ACC, HIMSS and RSNA
Integrating the Healthcare Enterprise

IHE Patient Care Coordination
Public Health Laboratory Report (PHLAB)
Supplement to the Technical Framework
Revision 2.0
2007-2008

For Public Comment

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Forward

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. And it organizes educational sessions and 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 not to define new integration standards, but rather to support the use of existing standards, HL7, DICOM, IETF, and others, as appropriate in their respective domains in an integrated manner, defining configuration choices when necessary. 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 American College of Cardiology (ACC), the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE Canada has also been formed. IHE Europe (IHE-EUR) 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 Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (DRG), the EuroPACS Association, Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), Société Francaise de Radiologie ([www.sfr-radiologie.asso.fr SFR]), and Società Italiana di Radiologia Medica (SIRM). In Japan IHE-J is sponsored by the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and Welfare; and [www.medis.or.jp 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). Other organizations representing healthcare professionals are actively involved and others are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

The IHE Technical Frameworks for the various domains (Patient Care Coordination, IT Infrastructure, Cardiology, Laboratory, Radiology, etc.) define specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal patient care. These are expanded annually, after a period of public review, and maintained regularly through the identification and correction of errata. The current version for these Technical Frameworks may be found at www.ihe.net.

The IHE 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. Volume I 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 clinical needs. Subsequent volumes provide detailed technical descriptions of each IHE transaction.

Content of the Technical Framework

This technical framework defines relevant standards and constraints on those standards in order to implement a specific use cases for the transfer of information between systems. This document is organized into 2 volumes as follows:

Volume 1 – Overview

This volume is provided as a high level overview of the profiles including descriptions of the use case, the actors involved, the process flow, and dependencies on other standards and IHE profiles. It is of interest to care providers, vendors' management and technical architects and to all users of the profile

Volume 2 – Transactions and Content Profiles

This volume is intended as a technical reference for the implementation of specific transactions in the use case including references to the relevant standards, constraints, and interaction diagrams. It is intended for the technical implementers of the profile.

How to Contact Us

IHE Sponsors welcome comments on this document and the IHE initiative. They should be directed to the discussion server at http://forums.rsna.org or to:

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Open Issues

1. Is what we have documented the best way to accomodate a non-human subject in a CDA? In the case in which we have both a human patient and a non-human subject (ex. rabies), there is no way to document the id of the non-human subject. This is a concern.
2. The PHLab profile text is based on several CPs that are (will) open against XDS-Lab and PCC Technical Framework. For a trial text of this profile, we will need to decide which of these CPs we can retain as text in this profile and which we have to defer, thus necessitating that we revert the text in the PHLab profile to a "pre-CP" state of XDS-Lab or the PCC TF.
3. How do we support the concept of a case number in this document?
4. Should we require XDSDocumentEntry.serviceStartTime, since in this context it correlates to either the original clinical encounter or the date of specimen collection (or recieve date) which is particulary important in public health?
5. Currently the scope of the document is a single order and any (all) specimens stemming from that order and any (all) reportable contditions found among those specimens. This is so the relationship of the order and the tests requestes and thier corresponding results is preserved. If multiple orders are allowed then this

relationship less obvious. Is this a concern? Or is it better to allow for multiple orders?

6. In documentation of the reportable condition in ClinicalDocument.component.structuredBody.component.section.entry.act.entryRelationship.organizer.specimen we encounter restricted vocabulary when it comes to the classCode on this element. "SPEC" is rather too general, but possible, and "ISLT" only applies when the laboratory section is microbiology. Do we need to extend the specimen classCode vocabulary?

1 Volume I

1.1 Public Health Laboratory Report Integration Profile

The motivation for developing this profile is as follows:

- Show that the same standards that support the current IHE profiles for clinical care interoperability can be leveraged by public health.
- Encourage the public health community to come forward to IHE with use cases to further enhance data sharing.

Our goal with this profile is to adapt XDS-LAB integration content profile to accommodate data for a public health laboratory report. Modifications to XDS-LAB will be needed to accommodate non-human subjects, document participants in the laboratory testing process, and to group tests for a reportable condition in a consistent manner. Leveraging the CDA R2 standard and XDS-LAB make the resultant document consumable by public health and incorporable in an effected patient's medical record thereby completing a communication loop between individual and public care.

1.1.1 Dependencies

Add the following row(s) to the list of dependencies

Integration Profile	Dependency	Dependency Type	Purpose
PHLab	XDS-Lab	PHLab is a conformant XDS-Lab document	XDS-Lab constrains CDA R2 for the purposes of communicating any Laboratory Report

1.1.2 Actors/Transaction

There are two actors in the PHLab profile, the Content Creator and the Content Consumer. Content is created by a Content Creator and is to be consumed by a Content Consumer. The sharing or transmission of content from one actor to the other is addressed by the appropriate use of IHE profiles described below, and is out of scope of this profile. A Document Source or a Portable Media Creator may embody the Content Creator Actor. A Document Consumer, a Document Recipient or a Portable Media Importer may embody the Content Consumer Actor. The sharing or transmission of content or updates from one actor to the other is addressed by the use of appropriate IHE profiles described in the section on Content Bindings with XDS, XDM and XDR.

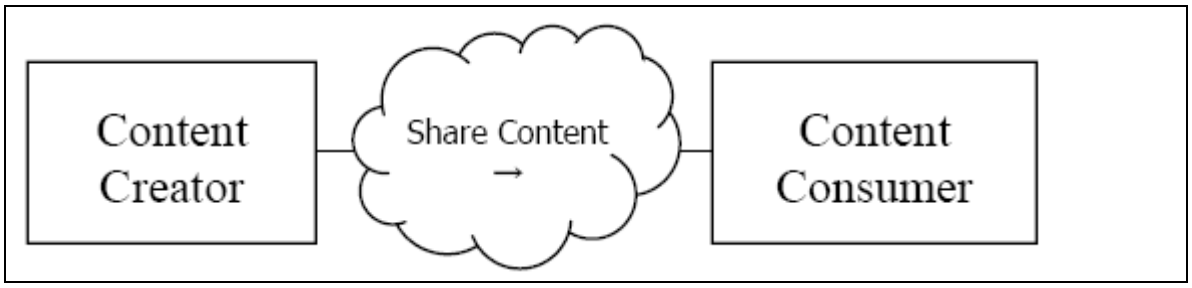

Figure 1.1-1 PHLab Actor Diagram

1.1.3 Options

Actor	Option
Content Consumer	View Option (1)
	Document Import Option (1)
	Section Import Option (1)
	Discrete Data Import Option (1)

Table 1.1-1 PHLab Options

Note 1: The Actor shall support at least one of these options.

1.1.4 Content Consumer Options

1.1.4.1 View Option

This option defines the processing requirements placed on Content Consumers for providing access, rendering and management of the medical document. See the View Option in PCC TF-2 for more details on this option.

1.1.4.1.1 Display Transform

A Content Creator Actor should provide access to a style sheet that ensures consistent rendering of the medical document content as was displayed by the Content Consumer Actor.

The Content Consumer Actor must be able to present a view of the document using this style sheet if present.

1.1.4.2 Document Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing the entire medical document and managing it as part of the patient record. See the Document Import Option in PCC TF-2 for more details on this option.

1.1.4.3 Section Import Option

This option defines the processing requirements placed on Content Consumers for providing access to, and importing the selected section of the medical document and

managing them as part of the patient record. See the Section Import Option in PCC TF-2 for more details on this option.

1.1.4.4 Discrete Data Import Option

This option defines the processing requirements placed on Content Consumers for providing access, and importing discrete data from selected sections of the medical document and managing them as part of the patient record. See the Discrete Data Import Option in PCC TF-2 for more details on this option.

1.1.5 Coded Terminologies

This profile supports the capability to record entries beyond the IHE required coding associated with structured data. Content Creators and Content Consumers may choose to utilize coded data, but interoperability at this level requires an agreement between the communicating parties that is beyond the scope of this Profile.

To facilitate this level of interoperability, the applications that implement actors within this profile shall provide a link to their HL7 conformance profile within their IHE Integration statement. The conformance profile describes the structure of the information which they are capable of creating or consuming. The conformance profile shall state which templates are supported by the application (as a Content Creator or Content Consumer), and which vocabularies and/or data types are used within those templates. It should also indicate the optional components of the entry that are supported.
See the HL7 Refinement Constraint and Localization for more details on HL7 conformance profiles.

1.1.6 PHLab Content Bindings with XDS, XDM and XDR

It is expected that exchanges of Publc Health Laboratory Report will occur in an environment where the physician offices and hospitals have a coordinated infrastructure that serves the information sharing needs of this community of care. Several mechanisms are supported by IHE profiles:

- A registry/repository-based infrastructure is defined by the IHE Cross-Enterprise Document Sharing (XDS) and other IHE Integration Profiles such as patient identification (PIX & PDQ), and notification of availability of documents (NAV).
- A media-based infrastructure is defined by the IHE Cross-Enterprise Document Media Interchange (XDM) profile.
- A reliable messaging-based infrastructure is defined by the IHE Cross-Enterprise Document Reliable Interchange (XDR) profile.
- All of these infrastructures support Security and privacy through the use of the Consistent Time (CT) and Audit Trail and Node Authentication (ATNA) profiles.

For more details on these profiles, see the IHE IT Infrastructure Technical Framework, found here: http://www.ihe.net/Technical_Framework/.

Thus, implementors of the Content Consumer and Content Creator Actors must also implement either the ITI XDS, XDM or XDR Profiles to exchange content, using the bindings listed below.

Content	Binding	Actor	Optionality
Public Health Laboratory Report	Medical Document Binding to XD*	Content Creator	R
		Content Consumer	R

Table 1.1-2 Public Health Laboratory Report Bindings

1.1.7 PHLab Document Content Module

An Public Health Laboratory Report content document is a type of laboratory report, and incorporates the constraints defined for laboratory reports found in section the XDS-Lab specification. In addition, the PHLab profile modifies XDS-LAB integration content profile to accommodate data for a public health laboratory report. By leveraging the CDA R2 standard and XDS-LAB, a PHLab document is consumable by public health and incorporable in an effected patient's medical record thereby completing a communication loop between individual and public care.

1.1.8 PHLab Process Flow

NOTE: we are working with HITSP/PHDSC to refine this use case

1.1.8.1 Use Case 1: Case Report for a Public Health Reportable Condition with Laboratory Component

Reality Today:

John Doe, MD sees a patient and suspects that this patient has an enteric pathogen. The patient follows through on the doctor's orders and submits a stool specimen to the clinic's laboratory. Upon completion of laboratory analysis, the laboratory confirms the presence of Salmonella and performs susceptibility testing. When a microbiologist has time in the week, they gather all the reportable results and complete the forms for submission to the public health agency. Additionally, the clinical laboratory needs to submit the Salmonella specimen to the public health laboratory for serotyping and outbreak surveillance. This specimen is mailed along with a hand written requisition to the public health laboratory for epidemiological serotyping.

