CDAR2AIS0005R030

Additional Information Specification 0005:
Laboratory Results Attachment

(This specification replaces
Additional Information Message 0005:
Laboratory Results Attachment
May 2004)

Release 3.0
Based on HL7 CDA Standard Release 2.0,
with supporting LOINC® Tables

*Draft ~~November 2006~~**March 2007***

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1 Introduction

This publication provides the LOINC®[1] code values specific to a laboratory results attachment for the following applications.

- Those codes that ~~define~~ **identify** the attachment or attachment components used in transactions such as those defined by the ASC X12~~N~~ 277 *Health Care Claim Request for Additional Information* and the ASC X12~~N~~ 275 *Additional Information to Support a Health Care Claim or Encounter* Implementation Guides which are products of the insurance subcommittee, X12N, of Accredited Standards Committee X12.[2,3]
- ~~All of the codes~~**Those codes** ~~may be~~ used in HL7 Clinical Document Architecture (CDA) documents designed for inclusion in the BIN segment of the 275 transaction as described in the *HL7 Additional Information Specification Implementation Guide*[4]

The format of this document and the methods used to arrive at its contents are prescribed in the *HL7 Additional Information Specification Implementation Guide.*

Section 2 of this document describes how the HL7 CDA Standard is used to fulfill a request for laboratory results attachments. Section 3 includes the value table of LOINC codes specific to the components of a laboratory results attachment.

Section 0 presents coding examples, with a narrative scenario, an XML example, and a display image ~~of each example~~**of the** attachment using a popular browser. Section 5 **further** describes the code sets used in the response to each answer part of the attachment.

Note: All LOINC codes and descriptions are copyrighted by the Regenstrief Institute, with all rights reserved. See http://www.LOINC.org.

1.1 Business Purpose:

Additional Information Specifications (AIS) are used to convey information associated with a specific business purpose. AIS's are used to convey clinical and non-clinical **–additional information**~~documentation~~ to support other health care transactions**, such as the X12 837 claims and the X12 278 Health Care Services Review**.

This Laboratory Results Attachment is used to convey information about the results of examinations of blood, tissue and body fluids.

When this attachment is used for a HIPAA transaction, please refer to the "definition" sub-section of the Claims Attachment Final Rule in the Federal Register for the HIPAA regulated standard definition of Laboratory Results.

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[1] LOINC® is a registered trademark of Regenstrief Institute and the LOINC Committee. The LOINC database and LOINC Users' Guide are copyright 1998-~~2004~~ **2006** Regenstrief Institute and the LOINC Committee and the LOINC database codes and names are available at no cost from http://www.LOINC.org. ~~Regenstrief Institute, 1050 Wishard Blvd., Indianapolis, IN 46202~~ Email: LOINC@regenstrief.org

[2] Information on this and other X12~~N~~/HIPAA-related implementation guides is available from the Washington Publishing Company, ~~177th Lane NE, Bellevue, WA 98008. Phone: 425-562-2245 or~~ http://www.wpc-edi.com/

[3] Within this Health Level Seven document, references to the transaction defined by these X12~~N~~ implementation guides will be abbreviated by calling them 275**,** ~~and~~ 277**, and 278**.

[4] Health Level Seven, Inc. 3300 Washtenaw Ave., Suite 227, Ann Arbor, MI 48104-4250. (http://www.hl7.org)

1.2 LOINC Codes and Structure

LOINC codes are used for several purposes:

- In the 277 transaction set, LOINC codes identify the attachment type or attachment components being requested to support a claim or encounter.
- In the HL7 CDA document, LOINC codes are used to identify the attachment type, the attachment components, and their answer parts. LOINC codes may also identify the type of clinical document, if the provider has created the clinical document in CDA format. The HL7 CDA document is returned in the BIN segment of the 275 transaction set.
- LOINC modifier codes may be used in the 277 transaction to further define the specificity of a request.

For further information on the relationship and use of LOINC Codes with the X12~~N~~ Transactions, and HL7 CDA Documents, see section 1.5 in the *HL7 Additional Information Specification Implementation Guide.*

1.3 Revision History

Date	*Purpose*
Sept 30, 1998	Initial release as separate document.
Dec 2001	Revised title and date; reconciled HL7 ballot responses
August 2003	CDA Ballot
December 2003	Version 2.0 Publication
December 2003	Release 2.1 Ballot
May 2004	**May 2004 - Release 2.1 Publication (referenced by 9-23-2005** HIPAA NPRM)~~Release 2.1 Publication~~
November 2006	First **Informative Ballot for Release 3.0 Changes**
March 2007	**Second Informative Ballot for Release 3.0 Changes**

1.4 Privacy Concerns in Examples

The names of natural persons that appear in the examples of this book are intentionally fictional. Any resemblance to actual natural persons, living or deceased, is purely coincidental.

