

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

Title	Document Number	Document Section	Comment																				
Data Element identifiers	C154	Varies	<p>There are already field identifiers assigned by HL7. HITSP is assigning fields identifiers as well, sometimes the field is based on one document and sometimes another and the field prefix changes even within the document. This is overly complex and not necessary. HITSP should adopt HL7 field identifiers. If not, have a consistent process to identify fields so that one does not have to cross walk among multiple documents.</p> <p>Example: The ANSI data element assigned to PID.8 – Administrative Sex is '001111' but the C154 document refers to 'Gender' as DE-1.06-1).</p> <p>HL7 2.5.1 Standard Reference</p> <p style="text-align: center;">HL7 Attribute Table - PID - Patient Identification</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>SEQ</th> <th>LEN</th> <th>DT</th> <th>OPT</th> <th>RP/#</th> <th>TBL#</th> <th>ITEM#</th> <th>ELEMENT NAME</th> </tr> </thead> <tbody> <tr> <td>8</td> <td>1</td> <td>IS</td> <td>O</td> <td></td> <td>0001</td> <td>00111</td> <td>Administrative Sex</td> </tr> </tbody> </table> <p>C154 Data Dictionary Component Reference</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td style="width: 10%;">1.06</td> <td style="width: 15%;">Gender</td> <td style="width: 55%;">Gender is used to refer to administrative sex rather than biological sex and therefore should easily be classified into female and male. It is included in the exchange for purposes of linking to insurance information and other patient identification linkages and the value chosen by the patient should reflect the information under which any insurance or financial information will be filed, as well as the same information given to other healthcare providers, institutions or health data exchange networks</td> <td style="width: 20%;">C154-DE-1.06-1] Gender SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.1.2 V3 Administrative Gender</td> </tr> </table>	SEQ	LEN	DT	OPT	RP/#	TBL#	ITEM#	ELEMENT NAME	8	1	IS	O		0001	00111	Administrative Sex	1.06	Gender	Gender is used to refer to administrative sex rather than biological sex and therefore should easily be classified into female and male. It is included in the exchange for purposes of linking to insurance information and other patient identification linkages and the value chosen by the patient should reflect the information under which any insurance or financial information will be filed, as well as the same information given to other healthcare providers, institutions or health data exchange networks	C154- DE-1.06-1] Gender SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.1.2 V3 Administrative Gender
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8	1	IS	O		0001	00111	Administrative Sex																
1.06	Gender	Gender is used to refer to administrative sex rather than biological sex and therefore should easily be classified into female and male. It is included in the exchange for purposes of linking to insurance information and other patient identification linkages and the value chosen by the patient should reflect the information under which any insurance or financial information will be filed, as well as the same information given to other healthcare providers, institutions or health data exchange networks	C154- DE-1.06-1] Gender SHALL be coded as specified in HITSP/C80 Section 2.2.1.2.1.2 V3 Administrative Gender																				
Minimum Segments	C163	2.2, pg. 7	Document indicates Patient Visit (PV1) as a required segment for the OML message. This segment																				

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Title	Document Number	Document Section	Comment
Required: PV1		and 8 C163- [MSH-3]	should not be required as Patient Visit is typically applicable to a hospital setting and not an ambulatory setting. Information contained within the PV1 is not always applicable to a reference laboratory order. Additionally, this is an optional segment in accordance with HL7 standard.
Message number	C163	2.2, pg. 7-9	It is recommended that the message number be removed in favor of following HL7 standards for segment requirements. As documented, this adds confusion and is not providing additional guidance.
Message Type in Table (ORM)	C163	2.2, pg. 8	The table for Order Placer and Order Filler references an example of the ORM^21. This should be changed to OML^021 since the guide is suggesting conformance using the OML and ORL messages.
Work flow for repeating, continuous, reflex, or series orders	C163	2.2, pg. 9 3.1, pg. 19	Reflex needs to be removed from the work flow of repeating, continuous or series orders. Reflex is not related to these orders and does not inform or take away from the work flow of a repeating, continuous or series orders.
Message Header Segment - OID	C163	2.2.1.1, pg. 10	OIDs are not widely used within the industry and since conformance criteria requires strict adherence to all components of the document, the references to require OIDs for Sending Application, Sending Facility, Receiving Application and Receiving Facility will grossly limit the adoptability of this specifications. This requirement would dictate that all Clinicians, Hospitals and other order sending entities have a OID assigned for every sending and receiving component requirement. It is recommended that the guide may allow for usage of OIDs for entities that can support then, but do not mandate them for conformance.
SPM.4 – Segment Type	C163	2.2.1.10, pg. 16	The Specimen Table reference in C80, 2.2.3.6.13 mandates the usage of SNOMED CT codes to identify the specific values. While encouraging a standard value set is appreciated, mandating the usage of SNOMED CT may make several clinicians ineligible to support this document as SNOMED is not widely supported as the common specimen coding system. It's recommended that this field suggest usage of the table when applicable, but not restrict support the SPM segment electronically if SNOMED CT is not supported or understood by the ordering provider. SNOMED CT should be recommended.
SPM.8 – Specimen Source Site and	C163	2.2.1.10, pg. 17	C80 Section 2.2.3.2.1 Body Site indicates that SNOMED CT is the required coding set to be used. This will require that ordering physicians and EMR systems must support SNOMED CT to conform