The public health laboratory enters the partial information written on the requisition and identifies the Salmonella serotype. A nightly batch process reports the serotype to the submitting clinician. A monthly batch process generates a file for the Disease Control agency. Nearby surveillance regions have small clusters of cases with this same Salmonella serotype but without knowledge of the other cases, no outbreak investigation is initiated.

The Disease Control agency detects this anomaly as monthly reports are received when observed across surveillance regions and an outbreak protocol is started to investigate the potential outbreak. The Disease Control agency requests PFGE (pulse field gel

electrophoresis) on the known samples and the outbreak is finally confirmed two months later. Calls, faxes, and emails are used to transmit information to relevant regional and local programs as well as the submitters of outbreak samples. Significant efforts on identification, investigation, and resolution focus on getting the desired data to the necessary participants. The outbreak is investigated and linked to a restaurant supplier in a popular but off-season resort area.

After this profile is adopted:

Preconditions: The clinical laboratory creates a laboratory report identifying the organism as a Salmonella isolate and that further serotyping will be done at the Public Health Lab. The laboratory report is sent to the clinician, stored within the patient's electronic medical record, and registered in a clinical interoperability registry. The isolate is mailed to the public health lab.

Events: Upon arrival, the public health laboratory receiving department queries the clinical interoperability registry with the submitter's patient ID and views the initial laboratory report. The public health laboratory information system pulls forward the patient's demographic and specimen data from the initial laboratory report. The public health laboratory creates a new laboratory report identifying the Salmonella serotype. This report is sent to the clinician, stored within the patient's electronic medical record, registered in the clinical interoperability registry, registered in the regional public health interoperability registry, and registered in the national public health interoperability registry.

The Disease Control agency monitors the national public health registry for new cases of Salmonella. An anomaly is immediately detected in the number of new cases for this

particular Salmonella serotype when observed across regional surveillance boundaries and an outbreak protocol is started immediately to investigate the potential cross-border outbreak. The CDC requests PFGE (pulse field gel electrophoresis) on the current samples and alerts all public health laboratories to perform PFGE on new samples of this serotype. The outbreak is confirmed quickly and new cases are identified and tracked seamlessly.

Post conditions: Local, regional, and national epidemiologists and case workers have access to all laboratory reports within their respective interoperability registries and may potentially gain further access to the clinical interoperability registry for additional information, such as the ordering provider and care location, for initiating further investigation.

Key improvements include:

- avoid handwritten forms and data re-entry
- ease transition of data to and from clinical care and public health agencies
- ease transition of data from one public health agency to another
- monitor registries for anomalies in a real-time basis
- response protocols focus on response, not the access to data

1.1.8.1.1 Public Health Case Report types covered by Use Case 1

- Laboratory reportables
  Reportable conditions can be specified at local and national levels. Common laboratory criteria that is diagnostic of a reportable condition include (but are not limited to):
  - Anthrax - Bacillus anthracis
  - Botulism - Clostridium botulinum
  - Brucellosis - Brucella species
  - Campylobacter
  - Chlamydia trachomatis
  - Cholera - Vibrio cholerae
  - Dengue Fever - Dengue virus
  - Diphtheria - Corynebacterium diphtheriae
  - Escherichia coli O157:H7
  - Giardiasis - Giardia lamblia
  - Gonorrhea - Neisseria gonorrhoeae
  - Haemophilus ducreyi
  - Hepatitis virus
  - Herpes Simplex virus
  - HIV virus
  - Legionellosis - Legionella pneumophila
  - Leprosy - Mycobacterium leprae
  - Leptospirosis - Leptospira
  - Listeriosis - Listeria monocytogenes

- Lyme Disease - Borrelia burgdorferi
- Malaria - Plasmodium species
- Measles virus
- Meningococcal Disease - Neisseria meningitidis
- Mumps virus
- Pertussis - Bordetella pertussis
- Plague - Yersinia pestis
- Psittacosis - Chlamydia psittaci
- Rabies virus
- Rickettsia - Rickettsia rickettsii
- Rubella virus
- Salmonella
- Shigella
- Schistosomiasis
- Syphilis - Treponema pallidum
- Tuberculosis - Mycobacterium tuberculosis

1.1.9 Grouping with Other Actors

1.1.9.1 Cross Enterprise Document Sharing, Media Interchange and Reliable Messaging

The Content Creator and Content Consumer Actors shall be grouped with appropriate actors from the XDS, XDM or XDR integration profiles to support sharing of PHLab documents.

1.1.9.2 Document Digital Signature (DSG)

Content Creator actors should digitally sign all documents using the Digital Signature (DSG) Content Profile.
Content Consumer actors should verify the Digital Signature of the submission set before use of the information it contains.

2 Volume II

2.1 Bindings to XDS, XDR, XDM

This section describes how the payload used in a transaction of an IHE profile is related to and/or constrains the data elements sent or received in those transactions. This section is where any specific dependencies between the content and transaction are defined.

A content integration profile can define multiple bindings. Each binding should identify the transactions and content to which it applies.

The source for all required and optional attributes have been defined in in the bindings below. Three tables describe the three main XDS object types: XDSDocumentEntry, XDSSubmissionSet, and XDSFolder. XDSSubmissionSet and XDSDocumentEntry are required. Use of XDSFolder is optional.

The columns of the following tables are:

- **<XXX> attribute** – name of an XDS attribute, followed by any discussion of the binding detail.

- **Optional?** - Indicates the required status of the XDS attribute, and is one of R, R2, or O (optional). This column is filled with the values specified in the XDS Profile as a convenience.

- **Source Type** – Will contain one of the following values:

Source Type	Description
SA	Source document Attribute – value is copied directly from source document. The Source/Value column identifies where in the source document this attribute comes from. Specify the location in XPath when possible.
SAT	Source document Attribute with Transformation – value is copied from source document and transformed. The Source/Value column identifies where in the source document this attribute comes from. Specify the location in XPath when possible. Extended Discussion column must not be empty and the transform must be defined in the extended discussion
FM	Fixed (constant) by Mapping - for all source documents. Source/Value column contains the value to be used in all documents.
FAD	Fixed by Affinity Domain – value configured into Affinity Domain, all documents will use this value.
CAD	Coded in Affinity Domain – a list of acceptable codes are to be configured into Affinity Domain. The value for this attribute shall be taken from this list.
CADT	Coded in Affinity Domain with Transform - a list of acceptable codes are to be configured into Affinity Domain. The value for this attribute shall be taken from this list.
n/a	Not Applicable – may be used with an optionality R2 or O attribute to indicate it is not to be used.
DS	Document Source – value comes from the Document Source actor. Use Source/Value column or Extended Discussion to give details.
O	Other – Extended Discussion must be 'yes' and details given in an Extended Discussion.

- **Source/Value** – This column indicates the source or the value used.

The following tables are intended to be summaries of the mapping and transforms. The accompanying sections labeled 'Extended Discussion' are to contain the details as necessary.

2.1.1 XDSDocumentEntry Metadata

NOTE: This binding differs from that that is specified in Bindings. We are working to resolve any differences that are not particular to this profile. Please see the following CP on this topic.

Attribute	Opt ?	Source Type	Source/ Value
availabilityStatus	R	DS	Value assigned at point of submission. This metadata attribute is not present in the PCC_TF-2 binding. It was added to XDS in 2006-2007 cycle.
authorInstitution	R2	SAT	This attribute is the corresponding institution to the authorPerson below. Value is consistent with the PCC-TF-2 binding.
authorPerson	R2	SAT	Value is consistent with the PCC-TF-2 binding.
authorRole	R2	DS	Add value, if known. This metadata attribute is not present in the PCC_TF-2 binding. It was added to XDS in 2006-2007 cycle.
authorSpeciality	R2	DS	Value is consistent with the PCC-TF-2 binding.
classCode	R	CADT	Value is consistent with the PCC-TF-2 binding.
comments	O	DS	Optional, add if pertanant. This metadata attribute is not present in the PCC_TF-2 binding. It was added to XDS in 2006-2007 cycle.
confidentialityCode	R	CADT	Value is consistent with the PCC-TF-2 binding.
creationTime	R	SAT[1]	Value is consistent with the PCC-TF-2 binding.
entryUUID	R	DS	Assigned at time of submission by Document Source, Repository or Registry. This metadata attribute is not present in the PCC_TF-2 binding.
eventCodeList	R2	DS	ClinicalDocument / component / structuredBody / component / section / entry / act / entryRelationship / organizer / specimen / specimenRole / specimenPlayingEntity / code This binding is particular to a PHLab document. If the document pertains to a reportable condition, then this code shall be among those listed in the eventCodeList. This has been enhanced from the XDS profile from O to R2.
formatCode	R	FM	Value to be selected by the PCC Technical Committee.
healthcareFacilityTypeCode	R	CAD[2]	Value is consistent with the PCC-TF-2 binding.

[1] This value is slightly different from the PCC-TF-2 binding.

[2] This value is slightly different from the PCC-TF-2 binding.

intendedRecipient	R2	SAT	Value is consistent with the PCC-TF-2 binding.
languageCode	R	SA	Value is consistent with the PCC-TF-2 binding.
legalAuthenticator	O	SAT	Value is consistent with the PCC-TF-2 binding.
mimeType	R	FM	Fixed value “text/xml”. Value is consistent with the PCC-TF-2 binding.
parentDocumentRelationship	R[3]	DS	Context of a parent document in XDS cannot necessarily be derived from the CDA itself. This profile does not constrain this relation any further that originally specified in XDS. This metadata attribute is not not consistent PCC_TF-2 binding. We are working to resolve the differences.
parentDocumentId	R[4]	DS	Context of a parent document in XDS cannot necessarily be derived from the CDA itself. This profile does not constrain this relation any further that originally specified in XDS. This metadata attribute is not not consistent PCC_TF-2 binding. We are working to resolve the differences.
patientId	R	DS	ID of the patient in the shared infrastructure, which is not necessarily the same as the patient id in the CDA. This is to be supplied at point of submission. This metadata attribute is not not consistent PCC_TF-2 binding. We are working to resolve the differences.
practiceSettingCode	R	CAD	Value is consistent with the PCC-TF-2 binding.
serviceStartTime	R	SAT[5]	For PHLab documents, we recommend to increase reqirement of R2 to R and have this timestamp correlate with either the encounter, specimen collection, reception, time (in that preference order). Otherwise, value is consistent with the PCC-TF-2 binding.
serviceStopTime	R2	SAT[6]	Value is consistent with the PCC-TF-2 binding.
sourcePatientId	R	SAT	ClinicalDocument / recordTarget / patient / id This metadata attribute is not not consistent PCC_TF-2 binding. We are working to resolve the differences.
sourcePatientInfo	R	SAT	Assembled from various values within the ClinicalDocument / recordTarget / patient element. This metadata attribute is not not consistent PCC_TF-2 binding. We are working to resolve the differences.

