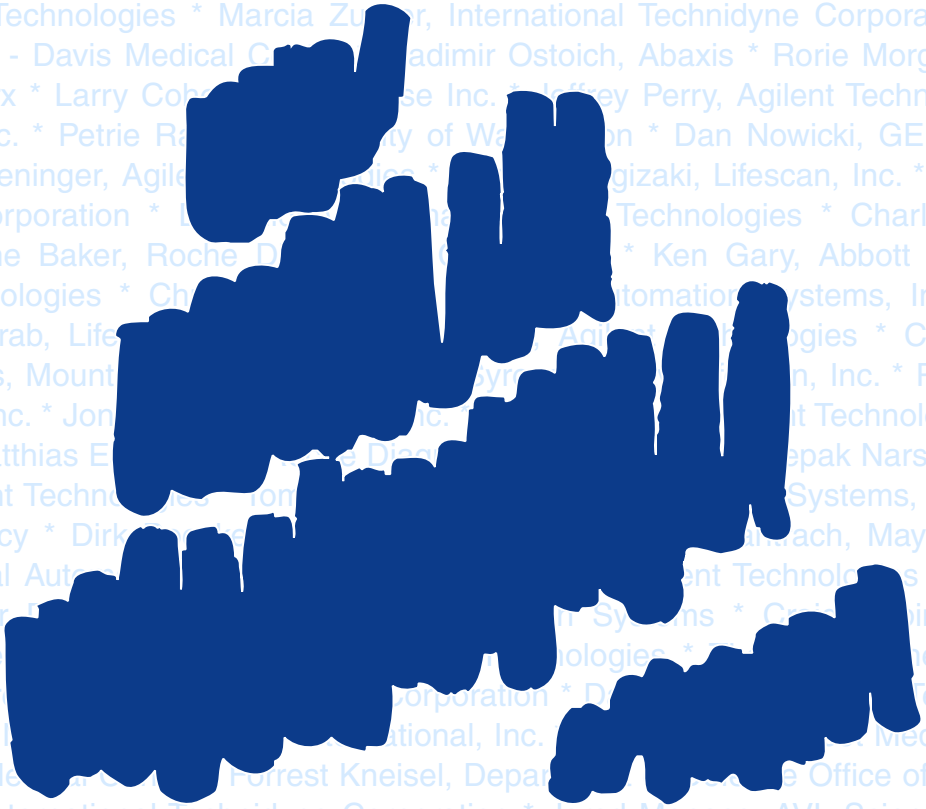

# Connectivity
## Industry Consortium

# AACC Milestone Status
# San Francisco - July 2000





www.poccic.org

# POINT-OF-CARE CONNECTIVITY INDUSTRY CONSORTIUM

AACC MILESTONE: JULY 22, 2000

## VISION

"The vision of the CIC is to expeditiously develop, pilot and transfer the foundation for a set of seamless 'plug and play' POC communication standards, ensuring fulfillment of the critical user requirements of bi-directionality, device connection commonality, commercial software interoperability, security, and QC/regulatory compliance."

## STRUCTURE

The CIC is an open, non-profit, industry-driven consortium comprised of device manufacturers, information system vendors and health care providers. It is chartered to address impediments to POC device connectivity with the objective of enabling seamless information exchange between POC devices and electronic medical records and laboratory information systems. Where possible, the consortium will leverage existing standards. The CIC does not intend to become a chartered standards development body. Rather, the Consortium plans to work with existing standards organizations to ensure the CIC standards are transferred to a chartered standards body for publication, extension, and maintenance.

## TIMELINE

The CIC will limit itself to a one-year lifetime. The Consortium will complete its development work by February 2001. At the CIC's sunset, these developed standards will be transferred to a chartered standards organization for maintenance.

## STATUS

This document outlines the CIC's architecture and interface proposals currently under development. The following chapters document the proposals under currently under review and development. Please note that the specifications in this document are not finished, balloted and ratified proposals. Over the next four months, the Consortium will continue to refine and develop these proposals. The finished specifications will be ratified by vote of the Consortium's members, prior to the CIC's sunset.

## THE COVER

Substantial contributions from a great number of individuals from the point-of-care industry directly account for the Consortium's progress and success to date. Indeed, the CIC's very existence is a tribute to the dedication and vision of these individuals, who believe that standardization of point-of-care testing connectivity will benefit the industry, healthcare providers, and patients. The cover is a tribute to the dedication and commitment of these individuals and organizations.

Jeff Perry
CIC V.P. – Chief Technical Officer
Representing Agilent Technologies

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# 1 Consortium Organization

In February 2000, the Connectivity Industry Consortium was incorporated in California as a non-profit organization. The *CIC Plan and Bylaws* document details the Consortium's objectives, structure, governance, funding, and timeline. All Consortium members have ratified this document.

## *1.1 Membership*

Membership in the Consortium is open to all individuals and organizations interested in the problem of point-of-care connectivity. The Consortium's membership is divided into five different classes:

- **Core Vendors**: Provide the bulk of the Consortium's funding as well as a dedicated technical resource. These organizations commit to strongly considering incorporating the CIC standards in future products
- **Core Providers**: These organizations provide point-of-care domain experts to aid in specifying requirements and reviewing the developed standards. These organizations promise to strongly consider requiring CIC standards compliance in all future point-of-care purchases. These organizations may also serve as pilot test sites for products based on the CIC standards.
- **Individual Providers**: These individuals commit to providing the Consortium with domain expertise
- **Supporting Vendors**: These commercial organizations provide resources to the technical teams to develop the CIC standards. These organizations provide funding to the Consortium based on their revenues.
- **Affiliates**: The CIC will establish working relationships with several international standards development organizations. Some of these organizations will provide international input to the requirements and review process. Affiliate organizations may eventually be transfer partners for the CIC's standards at the end of the Consortium's one-year lifetime.

As of July 15, 2000, 47 member organizations comprise the Connectivity Industry Consortium:

| Core Vendor | Core Provider |
|---|---|
| Abbott Laboratories | Banner Health System |
| Agilent Technologies | Bradford Royal Infirmary |
| AVL Scientific | Geisinger Medical System |
| Bayer Diagnostics | Johns Hopkins Medical Institutions |
| BD | Kaiser Permanente |
| Instrumentation Laboratory | Mayo Clinic |
| LifeScan/OCD | The Mount Sinai Hospital |
| Medical Automation Systems | Profil GmbH |
| Radiometer Medical | St. Vincent Mercy Medical Center |
| Roche Diagnostics | University of Iowa Healthcare |
| Sunquest | |

| Individual Provider |
| --- |
| Maurice Green, Ph.D. |
| Neil Halpern, MD |
| LTC Forrest Kneisel |
| Gerald Kost, MD, Ph.D. |
| Petrie Rainey, MD, Ph.D. |

| Liaison Organizations |
| --- |
| AACC |
| COLA |
| IFCC Scientific Division |

| Supporting Vendor |
| --- |
| Abaxis |
| Avocet Medical |
| Cerner |
| Citation Computer Systems |
| GE Marquette Medical Systems |
| HemoCue |
| HemoSense |
| i-STAT |
| ITC |
| InterComponentWare |
| Medtronic |
| Motorola |
| Pharmacia & Upjohn |
| SMS |
| STC Technologies |
| Sigma Diagnostics |
| Telcor |
| VIA Medical |

## *1.2 Governance*

A seven-person Board of Directors governs the Consortium. Five of these Director positions were elected by the Core Vendor organizations prior to the launch of the Consortium. The other two director positions are reserved for the President and the Chair of the Provider Review Committee. The elected members of the Board of Directors are:

Dr. Dirk Boecker, Agilent Technologies

Tom Braithwaite, Medical Autoamtion Systems

Dr. Joerg Schreiber, Roche Diagnostics

Dr. Sidney Goldblatt, Sunquest Information Systems

James LaFrance, Bayer Diagnostics

The Provider Review Committee is comprised of representatives from each of the Core Provider organizations. This committee elects a chairperson, who serves on the Board of Directors and is responsible for coordinating the provider's review of the CIC standards-in-progress. Dr. James Nichols, Johns Hopkins Medical Institutions, has been elected to this chairperson role.

The day-to-day management of the Consortium is entrusted to an Executive Staff, comprised of a President and four Vice Presidents. The Board of Directors appoints this staff. The Executive staff is comprised of:

President: Suzanne Cross, LifeScan/OCD

Vice President: Horst Merkle, AVL Scientific

Vice President, Chief Technology Officer: Jeff Perry

Vice President, Secretary: Chris Fetters, Medical Automation Systems

Vice President, Treasurer: Ken Levy, Roche Diagnostics

The technical teams, comprised of representatives from all CIC member organizations, report to the Vice-President, Chief Technology Officer. The two principle interface teams are lead by co-chairs, appointed by the Chief Technology Officer. These co-chairs are:

Device Interface:
Allan Greenburg, Roche Diagnostics
Bob Uleski

EDI Interface:
Rodney Kugizaki, LifeScan
Wayne Mullins, Medical Automation Systems

In addition to these two technical teams, there are several smaller workgroups, each lead by a chairperson:

Architecture: Jack Harrington, Agilent Technologies

POC Workflow: Marcy Anderson, Medical Automation Systems

Requirements: Teresa Prego, Bayer Diagnostics

This structure is illustrated in the following figure.

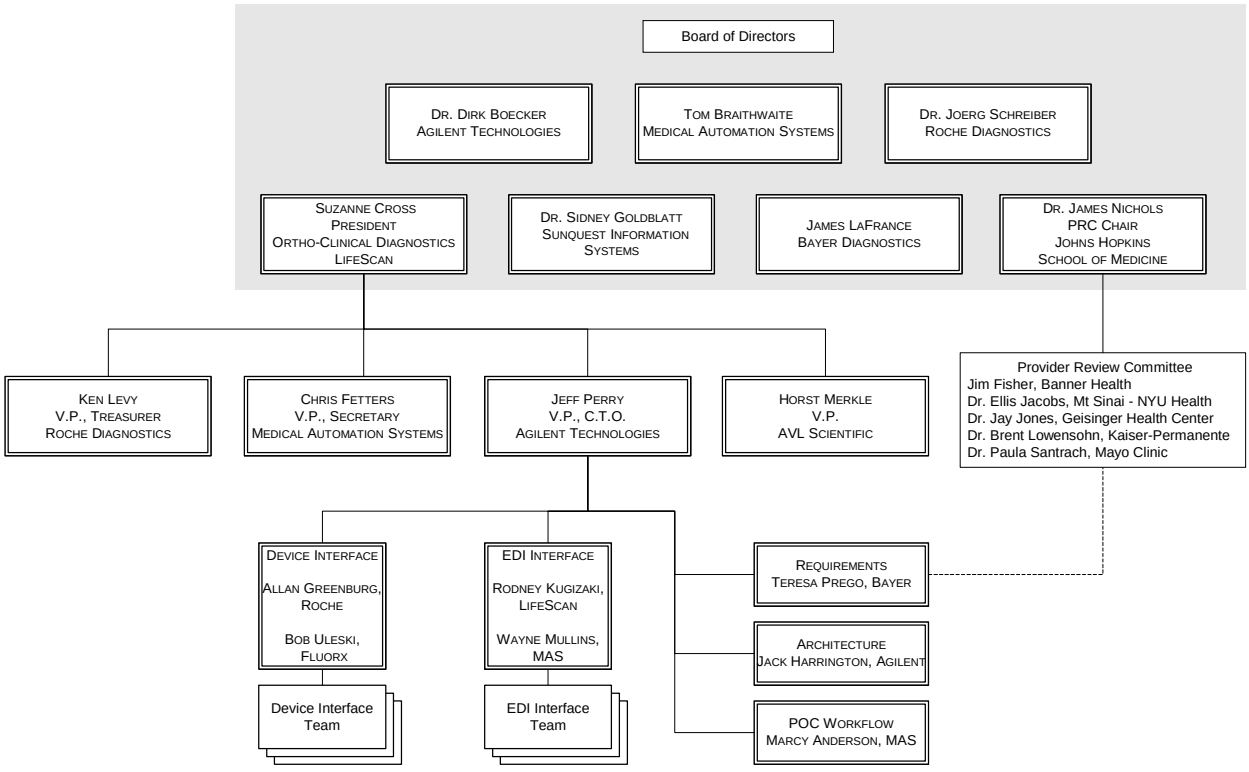



Figure 1: CIC Organization

## *1.3 Funding*

The Consortium's funding comes entirely from membership dues paid by the vendor members.

