

IHE Change Proposal

Tracking information:

IHE Domain	PaLM
Change Proposal ID:	
Change Proposal Status:	
Date of last update:	August 2024
Person assigned:	Raj Dash

Change Proposal Summary information:

Result Predicate Correction in LAB-80	
Submitter's Name(s) and e-mail address(es):	Raj Dash
Submission Date:	June 19, 2024
Integration Profile(s) affected:	DPIA
Actor(s) affected:	Acquisition Manager, Acquisition Modality
IHE Technical Framework or Supplement modified:	PaLM TF
Volume(s) and Section(s) affected:	2-3.z
Rationale for Change: DPIA currently proposes use of OBX segments (OBX3 and OBX5 question answer pairs) for conveying discrete data about the stain applied to tissue on a glass slide that has been digitized. This provides a machine readable field for the PACS. Upon further review by vendors, use of SPM-6 is preferred. This change is the focus of the current CP. Multiple errors are also corrected. In more detail: 1. Keep "Specimen Additive" name as stated in HL7 2. Make a note that indicates also incorporates specimen stain 3. Use SPM6.9 as free text to describe stain 4. Make repeatable field 1..*. 5. Added SPM-9 which was inadvertently omitted 6. Specimen source site and specimen role may not be needed if user has access to this information in the LIS. Thus these will be changed from [1..1] to [0..1] 7. A control specimen could be part of a LAB-80 message using the Specimen Role to indicate as such. A note will be added to this effect. 8. Numerous errata documented by the public have been addressed in this CP (listed below). 9. A note has been added (around line 658) that further clarifies that the scope of the acquisition modality generally includes the scanner, workstation and/or servers that drive the scanners, along with middleware that is proprietary and specific to the scanners from a single vendor. Therefore in the real world today, most LIS systems will "act" as both order filler and acquisition manager (thereby precluding the need for explicit transactions between these actors today).	

DPIA for Trial Implementation v1.2 lines 753 to 767 ** ORIGINAL **

When requesting an IWOS, the Acquisition Manager may use the OBSERVATION segment group to provide the Acquisition Modality with results or a variety of clinically relevant information that is obtained during the ordering or specimen collection process. The OBX segments of the OBSERVATION segment group are used for information specifically observed/measured as part of the ordering process (including specimen collection).

OBX-3 and OBX-5 of the OBX segment contained in the OBSERVATION segment group can be used to provide name/value paired information that is not otherwise captured in the SPM segment. At the moment only a single use is defined where OBX-3 = “Stain Name” and OBX-5 = “H&E”, “GMS”, “IHC” etc. This may assist the acquisition modality to properly configure and/or calibrate itself for the glass slide to be scanned.

Please note that the message structure proposed for this profile includes OBX segments associated with the order (ORC segment) and OBX segments associated with the specimen (SPM segment). The Study Instance UID represents an OBX segment to be associated with the order whereas the Stain Name represents an OBX segment to be associated with the specimen. Both of these represent required data elements in the message.

DPIA for Trial Implementation v1.2 lines 1179-1181 ** ORIGINAL **

OBX-3 is used in the current profile for conveying the following information.

Direction	Segment	Card.	Meaning	Example	Notes
Inbound [LAB-80]	OBX-3		Stain Name (like CID 8112)	104210008 Hematoxylin and eosin stain method (procedure)	OBX-3 = "Stain Name", OBX-5 = "H&E", "PAS", etc.

DPIA for Trial Implementation v1.2 lines 1319 to 1389 ** ORIGINAL **

A.5 SPM Segment

HL7 v2.5.1: chapter 7 (7.4.3 SPM – Specimen Segment).

The SPM segment is used to describe the characteristics of a single specimen. The SPM segment relays information about the type of specimen and the date/time the specimen was received. It differs from the intent of the OBR segment in that the OBR addresses order-specific information. It differs from the SAC segment in that the SAC addresses specimen container attributes and the ID that is normally encoded on the sample container (barcode, RFID tag, etc.).

In the case of an IWOS related to a single patient, the specimen role is “patient” (SPM-11 = P) and the specimen properties type, collection method, collection date, source site, source site modifier, and risk always represent the primary specimen that was collected from the patient, even in the case where the current specimen used by the IWOS is an aliquot or an isolate (a pure colony of a microorganism obtained after culture).