[3] (when applicable)

[4] (when parentDocumentRelationship is present)

[5] This value is slightly different from the PCC-TF-2 binding.

[6] This value is slightly different from the PCC-TF-2 binding.

title	O	SA	Value is consistent with the PCC-TF-2 binding.
typeCode	R	CADT[7]	Value is consistent with the PCC-TF-2 binding.
uniqueId	R	SAT	Value is consistent with the PCC-TF-2 binding.

Table 2.1-1 XDSDocumentEntry Metadata

[7] This value is slightly different from the PCC-TF-2 binding.

2.1.2 XDSSubmissionSet Metadata

395 This content profile does not restrict submission set metadata. This content profile does not restrict usage of the XDS Submission Set.

NOTE: This binding differs from that that is specified in Bindings. We are working to resolve any differences that are not particular to this profile. Please see the following CP on this topic.

Attribute	Optional?	Source Type	Source/ Value
availabilityStatus	R	DS	Value assigned at point of submission. This metadata attribute is not present in the PCC_TF-2 binding. It was added to XDS in 2006-2007 cycle.
authorInstitution	R2	DS	This metadata attribute is not not consistent PCC_TF-2 binding. We are working to resolve the differences.
authorPerson	R2	DS	This metadata attribute is not not consistent PCC_TF-2 binding. We are working to resolve the differences.
authorRole	R2	DS	Add value, if known. This metadata attribute is not present in the PCC_TF-2 binding. It was added to XDS in 2006-2007 cycle.
authorSpeciality	R2	DS	Add value, if known. This metadata attribute is not present in the PCC_TF-2 binding. It was added to XDS in 2006-2007 cycle.
contentTypeCode	R	CAD	Value is consistent with the PCC-TF-2 binding.
comments	O	DS	Optional, add if pertanant. This metadata attribute is not present in the PCC_TF-2 binding. It was added to XDS in 2006-2007 cycle.
entryUUID	R	DS	Assigned at time of submission by Document Source, Repository or Registry. This metadata attribute is not present in the PCC_TF-2 binding.
patientId	R	DS	ID of the patient in the shared infrastructure, which is not necessarily the same as the patient id in the CDA. This is to be supplied at point of submission. This metadata attribute is not not consistent PCC_TF-2 binding. We are working to resolve the differences.
sourceId	R	DS	Value is consistent with the PCC-TF-2 binding.
submissionTime	R	DS	Value is consistent with the PCC-TF-2 binding.
title	O	DS	Optional, add if pertanant. This metadata attribute is not present in the PCC_TF-2 binding. It was added to XDS in 2006-2007 cycle.
uniqueId	R	DS	Value is consistent with the PCC-TF-2 binding.

400 Table 2.1-2 XDS Submission Set Metadata

2.1.3 XDSFolder Metadata

NOTE: This binding is unique to PHLab documents, as PCC-TF-2 does not not specify specific XDSFolder Requirements

Attribute	Usage in XDS	Source Type	Source/ Value
availabilityStatus	R	DS	Value assigned at point of submission.
codeList	R	DS	If any document in a folder pertains to a reportable condition, then the code identifying the reportable condition shall be among those listed in the codeList. This has been further refined from the original specification in XDS.
comments	O	DS	Optional, add if pertanant.
entryUUID	R	DS	Assigned at time of submission by Document Source, Repository or Registry.
lastUpdateTime	R	O	Computed by the Registry upon folder access.
patientId	R	DS	ID of the patient in the shared infrastructure, which is not necessarily the same as the patient id in the CDA. This is to be supplied at point of submission.
title	O	DS	Optional, add if pertanant.
uniqueId	R	SAT	ClinicalDocument / component / structuredBody / component / section / entry / act / specimen / specimenRole / id. Documents pertaining to the same specimen shall be placed in a single folder identified by a global specimen id. See new CP in ITI for 'assoction' folder ids. As this is still in CP format, this aspect of the PHLab binding cannot be implemented until the CP is processed.

Table 2.1-3 XDS Doument Folder Metadata

2.2 CDA Release 2.0 Content Modules

This section contains content modules based upon the HL7 CDA Release 2.0 Standard, and related standards and/or implementation guides of the XDS-PHLab document.
It is assumed that the reader is familiar with both the HL7 CDA R2 specification as well as the XDS-Lab specification. Conformance statements made by either of those two specifications are implicitly understood to be required here, unless explicitly stated otherwise. We note that requirements specified below are to ensure the presence of a minimum amount of data in order to enhance description and facilitate sharing of the public health laboratory report document. Implementers of this profile can and should make use of additional annotation within the CDA document to provide richer context. The examples in the following sections contain the minimal amount of data, as specified, and in many cases do make use of additional CDA elements for enriched context.
We also take particular care to point out places where we suggest edits to the XDS-Lab profile. These elements are indicated with red section titles. These sections

outline the suggested edit to XDS-Lab as well as link to a formal CP a the conclusion of this section.

2.2.1 Preface

A PHLab document, much like a medical summary, serves the purpose of summarizing. While a medical summary captures a series of patient events from an EMR system resulting in a summary of a patient's current (and past) status, a PHLab document captures the series of events surrounding a biological sample resulting in a summary which documents the status of the sample (ie. what was found in it).
The scope of a PHLab document is confined, at this time, to a single order and any (all) specimens stemming from that order and any (all) reportable contditions found among those specimens.
There are three varieties of PHLab documents: Human (patient), Non-Human Subject, Human(patient) with Non-Human Subject. For each variety we provide a short scenaio below to aid in the distinction among the varieties.

- Human (patient): Shelly Winters appears at the hospital emergency room with a jar of recalled peanut butter and symptoms consistent with Salmonellosis. Her physician, Dr Patel, orders a stool culture and subscribes an initial antibiotic treatment. The hospital laboratory performs the stool culture test and identifies Salmonella group C. The patient's history and isolate are sent to the local public health laboratory for epidemiological testing and confirmation of the relationship to the known outbreak. The public health laboratory performs further testing and confirms the patient is part of the existing outbreak. The reportable condition is escalated to additional recipients indicated in the report that is shared with the care provider and additional public health agencies.
- Non-Human Subject: Water, milk, and meat samples are routinely tested to meet various regulatory requirements. Water testing includes municipal drinking water, well water, open swimming beaches, and public pools to test for coliform levels. Milk samples are tested for total bacteria counts prior to pasteurization. Meat is tested for harmful bacteria such as Escherichia coli 0157:H7.
- Human(patient) with Non-Human Subject: Animal control authorities bring to the public health laboratory the head of a ferret that ferociously pursued and bit a young child. The specimen is to be tested for Rabies to determine if the child must undergo Rabies immunization. The public health laboratory gets the incident information and performs the rabies test while the child's physician awaits the results. The rabies test is negative. A public health laboratory report is created for the physician that references the child as the patient and the test subject as the ferret.

2.2.2 Clinical Document Header

2.2.2.1 General Constraints on the Header

1. As in XDS-Lab, all entities in a PHLab document are required to be accompanied by a `name`, `address` and `telecom` unless otherwise specified below.
2. Header elements not further elaborated on in the following sections remain consistent in definition and as stated in CDA R2 and are subject only to refinements made in XDS-Lab.

2.2.2.2 ClinicalDocument Child-Less Header elements

```
<ClinicalDocument xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
                  xmlns="urn:hl7-org:v3" xmnls:lab="urn:oid:1.3.6.1.4.1.19376.1.3.2"
                  xsi:schemaLocation="urn:hl7-org:v3 CDA.xsd">
  <realmCode code="US"/>
  <typeId extension="POCD_HD000040" root="2.16.840.1.113883.1.3"/>
  <templateId root="PHLab template id to go here"/>
  <id root="1.19.6.11.13.103000012000025132.1181266627192.1"/>
  <code code="18725-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
        displayName="Microbiology Studies"/>
  <title>Public Health Laboratory Report</title>
  <effectiveTime value="20070607183707.0222-0700"/>
  <confidentialityCode code="N" codeSystem="2.16.840.1.113883.5.25"
displayName="Normal"/>
  <languageCode code="en-US"/>
  <setId extension="07SR012345" root="2.16.840.1.113883.1.3"/>
  <versionNumber value="1"/>
```

2.2.2.2.1 ClinicalDocument.realmCode

PHLab documents, like XDS-Lab documents, shall have a `realmCode`.

2.2.2.2.2 ClinicalDocument.typeId

PHLab does not constrain the use of this element beyond what is stated in the CDA R2 documentation.

2.2.2.2.3 ClinicalDocument.templateId

The PCC Technical committee will assign a templateId for PHLab documents.

2.2.2.2.4 ClinicalDocument.id

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation.

2.2.2.2.5 ClinicalDocument.code

PHLab documents shall use the codes specified by XDS-Lab for code.

2.2.2.2.6 ClinicalDocument.title

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation.

2.2.2.2.7 ClinicalDocument.effectiveTime

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation.

2.2.2.2.8 ClinicalDocument.confidentialityCode

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation.

2.2.2.2.9 ClinicalDocument.languageCode

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation.

2.2.2.2.10 ClinicalDocument.setId

PHLab does not constrain the use of this element beyond what is stated in the CDA R2 documentation.

2.2.2.2.11 ClinicalDocument.versionNumber

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation.

2.2.2.3 ClinicalDocument.RecordTarget

As previously mentioned, a PHLab document has three variations dependent on the lab test subject. Each of these cases require different representation in the `ClinicalDocument.recordTarget`.

2.2.2.3.1 Human Patient

When the lab test subject is a biological sample taken from a human patient, the following shall be present.