1.5 HL7 Attachment-CDA Document Variants

As described in the *HL7 Additional Information Specification Implementation Guide*, there are two variants of a CDA document when used as an attachment. **These are as follows:**

- **The human-decision variant (HDV) is used solely for information that will be rendered for a person to look at, in order to make a decision. The HDV is not required to have structured or coded answers. The only LOINC value used in an HDV CDA document is the LOINC for the *Attachment Type Identifier*. HL7 provides a non-normative style sheet for this purpose. There are two further alternatives within the human-decision variant.**
  - **It can be a single <nonXMLBody> element that contains a reference to an external file that provides the content for the body of the document, or**
  - **It can contain a <structuredBody> element containing free text in XML elements that organize the material into sections, paragraphs, tables and lists as described in the *HL7 Additional Information Specification Implementation Guide.***

- **The computer-decision variant (CDV) has the same content as the human-decision variant, but additional structured information and LOINC coded data is included so that a computer could provide decision support based on the document. Attachments in the CDV can be rendered for human decisions using the same style sheet that HL7 provides for rendering documents formatted according to the human-decision variant.**

These variants do not differ in functional content. All variants of the same attachment have required and optional content as specified in the Additional Information Specification document for that attachment. The variants only differ with regard to whether structured and coded data is mandated.

~~The **human-decision variant** is used solely for information that will be rendered for a person to look at, in order to make a decision. HL7 provides a non-normative style sheet for this purpose. There are two further alternatives within the human-decision variant.~~

~~? It can be a single <nonXMLBody> element that contains a reference to an external file that provides the content for the body of the document, or~~

~~? it can contain a <structuredBody> element containing free text in XML elements that organize the material into sections, paragraphs, tables and lists as described in the *HL7 Additional Information Specification Implementation Guide*.~~

~~The **computer-decision variant** has the same content as the human-decision variant, but additional coded and structured information is included so that a computer could provide decision support based on the document. Attachments in the computer-decision variant can be rendered for human decisions using the same style sheet that HL7 provides for rendering documents formatted according to the human-decision variant.~~

Both variants place constraints upon what information must be present in the CDA to support the ~~Claims~~ Attachment use case, described ~~above~~ in section 1.1. Additional CDA structures (document sections, entries, et cetera), may be present to support use cases other than those defined by this AIS. Anything not explicitly prohibited by this AIS may be present in the CDA document to support use cases other than those defined herein.

1.6 Request for Information versus Request for Service

This attachment is a "send-what-you-have" attachment. It is asking for laboratory results that have been produced in the course of the care process. **It is not asking for any additional data capture efforts.** For example, if the request for data is all Hematology test results, it is **not** asking the provider to run any specific hematology test procedure, rather it is asking for the provider to send those that happen to have been run during the time frame of the request.

In any attachment component answer part it may sometimes be impossible to send a required answer and necessary to send, instead, a reason why the information is not available using a "No Information" indicator. In the human decision variant the sender shall supplement the natural language explanation of why the information is not available. In the computer-decision variant the sender shall supplement the natural language explanation of why the information is not available with appropriate use of the @nullFlavor attribute value, as described in ~~the~~ **"No Information" Indicator under the Representation of** Data Types section of the *HL7 Additional Information Specification Implementation Guide.*

1.7 Specifying Laboratory Observations

When a payer sends a request for supporting documentation, the payer does not have to enumerate every specific test result of interest. LOINC provides codes for large classes of laboratory test results (e.g., chemistry tests) as well as codes for individual test results such as serum potassium concentration. Either kind of code can be used as a subject identifier. As of November 2006, there were more than 30,000 LOINC codes identifying various kinds of lab observations. Whereas most laboratory LOINC codes identify very specific test measurements, the categories (sets) defined in the LOINC Report Subject have sufficient breadth to allow the payer to request a useful subset of laboratory tests with a single code.

The provider will respond to these LOINC class code with the set of individual test results contained within these codes that have been performed on the patient.

In CDA documents, a laboratory result is structured as an observation entry. Structurally, the lab result observation represents a name-value pair, where the observation/code element identifies the laboratory test and the observation/value element identifies the value of the laboratory result.

1.8 Requirements for Sending Laboratory Results

Laboratory results are transmitted using the HL7 CDA document. There are a variety of implementation models for the CDA document in sending lab results. In order to describe a workable set of requirements for the receiving systems, the computer-decision variant for lab results in attachments imposes a specific set of implementation requirements that limit the information and format variations that may be sent as an attachment.

The requirements are:

- The patient must be identified.
- Observations must be fully contained in the transmitted CDA document, without reference to previous or subsequent messages.
- Antimicrobial susceptibility studies are not covered at this time

.

2 Use of the CDA for Laboratory Results

2.1 Human-Decision Variant, XML Body

When the provider sends a result using the CDA in the human-decision variant with an XML body, all laboratory results shall be presented in the following way:

a) Each battery or other logical grouping shall be sent as a <section> element.

b) Each such section shall contain a <title> element identifying the battery.

c) The <title> element shall include the producer's name for the battery. The producer is the entity who generated the results. For example, if an attachment is being prepared in response to a request for LOINC code 18720-3 (coagulation tests), and the local lab calls the battery that was ordered "pre operative coagulation studies," then the <title> element should include the text "pre operative coagulation studies."

d) Each such section shall contain a <table> element. Each row of this table except the header shall contain the individual observation.

e) The following columns of the table shall be present and must be clearly identifiable: Result Name, Result Value, Normal Range, Abnormal Flag and Date/Time.

f) A units column may be present, and must be clearly identifiable[5].

g) A table cell in the Result Name column shall have text that identifies the observation in that row.

h) A table cell in the Result Value column shall have the result, which may be a numeric value, a code, a string, or text. If the result is a number that has associated units, the units must appear in the appropriate location in the table.

i) Where the laboratory reported a normal range for an observation the normal range shall be included in the Normal Range column.

