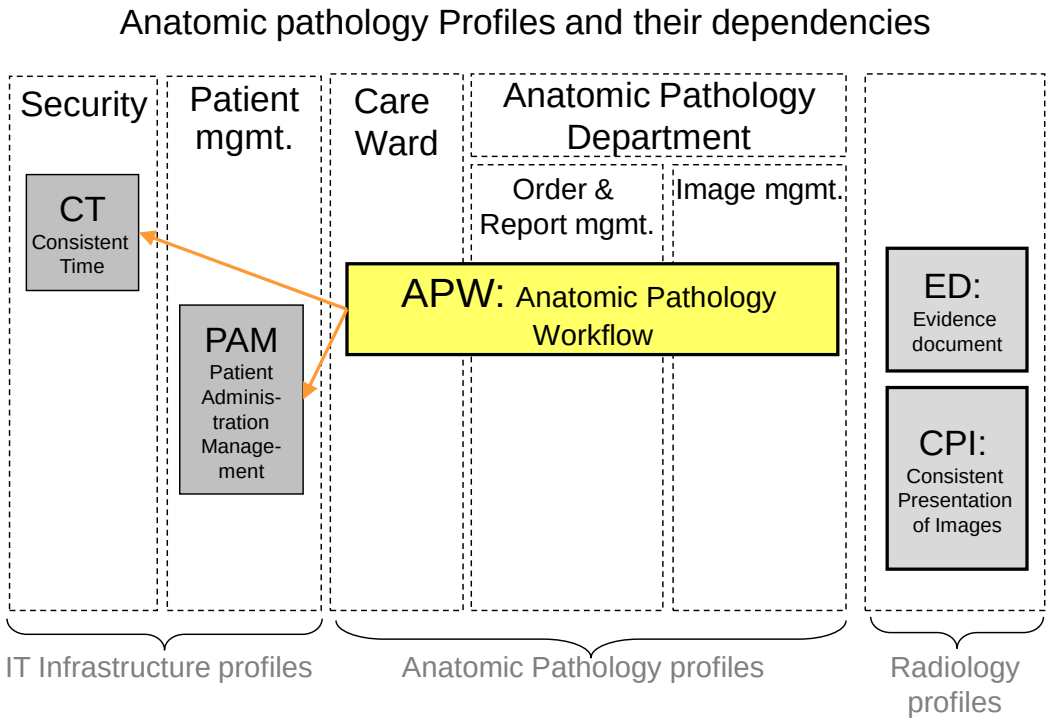

Figure 1.16-1: Integration Profiles in the Anatomic Pathology domain

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Note 1: ED and CPI profiles, specified by the Radiology domain are also usable without change in the Anatomic Pathology domain.

Note 2: The APW profile depends upon Consistent Time (CT) and Patient Administration Management (PAM) profiles from the IT Infrastructure Technical Framework.

1.17 Specifications of Dependencies among Profiles

Dependencies among IHE Integration Profiles exist when implementation of one integration profile is a prerequisite for achieving the functionality defined in another integration profile. Table 1.17-1 defines these dependencies in tabular form. Some dependencies require that an actor supporting one profile be grouped with one or more actors supporting other integration profiles. For example, Anatomic Pathology Workflow (APW) Profile requires that different participating actors be grouped with the Time Client Actor that participates in the Consistent Time (CT) Integration Profile. The dependency exists because APW actors must rely on consistent time in order to function properly.

Table 1.17-1: Anatomic Pathology Profiles Dependencies

Integration Profile	Depends on	Dependency Type	Purpose
Anatomic Pathology Workflow (APW)	PAM in ITI TF	Each of OP, OF and ORT Actors of APW shall be grouped with at least one of these combination of actors: Patient Demographics Supplier and Patient Encounter Supplier in PAM. Patient Demographics Consumer and Patient Encounter Supplier in PAM. Patient Demographics Consumer and Patient Encounter Consumer in PAM.	The Actors OP, OF and ORT must be provided with up-to-date patient data as soon as they need it.
Anatomic Pathology Workflow (APW)	CT in ITI TF	All actors of APW Integration Profile shall be grouped with the CT Time Client Actor.	Time synchronization required to manage and resolve conflicts in multiple updates.

Other IHE profiles like IT Infrastructure (ITI) profiles (Retrieve Information for Display - RID, Enterprise User Authentication – EUA, Patient Identifier Cross-referencing – PIX, Patient Synchronized Applications - PSA, Consistent Time - CT, Patient Demographics Query - PDQ, Audit Trail and Node Authentication - ATNA, Personnel White Pages - PWP, and Cross-Enterprise Document Sharing - XDS) are useful in pathology.

1.18 Profiles Overview

1.18.1 Anatomic Pathology Workflow (APW)

The Anatomic Pathology Workflow Integration Profile establishes the continuity and integrity of basic pathology examination data and images exchanged between the systems of the ordering care units, those of the performing pathology laboratory, and the systems producing, archiving, communicating or presenting images.

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Some actors and transactions of the Pathology Workflow Integration Profile are reused from existing profiles described within Radiology Technical Framework and Laboratory Technical Framework.

1.19 Actors Description

Actors are information systems or components of information systems that produce, manage, or act on information associated with operational activities in the enterprise. The following are the actors defined by IHE and referenced throughout the rest of this document (in alphabetic order).

Acquisition Modality: A system that acquires and creates medical images from a specimen, e.g. gross imaging station, a digital camera mounted on a microscope or a virtual slide scanner. A modality may also create other evidence objects such as Presentation States for the consistent viewing of images or Evidence Documents containing measurements.

Department System Scheduler/Order Filler: Synonym for Order Filler, used by transactions imported from Radiology Technical Framework

Evidence Creator: A system that creates additional evidence objects such as images, presentation states, Key Image Notes, and/or Evidence Documents and transmits them to an Image Archive. It also makes requests for storage commitment to the Image Manager for the data previously transmitted.

Image Archive: A system that provides long term storage of evidence objects such as images, presentation states, Key Image Notes and Evidence Documents.

Image Display: A system that offers browsing of patient's studies including anatomic pathology image folders. In addition, it may support the retrieval and display of selected evidence objects including sets of images, presentation states and Evidence Documents.

Image Manager: A system that provides functions related to safe storage and management of evidence objects. It supplies availability information for those objects to the Department System Scheduler.

Order Placer: A hospital or enterprise-wide system that generates orders for various departments and distributes those orders to the correct department, and appropriately manages all state changes of those orders. In some cases the Order Placer is responsible for collecting and identifying the specimens. Therefore, the transaction between Order Placer and Order Filler may carry specimen related information. There may be several Order placer actors in the same enterprise

Order Filler: A pathology department-based information system that provides functions related to the management of orders received from external systems or through the department system's user interface. The system receives orders from Order Placer actors, collects or controls the related specimens, accepts or rejects the order, schedules work orders, and sends them to processing room, receives the results of gross study (specimen status and adequacy), controls the status of each specimen, and appropriately manages all state changes of the order. In some cases, the Order Filler will create test orders itself (e.g. a paper order received from a department not connected to an Order Placer, or a paper order was received from a physician external to the organization). In some cases the Order Filler is responsible for

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collecting and identifying the specimens. An Order Filler may receive orders from various Order Placers.

Order Result Tracker – A system that stores pathology observations obtained for the patients of the healthcare institution, registers all state changes in the results notified by Order Fillers. This actor stores observations in the context of their Order or Order Group. This actor also stores reports outside the Pathology department.

1.20 Transaction Descriptions

Transactions are interactions between actors that transfer the required information through standards-based messages. The following are the transactions defined by IHE and referenced throughout the rest of this document.

PAT-1 Placer Order Management: This transaction contains all the messages required between the Order Placer and the Order Filler for the management of the life cycle of the order. Its main goal is to keep a consistent vision of the order, (content and status), between the two actors.

PAT-2 Filler Order Management: This transaction contains all the messages required between the Order Filler and the Order Placer for the notification of a new filler order, as well as the creation of the placer order that reflects it. Its main goal is to ensure that each filler order will be represented by a placer order, and will have both a filler order number and a placer order number.

PAT-3 Order Results Management: This transaction carries the results of an Order, as well as status changes, modifications, cancellations of these results, from the Order Filler to the Order Result Tracker.

PAT-4 Procedure Scheduled and Updated: The Department System Scheduler/Order Filler sends the Image Manager and Report Manager scheduled procedure information or procedure update.

PAT-5 Query Modality Worklist: Based on a query entered at the Acquisition Modality, a modality worklist is generated listing all the items that satisfy the query. This list of Scheduled Procedure Steps with selected demographic information **and information about specimen** is returned to the Acquisition Modality.

PAT-6 Modality Procedure Status Notification. After a Modality Worklist Item is selected at the Acquisition Modality for starting an Image Acquisition Proccess over a specimen, the Acquisition Modality notifies the Order Filler to let it update its Modality Worklist removing the started item from it. Upon completion of the Image Acquisition process the Acquisition Modality notifies the Order Filler that a DICOM instance has been stored. Also, if the Image Acquisition aborts the Acquisition Modality notifes this status to the Order Filler.

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RAD-8 Modality Images Stored: An Acquisition Modality sends acquired or generated images to the Image Archive. Defined in RAD TF-1:2.4, specified in RAD TF-2:4.8.

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RAD-10 Storage Commitment: A requestor (Acquisition Modality or Evidence Creator) requests that the Image Manager confirm ownership for the specified DICOM objects (images, GSPS objects, Key Image Notes, Evidence Documents or any combination thereof) that the requestor stored in the Image Archive, thus allowing the sender to delete those objects
700 now owned by the Image Manager. Defined in RAD TF-1:2.4, specified in RAD-TF-2:4.10.

RAD-14 Query Images: An Image Display queries the Image Archive for a list of entries representing images by patient, study, series, or instance. Defined in RAD TF-1:2.4, specified in RAD-TF-2:4.14.

705 **RAD-16 Retrieve Images**: An Image Display or an Imaging Document Consumer requests and retrieves a particular image or set of images from the Image Archive or an Imaging Document Source, respectively. Defined in RAD TF-1:2.4, specified in RAD-TF-2:4.16.

RAD-43 Evidence Document Stored: A source actor of Evidence Documents (Acquisition
710 Modality or Evidence Creator) sends recorded, measured or derived diagnostic evidence in the form of a DICOM Structured Report to the Image Archive. Defined in RAD TF-1:2.4, specified in RAD TF-3:4.43.