- `ClinicalDocument.recordTarget.patientRole.id`
- `ClinicalDocument.recordTarget.patientRole.addr`
- `ClinicalDocument.recordTarget.patientRole.telecom`
- `ClinicalDocument.recordTarget.patientRole.patient.name`
- `ClinicalDocument.recordTarget.patientRole.patient.administrativeGenderCode`
- `ClinicalDocument.recordTarget.patientRole.patient.birthTime`

PHLab does not further refine the meaning of these elements beyond what is stated in the CDA R2 documentation.


```
<recordTarget typeCode="RCT">
  <patientRole classCode="PAT">
     <id extension="sw54321" root="1.19.6.11.13"/>
    <addr>
       <streetAddressLine>1313 Mockingbird Lane</streetAddressLine>
       <city>Janesville</city>
       <state>WI</state>
       <postalCode>53545</postalCode>
       <country>USA</country>
    </addr>
    <telecom value="608-555-5555"/>
    <patient classCode="PSN">
      <name><family>Winters</family><given>Shelly</given></name>
      <administrativeGenderCode code="F"/>
      <birthTime value="19401213"/>
    </patient>
  </patientRole>
</recordTarget>
```

If in the event a unit of information about the patient is not known or has been de-identified, the use of `nullFlavor` is appropriate.

```
<recordTarget typeCode="RCT">
  <patientRole classCode="PAT">
     <id extension="sw54321" root="1.19.6.11.13"/>
    <addr>
       <streetAddressLine nullFlavor="MSK"/> <!-- masked value -->
       <city nullFlavor="MSK"/> <!-- masked value -->
       <state nullFlavor="MSK"/> <!-- masked value -->
       <postalCode>53545</postalCode>
       <country>USA</country>
    </addr>
    <telecom nullFlavor="UNK"/> <!-- unknown value -->
    <patient classCode="PSN">
      <name nullFlavor="MSK"/> <!-- masked value -->
      <administrativeGenderCode code="F"/>
      <birthTime value="19401213"/>
    </patient>
  </patientRole>
</recordTarget>
```

2.2.2.3.2 Non-Human Subject

When the lab test subject is a sample taken from a non-human subject, such as an animal, a lake, soil or other environmental element, the following shall be present.

- `ClinicalDocument.recordTarget.patientRole.id` shall be present and shall represent the id of the non-human subject.
- The record target shall have a `patient` sub-element and it's `nullFlavor` shall be set to `"OTH"`. This indicates that other information pertaining to the non-human subject can be found in the body of the document in section.entry.act.subject.


```
<recordTarget typeCode="RCT">
  <patientRole classCode="PAT">
     <id extension="66373839" root="1.19.6.11.13"/>
    <patient nullFlavor="OTH">
  </patientRole>
</recordTarget>
```

2.2.2.3.3 Human Patient with Non-Human Subject

When the lab test subject is a sample taken from a non-human subject, such as an animal, a lake, soil or other environmental element, but the lab result findings directly impact a single patient (such as in the case of rabiies) the following shall be present.

- `ClinicalDocument.recordTarget.patientRole.id`
- `ClinicalDocument.recordTarget.patientRole.addr`
- `ClinicalDocument.recordTarget.patientRole.telecom`
- `ClinicalDocument.recordTarget.patientRole.patient.name`
- `ClinicalDocument.recordTarget.patientRole.patient.administrativeGenderCode`
- `ClinicalDocument.recordTarget.patientRole.patient.birthTime`

PHLab does not further refine the meaning of these elements beyond what is stated in the CDA R2 documentation. Information pertaining to the non-human subject of the laboratory testing is in the body of the document in section.entry.act.subject.

```
<recordTarget typeCode="RCT">
  <patientRole classCode="PAT">
     <id extension="sw54321" root="1.19.6.11.13"/>
    <addr>
       <streetAddressLine>1313 Mockingbird Lane</streetAddressLine>
       <city>Janesville</city>
       <state>WI</state>
       <postalCode>53545</postalCode>
       <country>USA</country>
    </addr>
    <telecom value="608-555-5555"/>
    <patient classCode="PSN">
      <name><family>Winters</family><given>Shelly</given></name>
      <administrativeGenderCode code="F"/>
      <birthTime value="19401213"/>
    </patient>
  </patientRole>
</recordTarget>
```

If in the event a unit of information about the patient is not known or has been de-identified, the use of `nullFlavor` is appropriate. Please see ClinicalDocument.RecordTarget - Human Patient for an example usage of `nullFlavor`.

2.2.2.4 ClinicalDocument.Author

A PHLab document author remains consistent in definition with the HL7 CDA R2 specification. We explictly note that XDS-Lab has constrained the use of the `author` in Please see the following CP to XDS-Lab for additional comments we have regarding this constraint on the `author`.

2.2.2.5 ClinicalDocument.DataEnterer

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation.

2.2.2.6 ClinicalDocument.Informant

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation.

2.2.2.7 ClinicalDocument.Custodian

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation.

2.2.2.8 ClinicalDocument.InformationRecipient

A PHLab document intendedRecipient remains consistent in definition with the HL7 CDA R2 specification. The `informationRecipient` may be present in a PHLab document, and inclusion of such information is beneficial. In public health, it is common for a public health laboratory identified reportable condition to be intended for delivery to several additional organizations. Inclusion of a list of `informationRecipient` elements could enable notifications in a shared public health repository environment as well as alert clinicians within the clinical repository of the organizations that have been notified.

2.2.2.9 ClinicalDocument.LegalAuthenticator

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation.

2.2.2.10 ClinicalDocument.Authenticator

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation.

2.2.2.11 Order Information

No different from the clinical laboratory setting, a public health laboratory executes test in response to an order. The entity that gives an order to a laboratory is called the 'Order Placer'. Documentation of the order information may be present in a PHLab document. If it is to be present, it shall follow the structure specified below. We note that documentation of the ordering process her differs from XDS-Lab. Please see the following CP to XDS-Lab for more information regarding documentaiton of the order.

2.2.2.11.1 ClinicalDocument.Participant (typeCode = 'REF')

This participant, consistent in definition with XDS-Lab, represents the 'Order Placer Provier' (often a physician that creates and gives an order) which is defined by the HL7 v2.5 messaging specification (ORC-12). This participant may be present in a PHLab document.

If this participant is present, the following *shall* then be present:

- `Participant.typeCode`

shall be present and shall be set to `"REF"` to indicate that this participant is the 'Order Placer Provider'.

- `Participant.associatedEntity.id`

shall be present and represents the id of the 'Order Placer Provier' which is defined by the HL7 v2.5 messaging specification (ORC-12)

- `Participant.associatedEntity.addr`

shall be present and represents the address of the organization of the 'Order Placer Provider', which is defined by the HL7 v2.5 messaging specification (ORD-21, 22, 23, 24)

- `Participant.associatedEntity.telecom`

shall be present and represents the telecom of the organization of the 'Order Placer Provider', which is defined by the HL7 v2.5 messaging specification (ORD-21, 22, 23, 24)

- `Participant.associatedEntity.associatedPerson.name`

shall be present and represents the name of the 'Order Placer Provider', which is defined by the HL7 v2.5 messaging specification (ORC-12)

If this participant is present, the following *may* then be present:

- `Participant.time`

may be present and shall represent the 'Order Placer Order Effective Time' which is defined by HL7 v2.5 messaging specification (ORC-15).


```
<participant typeCode="REF">
  <time>
    <low value="200706080600"/>
    <high value="200706081200"/>
  </time>
  <associatedEntity>
    <id extension="90573" root="1.19.6.11.13"/>
    <addr>
         <streetAddressLine>3113 Hospital Drive</streetAddressLine>
         <city>Chicago</city>
         <state>IL</state>
         <postalCode>60622</postalCode>
         <country>USA</country>
    </addr>
    <telecom value="312-555-5555"/>
    <associatedPerson>
      <name><family>Patel</family><given>Kiran</given><prefix>Dr</prefix></name>
    </associatedPerson>
  </associatedEntity>
</participant>
```

If in the event a unit of information about the 'Order Placer Provider' is not known or has been de-identified, the use of `nullFlavor` is appropriate. Please see ClinicalDocument.RecordTarget - Human Patient for an example usage of `nullFlavor`.

2.2.2.11.2 ClinicalDocument.Participant (typeCode = 'ENT')

This participant represents the 'Order Placer Enterer' (often a physician that creates and gives an order) which is defined by the HL7 v2.5 messaging specification (ORC-10). This participant may be present in a PHLab document.

If this participant is present, the following *shall* then be present:

- `Participant.typeCode`

shall be present and shall be set to `"ENT"` to indicate that this participant is the 'Order Placer Enterer'.

- `Participant.associatedEntity.id`

shall be present and represents the id of the 'Order Placer Enterer' which is defined by the HL7 v2.5 messaging specification (ORC-10)

- `Participant.associatedEntity.addr`

shall be present and represents the address of the the organization of the 'Order Placer Enterer', which is defined by the HL7 v2.5 messaging specification (ORC-13, 17, 18)

- `Participant.associatedEntity.telecom`

shall be present and represents the telecom of the organization of the 'Order Placer Enterer', which is defined by the HL7 v2.5 messaging specification (ORC-13, 17, 18)

- `Participant.associatedEntity.associatedPerson.name`

shall be present and represents the name of the 'Order Placer Enterer', which is defined by the HL7 v2.5 messaging specification (ORC-10)

If this participant is present, the following *may* then be present:

- `Participant.time`

may be present and shall represent the 'Order Placer Enterer Order Date/Time' which is defined by HL7 v2.5 messaging specification (ORC-9).

```
<participant typeCode=”ENT”>
   <time value="20070604"/>
   <associatedEntity>
     <id extension="90577" root="1.19.6.11.13"/>
     <addr>
          <streetAddressLine>3113 Hospital Drive</streetAddressLine>
          <city>Chicago</city>
          <state>IL</state>
          <postalCode>60622</postalCode>
          <country>USA</country>
     </addr>
     <telecom value="312-555-5555"/>
      <associatedPerson>
          <name>
              <given>Samantha</given>
              <family>Goodrich</family>
          </name>
       </associatedPerson>
   </associatedEntity>
</participant>
```

We note that the concept of the 'Order Placer Enterer Authorization' definded by the HL7v2.5 messagins specification (ORC-30) cannot be represented in a CDA participant element. Therefore this information is missing. If in the event a unit of information about the 'Order Placer Enterer' is not known or has been de-identified, the use of `nullFlavor` is appropriate. Please see ClinicalDocument.RecordTarget - Human Patient for an example usage of `nullFlavor`.

2.2.2.11.3 ClinicalDocument.InFulfillmentOf

This element documents the order number(s) from the 'Order Placer Provider' or 'Order Placer Enterer'. This element may be present in a PHLab document when either the 'Order Placer Provider' participant or the 'Order Placer Enterer' participant is present. If one of the above participants is present, and if the `inFulfillmentOf` is present, the following *shall* then be present:

- `InfFulfillmentOf.Order.code`

Exactly one code shall be present for each type of laboratory test ordered and it's value shall be selected from among the LOINC universal test IDs.