Table A.5-1: SPM Segment

SE Q	LEN	DT	Usage Acquisition Manager [LAB-80]	Usage Acquisition Modality [LAB-82]	Card.	TBL#	ITEM #	Element name
2	80	EIP	M	DPIA_SPECIMEN (RE/X)	[1..1]		01755	Specimen ID
3	80	EIP	M	DPIA_SPECIMEN (RE/X)	[1..1]		01756	Specimen Parent IDs
4	250	CWE	DPIA_SPECIMEN (RE/X)	X	[0..1]	0487	01900	Specimen Type
6	250	CWE	DPIA_SPECIMEN (RE/X)	X	[0..1]			Specimen Additive
7	250	CWE	DPIA_SPECIMEN (RE/X)	X	[0..1]	0488	01759	Specimen Collection Method
8	250	CWE	M	X	[1..1]		01901	Specimen Source Site
11	250	CWE	M	X	[1..1]	0369	01762	Specimen Role
14	250	ST	DPIA_SPECIMEN (RE/X)	X	[0..1]		01764	Specimen Description
17	26	DR	DPIA_SPECIMEN (RE/X)	DPIA_SPECIMEN (RE/X)	[0..1]		01765	Specimen Collection Date/Time
18	26	TS	DPIA_SPECIMEN (RE/X)	X	[0..1]		00248	Specimen Received Date/Time
27	250	CWE	DPIA_SPECIMEN (RE/X)	X	[0..1]		01773	Container Type
30	250	CX	M	X	[1..1]		02314	Accession ID

SPM-2 Specimen ID (EIP), required if available (Acquisition Manager with DPIA_SPECIMEN), required if available from Acquisition Modality (Acquisition Modality with DPIA_SPECIMEN).

This field contains the specimen identifier. It may be the enterprise-wide unique specimen identifier.

Table A.5-2: Element SPM-2 Specimen ID (EIP)

Component/Sub-Component	Usage	LEN	Comment
Placer Assigned Identifier (EI)	R		
Entity Identifier (ST)	R	20	
Namespace ID (IS)	C (R/RE) ¹	20	
Universal ID (ST)	C (R/RE) ¹	199	
Universal ID Type (ID)	C (R/RE) ¹	6	

Note 1: Predicate: Either Placer Assigned Identifier.2 (Namespace ID) or both sub-components Placer Assigned Identifier.3 (Universal ID) and Placer Assigned Identifier.4 (Universal ID Type) are required. Sub-components 2, 3 and 4 may all be present.

SPM-3 Specimen Parent ID (EIP), required (Acquisition Modality with DPIA_POOL_NOAN), required if available (Acquisition Manager with DPIA_SPECIMEN), required if available from Acquisition Modality (Acquisition Modality with DPIA_SPECIMEN).

This field contains the identifiers for the specimen or specimens that contributed to the specimen that is described by the segment instance.

When used with the DPIA_POOL_NOAN Profile Option, this required field will contain the specimen identifiers of the specimens that were pooled.

Table A.5-3: Element SPM-3 Specimen Parent IDs (EIP)

Component/Sub-Component	Usage	LEN	Comment
Placer Assigned Identifier (EI)	R		
Entity Identifier (ST)	R	20	
Namespace ID (IS)	C (R/RE)1	20	
Universal ID (ST)	C (R/RE)1	199	
Universal ID Type (ID)	C (R/RE)1	6	

Note 1: Predicate: Either Placer Assigned Identifier.2 (Namespace ID) or both sub-components Placer Assigned Identifier.3 (Universal ID) and Placer Assigned Identifier.4 (Universal ID Type) are required. Sub-components 2, 3 and 4 may all be present.

SPM-4 Specimen Type (CWE), mandatory.

This field describes the precise nature of the entity that will be the source material for the observation. The values defined in HL7 Table 0487 – Specimen Type will be used. The Acquisition Modality may define extensions to the table, and the Acquisition Modality may identify a subset of specimen types that are supported.

This field is populated with a value from HL7 Table 0487 – Specimen Type if the SPM-11 Specimen Role is “P” (Patient specimen). This field is populated with NULL ("") if the SPM-11 Specimen Role is “Q” (Control specimen) or “U” (Unknown specimen as part of a Negative Query Response).