j) Where the laboratory determined that the reported value is abnormal, the Abnormal Flag column shall contain text consistent with the codes present in the HL7 vocabulary table ObservationInterpretation.

k) The Date/Time columns shall include a text value that conveys the physiologic date and time (for lab test the time the specimen was drawn).

l) For attachments sent between US providers and US payers dates in the human decision variant shall be formatted according to one of the formats customary in the US (i.e., they shall *not* be formatted as a numeric day preceding a numeric month indicator). For other geographies the date format for the human decision variant shall be determined by trading partner agreement. *Note: when the language of discourse has been established, a date in the human decision variant that has the month name spelled out, or a standard alphanumeric abbreviation for the month will avoid any date ambiguity.*

m) The data in the Result Value column must represent the information described by the CDA title for the result. If a specimen was taken, but results cannot be obtained, it is acceptable to send nothing in the value column and the reason that results cannot be obtained in a comment.

n) Comments that apply to an individual row in the table may be entered in that row as a footnote in the appropriate column. Such comments may describe or explain a specific result (or lack thereof), but must not alter the meaning of the result.

[5] Placing the units in the same cell as the result can make the lab report difficult to read when units are reported in values like 10*3/mm3 (1000s per cubic mm).

o) Comments that apply to an entire section may appear as CDA content (paragraphs, list, or tables) before the <table> element that conveys the results for the section. Such comments may describe or explain a result but must not alter the meaning of the result.

p) The sender may use the align attribute on <td> and table header (<th>) elements to improve the display. For example:

```
<td align="center">4.94</td>
```

2.2 Additional Requirements for the Computer-Decision Variant

Except as described in this section, the requirements for Human-Decision Variant shall also be followed for lab results reported using CDA documents in the computer-decision variant. The following requirements supplement or modify the above requirements.

a. Each <section> element shall contain a <code> element that includes the LOINC code for the section.

b. Each row corresponding to an observation in the lab report shall have a unique identifier stored in tr/@ID.

c. Each cell corresponding to a portion of an observation in the lab report should have a unique identifier stored in td/@ID or th/@ID.

d. Each row in the table shall have an associated <observation> element, appearing in an <entry> element in the <section>. This <observation> element shall provides the machine-readable content of the observation reported in the row.

e. The value of observation/text/reference/value shall be #uid where uid is the unique identifier of the table row associated with the observation.

f. The value of observation/code shall be the LOINC code of the analyte being reported.

g. The value of observation/effectiveTime shall be the physiologic time related to the observation being reported.

h. The value of observation/value shall report the measured result.

- Numeric results shall be reported using the PQ data type. When units of measure are present, these shall be reported using UCUM.
- Nominal (coded) results shall be reported using the CD data type.
- Text results shall be reported using the ST data type.

i. The value of observation/interpretationCode shall contain the coded representation of the abnormal flag.

j. If a reference range is present in the observation, observation/referenceRange shall be present.

- The value of referenceRange/text/reference/value shall be *#cuid*, where *cuid* is the unique ID of the table cell containing the reference range of this observation.
- The value of referenceRange/value shall indicate the reference range.
- The value of referenceRange/interpretationCode shall be present, and shall contain the coded representation of what kind of value is represented by this range.

For further information, see the CDA Entries and Data Types sections of the *HL7 Additional Information Specification Implementation Guide.*

3 LOINC Codes

3.1 Laboratory Results Supporting Documentation

Table 3.1 defines the LOINC code used to request a complete attachment data set specific to laboratory results. The use of this code in the 277 request in the STC segment represents an explicit request for the complete set of data components relevant to the laboratory results.

The provider shall return all data components for which data is available.

Table 3.1 lists the LOINC codes that represent the current major classes of laboratory results. The LOINC database includes a tree structure that links the LOINC term, "all laboratory studies" (LOINC 26436-6), to each of its major classes (see Table 3.1) and further links each of these classes to the LOINC codes for the individual laboratory test observations they contain. Any of the LOINC codes in this hierarchy are valid LOINC report subject codes for the 277-request for supporting documentation message. When a requestor asks for 26436-6 (all laboratory studies (set)), the organization answering that request will return all laboratory results related to a given claim that also satisfy the constraints imposed by the modifier codes submitted in the 277. When a requestor asks for a class of laboratory tests e.g., coagulation tests (set) (LOINC 18720-3) or chemistry tests (set) (LOINC 18719-5), the organization answering that request would return all coagulation tests or all chemistry tests respectively. When a requestor asks for a single LOINC code (e.g., 2974-1 blood sodium concentrate) the organization returns the test results for that sodium value only.