If one of the above participants is present, and if the `inFulfillmentOf` is present, the following *may* then be present:

- `InFulfillmentOf.Order.id`

At least one id may be present and this id(s) shall represent the 'Order Placer Order Number(s)' which is defined by HL7 v2.5 messaging specification (ORC-2).

```
<inFulfillmentOf>
  <order>
    <id extension="28902809" root="2.16.840.1.113883.1.3"/>
    <code code="20951-0" codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC" displayName="Salmonella Serotype"/>
  </order>
</inFulfillmentOf>
```

2.2.2.12 ClinicalDocument.DocumentationOf

A PHLab document, much like a medical summary, serves the purpose of summarizing. While a medical summary captures a series of patient events from an EMR system resulting in a summary of a patient's current (and past) status, a PHLab document captures the series of events surrounding a biological sample resulting in a summary which documents the status of the sample (ie. what was found in it). The `ClinicalDocument.DocumentationOf` element is used to this effect.
The `ClinicalDocument.DocumentationOf` shall be present and *shall* have the following:

- `ServiceEvent.effectiveTime` shall be present and shall be specified using the `low` and `high` subelements. These times shall represent the time span of events described in the PHLab document.
    - The `low` time shall correleate to the Encounter Time or the Specimen Collection Date/Time or the Specimen Recieved Date/Time, in that preference order.
    - The `high` time shall correleate to chronologically latest time of authentication or legal authentication that is documented in the PHLab document.

The `ClinicalDocument.DocumentationOf` shall be present and *may* have the following:

- A PHLab document may make use of the CDA R2 extension `ServiceEvent.statusCode` in accordance with the XDS-Lab specification. Therefore, `ServiceEvent.statusCode` may be present.

- `ServiceEvent.performer` may be present and shall represent the primary individual and laboratory organization that produced the Result Event. Results produced by assisting laboratories shall override this information in the body of the document. It is permissable to document all performers in the body of the document in thier respective places. the `ServiceEvent.performer` is subject to the following refinements:
  - `performer.assignedEntity.id`, `performer.assignedEntity.addr`, `performer.assignedEntity.telecom`, `performer.assignedEntity.assignedPerson.name` *shall* be present and shall represent the performer which is equivalent in concept to the HL7v2.5 messaging concept Responsible Observer (OBX-15,OBX-16).
  - `performer.time` *may* be present and shall represent the HL7 v2.5 messaging concept Date/Time of Analysis (OBX-19).

Please additionally see the following CP to XDS-Lab for more information regarding the performer.


```
  <documentationOf>
    <serviceEvent>
      <effectiveTime>
        <low value="20070604"/>
        <high value="20070608"/>
      </effectiveTime>
      <performer/>
      <performer typeCode="PRF">
        <assignedEntity>
          <id extension="rm83747" root="1.19.6.11.13"/>
          <addr>
             <streetAddressLine>7000 Hospital Drive</streetAddressLine>
             <city>Chicago</city>
             <state>IL</state>
             <postalCode>60622</postalCode>
             <country>USA</country>
          </addr>
          <telecom value="312-555-5555"/>
          <assignedPerson>

<name><family>Trenton</family><given>Douglas</given><prefix>Dr.</prefix></name>
          </assignedPerson>
          <representedOrganization>
            <id extension="rm83747" root="1.19.6.11.13"/>
            <name>Hospital Laboratory</name>
            <telecom value="312-555-5555"/>
            <addr>
             <streetAddressLine>7000 Hospital Drive</streetAddressLine>
             <city>Chicago</city>
             <state>IL</state>
             <postalCode>60622</postalCode>
             <country>USA</country>
            </addr>
          </representedOrganization>
        </assignedEntity>
      </performer>
    </serviceEvent>
  </documentationOf>
```

2.2.2.13 ClinicalDocument.RelatedDocument

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation.

2.2.2.14 ClinicalDocument.Authorization

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation, though we have a question regarding its use in XDS-Lab. See the following CP.

2.2.2.15 ClinicalDocument.componentOf

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation.


```
  <componentOf>
    <encompassingEncounter>
      <id extension="ENC1234" root="1.19.6.11.13"/>
      <effectiveTime value="20070604"/>
      <location>
        <healthCareFacility>
          <code code="HU" codeSystem="2.16.840.1.113883.5.10588" displayName="Hospital
Unit"/>
        </healthCareFacility>
      </location>
    </encompassingEncounter>
  </componentOf>
```

2.2.3 Clinical Document Body

2.2.3.1 General Constraints on the Body

1. As in XDS-Lab, all entities in a PHLab document are required to be accompanied by a `name`, `address` and `telecom` unless otherwise specified below.
2. Body elements not further elaborated on in the following sections remain consistent in definition and as stated in CDA R2 and are subject only to refinements made in XDS-Lab.
3. The body of a PHLab document is consistent in structure with XDS-Lab (Microbiology section 7.3.3.5.3 and example 9.3.4), though we extend it's use here beyond microbiology.
    - Each `Section` corresponds to a single laboratory section (as in XDS-Lab). At least one `Section` shall be present.
    - There shall be at least one `Entry` in each `Section` and this `Entry` shall us the 'Lab.Report.Data.Processing.Entry' `templateId`.
    - Each `Entry` in a shall contain a single `Act` sub-element. This `Act` is hereafter referred to as the 'Specimen Act'. There shall be exactly one `Entry` with one 'Specimen Act' for each documented specimen under a particular laboratory section.
    - Each 'Specimen Act' shall contiain one or more `EntryRelationship` elements.
    - This `EntryRelationship` shall contain a single `Organizer` element. This `Organizer` is hereafter referred to as the 'Reportable Condition Organizer'. Laboratory test results and identification of the reportable condition are grouped under the 'Reportable Condition Organizer'. If multiple reportable conditions are found they shall be documented under separate `EntryRelationship` elements in their respective 'Reportable Condition Organizer' element.
    - Other `Sections` conformant to XDS-Lab document specifications which detail conditions or findings that are not required to be reported may be present, so long as the structure of the `Sections` containing the reportable condition findings remain conformant to this specification.

2.2.3.2 Section

Each `Section` corresponds to a single laboratory section (as in XDS-Lab). At least one `Section` shall be present.

A `Section` *shall* have the following:

- `Section.text` shall be present. Each result presented here in text shall be linked using xml "ID" with corresponding result markup in the structured `Entry`.

A `Section` *may* have the following:

- `Section.code`

may be present and shall be chosen among the coded specialities specified in XDS-Lab (7.1.1) and shall be consistent with `ClinicalDocument.code`

- `Section.title`

may be present and its use is encouraged.

- `Section.text.renderMultimedia`

may be present. Inclusion of images or other external content associated with a particular result shall be structured according to CDA documentation. Additionally see Observation Media.


```
<component typeCode="COMP">
 <structuredBody classCode="DOCBODY" moodCode="EVN">
   <component typeCode="COMP">
     <section classCode="DOCSECT">
       <code code="18725-2" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
             displayName="Microbiology Studies"/>
       <title>Public Health Laboratory Report</title>
       <text><table>
           <thead ID="isoTest">
             <tr>
               <th>Organism Isolated*</th>
               <th>Specimen Type</th>
               <th>Comments</th>
             </tr>
           </thead>
           <tbody>
             <tr>
               <td>Salmonella Group C</td>
               <td>stool</td>
               <td></td>
             </tr>
             <tr>
               <td>*Performed at Hospital Laboratory</td>
               <td></td>
               <td></td>
             </tr>
           </tbody>
         </table><table>
           <thead ID="serotypeTest">
             <tr>
               <th>Salmonella Serotype</th>
               <th>LOINC</th>
               <th>SNOMED</th>
             </tr>
           </thead>
           <tbody>
             <tr>
               <td>Salmonella tennessee 6,7,14;z29;1,2,7</td>
               <td>6463-4</td>
               <td>79153007</td>
             </tr>
           </tbody>
         </table><table>
           <thead>
             <tr>
               <th>Salmonella Susceptibility</th>
               <th>Interpretation</th>
               <th>Comments</th>
             </tr>
           </thead>
           <tbody>
             <tr ID="a1">
               <td>Tetracycline</td>
               <td>Susceptible</td>
               <td></td>
             </tr>
             <tr ID="a2">
               <td>Ciprofloxacin</td>
               <td>Susceptible</td>
               <td></td>
             </tr>
             <tr ID="a3">
               <td>Trimethprim + Sulfamethoxazole</td>
               <td>Susceptible</td>
               <td></td>
             </tr>
             <tr ID="a4">
```



```
                <td>Ampicillin</td>
                <td>Susceptible</td>
                <td></td>
              </tr>
              <tr ID="a5">
                <td>Chloramphenicol</td>
                <td>Susceptible</td>
                <td></td>
              </tr>
              <tr ID="a6">
                <td>Ceftriaxone</td>
                <td>Susceptible</td>
                <td></td>
              </tr>
            </tbody>
          </table>
        </text>
```

2.2.3.3 Specimen Act

There shall be at least one `Entry` in each `Section` and this `Entry` shall us the 'Lab.Report.Data.Processing.Entry' `templateId`. Each `Entry` in a shall contain a single `Act` sub-element. This `Act` is hereafter referred to as the 'Specimen Act'. There shall be exactly one `Entry` with one 'Specimen Act' for each documented specimen under a particular laboratory section.

```
        <entry typeCode="DRIV">
          <templateId extension="Lab.Report.Data.Processing.Entry"
                      root="1.3.6.1.4.1.19376.1.3"/>
          <act classCode="ACT" moodCode="EVN">
            <statusCode code="completed"/>
```

2.2.3.3.1 Act.Subject

When the lab test subject is a sample taken from a non-human subject, such as an animal, a lake, soil or other environmental element, the `Act.Subject` shall be present and shall represent the non-human subject of laboratory testing. When `RecordTarget.PatientRole.Patient.nullFlavor` is set to `"OTH"`, then `RecordTarget.PatientRole.id` shall represent the id of the non-human laboratory test subject. For more information, refer back to ClinicalDocument.RecordTarget.

When `Act.Subject` is present the following *shall* be present:

- `Subject.code` shall be present and shall represent the type of animal or material tested (ex. Chicken, Fish, egg salad, water, soil, air, paint, etc.).