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

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SPM-10 – Specimen Collection Site			<p>to this guide. SNOMED should be recommended as the preferred source, but not restricted as the only source to prevent adoption issues of the guide.</p> <p>SNOMED CT should be recommended.</p>
SPM.18 – Specimen Received Date/Time, SPM.20 – Specimen Availability, SPM.21 – Specimen Rejection Code	C163	2.2.1.10, pg. 17	<p>The SPM.18 – Specimen Received Date/Time, SPM.20 – Specimen Availability, and SPM.21 – Specimen Rejection Code fields should be removed only in the data mapping section. The Additional Specification indicates that the data SHALL be populated in the OML message sent by the Order Filler. However, it is not anticipated the Order Filler will be submitting the laboratory order.</p> <p>Considerations could be made to make these fields CE (Conditional, but may be empty), rather than RE if the committee feels there is value to allowing these fields on the electronic order.</p>
OBR.4 – Universal Service Identifier	C163	2.2.1.8	<p>It may be premature and presumptive for the C163 OBR.4 field to require the use of LOINC as the Universal Service Identifier. There is still much consideration to the determination of the validity of this common vocabulary for orders.</p> <p>It is recommended that the verbiage be changed to state, “When appropriate for the Universal Service Identifier LOINC may be used.”</p>
OBR.11 – Specimen Action Code	C163	2.2.1.8, pg. 15	<p>OBR.11 – Specimen Action Code is R2 (Required if Known). Based on the values in the HL7 2.5.1 table (C80 Table 2-117, pg. 81) the guide is presuming functionality for all the Specimen Action Codes to be supported. This additional functionality may not be supported wholly by all entities sending and / or receiving electronic orders. For example, Add Order Tests to existing specimen could require more construct to constrain the Add Order Test function to be restricted if the result has already been processed by the lab.</p> <p>It is recommended that this field be changed to Optional and ACLA review this for viability.</p> <p>C80/pg 81 2-117 Specimen Action Code Value Set Definition</p> <p>Concept Name</p>

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

Title	Document Number	Document Section	Comment
			<p>Add ordered tests to the existing specimen Generated order; reflex order Lab to obtain specimen from patient Specimen obtained by service other than Lab Pending specimen; Order sent prior to delivery Revised order Schedule the tests specified below</p>
Ordering Callback Number	C163	2.2.1.8, pg. 15	Under 'New data elements to be considered' Ordering Callback Number is referenced. However, it is not shown in Table 2-10 Data Mapping – Observation Request Segment.
OBR.28 – Result Copies To	C163	2.2.1.8, pg. 15	<p>Restrictions should be indicated to indicate that results copies within an entity should not be the responsibility of the laboratory to share within the same practice or organization of the ordering provider. For example, if Physician A orders a test from ABC Clinics he should not use the OBR.28 to request a copy of the laboratory result be sent to Physician B from ABC Clinics.</p> <p>Additionally, it should be noted that electronic delivery of the result copy may be restricted due to complex matching criteria between different EMR vendor systems.</p> <p>Finally, routing based on Physician NPI is not recommended as physicians are often tied to multiple accounts to support their patients (Clinic, Hospital, HIE, etc.).</p>
OBX Segment Fields	C163	2.2.1.9, pg. 16	<p>For laboratory orders, OBX segments are used for Observations pertaining to the order. The sender of the lab order should not identify the OBX.7 - Reference Range, OBX.8 - Abnormal Flag or the OBX.14 - Date/Time of Observation. These fields are applicable to laboratory results.</p> <p>It is recommended that OBX.7, OBX.8 and OBX.14 be removed from consideration for Table 2-11 Data Mapping – Observation/Result Segment section.</p>
OBX.2 – Value Type, OBX.6 - Units	C163	2.2.1.9, pg. 16	<p>Restricting the OBX value for OBX.2 NM (Numeric), SN (Structured Numeric) and OBX.6 (UCUM) for orders observations may not be pertinent for observation details pertinent to an order.</p> <p>For OBX.2, an observation of Fasting could be reported in time ('NM' value type) or as a Yes, No, Unknown type of response ('CF' value type). An observation of Post Menopausal Date would need to be reported as a value type 'DT' since the OBX.5 response would contain a date format.</p>