- Core Vendors: $50,000

- Supporting Vendors: $10,000 if revenues greater than $1M, otherwise $5,000.

# 2 Timeline

The Connectivity Industry Consortium was launched in February 2000, after the point-of-care industry had wrestled with trying to find solutions to the connectivity problem. The following is a summary of the events which directly led to the formation of the CIC:

- AACC 1998 – AACC POC Division determines that connectivity is its most important and pressing problem
- 1998-1999 – POC Division studies options to address the connectivity problem, and asks Agilent Laboratories to propose an approach to solve the problem
- AACC 1999 – Agilent Laboratories' plan to address connectivity problems via an industry consortium (CIC) gets overwhelming support
- Aug-Sep 1999 – Dirk Boecker, Jeff Perry (Agilent) and Emery Stephans (AACC) visit key core members to present CIC mission.
- Oct 2, 1999 – Leading healthcare provider institutions meet in Palo Alto to prioritize POC connectivity user requirements.
- Oct 20, 1999 – Agilent Technologies hosts a meeting to discuss and refine the proposal for the Connectivity Industry Consortium. 122 individuals from the point-of-care industry attend this meeting in Redwood City, CA.
- Nov 1999 – Roche Diagnostics sponsors a CIC update meeting for European healthcare providers and vendors at Medica in Dusseldorf
- Feb 22, 1999 – Sunquest Information Systems sponsors the CIC launch meeting in Tucson, AZ.

The Consortium's bylaws dictate a one-year lifespan for the organization. By the end of that lifespan, in February 2001, the CIC will have developed, prototyped, and piloted standards to enable point-of-care connectivity. Also by the end of this timeline, the Consortium will have transferred the development and maintenance of these standards to a chartered standards maintenance organization.

The Consortium's timeline is divided into sections, punctuated by milestones held in conjunction with major industry meetings and events.

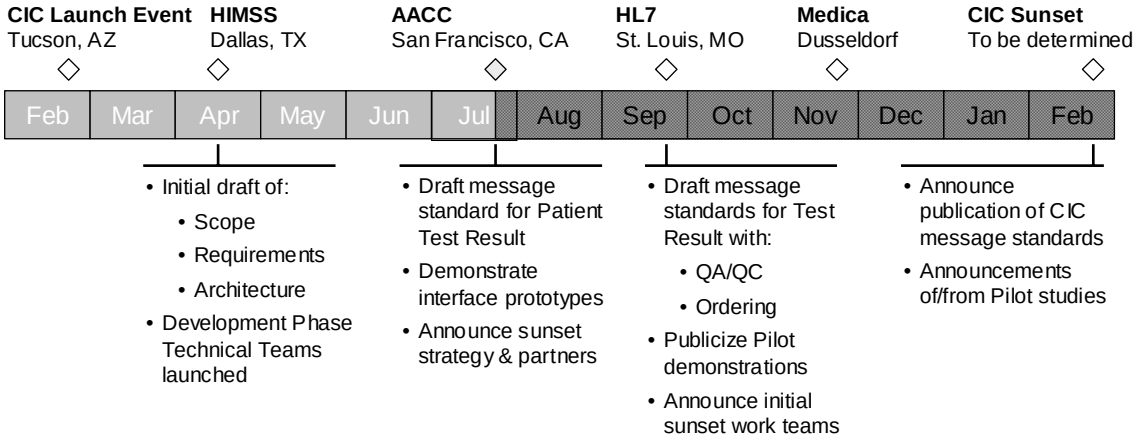



Figure 2: CIC One-Year Timeline

The Consortium is has made excellent progress toward its goals and objectives. Every milestone has been successfully met to date. The Consortium is on schedule for completing its mission in February 2000.

# 3 Technical Status

The CIC Technical Teams (Device, EDI) are currently engaged in three activities:

- Developing the architecture proposal in to workable interface specifications
- Prototyping the interfaces under development
- Planning Pilot demonstrations to validate the entire architecture and approach

. The following chapters document the proposals under currently under review and development. Please note that the specifications in this document are not finished, balloted and ratified proposals. Over the next four months, the Consortium will continue to refine and develop these proposals. The finished specifications will be ratified by vote of the Consortium's members, prior to the CIC's sunset.

# 4 Connectivity Architecture

The architecture proposed for the CIC's approach to point-of-care connectivity was developed over the first six weeks of the Consortium's lifetime. The Architecture workgroup, led by Jack Harrington (Agilent Technologies), accepted the following mission:

> *To develop a draft Architecture statement that will be used to guide the technical team's design and development efforts. This workgroup will interact with the Requirements and Scope teams to produce a draft by the end of Phase 0. During the Consortium's lifetime, this team will refine and maintain the Architecture document.*

The team employed the following principles in developing the architecture

- Base the process on proven approach and express architecture in standard notation (Rational Unified Method/Unified Modeling Language)
- Where possible leverage existing standards and architectural patterns
- Minimize what needs to be standardized
- Focus on services to enable interoperability of value added functionality
- Separate specification from implementation, allow for multiple physical realizations
- Minimize complexity of device communications
- Facilitate migration of existing proprietary approaches

The Architecture team identified two opportunities to employ standardization to simplify point-of-care device connectivity: a Device Interface and an EDI Interface. Schematically, these interfaces may be employed to connect point-of-care devices to enterprise information systems as shown in the following figure.

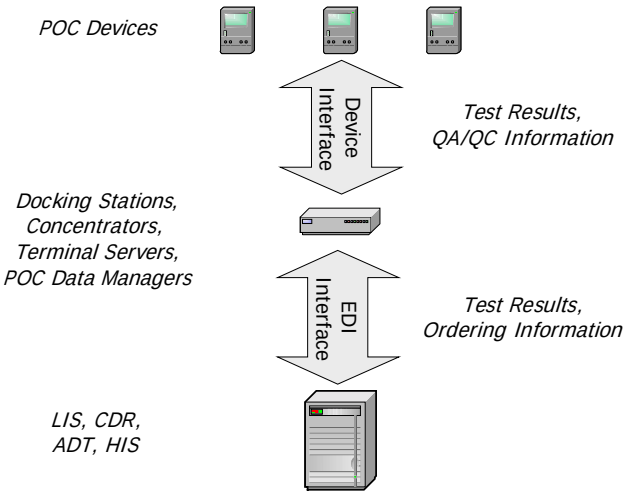



Figure 3: CIC Interfaces

The Architecture workgroup also developed design proposals for these interfaces, in accordance with the team's guiding principles. The design proposals for both interfaces are summarized in the following figure.

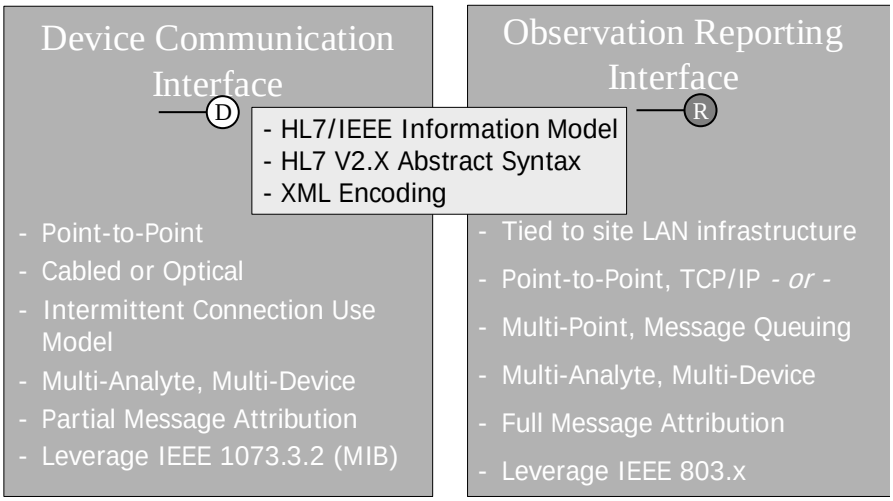



Figure 4: CIC Interface Attributes

At the application message level, both interfaces are built on the Health Level 7 (HL7) information model and message syntax. By using a common model and syntax across both interfaces, this architecture reduces the complexity that intermediary systems must deal with. Also, by leveraging the proven HL7 messaging standard, the Consortium was able to take advantage of lessons learned by years of healthcare enterprise communication development experience.

The lower layers of the Device Interface are built on the IEEE 1073.3.2 standard, also known as the Medical Information Bus (MIB). This standard provides for both infrared and cabled connectivity.

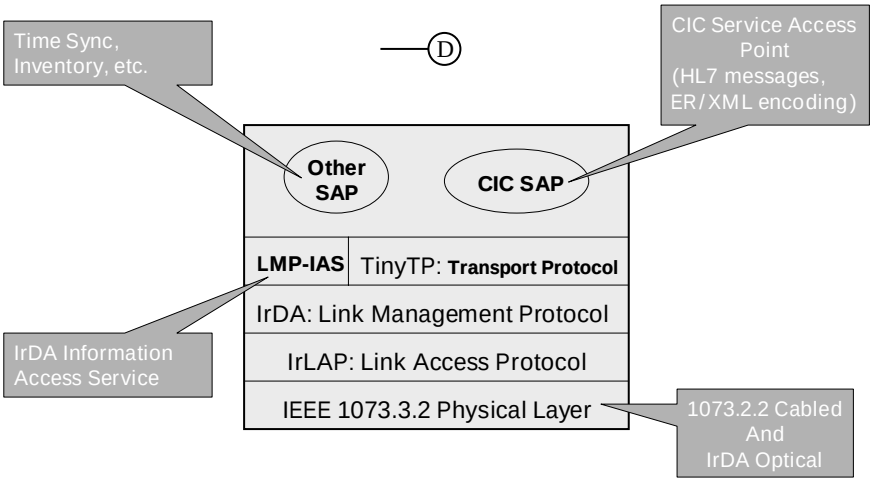



Figure 5: Device Interface

The Device Interface architecture proposal employs several elements of the Infrared Data Association (IrDA) protocol suite: IrLAP, IrLMP, LMP-IAS, and TinyTP. These IrDA standards are widely utilized in consumer products, such as cell phones, palmtop computers, and laptop computers. By adopting these standards, the point-of-care industry will be able to take advantage of the economies of scale afforded by these other markets.

Another significant feature of this architecture is that it allows proprietary services to be easily built and incorporated alongside the CIC connectivity services. Such services might include device inventory, time synchronization, or firmware updating.

The EDI, or Observation Reporting, Interface is similarly built on existing messaging and network protocol standards. Like the Device Interface, the Observation Reporting interface uses the HL7 message syntax to communicate point-of-care results.