When `Act.Subject` is present the following *may* be present:

- `Subject.addr` may be present and shall represent the location where this subject was found or originated (ex. farm address, restaurant address, factory address, reservoir address, etc.)


```
<subject>
   <relatedSubject>
       <code code="FRT" codeSystem="0.0.0.0.3.3"
             codeSystemName="Animal Byte Identification System Name"
             displayName="Ferret species"/>
        <addr>
           <streetAddressLine>304 Portola Road</streetAddressLine>
           <city>San Jose</city>
           <state>CA</state>
           <postalCode>95120</postalCode>
           <country>USA</country>
        </addr>
   </relatedSubject>
</subject>
```

2.2.3.3.2 Act.Specimen

This element represents the specimen recieved by the public health lab and is consistent with the XDS-Lab documentation, including the optional `productOf` CDA R2 extension.

```
<specimen typeCode="SPC">
   <specimenRole classCode="SPEC">
      <id extension="55584739900388" root="1.19.6.11.13"/>
      <specimenPlayingEntity>
          <code code="STL" codeSystemName="2.16.840.1.113883.5.129"
                displayName="Stool"/>
       </specimenPlayingEntity>
       <lab:productOf classCode="PROC" moodCode="EVN">
          <effectiveTime value="20070604"/>
       </lab:productOf>
   </specimenRole>
</specimen>
```

2.2.3.3.3 Act.Performer

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation, though we have a question regarding its restricted use in XDS-Lab. See the following CP.

2.2.3.3.4 Act.Participant (typeCode = "PRF")

Zero or more `Act.Participant (typeCode="PRF")` may be present and shall represent the 'Equipment Instance', a concept further defined in HL7 v2.5 messaging (OBX-18), used to perform the lab test result.

The following *shall* be present for the 'Equipment Instance':

- `Participant.time`

shall be present and shall represent the 'Specimen Received Date/Time', a concept further from HL7 v2.5 messaging (OBR-14).

- `Participant.ParticipantRole.PlayingDevice`

shall be present and shall represent the 'Equipment Instance' device (OBX-18) which shall be represented using at least one of the following - `PlayingDevice.code`, `PlayingDevice.softwareName`, `PlayingDevice.manufacturerModelName`

The following *may* be present for the 'Equipment Instance':

- `Participant.ParticipantRole.ScopingEntity.id`

may be present and shall represent the 'Filler Order Number', a concept further defined in HL7 v2.5 messaging (OBR-3).

To our knowledge, this concept is not in XDS-Lab, therefore we pose the following CP.

2.2.3.3.5 Act.Participant (typeCode = "VRF")

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation, though we have a question regarding its use in XDS-Lab. See the following CP.

2.2.3.4 Reportable Condition Organizer

Each 'Specimen Act' shall contiain one or more `EntryRelationship` elements. This `EntryRelationship` shall contain a single `Organizer` element. This `Organizer` is hereafter referred to as the 'Reportable Condition Organizer'. Laboratory test results and identification of the reportable condition are grouped under the 'Reportable Condition Organizer'. If multiple reportable conditions are found they shall be documented under separate `EntryRelationship` elements in their respective 'Reportable Condition Organizer' element.
The 'Reportable Condition Organizer' *shall* have the following:

- `Organizer.classCode`

shall be present and shall have the value "CLUSTER".

- `Organizer.moodCode`

shall be present and shall have the value "EVN".

- `Organizer.statusCode`

shall be present and shall be set to a value apprpriate.


```
<entryRelationship typeCode="COMP">
  <organizer classCode="CLUSTER" moodCode="EVN">
    <statusCode code="completed"/>
    <effectiveTime value="20070608"/>
```

2.2.3.4.1 Organizer.Specimen

The `Organizer.Specimen` shall be present and shall represent the reportable condition.
The following *shall* be present:

- `Specimen.SpecimenRole`

shall be present and its `classCode` shall be set to `"ISLT"` when the lab section to which this reportable condition belongs is microbiology and set to ??? otherwise (see open issue #6).

- `Specimen.SpecimenRole.SpecimenPlayingEntity.code`

shall be present and shall contatian the code representing the reportable condition, preferably from either the SNOMED or LOINC coding systems.

The following *may* be present:

- `Specimen.SpecimenRole.SpecimenPlayingEntity.code.translation`

may be present and shall represent alternative coded values representing the reportable condition, or generalizations of the reportable condition. For example, the xml below indicates a reportable condition of Salmonella tenessee. A generalization of this code would be the code that represents the Salmonella species, as a whole.

```
<specimen>
  <specimenRole classCode="ISLT">
    <specimenPlayingEntity>
      <code code="79153007" codeSystem="2.16.840.1.113883.6.96"
            codeSystemName="SNOMED"
            displayName="Salmonella tennessee 6,7,14;z29;1,2,7"/>
    </specimenPlayingEntity>
  </specimenRole>
</specimen>
```

2.2.3.4.2 Organizer.Component.Organizer (Battery Test)

Test Results, when part of a battery test, shall appear as sub-elements of an `Organizer` element. This `Organizer` shall be hereafter reffered to as the a sub-elemenet of the 'Battery Test Organizer' and shall be a sub-element of th e'Reportable Condition Organizer'. Each battery test result shall be represented as an `Observation` element. The 'Battery Test Organizer' shall have two or more `component` elements each

containing an `Observation` element which shall be as documented specified in the following section.

The 'Battery Test Organizer' *shall* have the following:

- `Organizer.classCode`

shall be present and shall have the value "BATTERY".

- `Organizer.moodCode`

shall be present and shall have the value "EVN".

- `Organizer.statusCode`

shall be present and shall be set to a value apprpriate.

```
<component>
  <organizer classCode="BATTERY" moodCode="EVN">
    <code code="29576-6" codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC" displayName="Microbiology Susceptibility"/>
    <statusCode code="completed"/>
    <effectiveTime value="20070608"/>
    <component>
      <observation classCode="OBS" moodCode="EVN">
        <code code="18993-6" codeSystem="2.16.840.1.113883.6.1"
              codeSystemName="LOINC" displayName="Tetracycline">
          <originalText><reference value="a1"/></originalText>
        </code>
        <interpretationCode code="S" codeSystem="2.16.840.1.113883.11.10219"
                            displayName="Susceptible"/>
      </observation>
    </component>
    <component>
      <observation classCode="OBS" moodCode="EVN">
        <code code="18906-8" codeSystem="2.16.840.1.113883.6.1"
              codeSystemName="LOINC" displayName="Ciprofloxacin">
          <originalText><reference value="a2"/></originalText>
        </code>
        <interpretationCode code="S" codeSystem="2.16.840.1.113883.11.10219"
                            displayName="Susceptible"/>
      </observation>
    </component>
    <component>
      <observation classCode="OBS" moodCode="EVN">
        <code code="18995-5" codeSystem="2.16.840.1.113883.6.1"
              codeSystemName="LOINC"
              displayName="Trimethprim + Sulfamethoxazole">
          <originalText><reference value="a3"/></originalText>
        </code>
        <interpretationCode code="S"
                            codeSystem="2.16.840.1.113883.11.10219"
                            displayName="Susceptible"/>
      </observation>
    </component>
    <component>
      <observation classCode="OBS" moodCode="EVN">
        <code code="18864-9" codeSystem="2.16.840.1.113883.6.1"
              codeSystemName="LOINC" displayName="Ampicillin">
          <originalText><reference value="a4"/></originalText>
        </code>
```



```
        <interpretationCode code="S" codeSystem="2.16.840.1.113883.11.10219"
                            displayName="Susceptible"/>
      </observation>
    </component>
    <component>
      <observation classCode="OBS" moodCode="EVN">
        <code code="18903-5" codeSystem="2.16.840.1.113883.6.1"
              codeSystemName="LOINC" displayName="Chloramphenicol">
          <originalText><reference value="a5"/></originalText>
        </code>
        <interpretationCode code="S" codeSystem="2.16.840.1.113883.11.10219"
                            displayName="Susceptible"/>
      </observation>
    </component>
    <component>
      <observation classCode="OBS" moodCode="EVN">
        <code code="18895-3" codeSystem="2.16.840.1.113883.6.1"
              codeSystemName="LOINC" displayName="Ceftriaxone">
          <originalText><reference value="a6"/></originalText>
        </code>
        <interpretationCode code="S" codeSystem="2.16.840.1.113883.11.10219"
                            displayName="Susceptible"/>
      </observation>
    </component>
  </organizer>
</component>
```

2.2.3.4.3 Test Results

Test Results shall appear as sub-elements under the 'Reportable Condition Organizer' or, when part of a battery test, under the 'Battery Test Organizer' which shall be a sub-element of the 'Reportable Condition Organizer'. Each test result shall be represented as an `Observation` element. The 'Reportable Condition Organizer' may have zero or more `Observation` sub-elements and zero or more 'Battery Test Organizer' sub-elements with two or more `Observation` elements each.
For each `Observation`, the following *shall* be present:

- `Observation.code`

shall be present and shall represent the lab test id consistent in meaning with HL7 v2.5 message component OBR-4. The use of LOINC test identifiers is recommended. `Observation.code.originalText.reference` shall be present and shall reference the element of `Section.text` where this result is also documentd

- `Observation.value`
- `Observation.effectiveTime`

For each `Observation`, the following *may* be present:

- `Observation.referenceRange`
- `Observation.interpretationCode`
- `Observation.methodCode`

- `Observation.text`


```
<component>
  <observation classCode="OBS" moodCode="EVN">
    <code code="89029-0" codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC" displayName="Microbiology Culture">
      <originalText><reference value="isoTest"/></originalText>
    </code>
    <text>Isolation Test Result Comment</text>
    <statusCode code="completed"/>
    <effectiveTime value="20070608"/>
    <value xsi:type="CE" code="1116048001"
           codeSystem="2.16.840.1.113883.6.96" codeSystemName="SNOMED"
           displayName="Salmonella Group C"/>
    <performer typeCode="PRF">
      <assignedEntity>
        <id extension="rm83747" root="1.19.6.11.13"/>
        <addr>
            <streetAddressLine>7000 Hospital Drive</streetAddressLine>
            <city>Chicago</city>
            <state>IL</state>
            <postalCode>60622</postalCode>
            <country>USA</country>
        </addr>
        <telecom value="312-555-5555"/>
        <assignedPerson>
         <name>
            <family>Trenton</family>
            <given>Douglas</given>
            <prefix>Dr.</prefix>
         </name>
        </assignedPerson>
        <representedOrganization>
          <id extension="rm83747" root="1.19.6.11.13"/>
          <name>Hospital Laboratory</name>
          <telecom value="312-555-5555"/>
          <addr>
            <streetAddressLine>7000 Hospital Drive</streetAddressLine>
            <city>Chicago</city>
            <state>IL</state>
            <postalCode>60622</postalCode>
            <country>USA</country>
          </addr>
        </representedOrganization>
      </assignedEntity>
    </performer>
  </observation>
</component>
<component>
  <observation classCode="OBS" moodCode="EVN">
    <code code="20951-0" codeSystem="2.16.840.1.113883.6.1"
          codeSystemName="LOINC" displayName="Salmonella Serotype">
      <originalText><reference value="serotypeTest"/></originalText>
    </code>
    <text>Serotype Test Result Comment</text>
    <statusCode code="completed"/>
    <effectiveTime value="20070608"/>
    <value xsi:type="CE" code="79153007" codeSystem="2.16.840.1.113883.6.96"
           codeSystemName="SNOMED"
           displayName="Salmonella tennessee 6,7,14;z29;1,2,7"/>
  </observation>
</component>
```

2.2.3.4.3.1 Observation.EntryRelationship.ObservationMedia

Inclusion of images or other external content associated with a particular result shall be structured according to CDA documentation. When an image is included or other

external content as part of a result and a `Section.text.renderMultimedia` is present, `Observation.EntryRelationship.ObservationMedia` shall be present on the corresponging `Observation.`.
When `Observation.EntryRelationship.ObservationMedia` is present, the following *shall* be present:

- `ObservationMedia.value`

shall be present. It shall contain as #CDATA the base-64 encoded content. Additionally, `ObservationMedia.value.representation` shall be "B64" and `ObservationMedia.value.mediaType` shall be present.

```
<observationMedia classCode="OBS" moodCode="EVN" ID="PULSE_NET_IMAGE">
    <id root="2.16.840.1.113883.19.2.1"/>
    <value mediaType="image.gif" representation="B64">Here is the inline B64
content</value>
</observationMedia>
```

2.2.3.4.3.2 Observation.Performer

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation, though we have a question regarding its restricted use in XDS-Lab. See the following CP.