Table 3.1 – LOINC Report Subject Identifier Codes

LOINC Code	*Report Subject (or Response Specified)*
26436-6	**ALL LABORATORY STUDIES (SET)**
18716-1	ALLERGY TESTS (SET)
18717-9	BLOOD BANK TESTS (SET)
18767-4	BLOOD GAS TESTS (SET)
18718-7	CELL MARKER TESTS (SET)
18719-5	CHEMISTRY TESTS (SET)
26437-4	CHEMISTRY CHALLENGE STUDIES
18720-3	COAGULATION TESTS (SET)
26438-2	CYTOLOGY STUDIES (SET)
18722-9	FERTILITY TESTS (SET)
18723-7	HEMATOLOGY TESTS + CELL COUNTS (SET)
18724-5	HLA TESTS (SET)
18725-2	MICROBIOLOGY TESTS (SET)
26435-8	MOLECULAR PATHOLOGY STUDIES (SET)
18727-8	SEROLOGY TESTS (SET)
26439-0	PATHOLOGY REPORTS SECTIONS + STAINS (SET)
18721-1	TOXICOLOGY + THERAPEUTIC DRUG MONITORING TESTS (SET)
18729-4	URINALYSIS STUDIES (SET)

Note: *The above table does not include antibiotic susceptibilities because they are not covered in this specification.*

Table 3.1 – LOINC Report Subject Identifier Codes~~Table 3.1 – LOINC Report Subject Identifier Codes~~ shows the two top levels of the laboratory test hierarchy within LOINC. LOINC 26436-6 (all Laboratory Studies) is at the first level and classes (such as 18719-5 chemistry tests and 18720-3 coagulation tests) are at the second level in the hierarchy. The LOINC codes for the individual tests within a given class are listed in the LOINC database, but because there are more than 30,000 such LOINC codes they are not listed in this document. Users can view the list of LOINC observation contained within any level of the hierarchy through the HIPAA task in RELMA™[6], a LOINC browsing program, available at: http://www.LOINC.org.

The Regenstrief Institute and LOINC committee will add more refined classes within the existing major classes as requested by the industry to provide for more precisely targeted laboratory test subsets (for example, thyroid tests). Furthermore, to serve the needs of laboratory reporting, the Regenstrief Institute and the LOINC committee will also continue to add new laboratory LOINC codes as laboratory technology expands and new tests for biomarkers and biochemicals and other laboratory measurements are introduced. These new laboratory codes would be contained within the laboratory hierarchy (LOINC 26436-6) and would also be valid subject identifiers for report identifiers in 277-requests. As these new codes are added to the LOINC database, they may be used within the context of this specification.

Test results are often delivered grouped as batteries of individual observations ordered as a package. This standard reporting structure is also reflected in the HL7 CDA document returned in the 275 to the requester. The goal is to keep the messages sent in attachments as close as possible to be equivalent reports and HL7 messages used in daily care operations.

3.1.1 Contents of Laboratory test classes

The content of the laboratory test classes given in Table 3.1 should be obvious from the name. However some of these need more specification.

Microbiology includes all tests used to identify microorganisms and evidence for infection by specific organisms as well as cultures direct microscopic exams that identify organisms or prove evidence for present or past infection with specific organisms. Microbiology includes tests for antibodies, antigens, DNA and RNA. The serology class does not include measures of antibodies or antigens related to microorganisms. And molecular pathology class does not include RNA or DNA based tests for infectious organisms. (They are all included in microbiology.)

The class blood bank includes all blood bank testing including ABO-Rh testing. Allergies include testing to allergens (cat dander, trees, etc). Serology includes rheumatology autoantibodies, and antigen measures not covered by these two classes.

Hematology, as defined, excludes cell counts and differential counts which will be found in cell, differential counts, and coagulation studies, respectively. Measures of complement activity are included within hematology, not chemistry.

Chemistry does not include challenge tests such as Glucose tolerance, ACTH stimulation, etc. These have their own category, chemistry challenge tests.

3.1.2 Requests for individual results

When the LOINC report codes requested in the 277 is an atomic test result (like blood sodium, or prothrombin time-patient) then only a single observation row will be returned in the result table in the 275.

[6] RELMA™ is a trademark of Regenstrief Institute

3.1.3 Requests for classes of laboratory test results.

When the 277 request for supporting information asks for a LOINC code that is a class of laboratory observations, the CDA document returned will include one or more sections, each of which has a table that contains one or more result rows using the same general structure that would have been delivered to the hospital, or physician or clinic that ordered those tests in the first place. This allows reuse of existing CDA documents.

When the 277 request is for a class of tests, then the returned 275 will often contain multiple documents each with its own tables of results.

If chemistry tests (LOINC 18719-5) was requested in the 277, then the CDA document might include a blood sodium result, but in this case, the sodium result could be returned in the section for a battery that also contained other chemistry tests and the response might also include other chemistry test batteries. If the producer's name for this battery was "electrolytes panel," it would contain "electrolytes panel" in the PCDATA for the <title> element.

Within this table we would likely see at least four rows, one for sodium, potassium, chloride and bicarbonate results respectively, because those chemistry tests are often done together in batteries called "electrolytes" as shown in the following example shown in the human-decision variant.

```
<tbody>
    <tr>
        <th>SODIUM</th>
        <td>142</td>
        <td>mmol/L</td>
        <td>135-145</td>
        <td/><td>1 Nov 2006 2:25 PM</td>
    </tr>
    <tr>
        <th>POTASSIUM</th>
        <td>4.0</td>
        <td>mmol/L</td>
        <td>3.5-4.5</td>
        <td/><td>1 Nov 2006 2:25 PM</td>
    </tr>
    <tr>
        <th>CHLORIDE</th>
        <td>100</td>
        <td>mmol/L</td>
        <td>95-105</td>
        <td/><td>1 Nov 2006 2:25 PM</td>
    </tr>
    <tr>
        <th>BICARBONATE</th>
        <td>26</td>
        <td>mmol/L</td>
        <td>22-26</td>
        <td/><td>1 Nov 2006 2:25 PM</td>
    </tr>
</tbody>
```

3.2 Scope Modification Codes

The HL7 publication *LOINC Modifier Codes (for use with ASC X12~~N~~ Implementation Guides when Requesting Additional Information)* provides code values for further defining the specificity of a request for additional information. Both time window and item selection modifier codes are

defined. This publication is available from HL7, and is in the download package with the AIS documents.