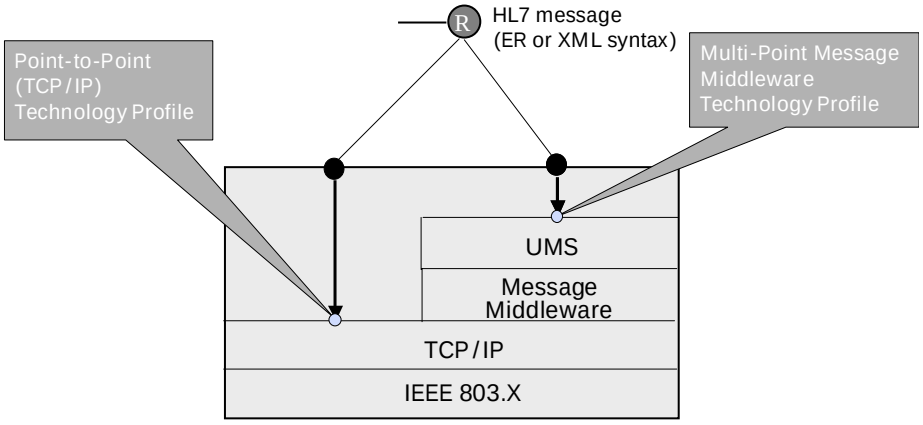



Figure 6: EDI (Observation Reporting) Interface

The EDI interface leverages the well-known IEEE 803.x network standards to provide transport of these messages. The 803.x standard suite provides for both cabled (Ethernet) and wireless (Radio Frequency) connection fabrics. The Internet standard TCP/IP protocol is layered on top.

For the case of point-to-point communication of observations and results, the combination of TCP/IP and 803.x is sufficient. When a single system must communicate with multiple recipient systems (e.g. a LIS and a CDR), the architecture specifies adding the Unified Middleware Service and an associated messaging middleware technology to the transport stack.

# 5 CIC Compatibility Proposal

## 5.1 Summary

This proposal summarizes the conclusions of the CIC Device Interface team during a conference call held on June 27 and follow-up discussions on June 29, July 6, and July 13, 2000.

The participants included Joe Rogers (I-stat), Imre Trefil (Lifescan), Jeff Perry (Agilent), Dan Nowicki (GE Marquette), Mark Maund (I-stat), Bob Anders (Agilent), Bob Uleski (FluorRX), Alan Greenberg (Roche), Kendra Whittier (Agilent), who took minutes during our calls, and Paul Schluter (GE Marquette), who wrote this summary and expanded it into a proposal.

## 5.2 Introduction

The CIC Device Interface team has attempted to strike a balance between the following goals and issues:

1. to promote POC device 'plug-and-play' interoperability by adopting a 'standard' CIC device interface wherever possible; and
2. to recognize that legacy implementations exist, many of which provide cost-effective solutions optimized for particular patient care areas.

The CIC Device Interface team proposes two solutions:

*First,* in order to promote POC device 'plug-and-play' interoperability, it is proposed that POC Devices, particularly those used in acute patient care areas, could be made 'CIC-compatible' at the Device Interface by adopting the CIC Device Interface upper-layer protocol and using either of the following transport and physical layers: 'TinyTP/IR' (IrDA TinyTP protocol over infrared) or 'TinyTP/cable' (IrDA TinyTP protocol over cable, as stipulated by the IEEE 1073.3.2 Standard for Medical Device Communications).

This proposal is particularly appropriate for acute care areas that plan to use the IEEE 1073.3.2 Medical Information Bus (MIB) for medical device communication. Portable computing platforms such as the Palm, Pocket PC, and other handheld 'personal digital assistants' (PDAs) can also use the IEEE 1073.3.2 communication infrastructure, since many of these devices already have IrDA serial infrared links.

Additional transport and physical layers may be considered in the future by the CIC Device Interface team, including those that would support remote modem access over analog phone lines.

*Second,* in order to promote the incorporation of CIC standards in existing legacy and proprietary systems, it is proposed that these systems could be considered 'CIC-compatible' at the EDI Interface, regardless of whether or not the POC Devices supported by those systems comply with CIC Device Interface standards.

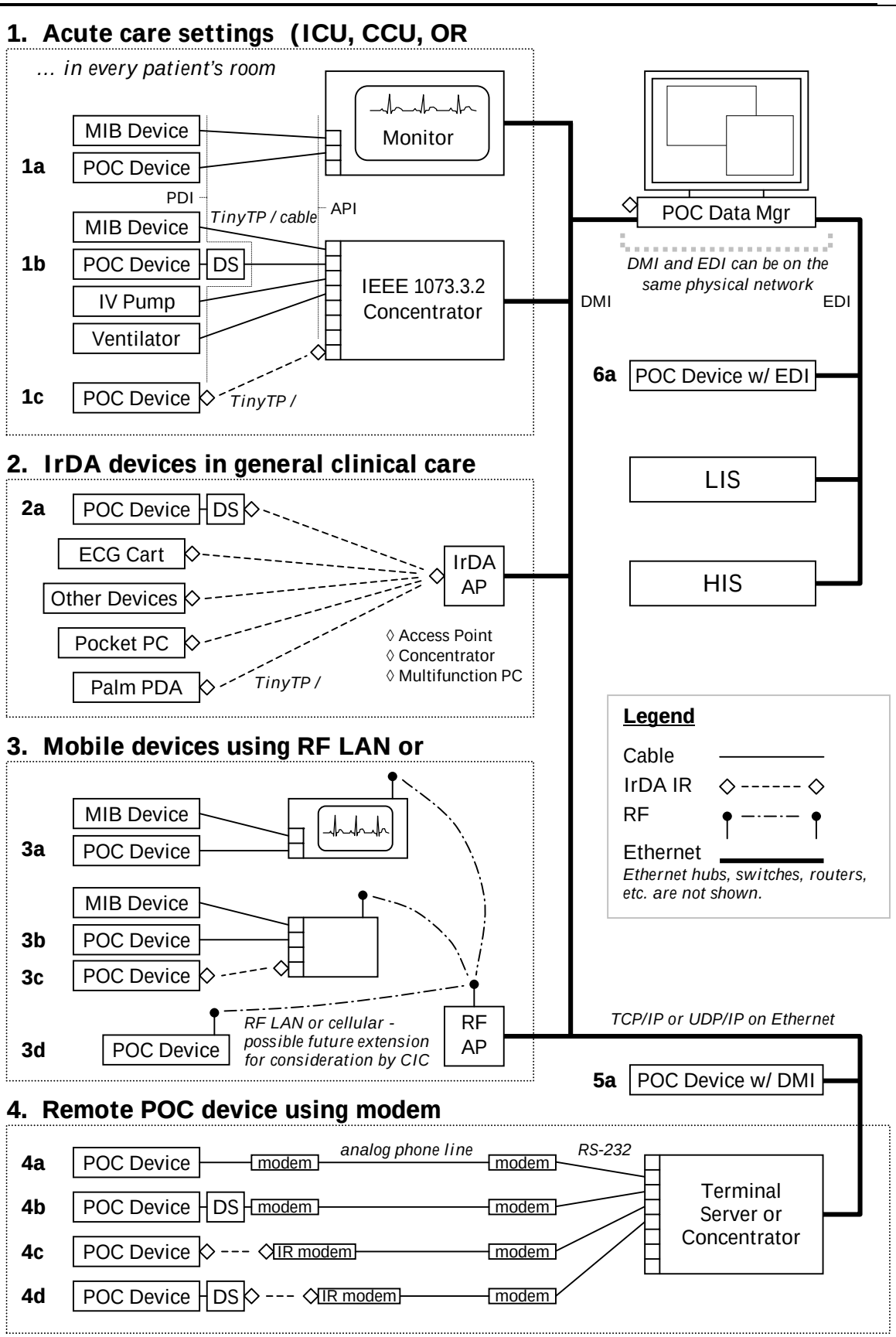
## 5.3 General Definitions

A '**POC System**' is defined as a collection of one or more devices and subsystems that can perform a POC measurement in the patient care area and report the results using an 'Electronic Data Interchange' (EDI) interface to a hospital 'Laboratory Information System' (LIS), 'Hospital Information System' (HIS) or other system that is the final repository for the POC measurement results. In most installations, the EDI interface uses the HL7 upper-layer protocol running over a network TCP/IP connection.

Devices, subsystems and principal interfaces (highlighted in gray) that comprise a POC System are defined below:

| | |
|---|---|
| **PD** | A '**POC Device**' performs the measurement(s) in the patient care area, and may use a |
| **DS** | '**Docking Station**' to provide a mechanical and electrical interface that supports the POC Device. The docking station may use a legacy mechanical interface, connector, protocol and power delivery methods. *This component is optional*. The POC Device or its Docking Station uses its |
| **PDI** | '**POC Device Interface**' to communicate the data (principally output) to an |
| **API** | '**Access Point Interface'** that specifies the (principally input) interface to an |
| **AP** | '**Access Point**' or '**Concentrator**' that consolidates the data from one or more Devices onto another communication link, possibly using a different physical layer and transport protocol. *This subsystem is optional.*<br>Several examples of a access point are listed below, and other implementations are permitted:<br>(a) a multi-port concentrator, typically connected to a local area network (LAN);<br>(b) a dedicated single-port access point, typically connected to a LAN; and<br>(c) an access point that is part of a multifunctional device such as a personal computer |
| **DMI** | The '**Data Manager Interface**' specifies the TCP/IP network interface to |
| **DM** | a '**Data Manager**' that may perform such functions as (1) device data storage and forwarding, (2) QA/QC and (3) other vendor specific functionality. |
| **EDI** | The '**EDI Interface**', typically provided by the Data Manager, is used to report the results to a hospital 'Laboratory Information System' (LIS), 'Hospital Information System' (HIS) or other system that is the final repository for the POC measurement results. The EDI interface typically uses HL7 over a network TCP/IP connection. |

Figures 1a - 6a on the following page illustrate how POC devices, subsystems and their principal interfaces can be used in a typical hospital environment, including remote-access configurations that employ modems and analog phone lines.




**Figures 1a - 6a. Local and Remote Access Examples for POC**

## 5.4 Requirements for a 'CIC-compatible Device'

A POC Device or POC Device and Docking Station that complies with the CIC Device Interface upper-layer protocol *and* supports at least one of the transport and physical layers listed below shall be considered 'CIC-compatible'.

1. ***TinyTP/cable**: IEEE 1073.3.2-2000 Standard for Medical Device Communications - Transport Profile - IrDA Based - Cable Connected.*

   This standard defines a cable-connected physical layer that uses CAT-5 cable, RJ-45 connectors at the concentrator, and RS-232 signaling. The Device participates as an IrDA 'secondary station' supporting the IrLAP, IrLMP and TinyTP protocols, comparable to the role of a 'Device Communication Controller' (DCC) defined in IEEE 1073.3.2.

2. ***TinyTP/IR**: IrDA Serial Infrared, up to 115.2 kBd, Standard or Low-Power Option.*

   The IrDA SIR standard supports the 'low-speed' data signaling rates of 2400, 9600, 19200, 38400, 57600 and 115200 Bd; 9600 Bd must be supported and higher speeds can be negotiated (the CIC excludes 2400 Bd since it is already excluded by the MIB standard and is rarely used in practice). The Device participates as an IrDA 'secondary station' supporting the IrLAP, IrLMP and TinyTP protocols. The IrDA SIR 'low-power' option supports link distances up to 20 cm and typically requires LED drive currents of 10 mA (average) and 30 mA (peak).