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

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			<p>It is recommended that HITSP adhere to the Value Types listed in HL7 Table 0125 – Value type.</p> <p style="text-align: center;">HL7 Table 0125 - Value type</p> <table border="1" data-bbox="852 451 1827 1352"> <thead> <tr> <th data-bbox="852 451 982 493">Value</th> <th data-bbox="982 451 1524 493">Description</th> <th data-bbox="1524 451 1827 493">Comment</th> </tr> </thead> <tbody> <tr><td>AD</td><td>Address</td><td></td></tr> <tr><td>CE</td><td>Coded Entry</td><td></td></tr> <tr><td>CF</td><td>Coded Element With Formatted Values</td><td></td></tr> <tr><td>CK</td><td>Composite ID With Check Digit</td><td></td></tr> <tr><td>CN</td><td>Composite ID And Name</td><td></td></tr> <tr><td>CP</td><td>Composite Price</td><td></td></tr> <tr><td>CX</td><td>Extended Composite ID With Check Digit</td><td></td></tr> <tr><td>DT</td><td>Date</td><td></td></tr> <tr><td>ED</td><td>Encapsulated Data</td><td></td></tr> <tr><td>FT</td><td>Formatted Text (Display)</td><td></td></tr> <tr><td>MO</td><td>Money</td><td></td></tr> <tr><td>NM</td><td>Numeric</td><td></td></tr> <tr><td>PN</td><td>Person Name</td><td></td></tr> <tr><td>RP</td><td>Reference Pointer</td><td></td></tr> <tr><td>SN</td><td>Structured Numeric</td><td></td></tr> <tr><td>ST</td><td>String Data.</td><td></td></tr> <tr><td>TM</td><td>Time</td><td></td></tr> <tr><td>TN</td><td>Telephone Number</td><td></td></tr> <tr><td>TS</td><td>Time Stamp (Date & Time)</td><td></td></tr> <tr><td>TX</td><td>Text Data (Display)</td><td></td></tr> <tr><td>XAD</td><td>Extended Address</td><td></td></tr> </tbody> </table>	Value	Description	Comment	AD	Address		CE	Coded Entry		CF	Coded Element With Formatted Values		CK	Composite ID With Check Digit		CN	Composite ID And Name		CP	Composite Price		CX	Extended Composite ID With Check Digit		DT	Date		ED	Encapsulated Data		FT	Formatted Text (Display)		MO	Money		NM	Numeric		PN	Person Name		RP	Reference Pointer		SN	Structured Numeric		ST	String Data.		TM	Time		TN	Telephone Number		TS	Time Stamp (Date & Time)		TX	Text Data (Display)		XAD	Extended Address	
Value	Description	Comment																																																																			
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MO	Money																																																																				
NM	Numeric																																																																				
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ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