For some Acquisition Modalities, the IWOS performed is not impacted by the Specimen Type. The field must also be set to NULL ("") when sent by an Acquisition Modality if the specimen type is not applicable for the IWOS(s).

The use of NULL ("") by the Acquisition Modality should not be interpreted as a requirement to delete specimen information from specimen data records maintained by the Acquisition Manager.

Table A.5-4: Element SPM-4 Specimen Type (CWE)

Component/Sub-Component	Usage	LEN	Comment
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Identifier (ST)	R	20	Code from HL7 Table 0487, code from a vendor-defined coding system.
Text (ST)	RE	199	Description from HL7 Table 0487, or vendor-defined description
Name of Coding System (ID)	R	12	Fixed “HL70487” or “99zzz” for a vendor-defined coding system (where z is an alphanumeric character)

SPM-7 Specimen Collection Method (CWE), required if available (Acquisition Manager, and Acquisition Modality supports DPIA_SPECIMEN), otherwise not supported.

This field describes the procedure or process by which the specimen was collected.

Table A.5-5: Element SPM-7 Specimen Collection Method (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Code from HL7 Table 0488 or a vendor-defined coding system
Text (ST)	RE	199	Description of the specimen collection method
Name of Coding System (ID)	R	12	Fixed “HL70488” or “99zzz” for a vendor-defined coding system (where z is an alphanumeric character)

SPM-8 Specimen Source Site (CWE), required if available (Acquisition Manager, and Acquisition Modality supports DPIA_SPECIMEN), otherwise not supported.

This field specifies the source from which the specimen was obtained.

Table A.5-6: Element SPM-8 Specimen Source Site (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Vendor-defined value
Text (ST)	RE	199	Vendor description of the specimen source site
Name of Coding System (ID)	R	12	Vendor-defined coding system name “99zzz” (where z is an alphanumeric character)

SPM-11 Specimen Role (CWE), mandatory.

This identifies the role of the specimen to be a Patient sample, QC specimen, or Unknown in support of the DPIA use cases and messaging constructs. However, an Acquisition Modality may extend the set with additional codes for HL7 Table 0369 or codes from a vendor-defined coding system.

Table A.5-7: Subset of HL7 User-defined Table 0369 – Specimen Role

Value	Description	Comment	LAB-28	DPIA_POOL_NOAN
P	Patient specimen		Permitted	Excluded
Q	Control specimen		Permitted	Excluded

Value	Description	Comment	LAB-28	DPIA_POOL_NOAN
U	Unknown specimen role	Unknown specimen role; used for negative query response in [LAB-80]; requires IHEDPIA for the Name of Coding System	Permitted	Excluded

Table A.5-8: Element SPM-11 Specimen Role (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	A code from the “Value” column of Table A.12-8 or HL70369, or a vendor-defined coding system
Text (ST)	RE	199	Text from the “Description” column of Table A.12-8 or HL70369, or a vendor-defined description
Name of Coding System (ID)	R	12	Fixed “HL70369” or “IHEDPIA” or “99zzz” for a vendor-defined coding system (where z is an alphanumeric character)

DPIA for Trial Implementation v1.2 lines 753 to 767 ** REVISED **

When requesting an IWOS, the Acquisition Manager may use **the SPECIMEN or OBSERVATION** segment group to provide the Acquisition Modality with results or a variety of clinically relevant information that is obtained during the ordering or specimen collection process. The OBX segments of the OBSERVATION segment group are used for information specifically observed/measured as part of the ordering process (including specimen collection).

OBX-3 and OBX-5 of the OBX segment contained in the OBSERVATION segment group can be used to provide name/value paired information that is not otherwise captured in the SPM segment. **For the specific use case for the Stain Name applied to a glass slide, the (CWE repeating) SPM-6 segment should be used rather than pairs of OBX3/5 (i.e. do NOT use OBX-3 = “Stain Name” and OBX-5 = “H&E”, “GMS”, “S100” etc.).** This may assist the acquisition modality to properly configure and/or calibrate itself for the glass slide to be scanned and helps to discretely convey (as a SCT code) the nature of the image that the pathologist needs to interpret.

Please note that the message structure proposed for this profile includes the possibility of OBX segments associated with the order (ORC segment) and for uses other than additives or stain name, OBX segments associated with the specimen (SPM segment). The Study Instance UID preferably is represented by an IPC segment similar to what happens in Radiology (but could also be represented as an OBX segment to be associated with the order). Stain name and Study Instance UID represent required data elements in the message.