   When either TinyTP/cable or TinyTP/IR is used, the CIC Device shall advertise itself with the IAS object class 'CIC:POC:DEV' with the attribute name 'IrDA:TinyTP:LsapSel' which returns an integer to the access point or concentrator that specifies the service connection endpoint for the CIC Device protocol to an IrDA TinyTP service.

## 5.5 Requirements for a 'CIC-compatible Access Point'

An Access Point or Concentrator that complies with the CIC Device Interface upper-layer protocol *and* is capable of supporting *all* of the transport and physical layers listed below shall be considered 'CIC-compatible'.

1. ***TinyTP/cable**: IEEE 1073.3.2-2000 Standard for Medical Device Communications - Transport Profile - IrDA Based - Cable Connected.*

   This standard defines a cable-connected physical layer that uses CAT-5 cable, RJ-45 connectors at the concentrator, and RS-232 signaling. The Access Point participates as an IrDA 'primary station' supporting the IrLAP, IrLMP and TinyTP protocols, comparable to the role of a 'Bedside Communication Controller' (BCC) defined in IEEE 1073.3.2.

2. ***TinyTP/IR**: IrDA Serial Infrared, up to 115.2 kBd, Standard or Low-Power Option.*

   The IrDA SIR standard supports the 'low-speed' data signaling rates of 2400, 9600, 19200, 38400, 57600 and 115200 Bd; 9600 Bd must be supported and higher speeds can be negotiated (the CIC excludes 2400 Bd since it is already excluded by the MIB standard and is rarely used in practice). The Access Point participates as an IrDA 'primary station' supporting the IrLAP, IrLMP and TinyTP protocols. The IrDA SIR 'low-power' option supports link distances up to 20 cm and typically requires LED drive currents of 10 mA (average) and 30 mA (peak).

   Some vendors may prefer to support only TinyTP/cable in their basic Access Point or Concentrator and provide TinyTP/IR as an adapter option, and this configuration shall also satisfy the requirements for a 'CIC-compatible' Access Point or Concentrator.

   When either TinyTP/cable or TinyTP/IR is used, the CIC Access Point or Concentrator shall advertise the services of a 'generic' CIC POC Data Manager to the Device with the IAS object class 'CIC:POC:MGR' with the attribute name 'IrDA:TinyTP:LsapSel' which returns an integer to the Device that specifies the service connection endpoint for the CIC Device protocol to an IrDA TinyTP service.

   The Access Point or Concentrator could also advertise the services of a 'generic' CIC POC Laboratory Information System with the IAS object class 'CIC:POC:LIS' in cases where the Device is capable to sending its results directly to a LIS system using the CIC EDI Interface protocol.

   Vendor specific services could also be advertised in the IAS by appending vendor suffixes to the 'generic' CIC IAS object classes. For example, the availability of a Lifescan POC Data Manager could advertised by the Access Point or Concentrator with the IAS object class 'CIC:POC:MGR:LFS'.

## 5.6 *Requirements for a 'CIC-compatible System'*

A POC System that provides an EDI Interface that complies with the CIC EDI Interface specification shall be considered 'CIC-compatible', regardless of whether or not the POC Devices supported by the system comply with the CIC Device Interface specification.

In this paper, such a system will be referred to as a 'CIC System'.

Note that this requirement allows a broad range of implementations:

(a) It permits the use of POC Devices with legacy protocols, docking stations and concentrators, provided that the POC System provides an EDI interface that is compatible with the CIC EDI interface specification. Typically the Data Manager would provide this interface, but it could also be provided at the output of the Concentrator or the POC Device.

(b) It permits more than one subsystem to be combined into a single physical component. For example, the POC Device could communicate directly to an LIS system using the CIC EDI Interface or directly to a CIC Data Manager without the need for a Concentrator.

In order to accommodate legacy systems, this proposal allows the use of POC Devices that may not necessarily comply with the CIC Device Interface specification. Although this does not guarantee 'plug and play' interoperability at the POC Device level, the Device Interface team was concerned that a standard that excluded legacy implementations could significantly hinder the widespread adoption of standards developed by the CIC.

# 6 Simple Patient Test Result Messaging Proposal

The CIC technical teams have adopted a phased approach to developing message sets to address POC connectivity use cases. The teams have chosen to first develop messages to support the communication of a simple patient test result from a device to a data repository. The messaging proposal developed by the EDI and Device teams to address this use case is outlined in the following sections of this document.

At the AACC milestone meeting in July 2000, both teams will conduct a technical review of this proposal. After an acceptable review, the teams will begin work on the next use cases to be addressed: QA/QC and Ordering.

## *6.1 Use Case Description*

The Simple Patient Test Result use case involves the transfer of a test result from a generic single-measurement meter (e.g. glucometer, coagulation meter) to a hospital enterprise data repository (e.g. Laboratory Information System).

The test is performed by a Nurse or Med Tech at or near a patient identified by a Patient ID. The Test is considered to have been previously ordered under “standing orders” or other hospital protocols, and an Accession Number identifies the test. The meter communicates the test result first to an Observation Reviewer, using the CIC Device Interface protocols. The Observation Reviewer subsequently transmits the result to the Observation Recipient (e.g. LIS), via the CIC EDI protocol.

This use case’s actors, operations and interactions are illustrated in the following figure.

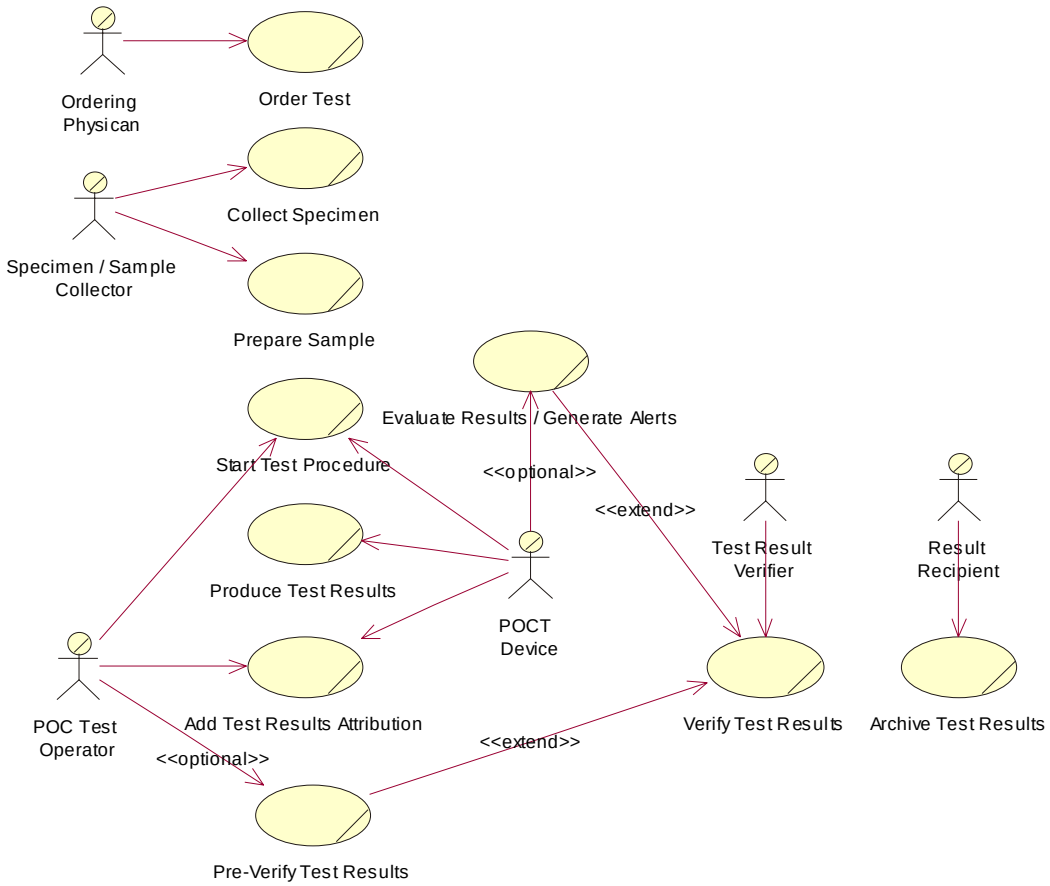



Figure 7: Simple Test Result Use Case Diagram

An activity diagram can also be constructed to describe this use case. This diagram illustrates the flow of data and activity between the Test Operator, the POC Device, the Result Verifier, and the Result Recipient.

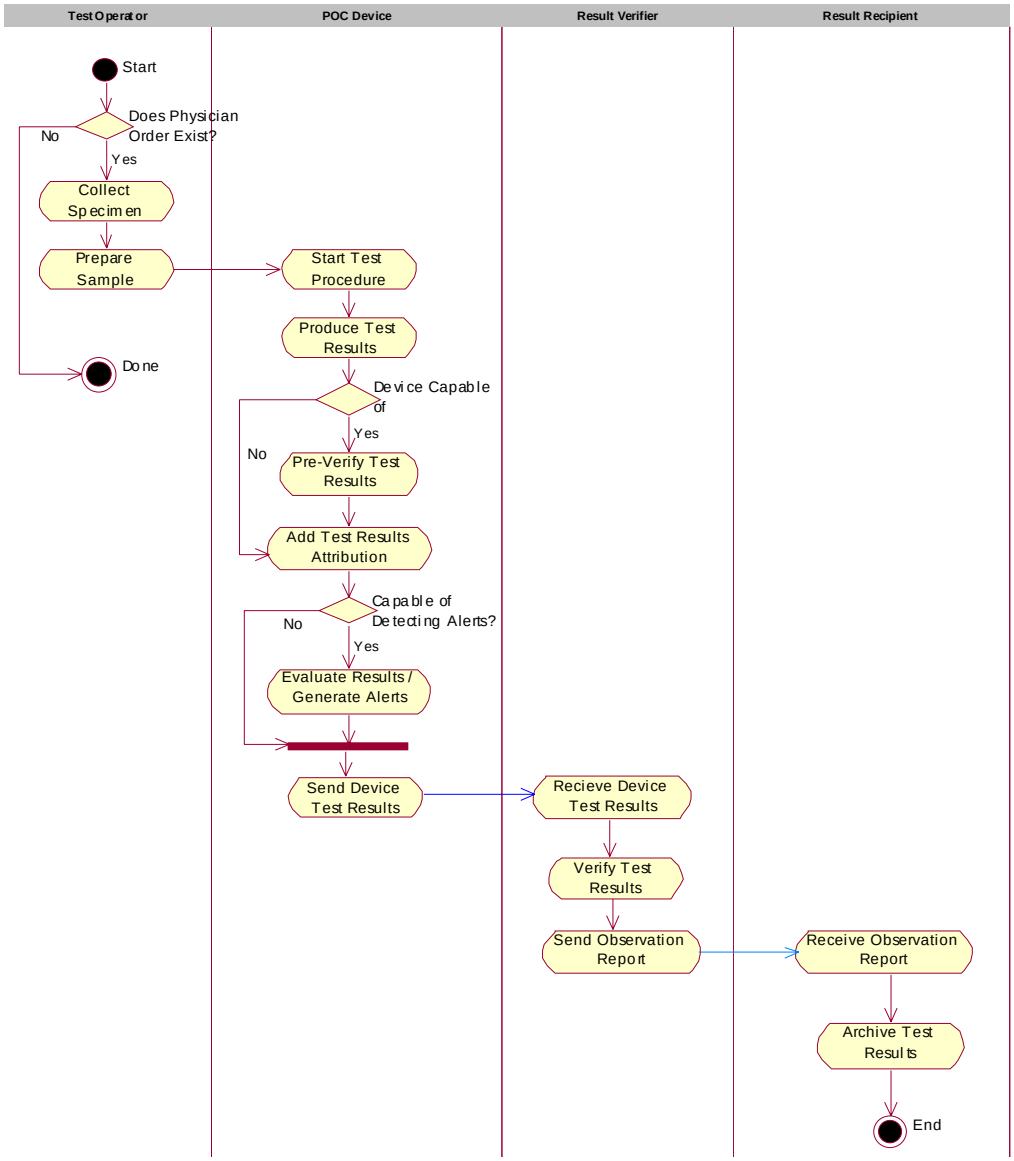



Figure 8: Simple Test Result Activity Diagram

## 6.2 Device Interface

The following sections describe the upper-layer messaging protocol used by all CIC compliant devices. The HL7 information and messaging models provide the basis for this protocol.