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			<table border="1"> <tr> <td>XCN</td> <td>Extended Composite Name And Number For Persons</td> <td></td> </tr> <tr> <td>XON</td> <td>Extended Composite Name And Number For Organizations</td> <td></td> </tr> <tr> <td>XPN</td> <td>Extended Person Name</td> <td></td> </tr> <tr> <td>XTN</td> <td>Extended Telecommunications Number</td> <td></td> </tr> </table> <p>For OBX.6, Units – Units of Measure (UoM) should not be pertinent to the lab order. This is most commonly used to identify the UoM reported for the laboratory results. Additionally, if the committee feels this field should remain in the specification, UCUM should not be the mandated UoM value used as it is not widely supported in the industry.</p>	XCN	Extended Composite Name And Number For Persons		XON	Extended Composite Name And Number For Organizations		XPN	Extended Person Name		XTN	Extended Telecommunications Number	
XCN	Extended Composite Name And Number For Persons														
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OID	C163	3.1, pg. 19	The OID requirements for MSH-3,4,5, & 6 are for the CLID ID provided by CMS. CMS has not assigned an OID to this data element.												
Profile – to provide unique header for profile or not	C163	3.2.3, pg. 23	<p>This is a complex question and very difficult to provide a single answer that will meet all requirements.</p> <p>There are profiles that are built because the test has multiple components performed on different instruments, but combined represent a single battery of tests for a single diagnostic issue. This scenario the lab might want to have a header defining the Profile. In other instances, the header will not help inform the clinician so therefore the header is not necessary.</p>												
Separate constructs for lab orders in inpatient and the outpatient settings	C163	3.2.6, pg. 23 3.2.7, pg. 24	<p>There are several issues that inform a lab message based on inpatient and outpatient settings:</p> <ol style="list-style-type: none"> 1. Standing orders are typical and normal in the inpatient setting. 2. Inpatient lab systems are typically tightly coupled to other systems within the environment and therefore additional information needed for the patient can be queried within that environment if needed. Outpatient lab systems expect all necessary information to be provided in the message including billing requirements and diagnosis information. 3. In the outpatient setting, once the order has been placed the likelihood of capturing additional specimen from the patient is highly unlikely. In the inpatient setting the 												

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

Title	Document Number	Document Section	Comment
			<p>specimen can usually be collected again.</p> <p>4. Billing is of low consideration in the inpatient setting. In outpatient setting billing information must be collected for each instances of care.</p> <p>The items above are a short list of what makes the inpatient and outpatient settings unique. It would be better to consider defining the differences and possibly the constructs for each setting. Unique constructs provide a source document for the implementer based on the setting they are addressing. Otherwise the implementer would need to filter the document based on their projects use case.</p>
Standardize lab ordering based on HL7 messages	C163	3.2.8, pg. 24	<p>HL7 lab messages are informed based on the use case involved. In the typical lab order message, the order codes become the key, because the physician is targeting a diagnosis and looks at order codes that will provide the diagnostic information to support the physician's analysis. Specimen is secondary to the decision process and typically handled down the road after the order codes have been selected.</p> <p>In public health they typically have the specimen, therefore the specimen informs what additional information needs to be gathered to process the order.</p> <p>Because work flow process is completely different then multiple messages are necessary to support laboratory messages. If the scope is narrowed then HL7 messages could be constrained.</p>
Missing Segments for OML^021	C163	varies	<p>The following segments are missing from the guide, which are pertinent to lab orders. The business need for these segments is also referenced:</p> <ul style="list-style-type: none"> • GT1 – Guarantor (HL7, Chapter 6). Guarantor information support insurance requirements for patient and third party billing. For example, this supports patient bill when the insurance company is not going to pay for a test for Medicare when an ABN is used. • DG1 – Diagnosis (HL7, Chapter 6). Diagnosis is required for the sender of the order to provide the proper diagnosis code to be submitted for third party billing requirements.

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

Title	Document Number	Document Section	Comment
Repeating, Continuous, Reflex or series orders often referred to as standing orders	C163	Varies 2.2, pg. 9 3.2, pg. 20 3.2.2, pg. 21 3.2.4, pg. 23 3.2.5	The problem is that the order management system and the phlebotomy systems have not been defined and therefore the construct has been difficult to manage. These systems exist, yet in many instances are not formally defined as such systems because they are often incorporated in the EHR, Patient Management System, Hospital Laboratory Information System or some other like system. Regardless if these systems exist as stand alone applications or are incorporated in a larger application (even if the solution is manual) a standing order is being managed. What the laboratory sees is a new order generated either because a patient presents themselves at the appropriate time for their standing order or a phlebotomy system receives a request to have a phlebotomist draw the patient, the end point the lab receives a new order. The management of the standing order is not inherently in the Laboratory Information System (LIS), it is typically an application that feeds the LIS even if it resides in the hospital. This is not a lab as the Filler issue.
Standards and Table References	C163 and C154	Several	<p>The C163 Lab Order Message Component is built on HL7 2.5.1 yet several of the tables that are referred to in the C154 -Data Dictionary and/or C80 / Clinical Document and Message Terminology Component documents reference other versions or standards. This could create inconsistency in adopting the HL7 2.5.1 standard as it relates to available table values in translation engines and violation of supporting the 2.x standards as a whole. For example, PID.8 - Administrative Sex (pg. 11 in C163) refers to 2.2.1.2.1.2 V3 Administrative Gender in HITSP/C80. The values for HL7 2.5.1 for PID.8 do not match the values recommended by HITSP. Efforts should be made by HITSP to ensure the tables references in the C163 - Lab Order Message Component document support the actual standards referenced in the guide.</p> <p>HL7 2.6 Standard values: 3.4.2.8 PID-8 Administrative Sex (IS) 00111 Definition: This field contains the patient's sex. Refer to User-defined Table 0001 - Administrative Sex for suggested values. User-defined Table 0001 - Administrative Sex Value Description Comment F Female M Male O Other U Unknown</p>