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2 Anatomic Pathology Workflow (APW)

2.1 Actors/Transactions

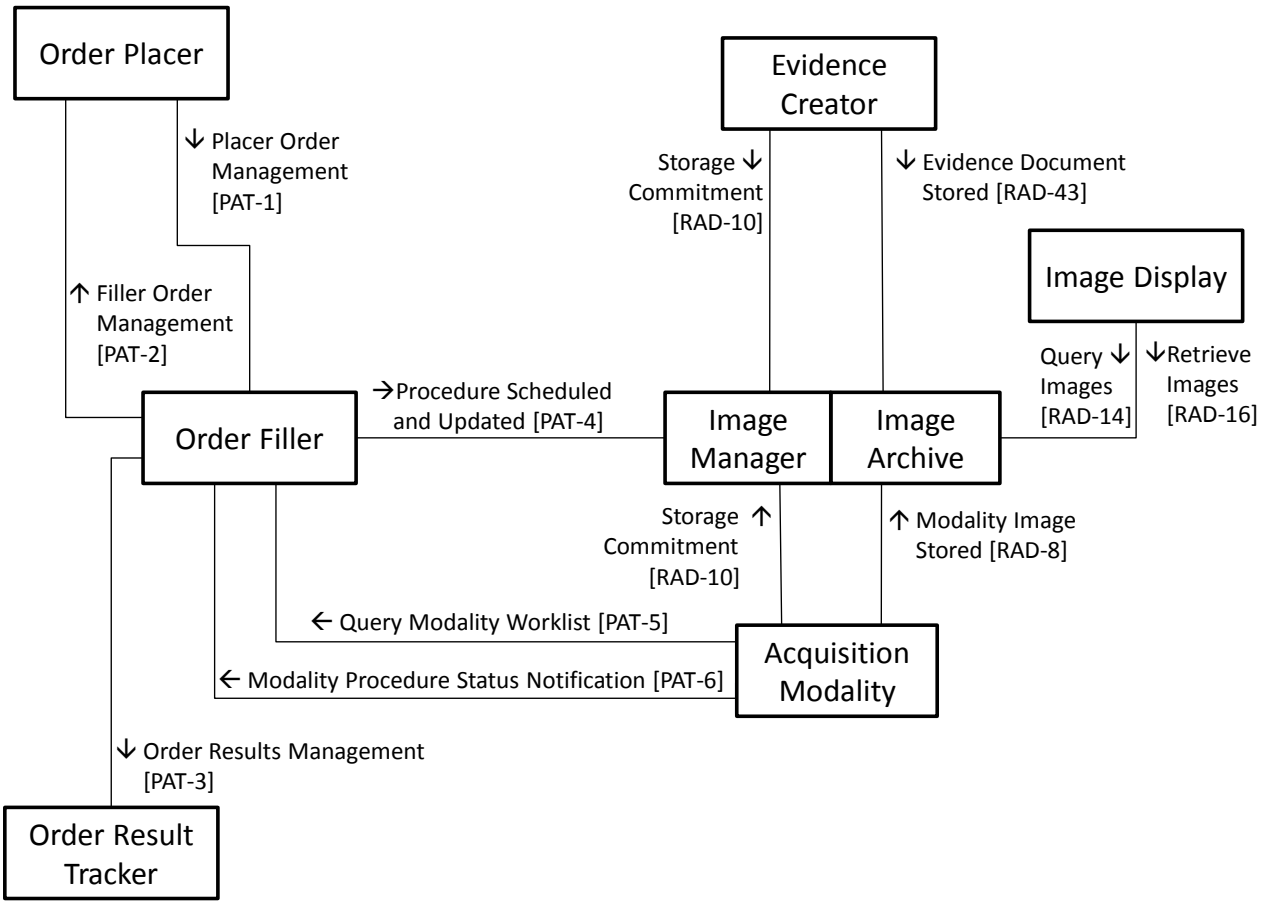

Figure 2.1-1: Anatomic Pathology Workflow (APW)

Table 2.1-1: Anatomic Pathology Workflow – Actors and Transactions

Actors	Transactions	Optionality	Documentary reference
Order Placer	Placer Order management (PAT-1)	R	Pathology TF-2:4
	Filler Order Management (PAT-2)	R	Pathology TF-2:5
Order Filler	Placer Order Management (PAT-1)	R	Pathology TF-2:4
	Filler Order Management (PAT-2)	R	Pathology TF-2:5
	Order Results Management (PAT-3)	R	Pathology TF-2:6
	Procedure Scheduled and Updated (PAT-4)	R	Pathology TF-2:7
	Query Modality Worklist (PAT-5)	R	Pathology TF-2:8
	Modality Procedure Status Notification (PAT-6)	R	Pathology TF-2:9
Acquisition Modality	Query Modality Worklist (PAT-5)	R	Pathology TF-2:8
	Storage Commitment (RAD-10)	R	Radiology TF-2 : 4.10
	Modality Image Stored (RAD-8)	R	Radiology TF-2 : 4.8
	Modality Procedure Status Notification (PAT-6)	R	Pathology TF-2:9

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Actors	Transactions	Optionality	Documentary reference
Image Manager/ Image Archive	Procedure Scheduled and Updated (PAT-4)	R	Pathology TF-2:7
	Storage Commitment (RAD-10)	R	Radiology TF-2 : 4.10
	Modality Image Stored (RAD-8)	R	Radiology TF-2 : 4.8
	Evidence Document Stored (RAD-43)	R	Radiology TF-2 : 4.43
	Query Images (RAD-14)	R	Radiology TF-2 : 4.14
	Retrieve Images (RAD-16)	R	Radiology TF-2 : 4.16
Image Display	Query Images (RAD-14)	R	Radiology TF-2 : 4.14
	Retrieve Images (RAD-16)	R	Radiology TF-2 : 4.16
Evidence Creator	Storage Commitment (RAD-10)	R	Radiology TF-2 : 4.10
	Evidence Document Stored (RAD-43)	R	Radiology TF-2 : 4.43
Order Result Tracker	Order Results Management (PAT-3)	R	Pathology TF-2:6

Note 1: All Actors of APW Integration Profile shall be grouped with the Actor Time Client from the CT Profile described in ITI TF-1:7.

Note 2: Actors OP, OF and ORT shall be grouped with one of the following combinations of Actors from the PAM profile described in ITI TF-1:14:

Patient Demographics Supplier and Patient Encounter Supplier

Patient Demographics Consumer and Patient Encounter Supplier

Patient Encounter Consumer and optionally Patient Demographics Consumer

2.2 Process Flow

Process flow is expressed with the following UML sequence diagrams, with time scale from top to bottom.

The blue dashed message flows (Order status change notified by the Order Filler to the Order Placer) in the figures below happen only when the Order Placer and the Order Results Tracker are distinct applications.

Whenever the Order Placer and the Order Results Tracker are grouped in the same application, the PAT-3 message carrying the status change and possible new results is sufficient to inform that application of the new status of the Order. A “Order status change” message in PAT-1 would be redundant in that case.

Therefore, when exchanging with a grouped Order Placer/Order Results Tracker, the Order Filler SHALL NOT send these redundant messages over Transaction PAT-1, which appear as dashed blue arrows in all figures below). A system implementing the Order Filler actor SHALL have an internal setting to adjust this filtering on each on its PAT-1 transactions.

2.2.1 Pathology General Workflow without image acquisition

A physician or a surgeon in a care department orders for macroscopic and microscopic examination of specimen collected from the patient. Each order may contain one or more Requested Procedure possibly reported by different pathologists. It must be possible to add or link rough drawings, photographs (gross imaging) or vocal messages to an order.

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The **Order Placer** sends the Order and pertinent related information to the **Order Filler (PAT-1).**

The **Order Filler** translates the received Orders into Requested Procedure(s), automatically assigns Study Accession Numbers[1]. The pathology Department staff checks the order and ensures that all required parts are available and conform to the order. Containers are labeled and specimen (parts) are identified.[2] Order and specimen(s) conformance statuses are sent to the **Order Placer (PAT-1, PAT-2).**

The pathology department staff performs a macroscopic examination of the specimens and processes specimen for tissue banking and/or microscopic examination.

After slide examination, the pathologist sends observations and/or reports. The **Order Filler** sends observations and/or reports to the **Order Result Tracker** and provides the **Order Result Tracker** with up-to-date information and statuses of the observations and/or the report (**PAT-7**).

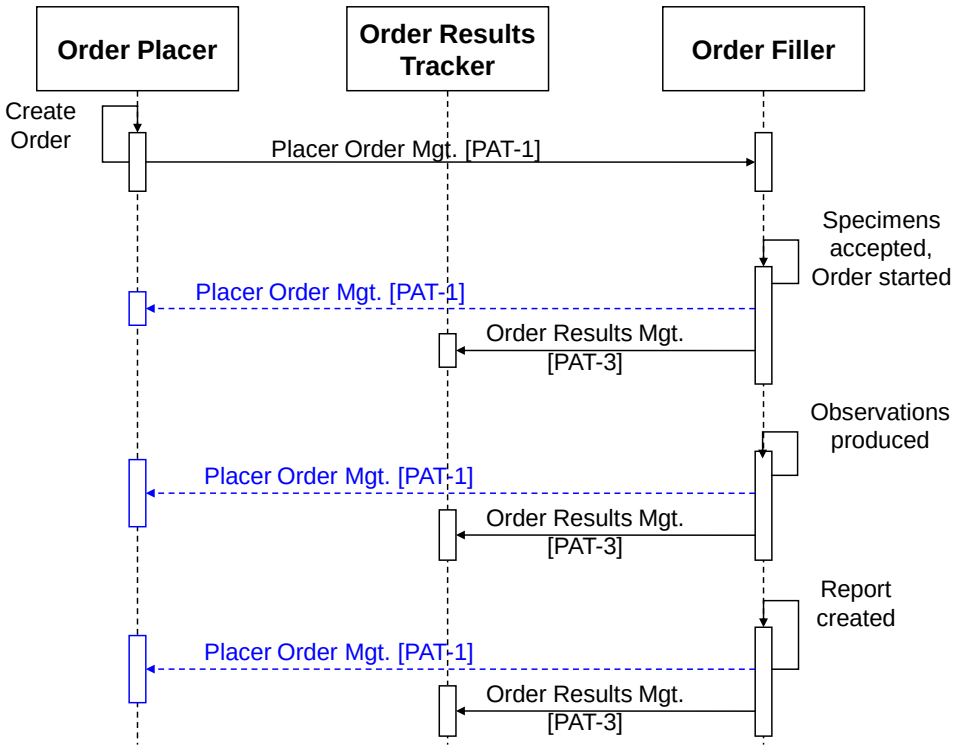

Figure 2.2-1 Anatomic Pathology General Workflow without acquisition of images

Note 1: Dashed blue exchanges happen only if Order Result Tracker and Order Placer are implemented in two distinct systems

2.2.2 Pathology General Workflow with acquisition of images

Gross imaging and/or microscopic imaging is performed using the **Acquisition Modality**. The technician queries the **Order Filler** to retrieve the information about the specimen and

1 *The pathology department can modify the breakdown of the order in Requested Procedures.*

2 *This intrinsic pathology department Specimen ID (Specimen Accession Number) is linked to the corresponding (clinical) Specimen ID that is stored by the Order Filler.*

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the corresponding Requested Procedure **(PAT-5)**. While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** (**RAD-8, RAD-10**) and available for the **Image Display**. The Order Filler is notified of every status change of the imaging procedure ("in progress" at the stat, "competed" or "aborted" at the end).