To develop these specifications, the technical teams first analyzed the simple patient test result use case to produce a Message Profile. This profile defines the objects and attributes to be communicated, as well as the cardinality relationship between message elements. The technical teams then defined the data types and coding standards to use for each element in the message profile.

From this message profile, both HI7-ER and XML syntax messages may be constructed. Example exchanges using both of these encoding schemes are shown in the following sections.

### 6.2.1 Message Profile

| Version ID | 9eda6bba-fa6f-43ea-a45e-eddfa1f48117 | | | | | |
|---|---|---|---|---|---|---|
| **Class** | **Attribute** | **Min. Card** | **Max. Card** | **Coding Stand.** | **Comments/Questions** | **v2.x Seg. Used** |
| **POC Device** | | **1** | **1** | | | |
| | Identifier(1) | 1 | 1 | IEEE | Device Type / Serial number / GUID<br>- could be “Manual” for manual test? | OBX-15 |
| **Operator** | | **1** | **1** | | | |
| | Identifier | 1 | 1 | | Could be empty. Though desired in the US, it is not in other countries (see note 6) | OBX-16 |
| **Patient** | | **1** | **1** | | | |
| | Identifier | 1 | 1 | | Could be empty (see note 6) | PID-3 |
| **Specimen** | | **1** | **1** | | | |
| | Identifier | 1 | 1 | | Accession number | OBR-2 |
| | Role | 1 | 1 | | Identifies patient, control, linearity, etc. | |
| | Type | 1 | 1 | | Identifies sample – venous, capillary, etc. | |
| **Observation** | | **1** | **1** | | | |
| | Analysis Date & Time(3) | 1 | 1 | HL7 | ccyymmddhhmmss plus optional timezone information(7) | OBX-14 |
| | Comment(4) | 1 | 3 | | Describes conditions, events or circumstances that may need to be considered when using the observation. | NTE-3 |
| **Result**[5] | | 1 | * | | | |
| | Service Identifier | 1 | 1 | ISO or LOINC | | OBR-4 |
| | Value | 1 | 1 | | Examples: “150”, “<50”, “>550”, “HI”, “LO” | OBX-5 |
| | Units | 1 | 1 | | Units of measurement | OBX-6 |
| | Value Flag | 1 | 4 | | Any flags or alarms associated with result.<br>Temp error, expired strip, etc. | OBX-8 |

NOTES:

| # | Date | Who | Note |
|---|---|---|---|
| 1 | 6/8/00 | Device Team | Identifier should be globally unique. IEEE format consists of IEEE-assigned organization id field, followed by organization-assigned id. |
| 2 | 6/8/00 | Device Team | Order group deleted, and Identifier moved to Specimen object, as the accession number is related to the specimen. |
| 3 | 6/8/00 | Device | One-second resolution was felt to be adequate for POCT result reports. |
| 4 | 4/8/00 | Rick Lebo | Refer to Rick Lebo's comment field use case document |
| 5 | 6/15 | Device Team | Range reporting struck. Rational: Reference and Critical range not likely known by device, and Measurement Range is only useful internally: e.g. to format the Value field ('<50') |
| 6 | 6/15 | Device Team | Most devices can record, at most, one identifier – usually either operator, patient, or accession number<br>The identifier values for Operator and Patient may be left blank, if unknown/unspecified. If insufficient information is supplied to the Result Observer, an exception should be generated. |
| 7 | 6/15 | Device Team | Timezone qualification of the date/time is optional. If the timezone is omitted from the message, the time is assumed to be 'local time' (where the device is located). |
| | | | |

## 6.2.2 HL7 Message Specification

The following sections describe how to implement the Message Profile describe above, using either the HL7v2.x ER syntax or the XML encoding.

The Abstract Message Syntax in HL7 v2.3.1 specifies the arrangement of segments within a message. The simple patient test result message's structure is defined using this syntax as follows:

| STR | Point-of-care Simple Test Result |
|---|---|
| MSH | Message Header |
| { PID | Patient Identification |
| ORC | Common Order information |
| OBX | Observation result |
| { NTE } | Note or comments |
| } | |

The brackets and braces have the following meaning:

| HL7 ABSTRACT MESSAGE SYNTAX | OCCURRENCE |
|---|---|
| [] | Zero or one |
| {} | One or more |
| {[]} = [{}] | Zero or more |
| - no bracket or brace - | One exactly |

### 6.2.3 HL7 v2.x Equivalent (ER Syntax)

The Device Interface team has developed CIC HL7 v2.x segment tables from the Message Profiles. The following segment tables are intended to show how the information might be required to be encoded into HL7 per the 0.1 Draft specifications. Note the use of Message Profile Content information for the option status of fields.

### 6.2.3.1 MSH – Message Header Segment

DRAFT

| SEQ | LEN | DT | OPT | HL7 SEGMENT FIELD NAME | NOTES ON CIC USE |
|---|---|---|---|---|---|
| 1 | 1 | ST | R | Field Separator | "\|" unless otherwise required |
| 2 | 4 | ST | R | Encoding Characters | "^~\&" unless otherwise required |
| 3 | 180 | HD | RE | Sending Application | Vendor/Site Specific |
| 4 | 180 | HD | RE | Sending Facility | Vendor/Site Specific |
| 5 | 180 | HD | RE | Receiving Application | Vendor/Site/ Specific |
| 6 | 180 | HD | RE | Receiving Facility | Vendor/Site Specific |
| 7 | 26 | TS | R | Date/Time Of Message | CCYYMMDDHHMMSS |
| 8 | 40 | ST | X | Security | |
| 9 | 7 | CM | R | Message Type | Note (1) |
| 10 | 20 | ST | R | Message Control ID | Vendor Specific, Note (2) |
| 11 | 3 | PT | R | Processing ID | "T"/"D"/"P" (Training, Debug, Production) |
| 12 | 8 | ID | R | Version ID | 2.3 or higher |
| 13 | 15 | NM | X | Sequence Number | |
| 14 | 180 | ST | X | Continuation Pointer | |
| 15 | 2 | ID | R | Accept Acknowledgment Type | "AL" Note (3) |
| 16 | 2 | ID | R | Application Acknowledgment Type | "AL", "NE" Note (4) |
| 17 | 2 | ID | RE | Country Code | Empty for USA |

Any fields defined beyond Sequence 17 are ignored by this specification.

(1) ORU^R01 for Result without Order,
ACK^R01 for Application acknowledgment to ORU^R01

ACK for all Accept/Commit Level acknowledgments

(2) Message Control ID format is vendor specific. Receiver must be prepared to accept at least 32 characters and must return the identical Message Control ID in MSA-2 for both Accept/Commit Level and Application Level acknowledgments.

(3) All source messages (~~ORM~~, ORU, ORR, ACK^R01) should specify "AL" - Always Accept/Commit Acknowledge. Accept/Commit Acknowledgments (ACK) should specify "NE"

(4) For Original Acknowledge Mode all Order/Result messages (ORU) will specify "NE" - Never Application Acknowledge.
For Enhanced Acknowledge Mode all Order/Result messages (ORU) will specify "AL" – Always Application Acknowledge.
All Acknowledgment Messages (ORR, ACK) must specify "NE" – Never Application Acknowledge.

## 6.2.3.2 MSA – General Acknowledgment Segment

DRAFT

| SEQ | LEN | DT | OPT | HL7 SEGMENT FIELD NAME | DESCRIPTION and CIC USE |
|---|---|---|---|---|---|
| 1 | 2 | ID | R | Acknowledgment Code | “CA”, “CE”, ”CR”, ”AA”, ”AE”, ”AR”, Note (1) |
| 2 | 20 | ST | R | Message Control ID | From MSH-10 of associated message |
| 3 | 80 | ST | RE | Text Message | Note (2) |
| 4 | 15 | NM | X | Expected Sequence Number | |
| 5 | 1 | ID | X | Delayed Acknowledgment Type | |
| 6 | 100 | CE | RE | Error Condition | Error Code, Note (3) |

Any fields defined beyond Sequence 6 will be ignored by this specification.

(1) “CA”, “CE”, “CR” Accept/Commit Level Acknowledge, Error, or Rejected.
“AA”, “AE”, “AR” Application Level Acknowledge, Error, or Rejected.
’Use of CE vs. CR and AE vs. AR is vendor /site specific.

(2) “CA” – Should be empty
“AA” – Order Message Acknowledgments must specify Accession Number or other database “key” for order and result.
“CE”, “CR”, “AE”, “AR” – Must specify detailed error message

(3) Error Code corresponding to MSA-3, if any.

## 6.2.3.3 PID– Patient Identification Segment

DRAFT

| SEQ | LEN | DT | OPT | HL7 SEGMENT FIELD NAME | NOTES ON CIC USE |
|---|---|---|---|---|---|
| 1 | 4 | SI | X | Set ID - Patient ID | |
| 2 | 20 | CX | X | Patient ID (External ID) | |
| 3 | 20 | CX | R | Patient ID (Internal ID) | Patient ID Entered in the Instrument, Note (1) |
| 4 | 20 | CX | X | Alternate Patient ID – PID | |
| 5 | 48 | XPN | X | Patient Name | if available ???? |
| 6 | 48 | XPN | X | Mother's Maiden Name | |
| 7 | 26 | TS | X | Date/Time of Birth | if available ???? |
| 8 | 1 | IS | X | Sex | if available ???? |
| 9 | 48 | XPN | X | Patient Alias | |
| 10 | 1 | IS | X | Race | |
| 11 | 106 | XAD | X | Patient Address | |
| 12 | 4 | IS | C | Country Code | Empty for USA |
| 13 | 40 | XTN | X | Phone Number – Home | |
| 14 | 40 | XTN | X | Phone Number – Business | |
| 15 | 60 | CE | X | Primary Language | |
| 16 | 1 | IS | X | Marital Status | |
| 17 | 3 | IS | X | Religion | |
| 18 | 20 | CX | C | Patient Account Number | if required, Note (2) |
| 19 | 16 | ST | X | SSN Number – Patient | |

Any fields defined beyond Sequence 18 will be ignored for this test case.

(1) The Patient ID must be supplied as the value entered into the POC device. In the event that this is identical to the Patient Account Number, both this field and PID-18 should be provided.

(2) Account Number may be required to make Patient ID Unique as some facilities.