3.3 Value Tables for Specific Report Structures

The set of LOINC codes for laboratory observations is very large. The HIPAA task in RELMA can be used to produce reports for all of the components within the hierarchy as well as the hierarchy of LOINC codes that are described in all of the attachment *Additional Information Specifications.*

4 Coding Examples

4.1 Scenario

A payer was reviewing a claim for a male patient named Patient H. Sample who was born on 24 September 1932 for an encounter with George F. Carson, MD that occurred on October 2, 2006. The payer sends a 277 requesting information for LOINC codes 26436-6 (all laboratory tests). The request message included modifier codes that restrict the request to the last result for any laboratory test obtained during the relevant encounter.

The claim associated with this CDA document is identified by the value XA728302 in data element TRN02-Attachment Control Number of Loop 2000A-Payer/Provider Control Number.

Assume that patient has had only two test batteries performed during the encounter, a urinalysis and an automated blood count. Assume also that a response message was created on October 22, 2006 at 6:38:00 PM and that the patient's medical record ID at the sending institution is 6910828 and the billing account number for this encounter is 773789090.

The response includes results from the complete urinalysis and an automated blood count that was ordered for the patient. The two batteries are each in separate sections, and each such section contains a table with a row for each individual measurement that is part of their respective battery.

In the first section the <title> includes the producer's name for the battery, "Urinalysis complete." In the computer-decision variant the producer's name is supplemented with the LOINC code 24356-8 (urinalysis panel) in the <code> element. The table rows convey the information shown in the following table.

Table 4.1.1- First Battery

LOINC Code	*Result name*	*Result value*	*Units*	*Normal Range*	*Ab-normal flag*	*Clinically relevant date/time*
5778-6	urine color	STRAW				10/2/2006 6:38 PM
5767-9	urine appearance	CLEAR				10/2/2006 6:38 PM
5792-7	urine glucose (test strip)	1+		NEG	A	10/2/2006 6:38 PM
5770-3	urine bilirubin (test strip)	NEG		NEG		10/2/2006 6:38 PM
5797-6	urine ketones (test strip)	NEG		NEG		10/2/2006 6:38 PM
5811-5	urine specific gravity (test strip)	1.007		1.005-1.030		10/2/2006 6:38 PM
5803-2	urine pH (test strip)	6		5.0-8.0		10/2/2006 6:38 PM
20405-7	urine urobilinogen	0.2	mg/dL	0.2-1.0		10/2/2006 6:38 PM
13945-1	urine erythrocytes	1	/(hpf)	0-3		10/2/2006 6:38 PM

In the second section the <title> is "Hemogram, Platelets & Differential Panel" and, in the computer-decision variant the <code> element contains the LOINC code 24361-8 (Hemogram, Platelets & Differential Panel).

Table 4.1.2 - Second Battery

LOINC Code	*Result name*	*Result value*	*Units*	*Normal Range*	*Ab-normal flag*	*Clinically relevant date/time*
4544-3	hematocrit	45		39-49		10/2/2006 6:38 PM
789-8	erythrocytes count	4.94	10*6/mm3	4.30-5.90		10/2/2006 6:38 PM
787-2	mean corpuscular volume	91	fl	90-98		10/2/2006 6:38 PM
777-3	platelets count	233	10*3/mm3	150-450		10/2/2006 6:38 PM
6690-2	leukocytes count	25	10*3/mm3	3.2-9.8	H	10/2/2006 6:38 PM
770-8	neutrophils/100 leukocytes	83.1	%	37.0-80.0	H	10/2/2006 6:38 PM
706-2	basophils/100 leukocytes	10.1	%	10.0-50.0		10/2/2006 6:38 PM
5905-5	monocytes/100 leukocytes	6.3	%	0.0-12.0		10/2/2006 6:38 PM
713-8	eosinophils/100 leukocytes	0.3	%	0.0-7.0		10/2/2006 6:38 PM
706-2	basophils/100 leukocytes	0.2	%	0.0-2.0		10/2/2006 6:38 PM
751-8	neutrophils count	20.8	10*3/mm3	2.0-7.0	H	10/2/2006 6:38 PM
731-0	lymphocytes count	2.5	10*3/mm3	0.6-3.5		10/2/2006 6:38 PM
742-7	monocytes count	1.6	10*3/mm3	0.0-0.9	H	10/2/2006 6:38 PM
711-2	eosinophils count	0.08	10*3/mm3	0.00-0.70		10/2/2006 6:38 PM
704-7	basophils count	0.04	10*3/mm3	0.00-0.20		10/2/2006 6:38 PM

4.1.1 Human-Decision Variant Using Scanned Image

Below is a human-decision variant example showing use of a scanned image as the <nonXMLBody> element. For this example, the information is sent in GIF format.