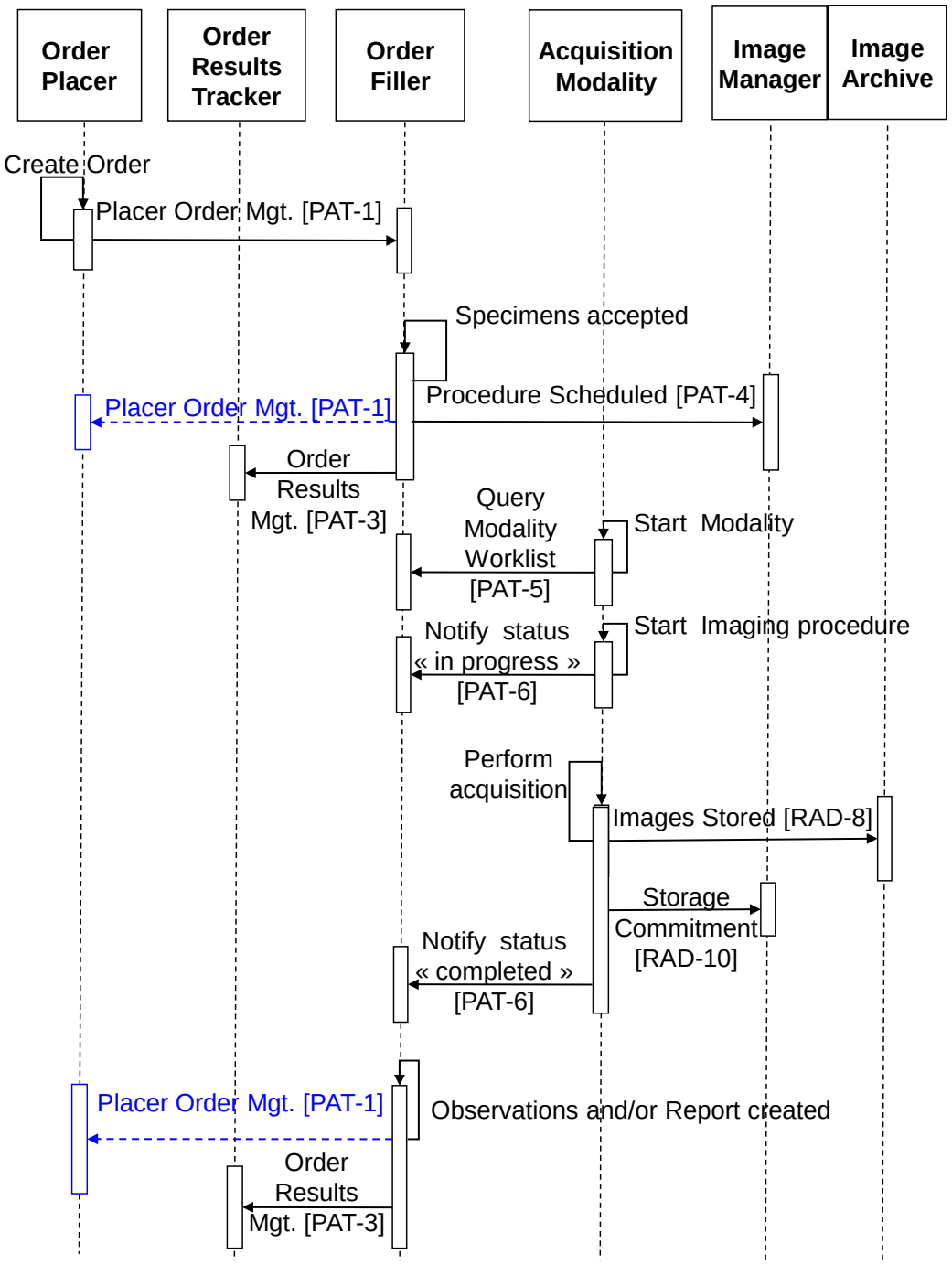

Figure 2.2-2 Anatomic Pathology General Workflow with acquisition of images

Note 1: Dashed blue exchanges happen only if Order Result Tracker and Order Placer are implemented in two distinct systems

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2.2.3 Pathology General Workflow with post processing

Post processing imaging is performed using the **Evidence Creator**. From their workstation, the technician queries (RAD-14) and retrieves (RAD-16) the images from the Image Archive. The query criteria may be the patient ID, study ID or Specimen ID). While performing Evidence Documents, a new STUDY and a new SERIES are created, stored in the **Image Archive** (**RAD-43, RAD-10**) and available for the **Image Display**.

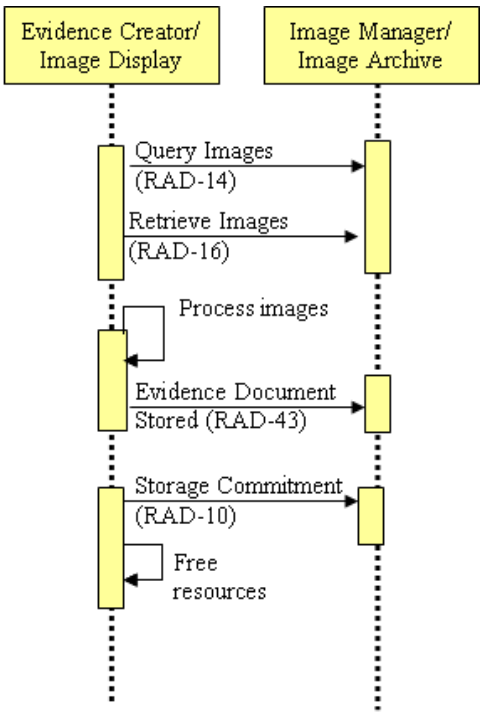

Figure 2.2-3-Pathology General Workflow with post processing

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3 Sub-specialties Use Cases

3.1 Use case 1: Surgical pathology – Operative specimen

3.1.1 Use case 1.1: Surgical pathology - one specimen per container

Luke Lung visits Sammy Surgeon for removal of a lung tumor. Sammy Surgeon orders the Requested Procedure "Lungectomy - Pathological examination" and sends six parts. A rough drawing and a vocal message are attached to the order (see PAT-1 in vol 2).

The **Order Filler** automatically accessions the Requested Procedure DP07110 (Accession Number). Terri Technician prints labels DP07110-A for "Left upper lobe", DP07110-B for "Upper division left upper apical posterior & anterior segments", DP07110-C for "AP Window, posterior lymph node biopsy", DP07110-D for "Anterior AP window, lymph node biopsy", DP07110-E for "12L, lymph node biopsy", DP07110-F for "Lymph node biopsy designated 8". The **Order Filler** sends to the **Order Placer** the order and specimen(s) conformance statuses (see PAT-1 in vol 2).

The **Order Filler** sends to the **Image Manager** the order and specimen(s) information (see PAT-4 in vol 2).

The pathology department staff performs a macroscopic examination of the specimens and processes part A for frozen section examination. After frozen section examination, the pathologist sends preliminary observations. The **Order Filler** sends the observations and/or a report and the status to the **Order Result Tracker** (see PAT-3 in vol 2).

The day after, the pathologist performs a macroscopic examination of the specimens and processes specimens for tissue banking and/or microscopic examination. Figure 3.1-1 depicts the sampling process of the specimens.

Patient ID / Order ID / Case ID (OF) / Part ID / Block ID / Slide ID

P072345: LUNG Luke

OR123: Lungectomy

DP07110 : Lungectomy

DP07110-A: Left upper lobe (gross image)

DP07110-A-1: Frozen section, mass

DP07110-A-1-1: FS

DP07110-A-1-2: H&E

DP07110-A-2: Entire stapled

DP07110-A-2-1: H&E

DP07110-A-3: Entire stapled

DP07110-A-3-1: H&E

DP07110-A-4: Entire stapled

DP07110-A-4-1: H&E

DP07110-A-5: Entire mass

DP07110-A-5-1: H&E (WSI)

DP07110-A-5-2: Elastic

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DP07110-A-6: Entire mass

DP07110-A-6-1: H&E

DP07110-A-6-2: Elastic

DP07110-A-7: Unvolved lung tissue

DP07110-A-7-1: H&E

DP07110-A-8: Unvolved lung tissue

DP07110-A-8-1: H&E

DP07110-B: Upper division left upper apical posterior & anterior segments

DP07110-B-1: Vascular margin

DP07110-B-1-1: H&E

DP07110-B-2: Bronchial margin

DP07110-B-2-1: H&E

DP07110-B-3: Stapled line margin

DP07110-B-3-1: H&E

DP07110-B-4 : Stapled line margin

DP07110-B-4-1: H&E

DP07110-B-5: Stapled line margin

DP07110-B-5-1: H&E

DP07110-B-6 : Lung tissue representative

DP07110-B-6-1: H&E

DP07110-B-7 : Lung tissue representative

DP07110-B-7-1: H&E

DP07110-B-8 : Lung tissue representative

DP07110-B-8-1: H&E

DP07110-C: AP Window, posterior lymph node biopsy

DP07110-C-1: Embedded entirely

DP07110-C-1-1: H&E

DP07110-D: Anterior AP window, lymph node biopsy

DP07110-D-1: Embedded entirely

DP07110-D-1-1: H&E

DP07110-E: 12L, lymph node biopsy

DP07110-E-1: Embedded entirely

DP07110-E-1-1: H&E

DP07110-F: Lymph node biopsy designated 8

DP07110-F-1 : Embedded entirely

DP07110-F-1-1: Level 1, H&E (WSI)

DP07110-F-1-2: Level 2, H&E

Figure 3.1-1: Use Case 1.1 - Sampling process (one specimen per container)

Gross imaging is performed on Part A “Left upper lobe” (***DP07110-A: Left upper lobe***). The technician queries the **Order Filler** to retrieve the information about the specimen and the

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Requested Procedure (see PAT-5 in vol 2). While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**.

Microscopic imaging is performed on two slides (***DP07110-A-5-1: Left upper lobe/Entire mass/H&E*** *and* ***DP07110-F-1-1: Lymph node biopsy 8/Embedded entirely/Level1,H&E***).
The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2). While performing images, a new STUDY and a new SERIES are created, stored in the Image **Archive** and available for the **Image Display**.

IMPORTANT NOTE : In conformance with DICOM supp122, the short textual description of a specimen retrieved from the Order Filler is a concatenation of the short description of the specimen and all the short descriptions of the specimen ancestry

Example for the short description of the slide ***DP07110-A-5-1***

DP07110-A: Left upper lobe

DP07110-A-5: Left upper lobe/Entire mass

DP07110-A-5-1: Left upper lobe/Entire mass/H&E (WSI)

Example for the short description of the slide ***DP07110-F-1-1***

DP07110-F: Lymph node biopsy designated 8

DP07110-F-1; Lymph node biopsy designated 8/Embedded entirely

DP07110-F-1-1: Lymph node biopsy 8/Embedded entirely/Level1,H&E (WSI)

In conformance with DICOM supp122, the same concatenation principle is applied to detailed textual specimen description

After image interpretation, the pathologist sends a final report. The **Order Filler** sends the report to the **Order Result Tracker** and provides the **Order Placer** and the **Order Result Tracker** with up-to-date information and statuses of the order (see PAT-1 and PAT-3 in vol 2).