## 6.2.3.4 ORC– Common Order Segment

DRAFT

| SEQ | LEN | DT | OPT | HL7 SEGMENT FIELD NAME | NOTES ON CIC USE |
|---|---|---|---|---|---|
| 1 | 2 | ID | R | Order Control | "RE" Note (1) |
| 2 | 22 | EI | X | Placer Order Number | |
| 3 | 22 | EI | X | Filler Order Number | |
| 4 | 22 | EI | X | Placer Group Number | |
| 5 | 2 | ID | X | Order Status | |
| 6 | 1 | ID | X | Response Flag | |
| 7 | 200 | TQ | X | Quantity/Timing | |
| 8 | 200 | CM | X | Parent | |
| 9 | 26 | TS | X | Date/Time of Transaction | |
| 10 | 120 | XCN | X | Entered By | |
| 11 | 120 | XCN | X | Verified By | |
| 12 | 120 | XCN | X | Ordering Provider | |
| 13 | 80 | PL | X | Enterer's Location | |
| 14 | 40 | XTN | X | Call Back Phone Number | |
| 15 | 26 | TS | X | Order Effective Date/Time | |
| 16 | 200 | CE | X | Order Control Code Reason | |
| 17 | 60 | CE | X | Entering Organization | |
| 18 | 60 | CE | X | Entering Device | |

Any fields defined beyond Sequence 1 will be ignored for this test case.

(1) "NW" – New Order for ORM^O01. "RE" – Observations Follow for ORU^R01

NOTE: Some fields specified for ORC duplicate fields in the OBR or OBX. HL7 encourages the use of ORC for such values; however, to provide backward compatibility with some vendors who currently do not process the ORC segment, this information is also allowed to be specified in the OBR and OBX.

## 6.2.3.5 OBR – Observation Request Segment

DRAFT

| SEQ | LEN | DT | OPT | HL7 SEGMENT FIELD NAME | NOTES ON CIC USE |
|---|---|---|---|---|---|
| 1 | 4 | SI | X | Set ID – OBR | |
| 2 | 75 | EI | R | Placer Order Number | Accession Number, if available |
| 3 | 75 | EI | X | Filler Order Number | |
| 4 | 200 | CE | R | Universal Service ID | e.g. GLU^GLUCOSE |
| 5 | 2 | ID | X | Priority | |
| 6 | 26 | TS | X | Requested Date/time | |
| 7 | 26 | TS | X | Observation Date/Time | |
| 8 | 26 | TS | X | Observation End Date/Time | |
| 9 | 20 | CQ | X | Collection Volume | |
| 10 | 60 | XCN | X | Collector Identifier | |
| 11 | 1 | ID | X | Specimen Action Code | |
| 12 | 60 | CE | X | Danger Code | |
| 13 | 300 | ST | X | Relevant Clinical Info. | |
| 14 | 26 | TS | X | Specimen Received Date/Time | |
| 15 | 300 | CM | X | Specimen Source | |
| 16 | 80 | XCN | X | Ordering Provider | |
| 17 | 40 | XTN | X | Order Callback Phone Number | |
| 18 | 60 | ST | X | Placer field 1 | |
| 19 | 60 | ST | X | Placer field 2 | |
| 20 | 60 | ST | X | Filler Field 1 | |
| 21 | 60 | ST | X | Filler Field 2 | |
| 22 | 26 | TS | X | Results Rpt/Status Chng – Date/Time | |
| 23 | 40 | CM | X | Charge to Practice | |
| 24 | 10 | ID | X | Diagnostic Serv Sect ID | |
| 25 | 1 | ID | X | Result Status | |
| 26 | 400 | CM | X | Parent Result | |
| 27 | 200 | TQ | X | Quantity/Timing | |
| 28 | 150 | XCN | X | Result Copies To | |
| 29 | 150 | CM | X | Parent | |
| 30 | 20 | ID | X | Transportation Mode | |
| 31 | 300 | CE | X | Reason for Study | |
| 32 | 200 | CM | X | Principal Result Interpreter | |
| 33 | 200 | CM | X | Assistant Result Interpreter | |
| 34 | 200 | CM | X | Technician | |
| 35 | 200 | CM | X | Transcriptionist | |
| 36 | 26 | TS | X | Scheduled Date/Time | |

Any fields defined beyond Sequence 4 will be ignored for this test case.

## 6.2.3.6 OBX – Observation Result Segment

DRAFT

| SEQ | LEN | DT | OPT | HL7 SEGMENT FIELD NAME | NOTES ON CIC USE |
|---|---|---|---|---|---|
| 1 | 10 | SI | X | Set ID - OBX | |
| 2 | 2 | ID | R | Value Type | CIC values “ST” (string) |
| 3 | 590 | CE | R | Observation Identifier | e.g. GLU or GLUCOSE (site specific) |
| 4 | 20 | ST | X | Observation Sub-ID | |
| 5 | 65536 | * | R | Observation Value | E.g. “150”, “<50”, “>550”, “HI”, “LO” |
| 6 | 60 | CE | R | Units | “mg/dl” or similar, see HL7 7.3.2.6 |
| 7 | 10 | ST | X | References Range | documentation use only |
| 8 | 5 | ID | RE | Abnormal Flags | documentation use only |
| 9 | 5 | NM | X | Probability | |
| 10 | 2 | ID | X | Nature of Abnormal Test | |
| 11 | 1 | ID | R | Observ Result Status | “F” (final result) |
| 12 | 26 | TS | X | Date Last Obs Normal Values | |
| 13 | 20 | ST | X | User Defined Access Checks | |
| 14 | 26 | TS | R | Date/Time of the Observation | CCYYMMDDHHMMSS from the device |
| 15 | 60 | CE | RE | Producer's ID | Instrument Type^Serial Number |
| 16 | 80 | XCN | RE | Responsible Observer | POC User ID |
| 17 | 60 | CE | X | Observation Method | |

Any fields defined beyond Sequence 16 will be ignored for this test case.

(1) Some devices can record “HI” or “LO” or similar as the result value when beyond the range of the instrument. In addition, some sites wish to have values outside site defined ranges to be specified in the form “< 50” or “>550”. The Reporter may also convert these values to some reference range limit at the Hospital’s request.

(2) Care must be exercised when providing Reference Range or Abnormal Flag Values in an Recipient transfer. Should these values be used by nursing or other personnel to adjust their treatment plan, it might well bring the interface under FDA regulation or open the interface vendor to possibility legal liabilities. While some sites may require such support, their wide spread use is discouraged by this standard.

## 6.2.3.7 NTE – Notes And Comments Segment

DRAFT

| SEQ | LEN | DT | OPT | ELEMENT NAME | |
|---|---|---|---|---|---|
| 1 | 4 | SI | X | Set ID - NTE | |
| 2 | 8 | ID | X | Source of Comment | application specific |
| 3 | 64k | FT | RE | Comment | Comment 1~Comment 2~Comment 3 |

## 6.2.4 HL7 v2.x Equivalent (XML Syntax)

The HL7 XML Special Interest Group has developed a recommendation for how to encode HL7 Version 2.3.1 message instances using XML. This recommendation is contained in *Using XML as a Supplementary Messaging Syntax for HL7 Version 2.3.1*. This document describes translation algorithms that may be applied to derive XML Document Type Declarations (DTDs) from the normative 2.3.1 message tables.

As the XML message syntax is derived directly from the standard encoded message definitions, the XML DTDs for the simple test result message are not listed here. An example of an XML-encoded test result exchange is provided in the following section.

## 6.2.5 Sample Message Exchange

These example exchanges use the following sample data:

- Device Type (“POCD”)
- Device Identifier (meter serial number “1A2B3”)
- User ID (“9876”)
- Patient ID of the Patient (MR# “12345678”)
- Accession Number of the ordered test (“A24680”)
- Test Date and Time (06/09/2000 10:21:35 AM UCT)
- Comment Codes or Text (“Stat”, “Physician Notified:)
- Service ID (“GLU” for Glucose)
- Test Result in mg/dl (105 mg/dl)
- Value Flag (empty)

The following sections illustrate example exchanges, using both the ER and XML encoding syntaxes.

### 6.2.5.1 HL7 v2.3.x Equivalent (ER Syntax)

**Note**: In the following samples individual segments are placed on separate lines for readability; this does not imply the presence of a <CR>, <LF>, or other end of line designation unless explicitly expressed.

ORU^R01 Observation Result Message From POCD Meter to RALS-G sent 6/10/00 1:03:55

```
<VT>
MSH|^~\&|POCD|POCD|RALS|RALS-G|
20000610010355||ORU^R01|20000610010355:023|P|2.3|||AL|AL|<CR>

PID|||12345678|<CR>

ORC|RE|<CR>

OBR||A24680||GLU^GLUCOSE|<CR>

OBX||ST|GLU^GLUCOSE||120|MG/DL|||||F|||20000609102135|POCD|1A2B3||<CR>

NTE|||STAT~PHYSICIAN NOTIFIED<CR>

<FS><CR>
```

RALS-G must reply immediately with either a Commit ACK specifying CA, CE, or CR. RALS-G generates its own Message Control ID and uses the Message Control ID field from the received message for MSA;2. For success:

```
<VT>

MSH|^~\&|RALS|RALS-G|POCD|POCD|
20000610010356||ACK|20000610010356CA|P|2.3|||NE|NE|<CR>

MSA|CA|20000610010355:023|<CR>

<FS><CR>
```

Otherwise, for a Commit error:

```
<VT>

MSH|^~\&|RALS|RALS-G|POCD|POCD|
20000610010356||ACK|20000610010356CE|P|2.3|||NE|NE|<CR>

MSA|CE|20000610010355:023|TCP COMM ERROR, INVALID HL7 MESSAGE|||3214<CR>

<FS><CR>
```

## 6.2.5.2 HL7 v2.3.x Equivalent (XML Syntax)

Using the HL7 v2.3.1 Document Type Definitions (DTDs) and the sample message values, the XML-encoded message would look like the following documents.

Note that the document type used for the primary message is a 'STR' ("Simple Test Result") type. The basis for this message organization is an ORU message, however, the CIC has specified different field optionality for this message. So, the novel name (STR) distinguishes this message type from the standard ORU message.

```
<!DOCTYPE STR SYSTEM "hl7_v231.dtd">
<STR>
<MSH>
        <MSH.1>|</MSH.1>                                <!-- Field seperator -->
        <MSH.2>^~\&amp;amp;</MSH.2>                     <!-- Encoding characters -->
        <MSH.7>20000610010355</MSH.7>                   <!-- Date/Time of message -->
        <MSH.9>                                         <!--Message type -->
                <CM_MSG_TYPE.1>STR</CM_MSG_TYPE.1>
                <CM_MSG_TYPE.2>R01</CM_MSG_TYPE.2>
        </MSH.9>
        <MSH.10>20000610010355:023</MSH.10>             <!--Message control ID -->
        <MSH.11><PT.1>P</PT.1></MSH.11>                 <!--Processing ID (Train/Debug/Prod)-->
        <MSH.12><VID.1>2.3.1</VID.1></MSH.12>           <!--Version ID -->
        <MSH.15>AL</MSH.15>                             <!--Accept Acknowledgement type -->
        <MSH.16>AL</MSH.16>                             <!--Application Acknowledgement type -->
</MSH>
<PID>
        <PID.3>12345678</PID.3>                         <!--Patient ID (internal) -->
</PID>
<ORC>
        <ORC.1>RE</ORC.1>                               <!--Order control (RE=obsv follows) -->
</ORC>
<OBR>
        <OBR.2>A24680</OBR.2>                           <!--Placer order number -->
        <OBR.4>GLU^GLUCOSE</OBR.4>                      <!--Universal service ID -->
</OBR>
<OBX>
        <OBX.2><CE.1>ST</CE.1></OBX.2>                  <!--Value type (ST=string) -->
```

```
        <OBX.3><CE.1>GLU^GLUCOSE</CE.1></OBX.3>   <!--Observation ID -->
        <OBX.5>120</OBX.5>                        <!--Observation value -->
        <OBX.6><CE.1>mg/dl</CE.1></OBX.6>         <!--Observation units -->
        <OBX.11>F</OBX.11>                        <!--Observation result status (F=final)-->
        <OBX.14>20000609102135</OBX.14>           <!--Observation time (from device) -->
        <OBX.15><CE.1>1A2B3</CE.1></OBX.15>       <!--Producer ID (device GUID) -->
        <OBX.16><XCN.1>9876</XCN.1></OBX.16>      <!--Responsible observer (user id) -->
</OBX>
<NTE>
        <NTE.3>Stat ~ Physician notified</NTE.3>  <!--Notes and comments -->
</NTE>
</STR>
```