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

Title	Document Number	Document Section	Comment
			<p>A Ambiguous N Not applicable</p> <p>HITSP/C80 Values: Table 2-38 Administrative Gender Value Set Definition Concept Code Concept Name Definition F Female M Male UN Undifferentiated - The gender of a person could not be uniquely defined as male or female, such as hermaphrodite</p>
<p>From the LOINC® database, Laboratory order concepts reproduced in Table 2-97 Laboratory Order Value Set. Developed in-conjunction with NLM</p>	<p>C80</p>	<p>2.2.3.6.2, pg. 67</p>	<p>The proposed Laboratory Order Value Set was originally described as encompassing 95% of all laboratory orders. Based upon the analysis of ACLA member laboratories, the list actually represents 60-70% of commonly ordered laboratory tests. This means that approximately 30-40% of the proposed list with the specified LOINC codes may not be available for ordering from the representative labs which will reduce the effectiveness of the list.</p> <p>NOTE: The table being referenced in the document is labeled as Table 2-98 instead of 2-97 as indicated in the Description.</p>
<p>From the LOINC® database, Laboratory order concepts reproduced in Table 2-97 Laboratory Order Value Set. Developed in-conjunction with</p>	<p>C80</p>	<p>2.2.3.6.2, pg. 67</p>	<p>Use of panel LOINC codes, including those assigned to the AMA panels, is very problematic. Most of our laboratories found that the components of the LOINC panels do not match with the components routinely offered. For example, the Comprehensive Metabolic 2000 LOINC Panel includes a calculated Osmolality (which is outdated; the majority of labs do not offer) and does not include such calculations as the calculated Globulin, EGFR and A/G ratio (which are routinely reported). There are also other calculations included that vary by laboratory. The mismatch in panel components would render the proposed LOINC panel codes unusable as a universal order code in many, if not most, laboratories. EHR vendors would be required to make changes to their systems to accommodate the mismatches in panel components, which would be burdensome and</p>

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

Title	Document Number	Document Section	Comment
NLM			costly to them. It is recommended that panel LOINC codes should not be included in the list until the issue of mismatching components can be resolved.
From the LOINC® database, Laboratory order concepts reproduced in Table 2-97 Laboratory Order Value Set. Developed in-conjunction with NLM	C80	2.2.3.6.2, pg. 67	Based upon analysis by ACLA member laboratories, there are additional LOINC order codes/assays missing from the proposed list that are frequently ordered and should be included. To make the list more complete, recommended additions are being forwarded to the Care Management and Health Record (CMHR) Domain Technical Committee through the CMHR list server by Ken McCaslin.
From the LOINC® database, Laboratory order concepts reproduced in Table 2-97 Laboratory Order Value Set. Developed in-conjunction with NLM	C80	2.2.3.6.2, pg. 67	There is an issue with multiple applicable LOINC codes that exist for the same test (based on methodology, specimen type, etc.). Different laboratories may use different LOINC codes for the same test, which creates inconsistencies with the use of one proposed universal order code. We have identified some of these issues on a spreadsheet of recommended additions to the universal order code list and, in some cases, have proposed the use of alternate codes. These have been identified and are being forwarded to the Care Management and Health Record (CMHR) Domain Technical Committee through the CMHR list server by Ken McCaslin.
From the LOINC® database, Laboratory order concepts reproduced in Table 2-97 Laboratory Order Value Set. Developed in-conjunction with	C80	2.2.3.6.2, pg. 67	There is a concern regarding ownership and continuing maintenance of the proposed universal test and order list. Who will be responsible for updating the order codes when changes are made within the LOINC database and for distributing the information to the end users so changed could be made in their respective systems? The responsible group would require the use of medical laboratory specialists who have the expertise to make the decision regarding addition, deletion and changes to the order codes based on their knowledge of laboratory testing, processes and practices. It should be noted that the development of laboratory "order codes" is more complex than defining a single analyte "LOINC result" code. In many case, order codes are constructed around the intended diagnostic use of the test. These decisions may require extensive knowledge