3.1.2 Use case 1.2: Surgical pathology - more than one specimen per container

Barbara Breast visits Sammy Surgeon for removal of a breast tumor. Sammy Surgeon orders the Requested Procedure “Breast surgical specimen with axillary lymph node - Frozen sections & pathological examination” and sends six parts. A rough drawing and a vocal message are attached to the order (see PAT-1 in vol 2).

The **Order Filler** automatically accessions the Requested Procedure DP07120. Terri Technician prints labels DP07120-A for “Tumorectomy”, DP07120-B for “Lymph node 1” and DP07120-C for “Lymph node 2”. The **Order Filler** sends to the **Order Placer** the order and specimen(s) conformance statuses (see PAT-1 in vol 2).

The **Order Filler** sends to the **Image Manager** the order and specimen(s) information (see PAT-4 in vol 2).

The pathology department staff performs a macroscopic examination of the specimens.

Gross imaging is performed on Part A “Tumorectomy” (***DP07120-A: Tumorectomy***). The technician queries the **Order Filler** to retrieve the information about the specimen and the the

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Requested Procedure (see PAT-5 in vol 2). While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**.

The day after, the pathologist performs a macroscopic examination of the specimens and processes specimens for tissue banking and/or microscopic examination. Figure 3.1-2 depicts the sampling process of the specimen.

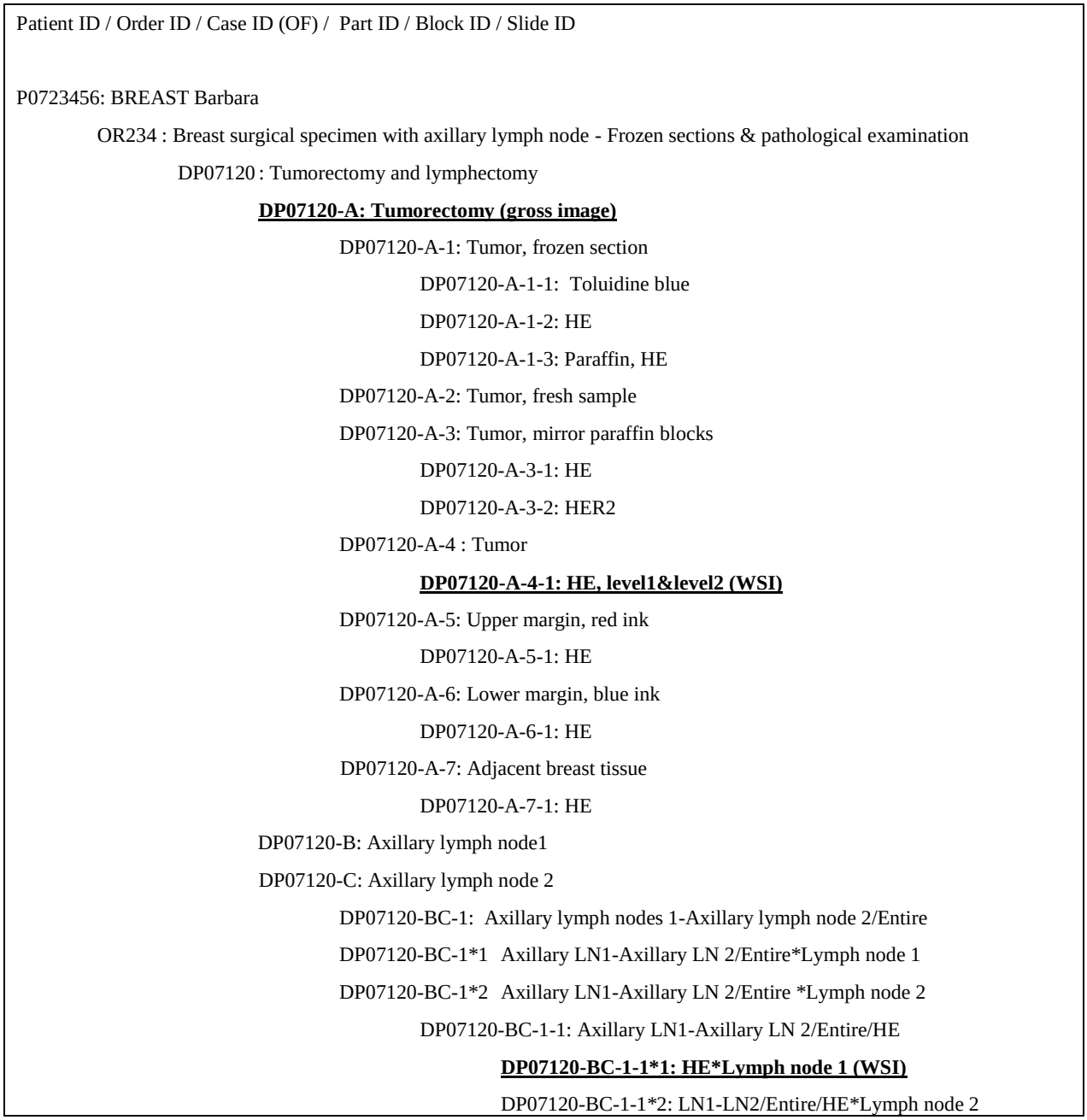

Figure 3.1-2: Use Case 1.2 - Sampling process (more than one specimen per container)

Microscopic imaging is performed on slide (***DP07120-A-4-1***: ***Tumorectomy/Tumor/HE, level1&level2).*** The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

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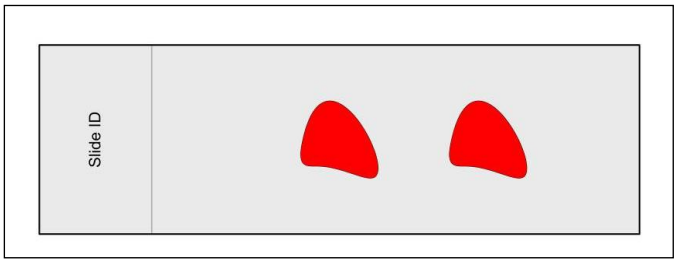

Figure 3.1-3: Two tissue items from the same tissue in block but different levels

In this example, specimen ID and Container ID are the same (DP07120-A-4-1)

Microscopic imaging is performed on slide (***DP07120-BC-1-1*1 Axillary lymph nodes 1-Axillary lymph node 2/Entire/HE*Lymph node 2).*** The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

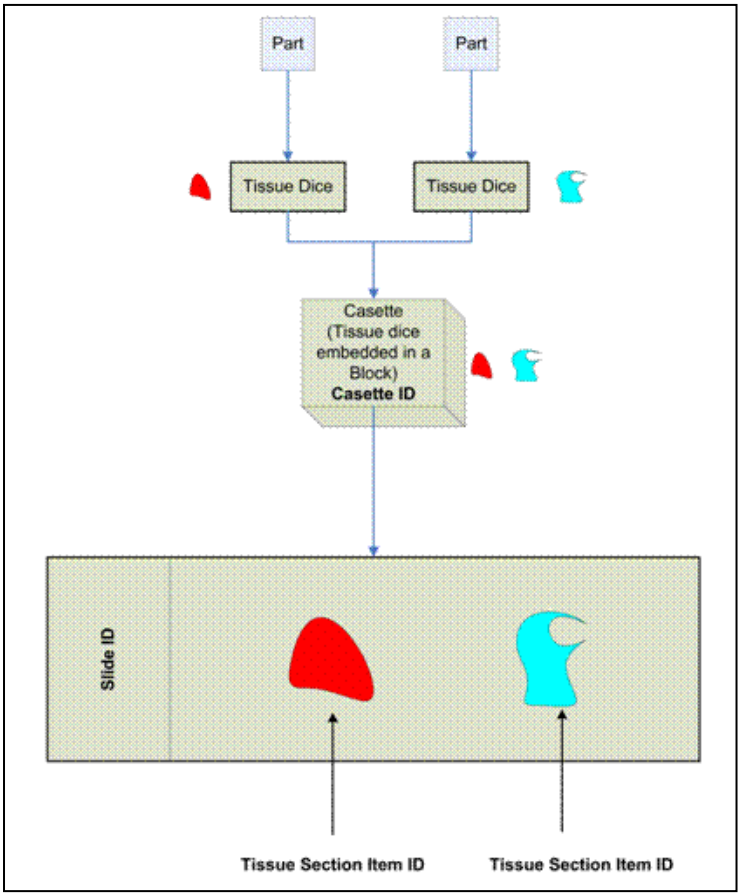

Figure 3.1-4: Two tissue items from two different parts of the same tissue

In this example specimen ID (DP07120-BC-1-1*1 and DP07120-BC-1-1*2) and container ID (DP07120-BC-1-1) are different.

While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**.

After image interpretation, the pathologist sends a final report. The **Order Filler** sends the report to the **Order Result Tracker** and provides the **Order Placer** and the **Order Result**

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Tracker with up-to-date information and statuses of the order (see PAT-1 and PAT-3 in vol 2).

3.1.3 Use case 1.3: Surgical pathology – two requested procedure

P0734567: NAEVUS Natalia

OR345: Breast tumorectomy and naevus

DP07130 : Tumorectomy and lymphectomy

DP07130-A: Tumorectomy

DP07130-A-1: Tumor (gross image)

DP07130-A-1-1: HE

DP07130-A-2: Tumor

DP07130-A-2-1: HE

DP07130-A-3: Tumor

DP07130-A-3-1 DP07130-A-3-1 Tumorectomy/Tumor/HE

DP07130-A-4: Upper margin, red ink

DP07130-A-4-1: Tumorectomy/Upper margin, red ink/HE (WSI)

DP07130-A-5: Lower margin, blue ink

DP07130-A-5-1: HE

DP07140 : Naevus excision

DP07140-A: Naevus

DP07140-A-1: Entirely embedded

DP07140-A-1-1: Naevus/Entirely embedded/HE (WSI)

Figure 3.1-5 Sampling process of the specimen.

Figure 3.1-5: Two requested procedures

3.1.4 Use case 1.4: Surgical pathology – creating an order in the Order Filler

Peter Patient visits Sammy Surgeon for removal of a naevus. Sammy Surgeon sends the naevus to the pathology department without any order.

Terri Technician accessions a new Requested Procedure "Naevus - Pathological examination" DP07140 in the **Order Filler**. The **Order Filler** sends to the **Order Placer** the order, Requested Procedure and specimen(s) conformance statuses (see PAT-2 in vol 2).

3.2 Use case 2: Surgical pathology – Biopsies

3.2.1 Use case 2.1: Biopsies – one specimen per container

Pakkun Patient visits Eisaku Endoscopist for endoscopy examination of Stomach and Duodenum. During the observation, Eisaku Endoscopist finds doubtful places of malignancy. Eisaku Endoscopist performs biopsies from the two organs. Eisaku Endoscopist orders the

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Requested Procedure “Stomach and Duodenum biopsy specimen - Pathological examination” and sends 4 parts: 2 “Endoscopic biopsies of Stomach” and 2 “Endoscopic biopsies of Duodenum”. A rough drawing of collected places of organs is attached to the order (see PAT-1 in vol 2).