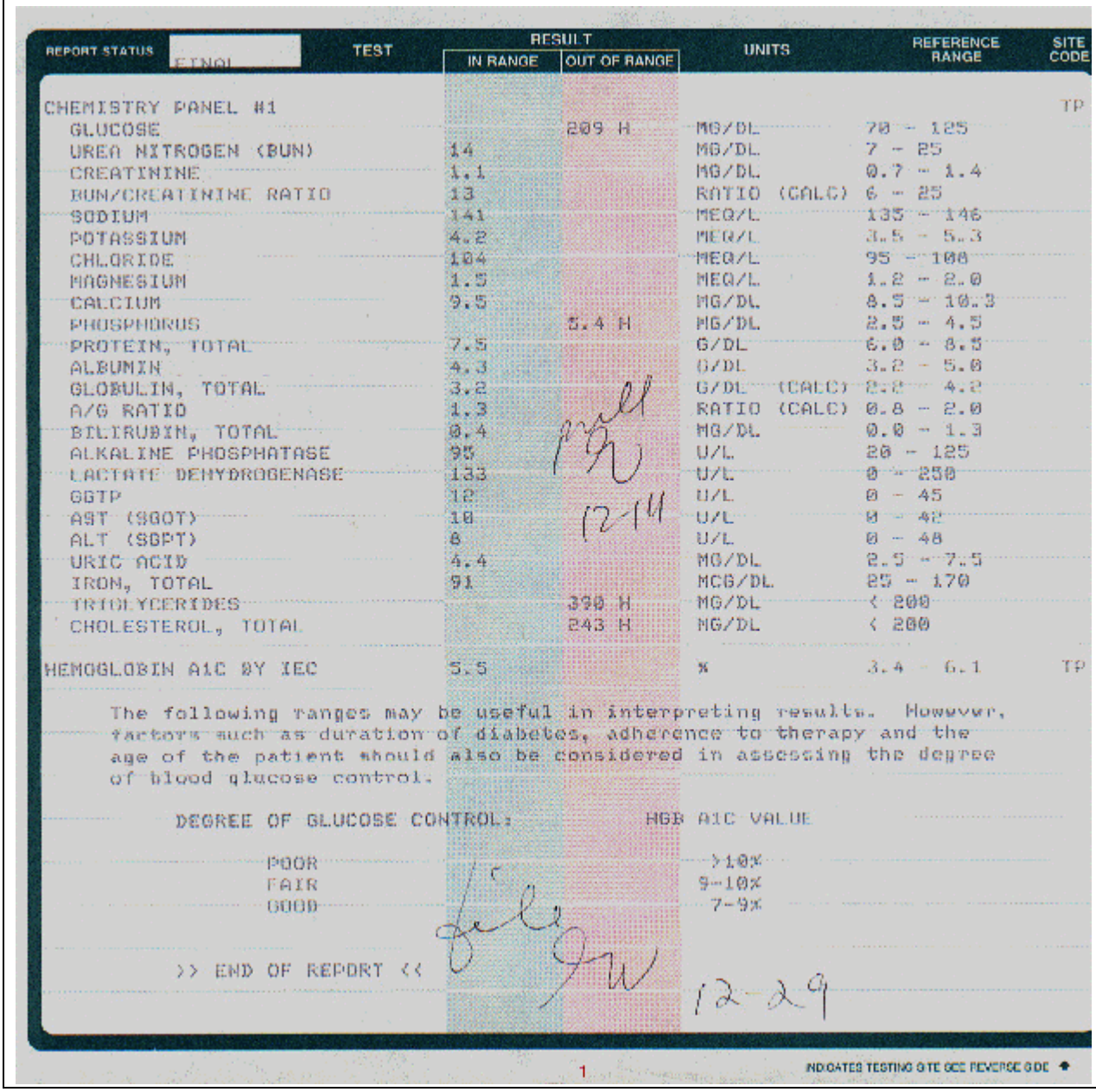
The HDV <nonXMLBody> example file that will be included within the 275 response can be found in the **labhdvNonXML** file included ~~in the ballot pack~~**with the supplemental files available with these documents.**~~age~~. The file includes the scanned image in MIME format.

Figure 4.1-1~~Figure 4.1-1~~ shows how the HDV with a scanned image would be displayed.

Figure 4.1-1 Display of Scanned Image

All Laboratory Studies

Provider: George F Carson, MD
Patient: Sample H Patient **Provider's Pt ID:** 6910828 **Sex:** Male
Birthdate: 24 Sep 1932
Attachment Control Number: XA728302



REPORT STATUS: FINAL

TEST	RESULT IN RANGE	RESULT OUT OF RANGE	UNITS	REFERENCE RANGE	SITE CODE
CHEMISTRY PANEL #1					TP
GLUCOSE		209 H	MG/DL	70 - 125	
UREA NITROGEN (BUN)	14		MG/DL	7 - 25	
CREATININE	1.1		MG/DL	0.7 - 1.4	
BUN/CREATININE RATIO	13		RATIO (CALC)	6 - 25	
SODIUM	141		MEQ/L	135 - 146	
POTASSIUM	4.2		MEQ/L	3.5 - 5.3	
CHLORIDE	104		MEQ/L	95 - 108	
MAGNESIUM	1.5		MEQ/L	1.2 - 2.0	
CALCIUM	9.5		MG/DL	8.5 - 10.3	
PHOSPHORUS		5.4 H	MG/DL	2.5 - 4.5	
PROTEIN, TOTAL	7.5		G/DL	6.0 - 8.5	
ALBUMIN	4.3		G/DL	3.2 - 5.0	
GLOBULIN, TOTAL	3.2		G/DL (CALC)	2.0 - 4.2	
A/G RATIO	1.3		RATIO (CALC)	0.8 - 2.0	
BILIRUBIN, TOTAL	0.4		MG/DL	0.0 - 1.3	
ALKALINE PHOSPHATASE	95		U/L	20 - 125	
LACTATE DEHYDROGENASE	133		U/L	0 - 250	
GGTP	12		U/L	0 - 45	
AST (SGOT)	10		U/L	0 - 42	
ALT (SGPT)	8		U/L	0 - 48	
URIC ACID	4.4		MG/DL	2.5 - 7.5	
IRON, TOTAL	91		MCG/DL	25 - 170	
TRIGLYCERIDES		320 H	MG/DL	< 200	
CHOLESTEROL, TOTAL		243 H	MG/DL	< 200	
HEMOGLOBIN A1C BY IEC	5.5		%	3.4 - 6.1	TP

