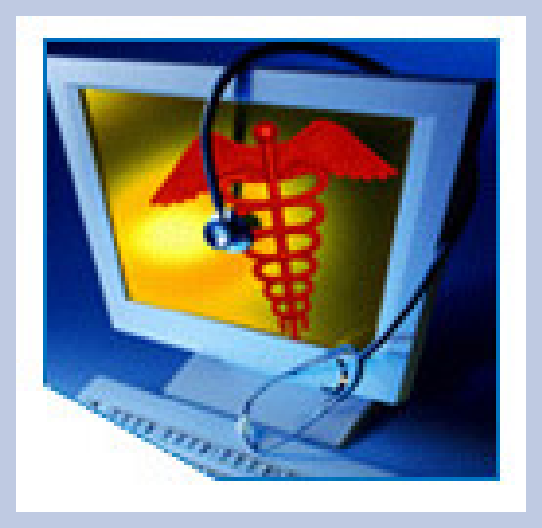
August 27, 2008
Version 2.2

HITSP Lab Result Terminology Component

HITSP/C35



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DOCUMENT CHANGE HISTORY

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1.0	Final Draft	Biosurveillance Technical Committee Electronic Health Record Technical Committee	August 18, 2006
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TABLE OF CONTENTS

FIGURES AND TABLES

1.0 INTRODUCTION

As an introduction to the HITSP Lab Result Terminology Component, this section provides a high level overview of the information sharing scenario enabled by following this specification, provides a document map of the construct relationships for this specification, acknowledges the copyright protections that pertain, and provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.0 Component Definition.

1.1 OVERVIEW

This section describes the contents of this specification and provides a high level definition of this Component and background information about the underlying standards that the Component is based on.

The purpose of this document is to define the vocabulary for either message-based or document-based laboratory results reporting. The goals supported by this terminology Component specification are stated in the AHIC Electronic Health Records (EHR) Laboratory Results Reporting Use Case:

- Deploy standardized, widely available, secure solutions for accessing laboratory results and interpretations in a patient-centric manner for clinical care by authorized parties
- Provide the following functionality for laboratory results reporting and notification, and is applicable to many types of laboratory tests, including but not limited to: clinical chemistry, hematology, serology and microbiology

The Use Case notes that there are obstacles to achieving the stated goals. In particular, the following obstacle is delineated:

- Lack of harmonization among data interoperability standards including vocabulary, laboratory and other messaging standards

This Lab Result Terminology Component is the result of a considered assessment of the terminologies available and the current practices in electronic laboratory results reporting for the purpose of moving forward in the harmonization of those terminologies. Without standard terminologies, interoperability is severely limited. This specification describes the vocabularies needed to implement the communication of an electronic standards-based laboratory result. A guiding principle for these selections was to follow the Consolidated Heath Informatics (CHI) Initiative standards selections as appropriate. The following sections describe the selected terminologies, the events that are supported by those standards and the reason for their selection. Also described are the organizations that maintain the standards and where to obtain more information.

This Component specification is part of a series of documents to establish Interoperability Standards for laboratory results reporting.

1.2 COMPONENT DOCUMENT MAP

Each HITSP specification describes how to integrate and constrain existing standards and specifications that will satisfy the requirements for the HITSP construct. There are four types of HITSP constructs called Interoperability Specifications (IS), Transaction Packages (TP), Transactions (T), and Components (C). Interoperability Specifications define the context(s) in which any other HITSP construct may be used. The current Lab Result Terminology specification does not depend on any other HITSP constructs, however, it is used with other constructs to meet the requirements of one or more ISs. Review Section 1.2 Interoperability Specification Document Map from the relevant IS to better understand the context, dependencies, and relationships between the constructs used to meet the IS requirements.

1.3 COPYRIGHT PERMISSIONS

1.4 REFERENCE DOCUMENTS

This section provides a list of key reference documents and background material. If you are already familiar with this information, proceed to Section 2.

A list of key reference documents and background material is provided in the table below. These documents can be retrieved from the www.hitsp.org Web Site.