The **Order Filler** automatically accessions the Requested Procedure DP07210. Terri Technician prints labels DP07210-A for “Fundus”, DP07210-B “Antrum”, DP07210-C for “D1”, DP07210-D for “D2”.

The **Order Filler** sends to the **Image Manager** the order and specimen(s) information (see PAT-4 in vol 2).

The technician processes the specimens. Figure 3.2-1 depicts the sampling process of the specimen.

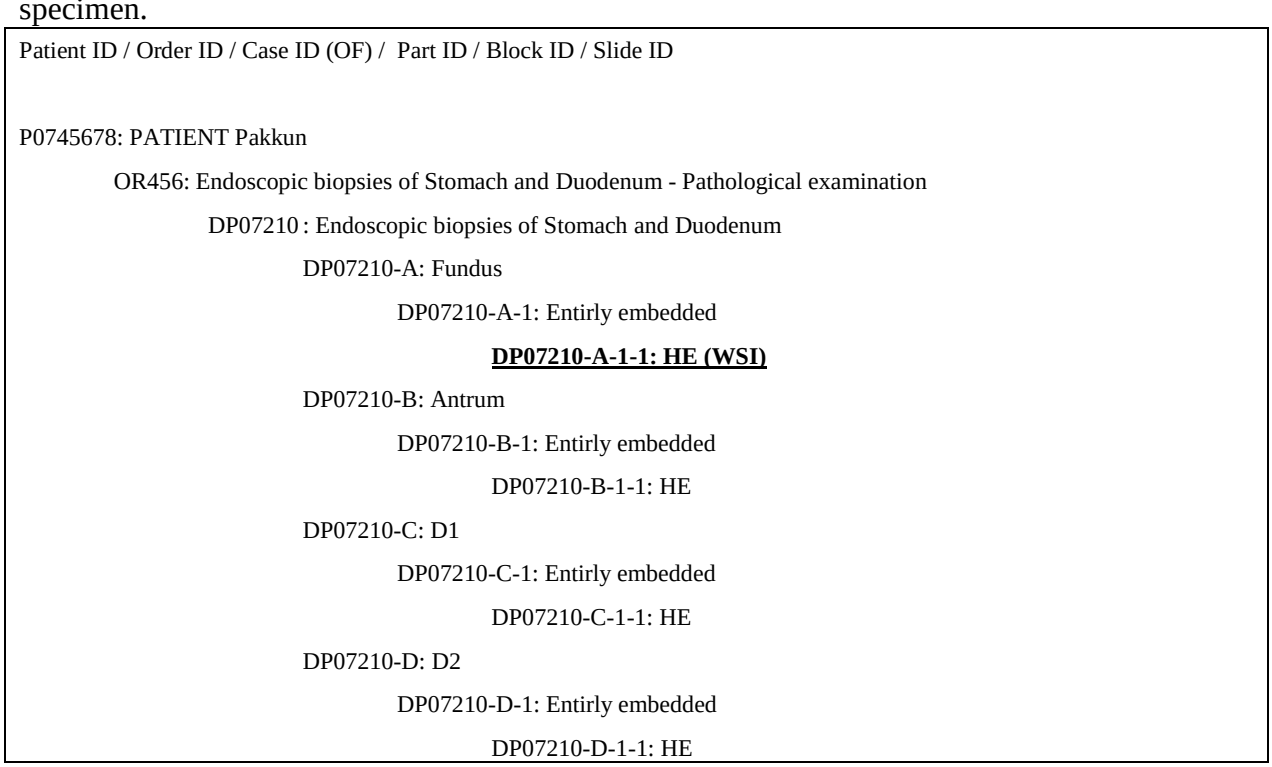

Figure 3.2-1: Sampling process for biopsy (one specimen per container)

Microscopic imaging is performed on the slide (***DP07210-A-1-1 Fundus/Entirly embedded/HE).*** The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**. After image interpretation, the pathologist sends structured observations. The **Order Filler** sends the observations to the **Order Result Tracker** and provides the **Order Placer** and **Order Result Tracker** with up-to-date information and statuses of the order (see PAT-1 and PAT-3 in vol 2).

3.2.2 Use case 2.2: Biopsies – more than one specimen per container

Pakkun Patient visits Eisaku Endoscopist for endoscopy examination of Stomach and Duodenum. During the observation, Eisaku Endoscopist finds doubtful places of malignancy. Eisaku Endoscopist performs biopsies from the two organs. Eisaku Endoscopist orders the Requested Procedure “Stomach and Duodenum biopsy specimen - Pathological examination”

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and sends 6 parts in one 6 partitioned tissue cassette: “Endoscopic biopsies of Stomach” and “Endoscopic biopsies of Duodenum”. A rough drawing of collected places of organs is attached to the order (see PAT-1 in vol 2).

905 The **Order Filler** automatically accessions the Requested Procedure DP07220. Terri Technician prints labels DP07220-A for “Fundus”, DP07220-B for “Fundus”, DP07220-C “Antrum”, DP07220-D for “Antrum”, DP07220-E for “D1”, DP07220-F for “D2”.

The **Order Filler** sends to the **Image Manager** the order and specimen(s) information (see PAT-4 in vol 2).

910 The technician processes the specimens. Figure 3.2-2 depicts the sampling process of the specimen.

Patient ID / Order ID / Case ID (OF) / Part ID / Block ID / Slide ID

P0745678: PATIENT Pakkun

OR456: Endoscopic biopsies of Stomach and Duodenum - Pathological examination

DP07220 : Endoscopic biopsies of Stomach and Duodenum

DP07220-A: Fundus

DP07220-B: Fundus

DP07220-C: Antrum

DP07220-D: Antrum

DP07220-E: D1

DP07220-F: D2

DP07220-ABCDEF-1: Entirely embedded

DP07220-ABCDEF-1-1: HE

DP07220-ABCDEF-1-1*1: HE*Fundus (WSI)

DP07220-ABCDEF-1-1*2: HE*Fundus (WSI)

DP07220-ABCDEF-1-1*3: HE*Antrum

DP07220-ABCDEF-1-1*4: HE*Antrum

DP07220-ABCDEF-1-1*5: HE*D1

DP07220-ABCDEF-1-1*6: HE*D2

Figure 3.2-2: Sampling process for biopsy (more than one specimen per container)

915 Microscopic imaging is performed on two slides (DP07220-ABCDEF-1-1*1: Fundus-Antrum-D1-D2/Entirly embedded/HE*Fundus and DP07220-ABCDEF-1-1*2: Fundus-Antrum-D1-D2/Entirly embedded/HE*Fundus). The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

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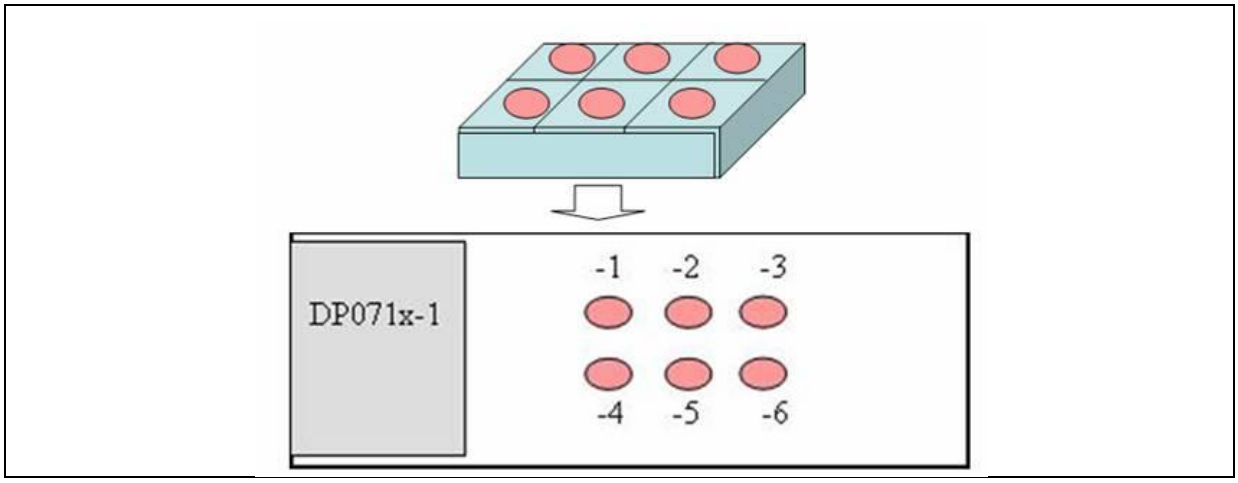

Figure 3.2-3: Six tissue items from the same cassette but different organs.

*Specimen ID (DP07220-ABCDEF-1-1*1, DP07220-ABCDEF-1-1*2, DP07220-ABCDEF-1-1*3, DP07220-ABCDEF-1-1*4,DP07220-ABCDEF-1-1*5,DP07220-ABCDEF-1-1*6) and Container ID (DP07220-ABCDEF-1-1) are different.*

While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**.

After image interpretation, the pathologist sends structured observations. The **Order Filler** sends the observations to the **Order Result Tracker** and provides the **Order Placer** and **Order Result Tracker** with up-to-date information and statuses of the order (see PAT-1 and PAT-3 in vol 2).

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3.3 Use case 3: Cytology

3.3.1 Use case 3.1: Cytology – one specimen per container

Bernard Bronchus visits Paul Pneumologist to receive a bronchoscopy with cytological examination. During the bronchoscopy two samples are taken. The material from Bronchus S1 is placed on a glass slide and the material from Bronchus S1 is placed into a test tube. Paul Pneumologist orders the requested procedure – Cytology using the **Order Placer** and sends the glass slide and test tube to the Pathology Department (see PAT-1 in vol 2).

The **Order Filler** automatically accessions the Requested Procedure DP07310. Terri Technician prints labels DP07310-A for "Bronchus S1" and DP07310-B for "Bronchus S5". The **Order Filler** sends to **the Order Placer** the order and specimen(s) conformance statuses (see PAT-1 in vol 2).

The **Order Filler** sends to the **Image Manager** the order and specimen(s) information (see PAT-4 in vol 2).

*In case of the automated slide scanning, the **Order Filler** sends a message to the **Acquisition Modality**.*

The pathologist processes specimens for microscopic examination. Figure 3.3-1 depicts the sampling process of the specimen.

Patient ID / Order ID / Case ID (OF) / Part ID / Block ID / Slide ID

P0756789: BRONCHUS Bernard

OR567: Bronchoscopy with cytological examination

DP07310 : Cytology

DP07310-A: Bronchus S1

DP07310-A-1: HE (WSI)

DP07310-B: Bronchus S5

DP07310-B-1: HE

DP07310-B-2: HE (WSI)

DP07310-B-3: HE

DP07310-B-4: HE

Figure 3.3-1: Use Case 3.1 - Sampling process (one specimen per container)

Microscopic imaging is performed on two slides (***DP07310-A-1 Bronchus S1/HE and DP07310-B-2: Bronchus S5/HE***). The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**.

After image interpretation, the pathologist sends a final report. The **Order Filler** sends the report to the **Order Result Tracker** and provides the **Order Result Tracker** and the **Order Placer** with up-to-date information and statuses of the order and the report (see PAT-1 and PAT-3 in vol 2).