DPIA for Trial Implementation v1.2 lines 1179-1181 ** REVISED **

SPM-6 is used in the current profile for conveying the following information.

Direction	Segment	Card.	Meaning	Example	Notes
Inbound [LAB-80]	SPM-6		Stain Name (like CID 8112)	104210008 Hematoxylin and eosin stain method (procedure)	CWE repeatable SCT code

DPIA for Trial Implementation v1.2 lines 1319 to 1389 ** REVISED **

A.5 SPM Segment

HL7 v2.5.1: chapter 7 (7.4.3 SPM – Specimen Segment).

The SPM segment is used to describe the characteristics of a single specimen. The SPM segment relays information about the type of specimen and the date/time the specimen was received. It differs from the intent of the OBR segment in that the OBR addresses order-specific information. It differs from the SAC segment in that the SAC addresses specimen container attributes and the ID that is normally encoded on the sample container (barcode, RFID tag, etc.).

In the case of an IWOS related to a single patient, the specimen role is “patient” (SPM-11 = P) and the specimen properties type, collection method, collection date, source site, source site modifier, and risk always represent the primary specimen that was collected from the patient, even in the case where the current specimen used by the IWOS is an aliquot or an isolate (a pure colony of a microorganism obtained after culture).

Table A.5-1: SPM Segment

SE Q	LEN	DT	Usage Acquisitio n Manager [LAB-80]	Usage Acquisition Modality [LAB-82]	Card.	TBL#	ITEM #	Element name
1	4	SI	M	M	[1..1]		01754	Set ID-SPM
2	80	EIP	M	M	[1..1]		01755	Specimen ID
3	80	EIP	RE	RE	[0..1]		01756	Specimen Parent IDs
4	250	CWE	M	M	[0..1]	0487	01900	Specimen Type
6	250	CWE	M	X	[1..*]			Specimen Additive/S tain
7	250	CWE	RE	X	[0..1]	0488	01759	Specimen Collection Method
8	250	CWE	RE	X	[1..1]		01901	Specimen Source Site
9	250	CWE	RE	X	[0..*]			Source site modifier (e.g., laterality)

SE Q	LEN	DT	Usage Acquisitio n Manager [LAB-80]	Usage Acquisition Modality [LAB-82]	Card.	TBL#	ITEM #	Element name
11	250	CWE	RE	X	[0..1]	0369	01762	Specimen Role
14	250	ST	RE	X	[0..1]		01764	Specimen Descriptio n
17	26	DR	RE	X	[0..1]		01765	Specimen Collection Date/Time
18	26	TS	RE	X	[0..1]		00248	Specimen Received Date/Time
27	250	CWE	RE	X	[0..1]		01773	Container Type
30	250	CX	M	X	[1..1]		02314	Accession ID

SPM-1 Set ID. Mandatory. Populate as “1” if only one specimen in the message.

SPM-2 Specimen ID (EIP), required if available (Acquisition Manager with DPIA_SPECIMEN), required if available from Acquisition Modality (Acquisition Modality with DPIA_SPECIMEN).

This field contains the specimen identifier. It may be the enterprise-wide unique specimen identifier.

Table A.5-2: Element SPM-2 Specimen ID (EIP)

Component/Sub-Component	Usage	LEN	Comment
Placer Assigned Identifier (EI)	R		
Entity Identifier (ST)	R	20	
Namespace ID (IS)	C (R/RE) ¹	20	
Universal ID (ST)	C (R/RE) ¹	199	
Universal ID Type (ID)	C (R/RE) ¹	6	

Note 1: Predicate: Either Placer Assigned Identifier.2 (Namespace ID) or both sub-components Placer Assigned Identifier.3 (Universal ID) and Placer Assigned Identifier.4 (Universal ID Type) are required. Sub-components 2, 3 and 4 may all be present.

SPM-3 Specimen Parent ID (EIP), required if available (Acquisition Manager with DPIA_SPECIMEN), required if available from Acquisition Modality (Acquisition Modality with DPIA_SPECIMEN).

This field contains the identifiers for the specimen or specimens that contributed to the specimen that is described by the segment instance.