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

Title	Document Number	Document Section	Comment
NLM			of not only the method used to perform the test, but also the medical reason why the clinician has ordered the test. These decisions often result in different reference ranges or interpretative information provided with the results and are clinically necessary for clinical care. ACLA should be engaged in any further development of this vocabulary data set for Universal Laboratory Order Codes.
Table 2-98; Concept Code: 1841-6; Concept Name: Ammonia in serum or plasma; Definition: Ammonia [Molecules/volume] in serum	C80	2.2.3.6.2, pg. 68	The Concept Code does not match the Concept Name. The Concept Code is for “Ammonia [Molecules/volume] in Serum” and does not include a plasma specimen type. The Concept Codes should be 22763-7 for “Ammonia [Mass/volume] in Plasma” and 16362-6 for “Ammonia [Molecules/volume] in Plasma” Concept Code 1841-6 in Table 2-98 should be replaced with ammonia testing using plasma since this is the industry standard.
Table 2-98 Concept Codes: 1971-1 and 14630-8 Concept Name: Indirect bilirubin in serum or plasma	C80	2.2.3.6.2, pg. 71	Indirect bilirubin is a calculated result from the total and direct bilirubin values; therefore it is normally ordered as a component of a panel. In most laboratories, this test cannot be ordered independently. These two Concept Codes should be removed from the list.
Table 2-98 Concept Code: 1971-1 Concept Name: Bilirubin direct in serum or plasma Definition: Indirect bilirubin [Mass/volume] in serum or plasma	C80	2.2.3.6.2, pg. 71	The Concept Name does not match the Concept Code or Definition. The Concept Name should be corrected to “Bilirubin indirect in serum or plasma”.
Table 2-98	C80	2.2.3.6.2,	The Definition does not match the Concept Code or Concept Name. The Concept Code is for a

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

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<p>Concept Code: 21377-7</p> <p>Concept Name: Magnesium in blood</p> <p>Definition: Magnesium [Mass/volume] in serum or plasma</p>		pg. 71	whole blood specimen type. The Definition should be corrected to "Magnesium [Mass/volume] in Blood".
<p>Table 2-98</p> <p>Concept Code: 42637-9</p> <p>Concept Name: BNP in blood</p> <p>Definition: Natriutietic peptide B [Mass/volume] in serum or plasma</p>	C80	2.2.3.6.2, pg. 72	The Concept Code and Concept Name do not match the Definition. The Definition should be corrected to "Natriutietic peptide B [Mass/volume] in Blood".
<p>Table 2-98</p> <p>Concept Code: 14957-5</p> <p>Concept Name: Microalbumin in random Urine Detection limit <=20 mg/L AND HIV 1+2 antibody in serum or plasma quantitative</p> <p>Definition: Microalbumin [Mass/volume] in</p>	C80	2.2.3.6.2, pg. 72	Concept Code 14957-5 is listed twice with two different Concept Names but the same Definition. The Concept Code and Definition for Concept Name "HIV 1+2 antibody in serum or plasma, quantitative" should be added.