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3.3.2 Use case 3.2: Cytology – more than one specimen per container

Catherine Cervix visits Gina Gynecologist for a routine cytological screening test. Gina Gynecologist takes samples from the different regions and distributes the specimen with the brush in different directions. Both samples are on the same glass slide. Gina Gynecologist orders the requested procedure: "gynaecological cytology" using the **Order Placer** and sends the glass slide to the Pathology Department (see PAT1 in vol 2).

The Department of Pathology receives a glass slide and confirms the conformance of specimen. The **Order Filler** sends to the Order Placer the order and specimen(s) conformance statuses (see PAT-1 in vol 2).

The **Order Filler** automatically accessions the Requested Procedure DP07320. Terri Technician prints labels DP07320-AB-1 for "Cervix and Vagina".

The **Order Filler** sends to the **Image Manager** the order and specimen(s) information (see PAT-4 in vol 2).

*In case of the automated slide scanning, the **Order Filler** sends a message to the **Acquisition Modality**.*

The pathologist processes the glass slide for microscopic examination. Figure 3.3-2 depicts the sampling process of the specimen.

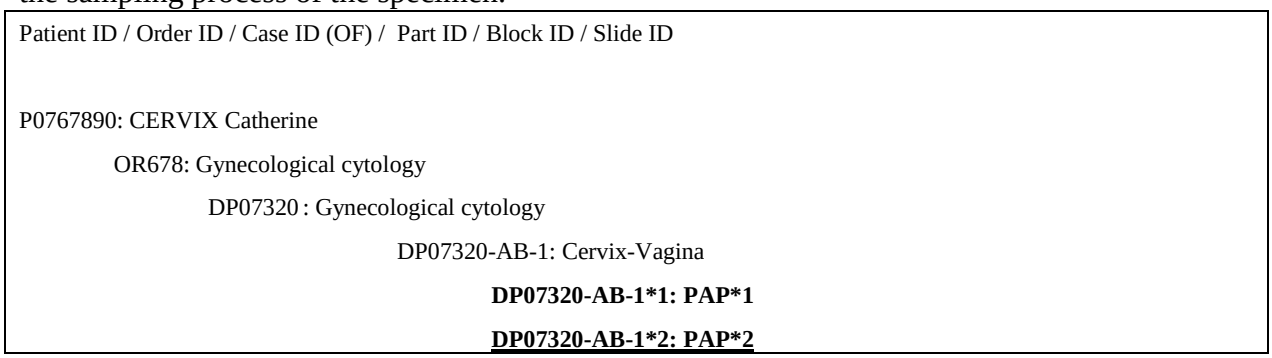

Figure 3.3-2: Use Case 3.2 – Sampling process (more than one specimen per container)

Microscopic imaging is performed on specimens on slide (***DP07320-AB-1*1: Cervix-Vagina/PAP*1 and DP07320-AB-1*2: Cervix-Vagina/PAP*2)***. The technician queries the **Order Filler** to retrieve the information about the specimens and the Requested Procedure (see PAT-3 in vol 2).

While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**.

After image interpretation, the pathologist sends a final report. The **Order Filler** sends the report to the **Order Result Tracker** and provides the **Order Result Tracker** and the **Order Placer** with up-to-date information and statuses of the order and the report (see PAT-1 and PAT-3 in vol 2).

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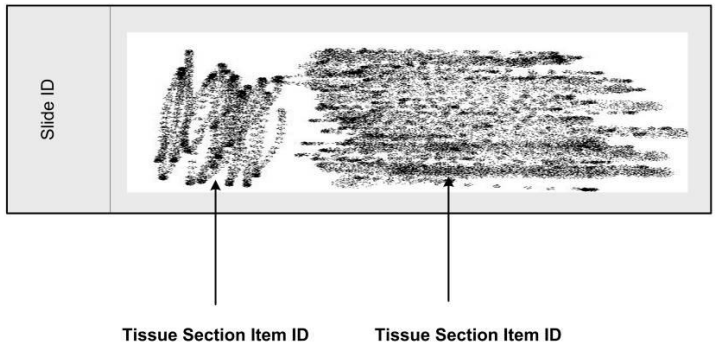

Figure 3.3-3: Two tissue items from different organs.

Specimen ID (DP07320-AB-1*1 (cervix), DP07320-AB-1*2 (vagina)) and Container ID (DP07320-AB-1) are different.

3.4 Use case 4: Autopsy

Pauline Patient is died in the hospital. Resident physician want to confirm the diagnosis and the treatment quality by an autopsy and sends a order to the Pathology Department using the **Order Placer**. The order contains the identification data of the patient, the causes of death and the request for an autopsy and is send to the **Department System Scheduler** (**Order Filler**) (see PAT-1 in vol 2).

The **Department System Scheduler** (**Order Filler**) automatically accessions the requested procedure A07400.

The pathologist performs the autopsy, collects some specimen and writes a preliminary report.

Terri Technician prints labels A07400-A for Heart Left Ventricle, A07400-B for Heart Right Ventricle, A07400-C for Liver, and A07400-D for Left kidney. The **Order Filler** sends to the **Order Placer** the order and specimen(s) conformance statuses (see PAT-1 in vol 2).

The **Order Filler** sends to the **Image Manager** the order and specimen(s) information (see PAT-4 in vol 2).

The day after, the pathologist performs a macroscopic examination of the specimens and processes specimens for tissue banking and/or microscopic examination. Figure 3.4-1 depicts the sampling process of the specimen.

Patient ID / Order ID / Case ID (OF) / Part ID / Block ID / Slide ID

P0713579: Pauline Patient

OR135: Autopsy

A07400: Autopsy

A07400-A: Heart Left Ventricle (gross image)

A07400-A-1: Necrosis

A07400-A-1-1: HE (WSI)

A07400-B: Heart Right Ventricle

A07400-B-1: Undefined

A07400-B-1-1: HE

A07400-C: Liver

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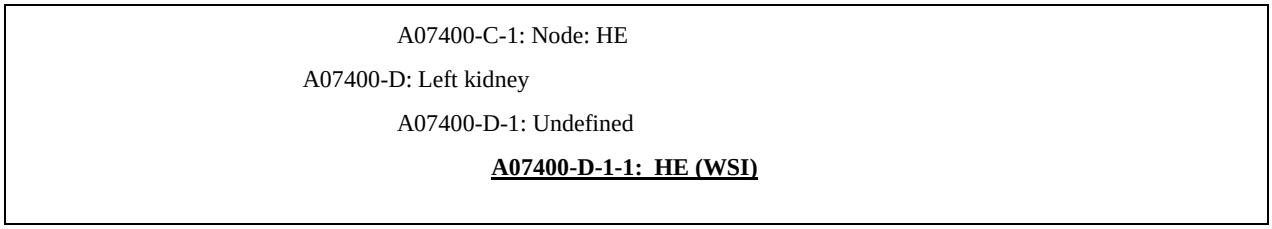

Figure 3.4-1: Use Case 4 - Sampling process

Gross imaging is performed on Part A "Left upper lobe" (***DP07400-A: Heart Left Ventricle*****)**. The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

Microscopic imaging is performed on slide (***A07400-A-1-1: Heart Left Ventricle/Necrosis/HE*** and ***A07400-D-1-1: Left kidney/Undefined/HE).*** The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**.

After image interpretation, the pathologist sends a final report. The **Order Filler** sends the report to the **Order Result Tracker** and provides the **Order Result Tracker** and the **Order Placer** with up-to-date information and statuses of the order and the report (see PAT-1 and PAT-3 in vol 2).

3.5 Use case 5: Tissue Micro Array (more than one specimen from more than one patient per container) (under construction)

Slides created from TMA block have small fragments of many different tissues coming from different patients all of which may be processed at the same time, under the same conditions by a desired technique. These are typically utilized in research.

The **Specimen (spot) ID** must be different from the Container (TMA Slide) ID. If the TMA slide is imaged, a single image must be created for each spot. A complete view of the TMA slide is created only as an "index" low resolution image

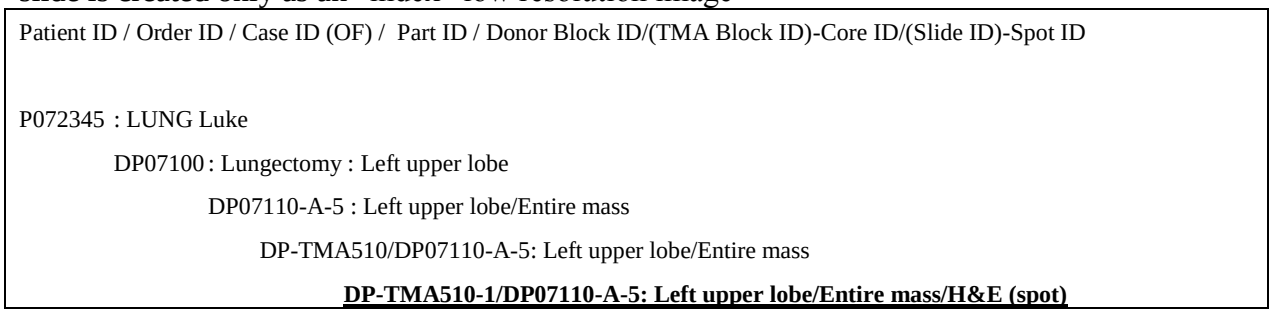

Figure 3. 5-1: Use Case 5 - TMA process (more than one specimen per container)

Microscopic imaging is performed on spot of the TM slide (***DP-TMA510-1/DP07110-A-5: Left upper lobe/Entire mass/H&E).*** The technician queries the **Order Filler** to retrieve the information about the specimen and the Requested Procedure (see PAT-5 in vol 2).

While performing images, a new STUDY and a new SERIES are created, stored in the **Image Archive** and available for the **Image Display**.

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After image interpretation, the pathologist sends a final report. The **Order Filler** sends the report to the **Order Result Tracker** and provides the **Order Result Tracker** and the **Order Placer** with up-to-date information and statuses of the order and the report (see PAT-1 and PAT-3 in vol 2).