Table A.5-3: Element SPM-3 Specimen Parent IDs (EIP)

Component/Sub-Component	Usage	LEN	Comment
Placer Assigned Identifier (EI)	R		
Entity Identifier (ST)	R	20	
Namespace ID (IS)	C (R/RE)1	20	
Universal ID (ST)	C (R/RE)1	199	
Universal ID Type (ID)	C (R/RE)1	6	

Note 1: Predicate: Either Placer Assigned Identifier.2 (Namespace ID) or both sub-components Placer Assigned Identifier.3 (Universal ID) and Placer Assigned Identifier.4 (Universal ID Type) are required. Sub-components 2, 3 and 4 may all be present.

SPM-4 Specimen Type (CWE), mandatory.

This field describes the precise nature of the entity that will be the source material for the observation. The values defined in HL7 Table 0487 – Specimen Type will be used. The Acquisition Modality may define extensions to the table, and the Acquisition Modality may identify a subset of specimen types that are supported.

This field is populated with a value from HL7 Table 0487 – Specimen Type if the SPM-11 Specimen Role is “P” (Patient specimen). This field is populated with NULL ("") if the SPM-11 Specimen Role is “Q” (Control specimen) or “U” (Unknown specimen as part of a Negative Query Response).

For some Acquisition Modalities, the IWOS performed is not impacted by the Specimen Type. The field must also be set to NULL ("") when sent by an Acquisition Modality if the specimen type is not applicable for the IWOS(s).

The use of NULL ("") by the Acquisition Modality should not be interpreted as a requirement to delete specimen information from specimen data records maintained by the Acquisition Manager.

Table A.5-4: Element SPM-4 Specimen Type (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Code from HL7 Table 0487, code from a vendor-defined coding system.
Text (ST)	RE	199	Description from HL7 Table 0487, or vendor-defined description
Name of Coding System (ID)	R	12	Fixed “HL70487” or “99zzz” for a vendor-defined coding system (where z is an alphanumeric character)

SPM-7 Specimen Collection Method (CWE), required if available (Acquisition Manager, and Acquisition Modality supports DPIA_SPECIMEN), otherwise not supported.

This field describes the procedure or process by which the specimen was collected.

Table A.5-5: Element SPM-7 Specimen Collection Method (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Code from HL7 Table 0488 or a vendor-defined coding system
Text (ST)	RE	199	Description of the specimen collection method
Name of Coding System (ID)	R	12	Fixed "HL70488" or "99zzz" for a vendor-defined coding system (where z is an alphanumeric character)

SPM-8 Specimen Source Site (CWE), required if available (Acquisition Manager, and Acquisition Modality supports DPIA_SPECIMEN), otherwise not supported.

This field specifies the source from which the specimen was obtained.

Table A.5-6: Element SPM-8 Specimen Source Site (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	Vendor-defined value
Text (ST)	RE	199	Vendor description of the specimen source site
Name of Coding System (ID)	R	12	Vendor-defined coding system name "99zzz" (where z is an alphanumeric character)

SPM-11 Specimen Role (CWE), required if available.

This identifies the role of the specimen to be a Patient sample, QC specimen, or Unknown in support of the DPIA use cases and messaging constructs. Since multiple specimens can be placed on the LAB-80 message, this field can be used to identify external control specimen slides, or slides that consist of an on slide control plus patient tissue. To accomplish this, an Acquisition Modality may extend the set with additional codes for HL7 Table 0369 or codes from a vendor-defined coding system.

Table A.5-7: Subset of HL7 User-defined Table 0369 – Specimen Role

Value	Description	Comment	LAB-28	DPIA_POOL_NOAN
P	Patient specimen		Permitted	Excluded
Q	Control specimen		Permitted	Excluded
U	Unknown specimen role	Unknown specimen role; used for negative query response in [LAB-80]; requires IHEDPIA for the Name of Coding System	Permitted	Excluded

Table A.5-8: Element SPM-11 Specimen Role (CWE)

Component/Sub-Component	Usage	LEN	Comment
Identifier (ST)	R	20	A code from the “Value” column of Table A.12-8 or HL70369, or a vendor-defined coding system
Text (ST)	RE	199	Text from the “Description” column of Table A.12-8 or HL70369, or a vendor-defined description
Name of Coding System (ID)	R	12	Fixed “HL70369” or “IHEDPIA” or “99zzz” for a vendor-defined coding system (where z is an alphanumeric character)