Table 1.4-1 Reference Documents

Reference Document	Document Description
HITSP Interoperability Specification Overview	Provides background information about the HITSP and its role in the overall U.S. efforts to realize large scale interoperability of health information. The document also provides a description of the HITSP process for healthcare standards harmonization and explains how to use the Interoperability Specifications and other related documents to inform your health IT product development or product refinement.
HITSP Conventions List	Describes the conventions that are used to convey the full descriptions and usage of standards in the HITSP specifications
HITSP Acronyms List	Lists and defines the acronyms used in this document
HITSP Glossary	Provides definitions for relevant terms used by HITSP documents
HITSP Harmonization Framework	Describes the current framework within which the Interoperability Specifications are built
TN900 - Security and Privacy Technical Note	Developed as a reference document to provide the overall context for use of the HITSP Security and Privacy constructs. It includes the following: • The scope, reference policy background, and Security and Privacy principles used in the development of the constructs • A detailed description and schematics of the conceptual relationship between the Security and Privacy constructs • A mapping of existing standards and constructs to be used in meeting the stated requirements of the AHIC Use Cases • A list of identified gaps and the recommended approaches to resolving those gaps • A roadmap for how the Security and Privacy constructs will evolve and eventually align with other HITSP Interoperability Specifications • A conceptual framework for Security and Privacy management, including reference information on privacy policies, risk assessment, and risk management • A glossary of terms used in all the Security and Privacy construct documents • A description of the application of the Security and Privacy constructs to the HITSP Interoperability Specifications for the three initial AHIC Use Cases – Biosurveillance, Electronic Health Records - Laboratory Results Reporting, and Consumer Empowerment HITSP will periodically update this Technical Note as required by the introduction of new contexts for use.

2.0 COMPONENT DEFINITION

A Component defines atomic constructs used to support an information exchange or to meet an infrastructure requirement. This is accomplished by:

(a) Referencing one or more underlying standards
(b) Specifying constraints and other rules for using the standards

2.1 CONTEXT OVERVIEW

This section provides a general description of the Component. It includes a detailed definition of the Component and the reason for its use. It also provides all the necessary background information that further describes the context in which the Component is needed and the base or composite standard that the Component is based on.

This Component defines the vocabularies and terminologies utilized by laboratories and clinicians to report the findings from laboratory tests. The context is defined by a common scenario where a laboratory has received an order to perform routine tests involving a specimen taken from a patient during an inpatient or outpatient encounter. The laboratory performs the tests. Electronic results are coded according to these specifications for electronic transmission. The sender could be the laboratory or an intermediary such as a clinical repository. The recipient could be an authorized public health agency, an EHR system or a non-EHR clinical system.

2.1.1 COMPONENT CONSTRAINTS

This section describes the constraints that limit the context in which the Component may be used. A constraint describes a rule that limits the use of the actors, actions or data within the given context, or to which the interactions must conform to be used within the described context. It is a description of the limits and scope of the interactions and can describe actions or events that are not part of the initial definition for the context.

The constraints on this terminology Component are imposed for the sake of defining a path to the future for healthcare interoperability. The lack of consistent terminologies across laboratories and institutions is well known. These inconsistent terminologies pose an obstacle to interoperability and must be addressed, but early adopters can use this specification by aligning with the recommended vocabularies and implement the supported scenarios.

Note that the Universal Service Identifier is a major gap in healthcare interoperability today. While acceptable standards exist for Observation ID and Observation Value, no complete terminology exists for Service Identifier. LOINC offers some coverage, but currently laboratory interfaces require a synchronization of master files to code and interpretation of the test being requested and performed.

Table 2.1.1-1 Component Constraints

Constraint	Constraint Section
A standard terminology must be defined for Service Identifiers (a code for the type of test). For this specification, the terminology for the Observation Identifier must be LOINC and the terminology for the observation value should be SNOMED CT for coding microbiology results	N/A
Typically, laboratories use local codes for Observation IDs and Values. To communicate results according to this Interoperability Specification, the results need to be transmitted in the specified vocabularies. This may be done using mapping tools available today	N/A
Some implementers of electronic laboratory results reporting today utilize some form of translation between terminologies, especially for Observation Value. It is recognized that the National Library of Medicine (NLM) maintains cross-maps of terms for some of the major coding systems. A subset of these cross-maps can be utilized by a Common Terminology Service (CTS) to provide an equivalent term for a concept in a different terminology	N/A

Additional constraints can be found below.

TERMINOLOGY CONSTRAINTS

Terminologies have subsets for each specific type of laboratory result. In particular, the laboratory subsets of LOINC and SNOMED, which are used to identify the type of result, have subsets defined by numerous private and public organizations in addition to the subsets defined within the terminology. The following tables provide additional information about these subsets.

Table 2.1.1-2 Lab LOINC

Code sets, vocabularies, terminologies and nomenclatures that need to be constrained
All LOINC lab result codes
Minimum attributes of the component
Minimum data set = HEDIS (Health plan Employer Data and Information Set) reported tests accounting for 95% of routine Lab orders (Note: ELINCS selections refer to 90% of HEDIS) Category A, B, & C bioterrorism agents/diseases Public Health jurisdiction and Federal reportable disease conditions. Minimum requirements to satisfy CLIA
Other Comments
The above represents what is needed for implementation as of this date, but future work is required for identifying other subsets.