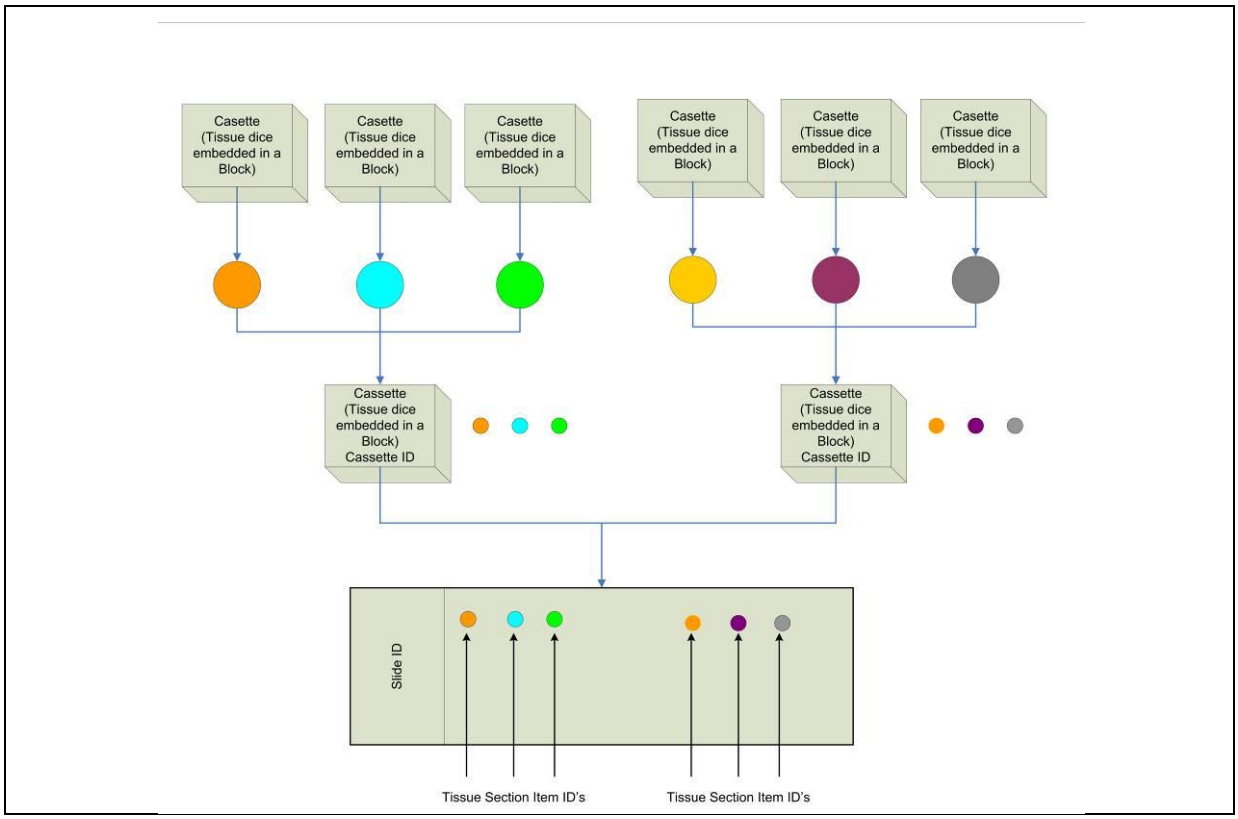

Figure 3.5-2: Spots come from the same TMA block (DP-TMA510) but different donor blocks, parts and patients. Specimen ID (DP-TMA510-1/DP07110-A-5) and Container ID (DP-TMA510-1/) are different.

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Appendix A Specimen Models

This section comes from joint efforts from DICOM WG26, HL7 Pathology SIG and IHE Pathology (see SS2.1 DICOM Supp 122-v.13)

Basic concept and definition

- Specimen

A physical object (or a collection of objects) is a specimen when the laboratory considers it a single discrete, uniquely identified unit that is the subject of one or more steps in the laboratory (diagnostic) workflow.

To say the same thing in a slightly different way: "Specimen" is defined as a role played by a physical entity (one or more physical objects considered as single unit) when the entity is identified uniquely by the laboratory and is the direct subject of more steps in a laboratory (diagnostic) workflow.

- Container

Specimen containers (or just "containers") play an important role in laboratory (diagnostic) processes. In most, but not all, process steps, specimens are held in containers, and a container often carries its specimen's ID. Sometimes the container becomes in intimately involved with the specimen (e.g. a paraffin block), and in some situations (such as examining tissue under the microscope) the container (the slide and coverslip) become part of the optical path.

Containers have identifiers that are important in laboratory operations and in some imaging processes (such as whole slide imaging). In many laboratories where there is one specimen per container, the value of the specimen ID and container ID will be same. However, there are use cases in which there are more than one specimen in a container. In those situations, the value of the container ID and the specimen IDs will be different.

Laboratory workflow and specimen types

In typical anatomic pathology practice, and in Laboratory Information Systems, there are conventionally three identified levels of specimen preparation – part, block, and slide. These terms are actually conflations of the concepts of specimen and container. Not all processing can be described by only these three levels.

A part is the uniquely identified tissue or material collected from the patient and delivered to the pathology department for examination. A box is a container for a part, and conveys the part unique identifier. Examples of parts would include a lung resection, colon biopsy at 20 cm, colon biopsy at 30 cm, peripheral blood sample, cervical cells obtained via scraping or brush, etc.

A block is a uniquely identified container, typically a cassette, containing one or more tissue dice. A dice is a sampling of a part. The tissue dice may optionally be separately identified, although most LIS do not presently have this capability.

A slide is a uniquely identified container, typically a glass microscope slide, containing tissue or other material. Common slide preparations include:

- "Tissue sections" created from Tissue Dice embedded in blocks. (1 slide typically corresponds to a tissue section coming from one block)
- "Touch preps" prepared by placing a slide into contact with unprocessed tissue.
- "Dispersions" are a thin layer of cells created from a suspension.

Relationship between Specimens and Containers

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Virtually all specimens in a clinical laboratory are associated with a container, and specimens and containers are both important in imaging. In most clinical laboratory situations there is a one to one relationship between specimens and containers. In fact, pathologists and LIS systems routinely consider a specimen and its container as single entity; e.g. the slide (a container) and the tissue sections (the specimen) are considered a single unit.

However, there are legitimate use cases in which a laboratory may place two or more specimens in the same container (see examples below).

Some Laboratory Information System may, in fact, not support multiple specimens in a container, i.e., they manage only a single identifier used for the combination of specimen and container. This is not contrary to the DICOM Standard; images produced under such a system will simply always assert that there is only one specimen in each container. However, a pathology image display application that shows images from a variety of sources must be able to distinguish between container and specimen IDs, and handle the 1:N relationship.

In the DICOM Specimen Module, in allowing for one container to have multiple specimens, the Specimen Module asserts that it is the Container, not the Specimen, that is the unique target of the image. In other words, one Container ID is required in the Specimen Module, and multiple Specimen IDs are allowed in the Specimen Sequence.

In the HL7 v2.5 SPM-Specimen segment, the SAC segment should be used only if the number of containers differs from the number of specimens (e.g. a specimen is split between several containers or multiple specimens placed in or on the same container). Otherwise, when there is one container for one specimen the SPM segment is sufficient and the SPM-2 Specimen ID provides both the specimen/container identifier. In case of multiple specimens placed in or on the same container, the message will contain as many SPM segment as specimens. All SPM segments will have the same Container ID but different Specimen ID. In case of a specimen split between several containers, the SPM segments will include multiple SAC segments with different Container ID.

Specimen identification examples

- One Specimen Per Container

In normal clinical practice, when there is one specimen per container, the value of the specimen identifier and the value of the container identifier will be the same. In Figure A-1, each slide is prepared from a single tissue sample from a single block (cassette).

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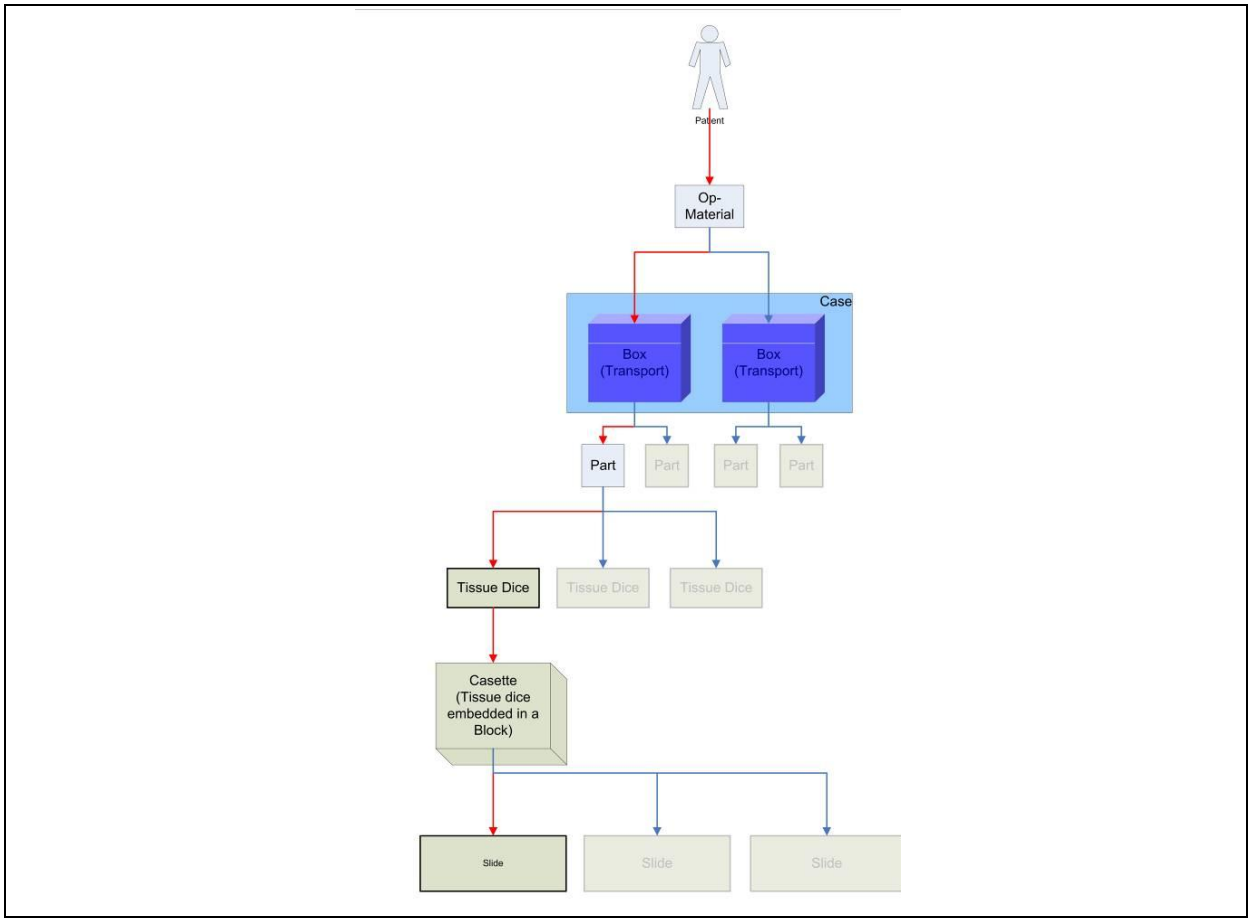

Figure A-1 Sampling for one specimen per container

- Multiple Items From Same Block

Figure A-2 shows more than one tissue item on the same slide coming from the same block (but cut from different levels). The laboratory information system considers two tissue sections (on the same slide) to be separate specimens.

Two Specimen ID's will be assigned, different from the Container (Slide) ID. The specimens may be localized, for example, by descriptive text "Left" and "Right".

If the slide is imaged, a single image with more than one specimen may be created. In this case, both specimens must be identified in the Specimen Sequence of the Specimen Module. If only one specimen is imaged, only its Specimen ID must be included in the Specimen Sequence; however, both IDs may be included (e.g., if the image acquisition system cannot determine which specimens in/on the container are in the field of view).