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

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Urine			
Table 2-98 Concept Code: 680-9 Concept Name: Wet prep for trichomas Vaginals & Cue cells Definition: Microscopic observation [Identifier] in Unspecified specimen by Wet preparation	C80	2.2.3.6.2, pg. 72	The Concept Code and Definition do not match with the Concept Name. From the LOINC® database, there are different and distinct Concept Codes for T. vaginalis and Clue (not Cue) cell identification using wet prep. The Concept Name should be corrected.
Table 2-98 Concept Code: 2947-0 Concept Name: Sodium in serum or plasma Definition: Sodium [Molecules/volume] in Blood	C80	2.2.3.6.2, pg. 73	Concept Code 2947-0 is duplicated on the list. The Concept Code for Concept Name “Sodium in Serum or Plasma” is 2951-2 and should be corrected. The Definition should also be corrected to “Sodium [Molecules/volume] in Serum or Plasma
Table 2-98 Concept Code: 3016-3 Concept Name: Thyrotopin (TSH) in serum or plasma-high sensitivity method	C80	2.2.3.6.2, pg. 73	The Concept Name and Definition do not match. From the LOINC® database, Concept Code 3016-3 does not indicate the test as being “high sensitivity method”. This information should be removed from the Concept Name and replaced with “test sensitivity not specified”.

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

Title	Document Number	Document Section	Comment
Definition: Thyrotropin [Units/volume] in Serum or Plasma			
Table 2-98 Concept Code: 11580-8 Concept Name: Thyrotropin (TSH) in serum or plasma - test sensitivity not specified Definition: Thyrotropin [Units/volume] in Serum or Plasma by Detection limit = 0.001 mU/L	C80	73	The Concept Name and Definition do not match. Thyrotropin testing with a detection limit=0.001 mU/L is considered to be “high sensitivity”. The Concept Name should be corrected to remove “test sensitivity not specified” and replaced with “high sensitivity method”.
Reflex Testing – Definition already adopted but required ACLA public comment	CAP99	2.1, pg. 7	<p>A Lab Order Catalogue will allow the clinician to order a test for one single “substance”, a “panel” or “profile” (multiple tests based on a single body system or function—Cardiac Panel, Renal Profile, etc.) or a “battery” (multiple tests to determine overall health). Though a “panel”, “profile” or “battery” contains requests for multiple tests, each is considered as one order. The Lab Order Catalogue may allow the prescriber to order one test and secondary test/s (on the same specimen sample) that the laboratory will perform when/if “triggered” by results from the initial test.</p> <p>This sentence needs to be replaced:</p> <p>A secondary or “triggered” test is referred to as a “REFLEX” test. A test with a “reflex” test is considered as one order.</p>

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

Title	Document Number	Document Section	Comment
			<p>This following sentence replaces the above:</p> <p>A secondary or “triggered” test is referred to as a “REFLEX” test and will be considered as a component of the same order.</p>
Panel, Battery as one order	CAP99	2.1, pg.7	This is an incorrect statement in the ambulatory setting. Often all tests ordered for an instance in care and sent to a laboratory would be considered one order regardless of how many specimen or order codes are needed for that instance. It should not be assumed that each battery or panel in the ambulatory setting creates an order.
Need ACLA response regarding Lab Test Catalog requirements	CAP99	5.2, pg. 17	The ACLA Test Compendium Framework for the electronic delivery of a Laboratory’s Directory of Service will be available for public comment beginning January 2010 with the comment period ending on March 1, 2010. The web page that provides the documents will be found off the main landing page at http://www.clinical-labs.org/ or you can contact ACLA at 202.637.9466. Using the public comments, ACLA will update the document for final publication.
Duplicate order checking – Ordering system validation	CAP99	6.1.1, Item J, sub iv, pg. 22	Duplicate order checking is also done by the Filler including across panel/profile codes as required by regulatory agencies. The requested test will be done only once under a unique instance of an order. It will result in the canceling of the duplicate analyte(s) and will be reported as such in the report message.
View status of lab orders Gap around queries and responses	CAP99	6.1.1, Item N. pg. 25	This gap will need to be addressed at two levels: workflow and message to support the workflow. It was noted that ACLA would be the organization to best document the solution. This will be discussed in the next ACLA HIT Committee meeting scheduled for December 10, 2009. The outcome of that discussion will be shared with HITSP. The current project consuming the committee is the ACLA Test Compendium Framework; therefore this could become a project in 2010. In addition the discussion will include the development of a process between HITSP and ACLA to identify and prioritize issues.