The following ranges may be useful in interpreting results. However, factors such as duration of diabetes, adherence to therapy and the age of the patient should also be considered in assessing the degree of blood glucose control.

DEGREE OF GLUCOSE CONTROL:	HGB A1C VALUE
POOR	>10%
FAIR	9-10%
GOOD	7-9%

>> END OF REPORT <<

12-14

12-29

1

INDICATES TESTING SITE SEE REVERSE SIDE

4.1.2 Human-Decision Variant Using Structured Text

For this example of the human-decision variant using an <structuredBody> element for the body, the information is sent in two tables, each in its own section. The first section and table capture information reported in the first test battery. The second section and table capture information sent in the second battery.

The HDV XML example file of a CDA document that will be included within the 275 response can be found in **the labhdv.xml** file ~~in the ballot package~~**included with the supplemental files available with these documents**. The file includes comments that explain the various sections of the CDA structure and contents.

Figure 4.1-2~~Figure 4.1-2~~ shows the rendering of the human-decision variant using the HL7-supplied stylesheet.

4.1.3 Computer-Decision Variant

In the computer-decision variant the information is sent twice, once for display and again in a manner suitable for computer extraction. In addition each row <section> element is identified with a LOINC code in the <code> element. This example follows the same scenario as the prior example.

A CDV example file of a CDA document that will be included within the 275 response can be found in **the labcdv.xml** file **included with the supplemental files available with these documents**~~in the ballot package~~. The file includes comments that explain the various sections of the CDA structure and contents.

The rendering of the computer-decision variant of the lab report appears the same as shown in **Figure 4.1-2**~~Figure 4.1-2~~ for the human-decision variant.

Figure 4.1-2 Two Lab Batteries Rendered with HL7 Stylesheet.

Laboratory Report

Patient: Sample Patient **MRN:** 6910828
Birthdate: September 24, 1932 **Sex:** Male
Created On: October 25, 2006

URINALYSIS COMPLETE

This is a comment that applies to the entire urinalysis complete battery.

Result name	Result value	Units	Normal Range	Abnormal flag	date/time
urine color	STRAW				10/2/2006 6:38 PM
urine appearance	CLEAR [a]				10/2/2006 6:38 PM
urine glucose (test strip)	1+		NEG	A	10/2/2006 6:38 PM
urine bilirubin (test strip)	NEG		NEG		10/2/2006 6:38 PM
urine ketones (test strip)	NEG		NEG		10/2/2006 6:38 PM
urine specific gravity (test strip)	1.007		1.005-1.030		10/2/2006 6:38 PM
urine pH (test strip)	6		5.0-8.0		10/2/2006 6:38 PM
urine urobilinogen	0.2	mg/dL	0.2-1.0		10/2/2006 6:38 PM
urine erythrocytes	1	/(hpf)	0-3		10/2/2006 6:38 PM

(a): This is a comment that applies to the urine appearance observation.

Hemogram, Platelets & Differential Panel

Result name	Result value	Units	Normal Range	Abnormal flag	Date/time
hematocrit	45		39-49		10/2/2006 6:38 PM
erythrocytes count	4.94	10*6/mm3	4.30-5.90		10/2/2006 6:38 PM
mean corpuscular volume	91	fl	90-98		10/2/2006 6:38 PM
platelets count	233	10*3/mm3	150-450		10/2/2006 6:38 PM
leukocytes count	25	10*3/mm3	3.2-9.8	H	10/2/2006 6:38 PM
neutrophils/100 leukocytes	83.1	%	37.0-80.0	H	10/2/2006 6:38 PM
basophils/100 leukocytes	10.1	%	10.0-50.0		10/2/2006 6:38 PM
monocytes/100 leukocytes	6.3	%	0.0-12.0		10/2/2006 6:38 PM
eosinophils/100 leukocytes	0.3	%	0.0-7.0		10/2/2006 6:38 PM
basophils/100 leukocytes	0.2	%	0.0-2.0		10/2/2006 6:38 PM
neutrophils count	20.8	10*3/mm3	2.0-7.0	H	10/2/2006 6:38 PM
lymphocytes count	2.5	10*3/mm3	0.6-3.5		10/2/2006 6:38 PM
monocytes count	1.6	10*3/mm3	0.0-0.9	H	10/2/2006 6:38 PM
eosinophils count	0.08	10*3/mm3	0.00-0.70		10/2/2006 6:38 PM
basophils count	0.04	10*3/mm3	0.00-0.20		10/2/2006 6:38 PM

5 Response Code Sets

This section describes response codes that may be used in the computer-decision variant in the <code> element to transmit a coded result or to send the units for a numerical result.