2.2.3.4.3.3 Observation.Participant (typeCode="PRF")

Zero or more `Observation.Participant (typeCode="PRF")` may be present and shall represent the 'Equipment Instance', a concept further defined in HL7 v2.5 messaging (OBX-18), used to perform the lab test result. Specifications for the 'Equipment Instance are identical to those in Act.Participant (typeCode="PRF") and may be specified on the test result when the 'Equipment Instance' for this test differes from that documented in the `Act` or when no 'Equipment Instance' is documented in the `Act`. To our knowledge, this concept is not in XDS-Lab, therefore we pose the following CP.

2.2.3.4.3.4 Observation.Participant (typeCode = "VRF")

PHLab does not constrain this element beyond what is stated in the CDA R2 and XDS-Lab documentation, though we have a question regarding its use in XDS-Lab. See the following CP.

3 Change Proposals to Other IHE Profiles

- CPs to XDS-Lab
  - ClinicalDocument.typeId (missing in samples)
  - ClinicalDocument.templateId (unspecified for XDS-Lab documents)
  - ClinicalDocument.id (missing in samples)
  - ClinicalDocument.recordTarget (meaning of identity is not clear)
  - ClinicalDocument.author (restricted use is not clear)
  - Participant and Performer Usage in XDS-Lab (questions and clarifications)
  - Usage of XDS-Lab (questions and clarifications)
  - Correlation with existing standard concepts and components (suggested enhancements)
  - Documentation of XDS-Lab CDA R2 extensions (include schema types)
  - XDS-Lab content bindings to XDS, XDR, XDM Metadata

- CPs to PCC Technical Framework
  - Metadata mapping edits (Bindings to XDS,XDM,XDR)

3.1 ClinicalDocument.typeId CP

Submitter's Name(s) and e-mail address(es):	Sarah Knoop and Sondra Renly
Submission Date:	Friday June 8, 2007
Integration Profile affected:	IHE Laboratory Technical Framework Supplement – Sharing Laboratory Reports
Version of IHE Technical Framework:	Supplement 2006-2007
Volume(s) and Section(s) affected:	Volume 2
Rationale for Change: XML CDA Samples are missing <typeId> elements.	
Suggested Edits: Include the <typeId> element in CDA XML examples, for completeness.	

3.2 ClinicalDocument.templateId CP

Submitter's Name(s) and e-mail address(es):	Sarah Knoop and Sondra Renly
Submission Date:	Friday June 8, 2007
Integration Profile affected:	IHE Laboratory Technical Framework Supplement – Sharing

	Laboratory Reports
Version of IHE Technical Framework:	Supplement 2006-2007
Volume(s) and Section(s) affected:	Volume 2
Rationale for Change: XDS-Lab does not specify a document templateId for XDS-Lab documents. A templateId is present for other CDA-based content profiles.	
Suggested Edits: Generate a templateId for XDS-Lab documents and create a section between 6.4 and 6.5.	

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3.3 ClinicalDocument.id CP

Submitter's Name(s) and e-mail address(es):	Sarah Knoop and Sondra Renly
Submission Date:	Friday June 8, 2007
Integration Profile affected:	IHE Laboratory Technical Framework Supplement – Sharing Laboratory Reports
Version of IHE Technical Framework:	Supplement 2006-2007
Volume(s) and Section(s) affected:	Volume 2
Rationale for Change: XML CDA Samples are missing <id> elements on the <ClinicalDocument> which renders the CDA invalid.	
Suggested Edits: Include the <id> element in CDA XML examples, for completeness and accuracy.	

3.4 ClinicalDocument.RecordTarget CP

Submitter's Name(s) and e-mail address(es):	Sarah Knoop and Sondra Renly
Submission Date:	Friday June 8, 2007
Integration Profile affected:	IHE Laboratory Technical Framework Supplement – Sharing Laboratory Reports
Version of IHE Technical Framework:	Supplement 2006-2007
Volume(s) and Section(s) affected:	Volume 2

Rationale for Change: It is unclear the meaning of the word “identity”. This word is not a concept we could associate within the CDA schema.
Suggested Edits: **6.12 ClinicalDocument/recordTarget** This element encapsulates the patient, target of this laboratory report, with its ID, ~~identity,~~ address and telecom.

3.5 ClinicalDocument.Author CP

Submitter’s Name(s) and e-mail address(es):	Sarah Knoop and Sondra Renly
Submission Date:	Friday June 8, 2007
Integration Profile affected:	IHE Laboratory Technical Framework Supplement – Sharing Laboratory Reports
Version of IHE Technical Framework:	Supplement 2006-2007
Volume(s) and Section(s) affected:	Volume 2

Rationale for Change:

Our interpretation of the XD*-LAB documentation as written is that it constrains the use of author on a distinction regarding whether the report comes from a laboratory system versus a physician system. In the case where the laboratory report is from a laboratory system the author is specified to be the laboratory software. In the case where the laboratory report is from a physician system the author is specified to be the physician. In both cases it is reasonable that a person and software system could be documented when applicable, but the verbage implies it should not be documented.

We recognize that being able to distinquish a report as being from a laboratory or a physician source is important, but this does not seem appropriate to restrict the CDA author element in this way to indicate the source. We recommend that in either case both a person and software system could be documented when applicable, as consistent with CDA R2 documentation. See also here

Suggested Edits:

6.12 ClinicalDocument/author
The author(s) of the laboratory report. ~~In use cases 2.2 and 2.4, the laboratory report is produced by a software system represented by the element: author/assignedAuthor/assignedAuthoringDevice/softwareName.~~
The author/time element carries the date&time the laboratory report was produced by the system. ~~In use cases 2.1, 2.3 and 2.5 the report is prepared by a physician who is the assignedPerson.~~

3.6 Paticipant and Performer Usage CP

Submitter's Name(s) and e-mail address(es):	Sarah Knoop and Sondra Renly
Submission Date:	Friday June 8, 2007
Integration Profile affected:	IHE Laboratory Technical Framework Supplement – Sharing Laboratory Reports
Version of IHE Technical Framework:	Supplement 2006-2007
Volume(s) and Section(s) affected:	Volume 2

Rationale for Change:

- Lab Test Order: When reading through and learning about XDS-Lab we started to draw many comparisons between it and concepts existing in HL7 v2.5 messaging. We feel this conceptual correlation is valuable to include in XDS-Lab. We also have added the concept of the 'Order Placer Enterer' in addition to the 'Order Placer Provider', already present in XDS-Lab, for completeness.
- Lab Test Performance:

- ClinicalDocument.DocumentationOf.ServiceEvent.Performer - When reading through and learning about XDS-Lab we started to draw many comparisons between it and concepts existing in HL7 v2.5 messaging. We feel this conceptual correlation is valuable to include in XDS-Lab.
- Act.Performer - Text in the XDS-Lab imples that this performer is only to be used when the laboratory testing is execued by a different lab than the one documented in the header (if present, otherwise this is a mute point). However, this seems to narrow CDA semantics in which use of this element would be appropriate if the person performing the laboratory test is different than the one in the header, regardless of which lab they are from.
- Act.Participant (typeCode='PRF') - XDS-Lab does not seem to include mark-up on the following concepts: Equipment Instance (OBX-18),Filler Order Number (OBR-3), Specimen Received Date/Time (OBR-14, SPM-18). We recommend that these be able to included at this level of the document body.
- Obervation.Performer - subject to same restriction as Act.Performer.
- Observation.Participant (typeCode='PRF') - XDS-Lab does not seem to include mark-up on the following concepts: Equipment Instance (OBX-18),Filler Order Number (OBR-3), Specimen Received Date/Time (OBR-14, SPM-18). We recommend that these be able to included at this level of the document body as well as in the act.

- Lab Test Verification: We completely agree with the usage of these kinds of participants, however question the use of the typeCode 'VRF' instead of the typeCode 'AUTHEN'. In the header, all verifiers are listed, en mass, as ClinicalDocument.authenticator, but in the body they are parsed out to their respective sections or observations as Participants with typeCode 'VRF', which means something slightly different. The key confusion here is what is the difference between 'authentication' and 'verification' from the laboratory perspective? The semantics seem to be mixed in the document

Suggested Edits:

- Lab Test Order: Please see the follwing section of this document: Ordering participants
- Lab Test Performance:
  - ClinicalDocument.DocumentationOf.ServiceEvent.Performer - Please see the follwing section of this document: ClinicalDocument.DocumentationOf
  - Act.Performer - Suggest lifiting the implied restriction.
  - Act.Participant (typeCode='PRF') - Please see the follwing section of this document: Act.Participant (typeCode='PRF')
  - Obervation.Performer - Suggest lifiting the implied restriction.

- Observation.Participant (typeCode='PRF') - Please see the follwing section of this document: Observation.Participant (typeCode='PRF')

- Lab Test Verification: Suggest to make all Lab Test Verifiers Participants with typeCode="VRF" throughout the header and the body of the document. "VRF" is defined as 'A person who verifies the correctness and appropriateness of the service (plan, order, event, etc.) and hence takes on accountability.' This seems most consistent with laboratory verification. Alternatively, one could change 'VRF' to 'AUTHEN' on relavant participants in the body, if in fact this is truly the case. Authenticator and 'AUTHEN' are defined as 'A verifier who attests to the accuracy of an act, but who does not have privileges to legally authenticate the act. An example would be a resident physician who sees a patient and dictates a note, then later signs it. Their signature constitutes an authentication'.