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

Title	Document Number	Document Section	Comment
Difficulty in reading documents	Multiple Documents		<p>In general, the documents were difficult to review since they have references to several other documents and standards. Unfortunately, it is anticipated that significant information for review and comment may be inadvertently overlooked while trying to manage the documents interactions.</p>
Timing for Public Comment	Multiple Documents		<p>The timing for this public comment period was limited to 26 total calendar days which is an insufficient time for full consideration of all documents. Additionally, the comment period stretched over a major holiday which limited the availability for comments even further. For example:</p> <hr/> <p>Greetings HITSP Technical Committee members,</p> <p>The Healthcare Information Technology Standards Panel (HITSP) announces the opening of the public comment period for the following Interoperability Specifications (IS), Capabilities (CAP), Requirements Design and Standards Selection (RDSS) and other construct documents (see below). The public comment period on these documents will be open from Monday, November 9th until Close of Business, Friday, December 4th. HITSP members and public stakeholders are encouraged to review these documents and provide comments through the HITSP comment tracking system www.hitsp.org.</p> <ul style="list-style-type: none"> • RDSS157 - Medical Home RDSS157 Specification • IS06 - Quality IS06 Specification • IS92 - Newborn Screening IS92 Specification • IS158 - Clinical Research IS158 Specification <hr/> <ul style="list-style-type: none"> • CAP99 - Communicate Lab Order Message Related Constructs <hr/> <ul style="list-style-type: none"> • CAP117 - Communicate Ambulatory and Long Term Care Prescription Related Constructs • CAP118 - Communicate Hospital Prescription Related Constructs

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

Title	Document Number	Document Section	Comment
			<ul style="list-style-type: none"> • CAP119 - Communicate Structured Document Related Constructs • CAP120 - Communicate Unstructured Document Related Constructs • CAP121 - Communicate Clinical Referral Request Related Constructs • CAP122 - Retrieve Medical Knowledge Related Constructs • CAP123 - Retrieve Existing Data Related Constructs • CAP126 - Communicate Lab Results Message Related Constructs • CAP127 - Communicate Lab Results Related Constructs • CAP128 - Communicate Imaging Reports Related Constructs • CAP129 - Communicate Quality Measure Data Related Constructs • CAP130 - Communicate Quality Measure Specification Related Constructs • CAP135 - Retrieve Pre-Populated Form for Data Capture Related Constructs • CAP138 - Retrieve Pseudonym Related Constructs • CAP140 - Communicate Benefits and Eligibility Related Constructs • CAP141 - Communicate Referral Authorization Related Constructs • CAP142 - Retrieve Communications Recipient Related Constructs • CAP143 - Consumer Preferences and Consent Management Related Constructs • TP13 - Manage Sharing of Documents Related Constructs • TP20 - Access Control Related Constructs • TP50 - Retrieve Form for Data Capture Related Constructs • T68 - Patient Health Plan Authorization Request and Response Related Constructs • TP22 - Patient ID Cross-Referencing Related Constructs • T23 - Patient Demographics Query Related Constructs • C34 - Patient Level Quality Data Message Related Constructs <hr/> <ul style="list-style-type: none"> • C80 - Clinical Document and Message Terminology Related Constructs <hr/> <ul style="list-style-type: none"> • C83 - CDA Content Modules Related Constructs • C105 - Patient Level Quality Data Using HL7 Quality Reporting Document Architecture

ACLA HITSP Responses for Public Comment (submitted on 12/04/2009)

Title	Document Number	Document Section	Comment
			<p>(QRDA) Related Constructs</p> <ul style="list-style-type: none"> • C106 - Measurement Criteria Document Related Constructs • C151 - Clinical Research Document Related Constructs • C152 - Labor and Delivery Report Related Constructs • C154 - Data Dictionary Related Constructs • C156 - Clinical Research Workflow Related Constructs • C161 - Antepartum Record Related Constructs <hr/> <ul style="list-style-type: none"> • C163 - Laboratory Order Message Related Constructs <hr/> <ul style="list-style-type: none"> • C164 - Anonymize Newborn Screening Results Related Constructs
Code and Vocabulary Requirements	Multiple Documents		<p>There is concern that these documents are folding in significant code and vocabulary changes that are not currently established with the installed base for electronic exchange of laboratory data. For example, the changes requested to support LOINC for order codes, Snomed, UCUM, and OIDs could require significant changes and resource allocation for infrastructure for both the sender and receiver of the order data. This will certainly challenge the adoptability of the guide in advance of the surge for Meaningful Use.</p> <p>Additionally, the expectation to conform to this guide is that both sender and receiver of the order document must adhere to these coding standards. This would require that all providers, hospitals, laboratories, and other entities adhere to these coding system standards before the HITSP Lab Order Standard is adopted.</p>