Table 2.1.1-3 SNOMED CT

Code sets, vocabularies, terminologies and nomenclatures that need to be constrained
SNOMED CT
Minimum attributes of the component
SNOMED CT VA Problem List Subset SNOMED CT Lab Test Findings Table SNOMED CT Organisms

Other Comments
VA Problem List Subset same as FDA/DoD/KP subset list

2.1.2 COMPONENT DEPENDENCIES

This section describes any specific mapping criteria for the standards underlying the Component. It elaborates on the relationships between different standards used by this Component, and how they map to each other. Additional required mapping criteria not currently enforced by the underlying standards, and any specific elements that are required for this mapping to succeed, are also provided.

Table 2.1.2-1 Component Dependencies

Standard/HITSP Component	Depends On (Name of standard/HITSP Component that it depends on)	Dependency Type (Pre-condition, Post-condition, General)	Purpose (Reason for this dependency)
No applicable dependencies			

2.2 RULES FOR IMPLEMENTING

The following section documents the content of the Component. It provides the basic elements and secondary standards that are supported by this Component and the constraints that are being placed on those standards. Specifically, it describes the subset or constraints that are required for this Component and the minimum attributes of the Component as it relates to the base or composite standards on which it is based.

This Lab Result Terminology Component specification supports the reporting of laboratory results. The value sets or Code Systems selected for each selected coded attribute in the laboratory results message are shown in the HL7 V2.5.1 Standard. Tables are included in the data mapping section that show the constraints or variances from HL7 published standards.

2.2.1 DATA MAPPING

This section describes the specific data elements used by this Component. Due to the potentially large number of data elements in a particular standard only the fields that HITSP is constraining differently from the standard will be described here.

Table 2.2.1-1 Data Mapping: HL7 V2.5.1 OBR – Observation Request Segment

SEQ	Data Element	LEN	DT	OPT	RP#	TBL#	Requirements/Pre-conditions	Additional Specification for Component
4	Universal Service Identifier	250	CE	RR			(Noted terminology gap)	See discussion under Section 2.1.1
31	Reason for	250	CE	O	Y		HITSP specifies that the VA/KP	

SEQ	Data Element	LEN	DT	OPT	RP#	TBL#	Requirements/Pre-conditions	Additional Specification for Component
	Study						Problem List Subset of SNOMED CT should be used	

Table 2.2.1-2 Data Mapping: HL7 V2.5.1 OBX – Observation/Result Segment

SEQ	Data Element	LEN	DT	OPT	RP#	TBL#	Requirements/Pre-conditions	Additional Specification for Component
3	Observation Identifier	250	CE	R			HITSP specifies use of LAB LOINC	
15	Producer's Reference	250	CE	O			HITSP specifies use of CLIA ID	May include allowed exceptions

The terminologies in this Component apply equally to both the HITSP/C36 - Lab Result Message and the HITSP/C37 - Lab Report Document. The HITSP Technical Committee is constructing a mapping between these two representations to make the correspondence between data elements explicit. This mapping will be presented to the Health Level Seven (HL7) committees that publish the two representations with the expectation that HL7 will maintain the mapping.

2.3 STANDARDS

It is important to understand that the standards selected here are within the context of the specific Use Case requirements and do not necessarily reflect selection in other contexts. The standards used by this Component specification fall into the following categories:

- Regulatory guidance is a legal or other authoritative declaration that HITSP must abide by in standards selection (see Section 2.3.1)
- Selected standards are necessary for interoperability. These are standards that are used to meet information exchange requirements of associated constructs. For example, they are used to realize direct information exchange, to provide the transport mechanism, to specify the content, or to address security (see Section 2.3.2)
- Informative reference standards provide additional background information or guidance, and are not required for interoperability. These standards are not required to implement the Component specification (see Section 2.3.3)

2.3.1 REGULATORY GUIDANCE

The following table provides a list of legal or other authoritative guidelines that HITSP must abide by, or has agreed to use as guidance in the selection of standards. Note that only the referenced sections of the regulations are relevant to this Component specification.

Table 2.3.1-1 Regulatory Guidance

Standard	Description
Clinical Laboratory Improvement Amendments (CLIA) of 1988	Establishes quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test is performed. The Centers for Medicare and Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. based on CLIA. For more information visit http://www.fda.gov and http://www.cms.hhs.gov

2.3.2 SELECTED STANDARDS

The following table provides a list of standards that are used to meet information exchange requirements of the Component specification, and a detailed description of each standard.