The Result Observer must reply immediately with either a Commit ACK specifying CA, CE, or CR. The Result Observer generates its own Message Control ID and uses the Message Control ID field from the received message for MSA;2. For success:

```
<!DOCTYPE STR SYSTEM "hl7_v231.dtd">
<ACK>
<MSH>
        <MSH.1>|</MSH.1>                          <!-- Field seperator -->
        <MSH.2>^~\&amp;amp;</MSH.2>               <!-- Encoding characters -->
        <MSH.7>20000610010356</MSH.7>             <!-- Date/Time of message -->
        <MSH.9>                                   <!--Message type -->
                <CM_MSG_TYPE.1>STR</CM_MSG_TYPE.1>
                <CM_MSG_TYPE.2>R01</CM_MSG_TYPE.2>
        </MSH.9>
        <MSH.10>20000610010356CA</MSH.10>         <!--Message control ID -->
        <MSH.11><PT.1>P</PT.1></MSH.11>           <!--Processing ID (Train/Debug/Prod)-->
        <MSH.12><VID.1>2.3.1</VID.1></MSH.12>     <!--Version ID -->
        <MSH.15>NE</MSH.15>                       <!--Accept Acknowledgement type -->
        <MSH.16>NE</MSH.16>                       <!--Application Acknowledgement type -->
</MSH>
<MSA>
        <MSA.1>CA</MSA.1>                         <!--Ack code (CA=commit accept) -->
        <MSA.2>20000610010355:023</MSA.2>         <!--Msg control ID (from MSH.10) -->
</MSA>
</ACK>
```

Otherwise, for a Commit error, the Result Observer would send a “Commit Error” message acknowledgement:

```
<!DOCTYPE STR SYSTEM "hl7_v231.dtd">
<ACK>
<MSH>
        <MSH.1>|</MSH.1>                          <!-- Field seperator -->
        <MSH.2>^~\&amp;amp;</MSH.2>               <!-- Encoding characters -->
        <MSH.7>20000610010356</MSH.7>             <!-- Date/Time of message -->
        <MSH.9>                                   <!--Message type -->
                <CM_MSG_TYPE.1>STR</CM_MSG_TYPE.1>
                <CM_MSG_TYPE.2>R01</CM_MSG_TYPE.2>
        </MSH.9>
        <MSH.10>20000610010356CE</MSH.10>         <!--Message control ID -->
        <MSH.11><PT.1>P</PT.1></MSH.11>           <!--Processing ID (Train/Debug/Prod)-->
        <MSH.12><VID.1>2.3.1</VID.1></MSH.12>     <!--Version ID -->
        <MSH.15>NE</MSH.15>                       <!--Accept Acknowledgement type -->
```

```
        <MSH.16>NE</MSH.16>                    <!--Application Acknowledgement type -->
</MSH>
<MSA>
        <MSA.1>CE</MSA.1>                      <!--Ack code (CE=commit error) -->
        <MSA.2>20000610010355:023</MSA.2>      <!--Msg control ID (from MSH.10) -->
        <MSA.3>Invalid HL7 Message<MSA.3>      <!--Error text message -->
        <MSA.6><CE.1>3214<CE.1><MSA.6>         <!--Error condition -->
</MSA>
</ACK>
```

## 6.3 EDI Interface

The following sections describe the upper-layer messaging protocol used by all CIC compliant Result Reviewers (e.g. POC Data Managers) to communication with Result Recipients (e.g. LIS, CDR). The HL7 information and messaging models provide the basis for this protocol.

To develop these specifications, the technical teams first analyzed the simple patient test result use case to produce a Message Profile. This profile defines the objects and attributes to be communicated, as well as the cardinality relationship between message elements. The technical teams then defined the data types and coding standards to use for each element in the message profile.

From this message profile, both Hl7-ER and XML syntax messages may be constructed. Example exchanges using both of these encoding schemes are shown in the following sections.

### 6.3.1 Message Profile

| Version ID | 2ad29160-935b-4a99-8d45-a308928e21fa | | | | | |
|---|---|---|---|---|---|---|
| **Class** | **Attribute** | **Min. Card** | **Max. Card** | **Coding Stand.** | **Comments/Questions** | **v2.x Seg. Used** |
| **Device** | | **1** | **1** | | | |
| | Identifier(1) | 1 | 1 | IEEE | Device Type / Serial number / GUID<br>- could be “Manual” for manual test? | OBX-15 |
| **Operator** | | **1** | **1** | | | |
| | Identifier | 1 | 1 | | Could be empty. Though desired in the US, it is not in other countries (see note 6) | OBX-16 |
| **Patient** | | **1** | **1** | | | |
| | Identifier | 1 | 1 | | Could be empty (see note 6) | PID-3 |
| **Specimen** | | **1** | **1** | | | |
| | Identifier | 1 | 1 | | Accession number | OBR-2 |
| | Role | 1 | 1 | | Identifies patient, control, linearity, etc. | |
| | Type | 1 | 1 | | Identifies sample – venous, capillary, etc. | |
| **Observation** | | **1** | **1** | | | |
| | Analysis Date & Time(3) | 1 | 1 | HL7 | ccyymmddhhmmss plus optional timezone information(7) | OBX-14 |
| | Comment(4) | 1 | 3 | | Describes conditions, events or circumstances that may need to be considered when using the observation. | NTE-3 |
| **Result**[5] | | **1** | **1** | | | |
| | Service Identifier | 1 | 1 | ISO or LOINC | | OBR-4 |
| | Value | 1 | 1 | | Examples: “150”, “<50”, “>550”, “HI”, “LO” | OBX-5 |
| | Units | 1 | 1 | | Units of measurement | OBX-6 |
| | Value Flag | 1 | 4 | | Any flags or alarms associated with result.<br>Temp error, expired strip, etc. | OBX-8 |

### 6.3.2 HL7 Message Definition

The following sections describe how to implement the Message Profile describe above, using either the HL7v2.x ER syntax or the XML encoding.

The Abstract Message Syntax in HL7 v2.3.1 specifies the arrangement of segments within a message. The simple patient test result message's structure is defined using this syntax as follows:

| STR | Point-of-Care Simple Test Result |
|---|---|
| MSH | Message Header |
| { PID | Patient Identification |
| ORC | Common Order information |
| OBX | **OBSERVATION RESULT** |
| { NTE } | Note or comments |
| } | |

The brackets and braces have the following meaning:

| HL7 ABSTRACT MESSAGE SYNTAX | OCCURRENCE |
|---|---|
| [] | Zero or one |
| {} | One or more |
| {[]} = [{}] | Zero or more |
| - no bracket or brace - | One exactly |

### 6.3.3 HL7 v2.x Equivalent (ER Syntax)

The following Segment tables are intended to show how the information might be required to be encoded into HL7 per the 0.1 Draft specifications. Note the use of Message Profile Content information for the option status of fields.

### 6.3.3.1 MSH – Message Header Segment

DRAFT

| SEQ | LEN | DT | OPT | HL7 SEGMENT FIELD NAME | NOTES ON CIC USE |
|---|---|---|---|---|---|
| 1 | 1 | ST | R | Field Separator | "\|" unless otherwise required |
| 2 | 4 | ST | R | Encoding Characters | "^~\&" unless otherwise required |
| 3 | 180 | HD | RE | Sending Application | Vendor/Site Specific |
| 4 | 180 | HD | RE | Sending Facility | Vendor/Site Specific |
| 5 | 180 | HD | RE | Receiving Application | Vendor/Site/ Specific |
| 6 | 180 | HD | RE | Receiving Facility | Vendor/Site Specific |
| 7 | 26 | TS | R | Date/Time Of Message | CCYYMMDDHHMMSS |
| 8 | 40 | ST | X | Security | |
| 9 | 7 | CM | R | Message Type | Note (1) |
| 10 | 20 | ST | R | Message Control ID | Vendor Specific, Note (2) |
| 11 | 3 | PT | R | Processing ID | "T"/"D"/"P" (Training, Debug, Production) |
| 12 | 8 | ID | R | Version ID | 2.3 or higher |
| 13 | 15 | NM | X | Sequence Number | |
| 14 | 180 | ST | X | Continuation Pointer | |
| 15 | 2 | ID | R | Accept Acknowledgment Type | "AL" Note (3) |
| 16 | 2 | ID | R | Application Acknowledgment Type | "AL", "NE" Note (4) |
| 17 | 2 | ID | RE | Country Code | Empty for USA |

Any fields defined beyond Sequence 17 are ignored by this specification.

(1) ORU^R01 for Result without Order,
ACK^R01 for Application acknowledgment to ORU^R01

(2) ACK for all Accept/Commit Level acknowledgments

(3) Message Control ID format is vendor specific. Receiver must be prepared to accept at least 32 characters and must return the identical Message Control ID in MSA-2 for both Accept/Commit Level and Application Level acknowledgments.

All source messages (ORU, ACK^R01) should specify "AL" - Always Accept/Commit Acknowledge. Accept/Commit Acknowledgments (ACK) should specify "NE"

For Original Acknowledge Mode: all Order/Result messages (ORU) will specify "NE" - Never Application Acknowledge.

For Enhanced Acknowledge Mode: all Order/Result messages (ORU) will specify "AL" – Always Application Acknowledge.

All Acknowledgment Messages (ACK) must specify "NE" – Never Application Acknowledge.

## 6.3.3.2 MSA – General Acknowledgment Segment

DRAFT

| SEQ | LEN | DT | OPT | HL7 SEGMENT FIELD NAME | DESCRIPTION and CIC USE |
|---|---|---|---|---|---|
| 1 | 2 | ID | R | Acknowledgment Code | "CA", "CE", "CR", "AA", "AE", "AR", Note (1) |
| 2 | 20 | ST | R | Message Control ID | From MSH-10 of associated message |
| 3 | 80 | ST | RE | Text Message | Note (2) |
| 4 | 15 | NM | X | Expected Sequence Number | |
| 5 | 1 | ID | X | Delayed Acknowledgment Type | |
| 6 | 100 | CE | RE | Error Condition | Error Code, Note (3) |

Any fields defined beyond Sequence 6 will be ignored by this specification.

(1) "CA", "CE", "CR" Accept/Commit Level Acknowledge, Error, or Rejected.
"AA", "AE", "AR" Application Level Acknowledge, Error, or Rejected.
'Use of CE vs. CR and AE vs. AR is vendor /site specific.

(2) "CA" – Should be empty
"AA" – Order Message Acknowledgments must specify Accession Number or other database "key" for order and result.
"CE", "CR", "AE", "AR" – Must specify detailed error message

(3) Error Code corresponding to MSA-3, if any.