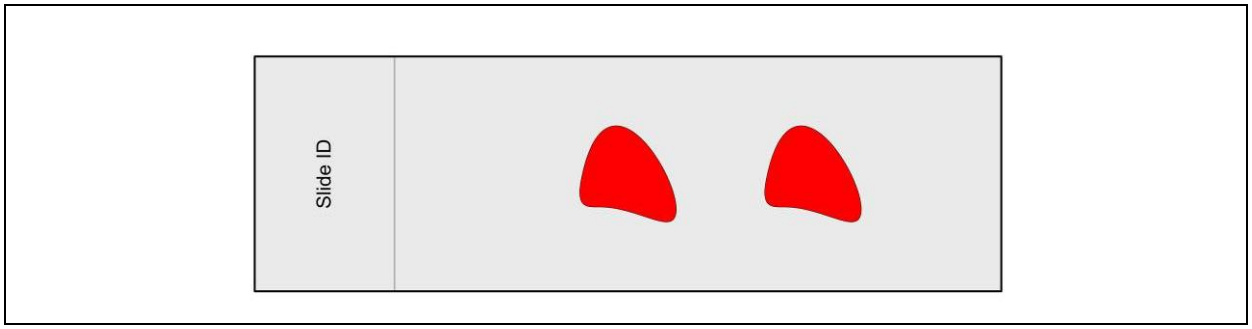

Figure A-2 Container with two specimens from same parent

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- Items From Different Parts in the Same Block

Figure A-3 shows processing where more than one tissue item is embedded in the same block within the same Cassette, but coming from different clinical specimens (parts). This may represent different lymph nodes embedded into one cassette, or different tissue dice coming from different parts in a frozen section examination, or tissue from the proximal margin and from the distal margin, and both were placed in the same cassette. Because the laboratory wanted to maintain the sample as separate specimens (to maintain their identity), the LIS gave them different IDs and the tissue from Part A was inked blue and the tissue from Part B was inked red.

The specimen IDs must be different from each other and from the container (cassette) ID. The specimens may be localized, for example, by descriptive text “Red” and “Blue” for Visual Coding of Specimen.

If a section is made from the block, each tissue section will include fragments from two specimens (red and blue). The slide (container) ID will be different from the section id (which will be different form each other).

If the slide is imaged, a single image with more than one specimen may be created but the different specimens must be identified and unambiguously localized within the container.

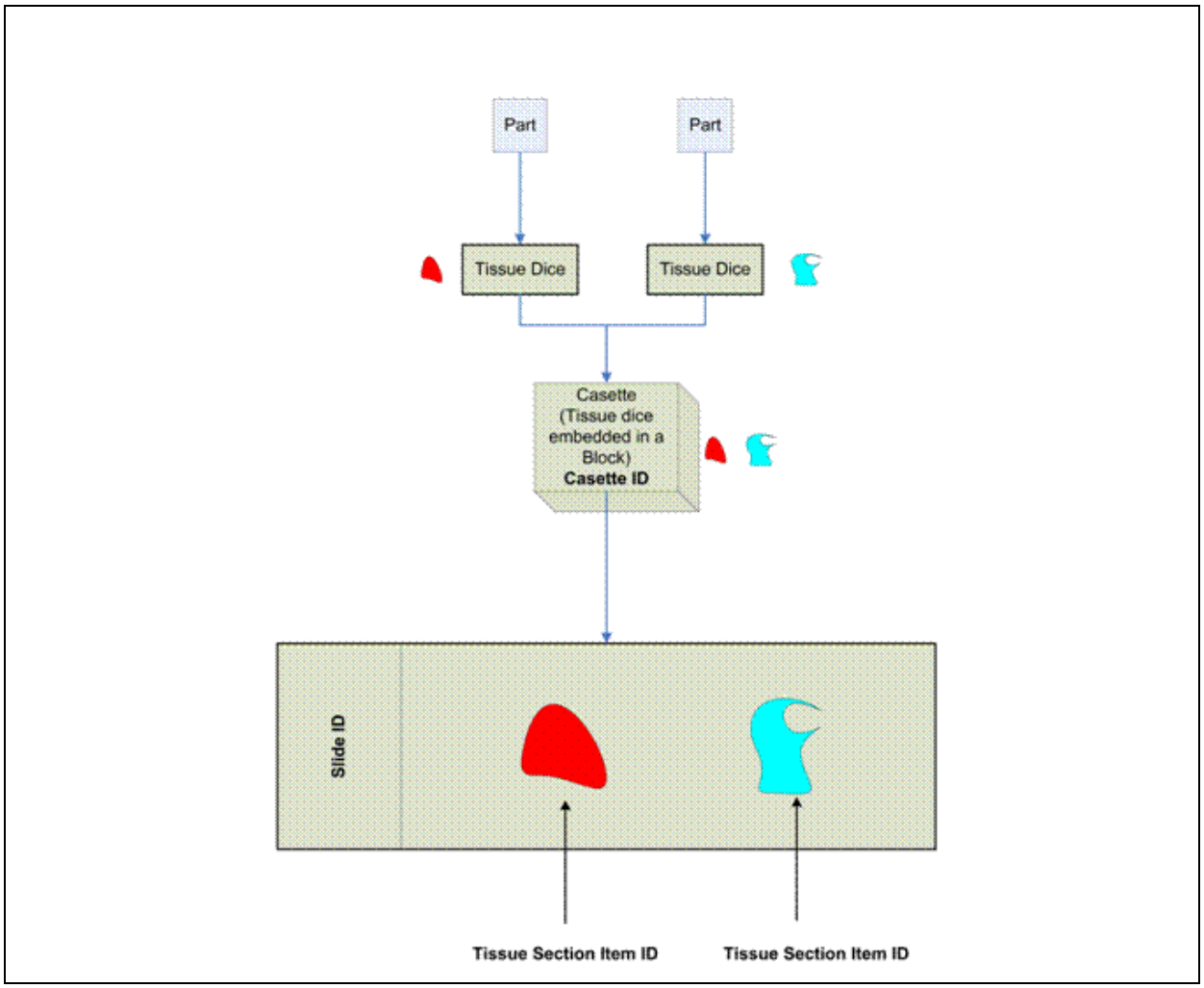

Figure A-3 Sampling for two specimens from different ancestors

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- Items From Different Parts on the Same Slide

Figure A-4 shows the result of two tissue collections placed on the same slide by the surgeon (e.g in gynecological smears the different directions of smears represent different parts (portio, cervix).

The specimen IDs must be different from each other and from the container (slide) ID. The specimens may be localized, for example, by descriptive text “Short direction smear” and “Long direction smear”.

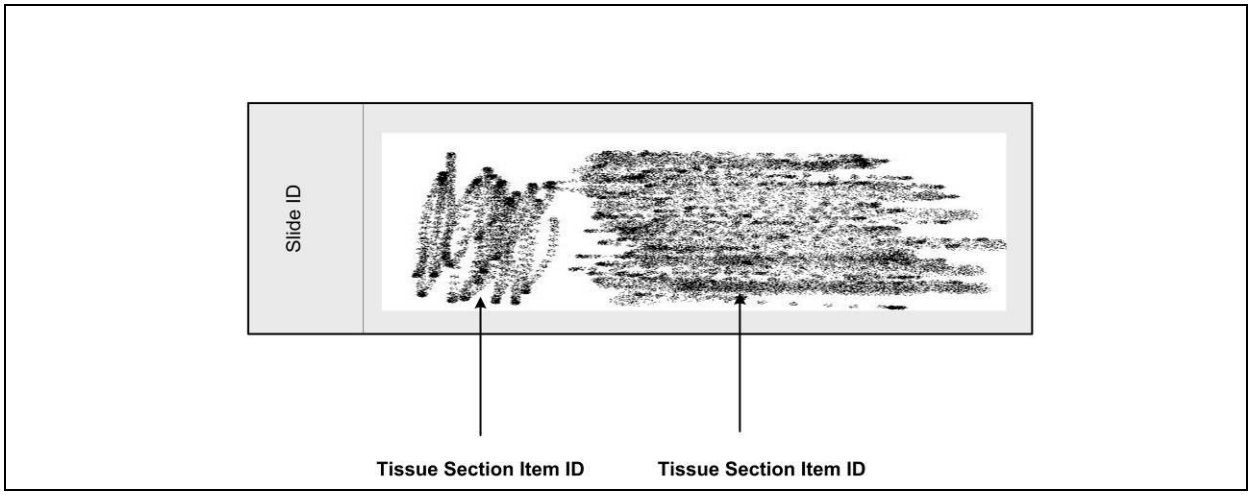

Figure A-4 Two specimens smears on one slide

- Tissue Micro Array

Slides created from TMA block have small fragments of many different tissues coming from different patients, all of which may be processed at the same time, under the same conditions by a desired technique. These are typically utilized in research. See Figure A.5. Tissue items (spots) on the TMA slide come from different tissue items (cores) in TMA blocks (from different donor blocks, different parts and different patients).

Each Specimen (spot) must have its own ID. The specimens may be localized, for example, by X-Y coordinates, or by a textual column-row identifier for the spot (e.g., “E3” for fifth column, third row).

If the TMA slide is imaged as a whole, e.g., at low resolution as an index, it must be given a “pseudo-patient” identifier (since it does not relate to a single patient). Images created for each spot should be assigned to the real patients.

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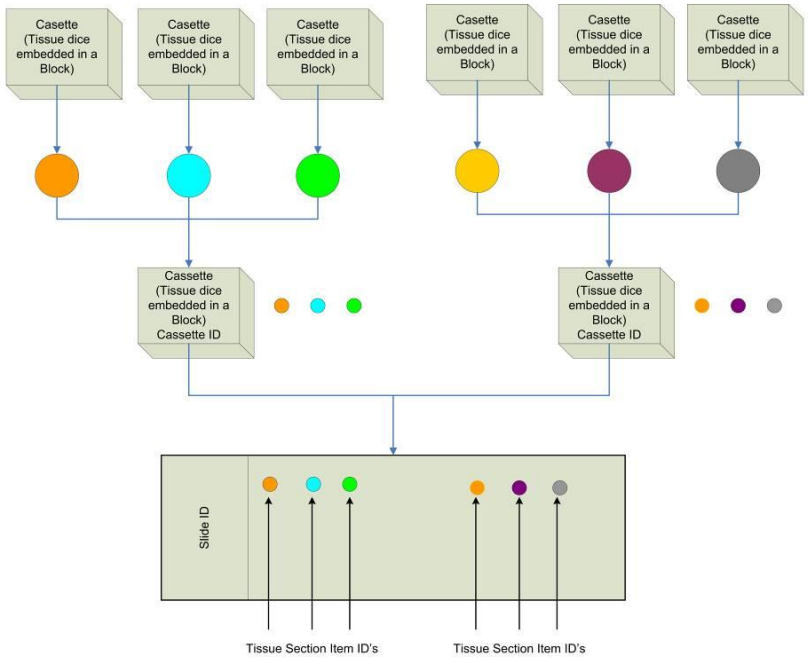

Figure A-5 Sampling for TMA Slide

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