Table 2.3.2-1 Selected Standards

Standard	Description
Health Level Seven (HL7) Version 2.5.1	The HL7 Version 2.5.1 Messaging Standard is an application protocol for electronic data exchange in healthcare. It and prior versions have widespread use in the U.S. and internationally. Both message formats and value sets / code tables (e.g., diagnosis type, gender, patient class, result status, specimen collection method, abnormal flags, observation result status codes interpretation, timestamp format) are contained in the standard. Of particular focus for HITSP Interoperability Specifications are message formats described in Chapters 2, 3, 4, 5, and 7 including patient demographic (ADT) and lab result reporting. These are also used within composite standards from IHE for Patient Identity Cross-Referencing and Feed (PIX), Patient Demographics Query (PDQ), and Acknowledgements. They are also used in HL7 order messages. For more information visit www.hl7.org
International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®)	SNOMED CT consists of a technical design, core content architecture and Core content. SNOMED CT Core content includes the technical specification of SNOMED CT and fully integrated multi-specialty clinical content. The Core content also includes a concepts table, description table, relationships table, history table, ICD-9-CM mapping and Technical Reference Guide. Additionally, SNOMED CT provides a framework to manage language dialects, clinically relevant subsets, qualifiers and extensions, as well as concepts and terms unique to particular organizations or localities. For more information visit www.ihtsdo.org
Logical Observation Identifiers Names and Codes (LOINC®)	A database of universal identifiers for laboratory and other clinical observations. The laboratory portion of the LOINC database contains the usual categories of chemistry, hematology, serology, microbiology (including parasitology and virology) and toxicology; as well as categories for drugs and the cell counts typically reported on a complete blood count or a cerebrospinal fluid cell count. Antibiotic susceptibilities are a separate category. The clinical portion of the LOINC database includes entries for vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastroendoscopic procedures, pulmonary ventilator management, selected survey instruments and other clinical observations. For more information visit www.loinc.org
Unified Code for Units of Measure (UCUM)	A code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans. For more information visit aurora.regenstrief.org

2.3.3 INFORMATIVE REFERENCE STANDARDS

The following table lists standards that provide additional background information or guidance; however, they are not required for the implementation of the Component specification.

Table 2.3.3-1 Informative Reference Standards

Standard Name	Description/Reason for Use
No applicable informative reference standards	

3.0 TECHNICAL IMPLEMENTATION

3.1 CONFORMANCE

This section describes the conformance criteria, which are objective statements of requirements that can be used to determine if a specific behavior, function, interface or code set has been implemented correctly.

3.1.1 CONFORMANCE CRITERIA

In order to claim conformance to this construct specification, an implementation must satisfy all the requirements and mandatory statements listed in this specification, the associated HITSP Interoperability Specification, its associated construct specifications, as well as conformance criteria from the selected base and composite standards. A conformant system must also be constrained as specified in Table 2.1.1-1 and implement all of the required actors, where defined, within the scope, subset or implementation option that is selected from the associated Interoperability Specification.

Claims of conformance may only be made for the overall HITSP Interoperability Specification with which this construct is associated.

3.1.2 CONFORMANCE SCOPING, SUBSETTING AND OPTIONS

A HITSP Interoperability Specification must be implemented in its entirety for an implementation to claim conformance to the specification. HITSP may define the permissibility for actor scoping, subsetting or implementation options by which the specification may be implemented in a limited manner. Such scoping, subsetting and options may extend to associated constructs, such as this construct. This construct must implement all requirements within the selected scope, subset or options as defined in the associated Interoperability Specification to claim conformance.

4.0 APPENDIX

The following sections include relevant materials referenced throughout this document.

No additional information at this time.

5.0 CHANGE HISTORY

The following sections provide the history of changes made to this document.

5.1 MAY 11, 2007

This document is now Released for Implementation.

5.2 MARCH 19, 2008

This document has been updated to include the HITSP Security and Privacy constructs and has been updated to reflect the new template.

The following changes have been made to the construct:

- Deleted from Table 2.3-1 List of Standards: the following standards because they are not addressed in C35
    - Modified table entry for Health Level Seven (HL7) Version 2.5/2.5.1 to more accurately reflect Health Level Seven (HL7) Version 2.5.1
    - Health Level Seven (HL7) Version 3.0
    - Health Level Seven (HL7) Version 3.0 Clinical Document Architecture (CDA/CDA R2)
- Deleted the standard Unified Code for Units of Measure (UCUM) from Table 2.3-1 List of Standards because the constructs, HITSP/C36 and HITSP/C37, that HITSP/C35 uses include UCUM

5.3 MARCH 27, 2008

Upon approval by the HITSP Panel on March 27, 2008, this document is now Released for Implementation.

The following change has been made to the construct:

- Added UCUM standard back into Table 2.3-1 because the Technical Committee indicated that the standard should remain in this document

5.4 AUGUST 20, 2008

This document has been modified to reflect the updated HITSP approach to categorizing standards as Regulatory Guidance, Selected Standards, and Informative References.

- The following standard was designated as Regulatory Guidance:
    - Clinical Laboratory Improvement Amendments (CLIA) of 1988

5.5 AUGUST 27, 2008

Upon approval by the HITSP Panel on August 27, 2008, this document is now Released for Implementation.