ISO object identifiers (OIDs) uniquely identify the organization responsible for issuing a code or entity identifier. The OID can be used to find more information regarding a coded data value or an identifier for a person, organization, or other entity. For more information, see the section on ISO Object Identifiers in the *HL7 Additional Information Specification Implementation Guide.*

The values for some code sets appear directly in this document. In other cases, the section cites another document as the source.

5.1 Placeholder OIDs Used in Examples

Some of the OIDs used in the narrative and examples of this specification are placeholder or demonstration ones. They will need to be changed upon site-specific implementation. The "HL7 Example" OID root is used for this purpose. The placeholder OIDs in this specification are:

Site-specific OIDs – these must change during implementation of the specification:

- 2.16.840.1.113883.19.2744.1.1 - representing the assigner of the CDA document instance ID
- 2.16.840.1.113883.19.2744.1.2 - representing the assigner of the patient identifier (may be appended with .1, .2, .3, etc. if an example shows multiple patient identifiers assigned by different assigners)
- 2.16.840.1.113883.19.2744.1.3 - representing the assigner of the doctor/provider identifier (may be appended with .1, .2, .3, etc. if an example shows multiple provider identifiers assigned by different assigners)
- 2.16.840.1.113883.19.2744.1.4 - representing the assigner of the visit/encounter
- 2.16.840.1.113883.19.2744.1.5 - representing the assigner of the attachment control number

5.2 UCUM: Unified Code for Units of Measure

The Unified Code for Units of Measure is 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. A typical application of The Unified Code for Units of Measure is electronic data interchange (EDI) protocols, but there is nothing that prevents it from being used in other types of machine communication.

~~**OID is not used with XML for UCUM units of measure.**~~**Any use of UCUM is fixed by HL7 data types; therefore, an OI~~**S**~~**D is not needed.**

Due to its length the table is included in the *HL7 Additional Information Specification Implementation Guide* rather than in this Additional Information Specification.

5.3 ObservationInterpretation: Abnormal Flags

Code set maintained by HL7. Table ObservationInterpretation encodes the flag values used for reporting normalcy of a result. Note: flags for susceptibility do not apply to this specification.

The OID for this table is 2.16.840.1.113883.5.83.

Table 5.3-1 HL7 ObservationInterpretation

Code	Abnormal Value Description
B	Better (of severity or nominal observations)
D	Significant change down (quantitative observations, does not imply B or W)
U	Significant change up (quantitative observations, does not imply B or W)
W	Worse (of severity or nominal observations)
<	**Below** absolute low-off instrument scale. This is statement depending on the instrument, logically does not imply LL or L (e.g., if the instrument is inadequate). If an off-scale value is also low or critically low one must also report L and LL respectively.[7]
>	**Above** absolute high-off instrument scale. This is statement depending on the instrument, logically does not imply LL or L (e.g., if the instrument is inadequate). If an off-scale value is also high or critically high one must also report H and HH respectively.[8]
N	Normal (for all service types)
A	Abnormal (for nominal observations, all service types)
AA	Abnormal alert (for nominal observations and all service types)
H	Above high normal (for quantitative observations)
HH	Above upper alert threshold (for quantitative observations)
L	Below low normal (for quantitative observations)
LL	Below lower alert threshold (for quantitative observations)
EX	Definition: The observation/test result is interpreted as being outside the inclusion range for a particular protocol within which the result is being reported. Example: A positive result on a Hepatitis screening test.
LX	Definition: The numeric observation/test result is interpreted as being below the low threshold value for a particular protocol within which the result is being reported. Example: A Total White Blood Cell Count falling below a protocol-defined threshold value of 3000/mm^3
HX	Definition: The numeric observation/test result is interpreted as being above the high threshold value for a particular protocol within which the result is being reported. Example: An ALT (SGOT) result above a protocol-defined threshold value of 2.5 times the upper limit of normal based on the subject's sex and age.
I	Intermediate (For microbial susceptibilities only)
MS	Moderately susceptible (For microbial susceptibilities only)
R	Resistant (For microbial susceptibilities only)
S	Susceptible (For microbial susceptibilities only)
VS	Very susceptible (For microbial susceptibilities only)

5.4 NPI: National Provider ID

On January 23, 2004, the Secretary of HHS published a final rule (Federal Register volume 69, page 3434) which establishes the standard for a unique health identifier for health care providers for use in the health care system, and announces the adoption of the National Provider Identifier (NPI) as that standard. It also establishes the implementation specifications for obtaining and using the standard unique health identifier for health care providers.

[7] Note that the < and > characters have special meaning in XML. To record these values within a CDA document, you must use the < and > constructs to represent these values.

[8] Note that the < and > characters have special meaning in XML. To record these values within a CDA document, you must use the < and > constructs to represent these values.

For more information contact the US Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), 7500 Security Blvd., Baltimore, MD 21244. The HHS Administration web site address is http://aspe.hhs.gov/admnsimp/.

The OID for this table is 2.16.840.1.113883.4.6.

5.5 Other Provider Identifiers

Other provider identifiers, such as those assigned by health care organizations may be used. See section 3.**7.4**~~8~~ Instance Identifier Data Type **(II)**~~s~~ in the *HL7 Additional Information Specification Implementation Guide* for more information.

--End of document--