3.7 Usage of XDS-Lab CP

Submitter's Name(s) and e-mail address(es):	Sarah Knoop and Sondra Renly
Submission Date:	Friday June 8, 2007
Integration Profile affected:	IHE Laboratory Technical Framework Supplement – Sharing Laboratory Reports
Version of IHE Technical Framework:	Supplement 2006-2007
Volume(s) and Section(s) affected:	Volume 1

Rationale for Change:

A statement is made in line 400 of the XDS-lab that is not necessarily true in all cases in which a laboratory report could be used.

Suggested Edits:

Volume 1, Line 400: In all use cases above, the laboratory report document is built and published ~~towards an EHR~~ **towards a document sharing resource**, generally after the order (or order group) is fulfilled.

3.8 Correlation with Existing Standards CP

Submitter's Name(s) and e-mail address(es):	Sarah Knoop and Sondra Renly
Submission Date:	Friday June 8, 2007
Integration Profile affected:	IHE Laboratory Technical Framework Supplement – Sharing Laboratory Reports

Version of IHE Technical Framework:	Supplement 2006-2007
Volume(s) and Section(s) affected:	Volume 2
Rationale for Change: Volume 1, lines 239-255 describe how the XDS-Lab profile is consistent with HL7v3, ELINCS, CCD and the HL7v2.5 based LAB-3 transaction. It would be particularly useful to implementers of this content profile if Volume 2 of the XDS-lab identified the which portions of the XDS-Lab document aligned (or correlated conceptually) with which portions of these standards.	
Suggested Edits: **Volume 2:** Identify which concepts/components of the list of Volume 1 standards are applicable to a particular XDS-Lab structure. See Order Information for a suggested method for enhancement.	

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3.9 Documentation of CDA Extensions CP

Submitter's Name(s) and e-mail address(es):	Sarah Knoop and Sondra Renly
Submission Date:	Friday June 8, 2007
Integration Profile affected:	IHE Laboratory Technical Framework Supplement – Sharing Laboratory Reports
Version of IHE Technical Framework:	Supplement 2006-2007
Volume(s) and Section(s) affected:	Volume 2, Section 10

Rationale for Change:

XDS-Lab makes optional extensions to the CDA. These are currently documented with narrative description, example XML and RIM diagrams. For implementors, it would be good to call out the CDA data types in schema format that are being used to represent the extensions. This would make the extensions available in all the documentation formats which CDA itself is available and understandable.

Suggested Edits:

Volume 2, Section 10: Add CDA data type information to the CDA extension documentation. Example: "productOf" extension for Specimen Collection documentation can be inferred as a participant type with a procedure sub-element. But are there other elements? Is the participation type like POCD_MT000040.Participant2 or POCD_MT000040.Participant1? Or is it somthing different:

```
<xs:complexType name="LAB.Participant">
   <xs:sequence>
  <xs:element name="realmCode" type="CS" minOccurs="0" maxOccurs="unbounded"/>
  <xs:element name="typeId" type="POCD_MT000040.InfrastructureRoot.typeId" minOccurs="0"/>
  <xs:element name="templateId" type="II" minOccurs="0" maxOccurs="unbounded"/>
  <xs:element name="time" type="IVL_TS" minOccurs="0"/>
  <xs:element name="procedure" type="POCD_MT000040.Procedure"/>
   </xs:sequence>
   <xs:attribute name="nullFlavor" type="NullFlavor" use="optional"/>
   <xs:attribute name="typeCode" type="ParticipationType" use="required" fixed="PRD"/>
   <xs:attribute name="contextControlCode" type="ContextControl" use="optional"
fixed="OP"/>
</xs:complexType>
OR
<xs:complexType name="LAB.Participant">
   <xs:sequence>
  <xs:element name="realmCode" type="CS" minOccurs="0" maxOccurs="unbounded"/>
  <xs:element name="typeId" type="POCD_MT000040.InfrastructureRoot.typeId" minOccurs="0"/>
  <xs:element name="templateId" type="II" minOccurs="0" maxOccurs="unbounded"/>
  <xs:element name="time" type="IVL_TS" minOccurs="0"/>
  <xs:element name="procedure" type="LAB.Procedure"/>
   </xs:sequence>
   <xs:attribute name="nullFlavor" type="NullFlavor" use="optional"/>
   <xs:attribute name="typeCode" type="ParticipationType" use="required" fixed="PRD"/>
   <xs:attribute name="contextControlCode" type="ContextControl" use="optional"
fixed="OP"/>
</xs:complexType>

<xs:complexType name="LAB.Procedure">
   <xs:sequence>
  <xs:element name="realmCode" type="CS" minOccurs="0" maxOccurs="unbounded"/>
  <xs:element name="typeId" type="POCD_MT000040.InfrastructureRoot.typeId" minOccurs="0"/>
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Schema snippets really help clarify this kind information for implementors who are not RIM-savvy.

3.10 XDS-Lab Bindings CP

Submitter's Name(s) and e-mail address(es):	Sarah Knoop and Sondra Renly
Submission Date:	Friday June 8, 2007
Integration Profile affected:	IHE Laboratory Technical Framework Supplement – Sharing Laboratory Reports
Version of IHE Technical Framework:	Supplement 2006-2007
Volume(s) and Section(s) affected:	Volume 2

Rationale for Change:

XDS-Lab does not present content bindings to XDS, XDR, XDM Metadata.

Suggested Edits:

Volume 2, Section 5.4: Recommend replacing this section with the following Bindings table presented in this document, minus the small additions specific to PHLab documents. Or to directly reference the content Bindings section of the PCC Technical framework which will hopefully reconcile with the table presented here.

3.11 PCC TF Bindings CP

Submitter's Name(s) and e-mail address(es):	Sarah Knoop and Sondra Renly
Submission Date:	Friday June 8, 2007
Integration Profile affected:	IHE Patient Care Coordination Technical Framework
Version of IHE Technical Framework:	Supplement 2006-2007
Volume(s) and Section(s) affected:	Volume 2

Rationale for Change:

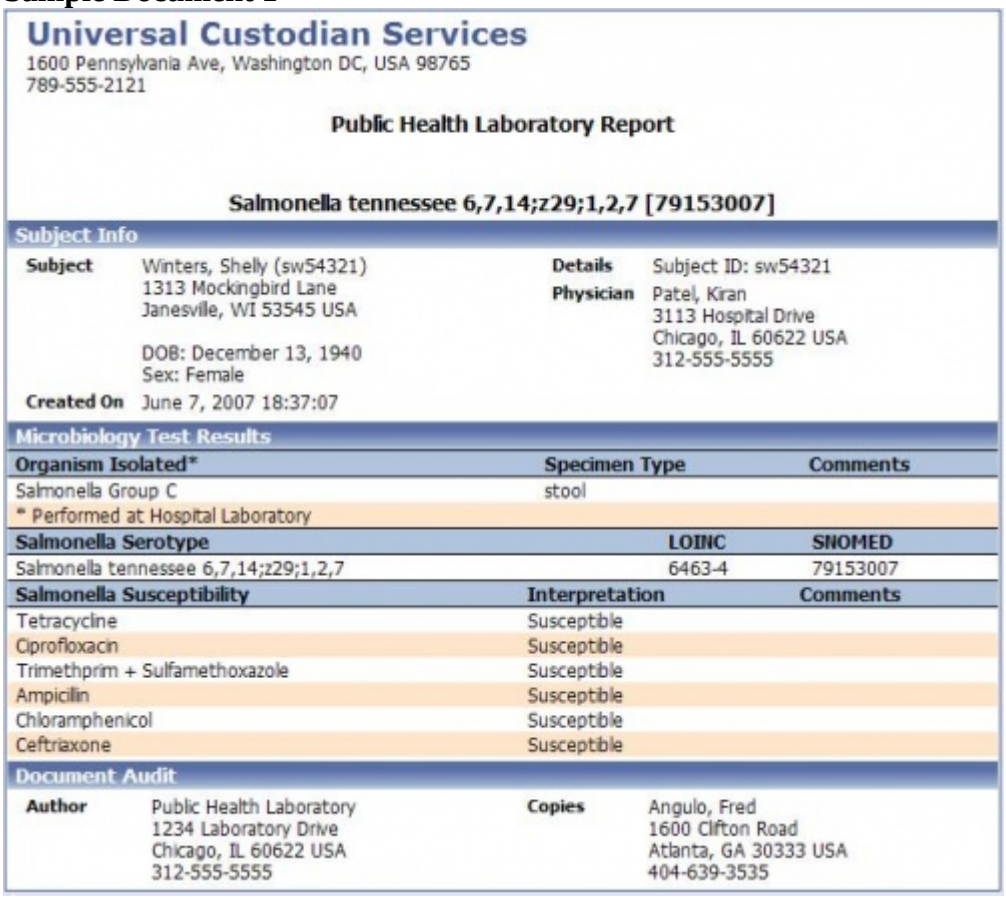
The XDS, XDR and XDM Bindings presented in the PCC TF Volume 2 are out of date with the XDS, XDR and XDM specifications. Additionally, some of the source values and source types do not appear to be valid in all use cases.

Suggested Edits:

See the Bindings table presented in this document. Discrepancies are in red.

Appendix A Sample Documents

Sample Document 1



Universal Custodian Services
1600 Pennsylvania Ave, Washington DC, USA 98765
789-555-2121

Public Health Laboratory Report

Salmonella tennessee 6,7,14;z29;1,2,7 [79153007]

Subject Info

Subject	Winters, Shelly (sw54321) 1313 Mockingbird Lane Janesville, WI 53545 USA DOB: December 13, 1940 Sex: Female	**Details** **Physician**	Subject ID: sw54321 Patel, Kiran 3113 Hospital Drive Chicago, IL 60622 USA 312-555-5555
Created On	June 7, 2007 18:37:07		

Microbiology Test Results

Organism Isolated*	Specimen Type	Comments
Salmonella Group C	stool	
* Performed at Hospital Laboratory		

Salmonella Serotype	LOINC	SNOMED
Salmonella tennessee 6,7,14;z29;1,2,7	6463-4	79153007

Salmonella Susceptibility	Interpretation	Comments
Tetracycline	Susceptible	
Ciprofloxacin	Susceptible	
Trimethprim + Sulfamethoxazole	Susceptible	
Ampicillin	Susceptible	
Chloramphenicol	Susceptible	
Ceftriaxone	Susceptible	

Document Audit

Author	Public Health Laboratory 1234 Laboratory Drive Chicago, IL 60622 USA 312-555-5555	**Copies**	Angulo, Fred 1600 Clifton Road Atlanta, GA 30333 USA 404-639-3535

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