## 6.3.3.3 PID– Patient Identification Segment

DRAFT

| SEQ | LEN | DT | OPT | HL7 SEGMENT FIELD NAME | NOTES ON CIC USE |
|---|---|---|---|---|---|
| 1 | 4 | SI | X | Set ID - Patient ID | |
| 2 | 20 | CX | X | Patient ID (External ID) | |
| 3 | 20 | CX | R | Patient ID (Internal ID) | Patient ID Entered in the Instrument, Note (1) |
| 4 | 20 | CX | X | Alternate Patient ID – PID | |
| 5 | 48 | XPN | X | Patient Name | if available ???? |
| 6 | 48 | XPN | X | Mother's Maiden Name | |
| 7 | 26 | TS | X | Date/Time of Birth | if available ???? |
| 8 | 1 | IS | X | Sex | if available ???? |
| 9 | 48 | XPN | X | Patient Alias | |
| 10 | 1 | IS | X | Race | |
| 11 | 106 | XAD | X | Patient Address | |
| 12 | 4 | IS | C | Country Code | Empty for USA |
| 13 | 40 | XTN | X | Phone Number – Home | |
| 14 | 40 | XTN | X | Phone Number – Business | |
| 15 | 60 | CE | X | Primary Language | |
| 16 | 1 | IS | X | Marital Status | |
| 17 | 3 | IS | X | Religion | |
| 18 | 20 | CX | C | Patient Account Number | if required, Note (2) |
| 19 | 16 | ST | X | SSN Number – Patient | |

Any fields defined beyond Sequence 18 will be ignored for this test case.

(1) The Patient ID must be supplied as the value entered into the POC device. In the event that this is identical to the Patient Account Number, both this field and PID-18 should be provided.

(2) Account Number may be required to make Patient ID Unique as some facilities.

## 6.3.3.4 ORC– Common Order Segment

DRAFT

| SEQ | LEN | DT | OPT | HL7 SEGMENT FIELD NAME | NOTES ON CIC USE |
|---|---|---|---|---|---|
| 19 | 2 | ID | R | Order Control | "RE" Note (1) |
| 20 | 22 | EI | X | Placer Order Number | |
| 21 | 22 | EI | X | Filler Order Number | |
| 22 | 22 | EI | X | Placer Group Number | |
| 23 | 2 | ID | X | Order Status | |
| 24 | 1 | ID | X | Response Flag | |
| 25 | 200 | TQ | X | Quantity/Timing | |
| 26 | 200 | CM | X | Parent | |
| 27 | 26 | TS | X | Date/Time of Transaction | |
| 28 | 120 | XCN | X | Entered By | |
| 29 | 120 | XCN | X | Verified By | |
| 30 | 120 | XCN | X | Ordering Provider | |
| 31 | 80 | PL | X | Enterer's Location | |
| 32 | 40 | XTN | X | Call Back Phone Number | |
| 33 | 26 | TS | X | Order Effective Date/Time | |
| 34 | 200 | CE | X | Order Control Code Reason | |
| 35 | 60 | CE | X | Entering Organization | |
| 36 | 60 | CE | X | Entering Device | |

Any fields defined beyond Sequence 1 will be ignored for this test case.

(1) "NW" – New Order for ORM^O01. "RE" – Observations Follow for ORU^R01

NOTE: Some fields specified for ORC duplicate fields in the OBR or OBX. HL7 encourages the use of ORC for such values; however, to provide backward compatibility with some vendors who currently do not process the ORC segment, this information is also allowed to be specified in the OBR and OBX.

## 6.3.3.5 OBR – Observation Request Segment

DRAFT

| SEQ | LEN | DT | OPT | HL7 SEGMENT FIELD NAME | NOTES ON CIC USE |
|---|---|---|---|---|---|
| 1 | 4 | SI | X | Set ID – OBR | |
| 2 | 75 | EI | R | Placer Order Number | Accession Number, if available |
| 3 | 75 | EI | X | Filler Order Number | |
| 4 | 200 | CE | R | Universal Service ID | e.g. GLU^GLUCOSE |
| 5 | 2 | ID | X | Priority | |
| 6 | 26 | TS | X | Requested Date/time | |
| 7 | 26 | TS | X | Observation Date/Time | |
| 8 | 26 | TS | X | Observation End Date/Time | |
| 9 | 20 | CQ | X | Collection Volume | |
| 10 | 60 | XCN | X | Collector Identifier | |
| 11 | 1 | ID | X | Specimen Action Code | |
| 12 | 60 | CE | X | Danger Code | |
| 13 | 300 | ST | X | Relevant Clinical Info. | |
| 14 | 26 | TS | X | Specimen Received Date/Time | |
| 15 | 300 | CM | X | Specimen Source | |
| 16 | 80 | XCN | X | Ordering Provider | |
| 17 | 40 | XTN | X | Order Callback Phone Number | |
| 18 | 60 | ST | X | Placer field 1 | |
| 19 | 60 | ST | X | Placer field 2 | |
| 20 | 60 | ST | X | Filler Field 1 | |
| 21 | 60 | ST | X | Filler Field 2 | |
| 22 | 26 | TS | X | Results Rpt/Status Chng – Date/Time | |
| 23 | 40 | CM | X | Charge to Practice | |
| 24 | 10 | ID | X | Diagnostic Serv Sect ID | |
| 25 | 1 | ID | X | Result Status | |
| 26 | 400 | CM | X | Parent Result | |
| 27 | 200 | TQ | X | Quantity/Timing | |
| 28 | 150 | XCN | X | Result Copies To | |
| 29 | 150 | CM | X | Parent | |
| 30 | 20 | ID | X | Transportation Mode | |
| 31 | 300 | CE | X | Reason for Study | |
| 32 | 200 | CM | X | Principal Result Interpreter | |
| 33 | 200 | CM | X | Assistant Result Interpreter | |
| 34 | 200 | CM | X | Technician | |
| 35 | 200 | CM | X | Transcriptionist | |
| 36 | 26 | TS | X | Scheduled Date/Time | |

Any fields defined beyond Sequence 4 will be ignored for this test case.

## 6.3.3.6 OBX – Observation Result Segment

DRAFT

| SEQ | LEN | DT | OPT | HL7 SEGMENT FIELD NAME | NOTES ON CIC USE |
|---|---|---|---|---|---|
| 1 | 10 | SI | X | Set ID - OBX | |
| 2 | 2 | ID | R | Value Type | CIC values “ST” (string) |
| 3 | 590 | CE | R | Observation Identifier | e.g. GLU or GLUCOSE (site specific) |
| 4 | 20 | ST | X | Observation Sub-ID | |
| 5 | 65536 | * | R | Observation Value | E.g. “150”, “<50”, “>550”, “HI”, “LO” |
| 6 | 60 | CE | R | Units | “mg/dl” or similar, see HL7 7.3.2.6 |
| 7 | 10 | ST | X | References Range | documentation use only |
| 8 | 40 | ID | RE | Abnormal Flags | documentation use only |
| 9 | 5 | NM | X | Probability | |
| 10 | 2 | ID | X | Nature of Abnormal Test | |
| 11 | 1 | ID | R | Observ Result Status | “F” (final result) |
| 12 | 26 | TS | X | Date Last Obs Normal Values | |
| 13 | 20 | ST | X | User Defined Access Checks | |
| 14 | 26 | TS | R | Date/Time of the Observation | CCYYMMDDHHMMSS from the device |
| 15 | 60 | CE | RE | Producer's ID | Instrument Type^Serial Number |
| 16 | 80 | XCN | RE | Responsible Observer | POC User ID |
| 17 | 60 | CE | X | Observation Method | |

Any fields defined beyond Sequence 16 will be ignored for this test case.

(1) Some devices can record “HI” or “LO” or similar as the result value when beyond the range of the instrument. In addition, some sites wish to have values outside site defined ranges to be specified in the form “< 50” or “>550”. The Reporter may also convert these values to some reference range limit at the Hospital’s request.

(2) Care must be exercised when providing Reference Range or Abnormal Flag Values in an Recipient transfer. Should these values be used by nursing or other personnel to adjust their treatment plan, it might well bring the interface under FDA regulation or open the interface vendor to possibility legal liabilities. While some sites may require such support, their wide spread use is discouraged by this standard.

## 6.3.3.7 NTE – Notes And Comments Segment

DRAFT

| SEQ | LEN | DT | OPT | ELEMENT NAME | |
|---|---|---|---|---|---|
| 1 | 4 | SI | X | Set ID - NTE | |
| 2 | 8 | ID | X | Source of Comment | application specific |
| 3 | 64k | FT | RE | Comment | Comment 1~Comment 2~Comment 3 |

### 6.3.4 HL7 v2.x Equivalent (XML Syntax)

The HL7 XML Special Interest Group has developed a recommendation for how to encode HL7 Version 2.3.1 message instances using XML. This recommendation is contained in *Using XML as a Supplementary Messaging Syntax for HL7 Version 2.3.1*. This document describes translation algorithms that may be applied to derive XML Document Type Declarations (DTDs) from the normative 2.3.1 message tables.

As the XML message syntax is derived directly from the standard encoded message definitions, the XML DTDs for the simple test result message are not listed here. An example of an XML-encoded test result exchange is provided in the following section.

### 6.3.5 Sample Message Exchange

The following information will be encoded in the sample message exchanges.

- Device Identifier (globally unique identifier '1A2B3' – IEEE format)
- User ID ("9876")
- Patient ID of the Patient (MR# "12345678")
- Accession Number of the ordered test ("A24680")
- Test Date and Time (06/09/2000 10:21:35 AM UCT)
- Comment Codes or Text ("00")
- Service ID ("GLU" for Glucose)
- Test Result in mg/dl (105 mg/dl)
- Value Flag (empty)

The following sections illustrate example exchanges, using both the ER and XML encoding syntaxes.

#### 6.3.5.1 HL7 v2.3.x Equivalent (ER Syntax)

**Note**: In the following samples individual segments are placed on separate lines for readability; this does not imply the presence of a <CR>, <LF>, or other end of line designation unless explicitly expressed.

ORU^R01 Observation Result Message From RALS-LIS to SunQuest Flexilab LIS sent 6/10/00 1:03:55

```
<ACK>
MSH|^~\&|RALS|RALS-LIS|SQ|FLEXILAB|20000610010355||ORU^R01|20000610010355:023|P|2.3|||AL|AL|<CR>
PID|||12345678|<CR>
ORC|RE|<CR>
OBR||A24680||GLU^GLUCOSE|<CR>
OBX||ST|GLU^GLUCOSE||120|MG/DL|||||F|||20000609102135|ROCHE^HQ|77777||<CR>
NTE|||STAT~PHYSICIAN NOTIFIED<CR>
<FS><CR>
```

SQ must reply immediately with either a Commit ACK specifying CA, CE, or CR. SQ generates its own Message Control ID and uses the Message Control ID field from the received message for MSA;2. For success:

<ACK>

MSH|^~\&|SQ|FLEXILAB|RALS|RALS-LIS|20000610010356||ACK|20000610010356CA|P|2.3|||NE|NE|<CR>

MSA|CA|20000610010355:023|<CR>

<FS><CR>

Otherwise, for a Commit error:

<ACK>

MSH|^~\&|SQ|FLEXILAB|RALS|RALS-LIS|20000610010356||ACK|20000610010356CE|P|2.3|||NE|NE|<CR>

MSA|CE|20000610010355:023|TCP COMM ERROR, INVALID HL7 MESSAGE|||3214<CR>

<FS><CR>

**If this were Original Acknowledgment Mode** (as may be specified in ORU Message MSH-16, this would be the end of the transfer communication.

**For Enhanced Acknowledge Mode** (as is specified in ORU Message MSH-16) the following exchanges apply:

Later, the LIS must send an ACK message as an Application Acknowledgment. This message is created similar to the Commit Acknowledgment except that the Message Type is ACK^R01 rather than ACK and the ACK code is AA, AE, or AR.

**Other Use Case Note**: For Use Cases where both an Order and a Result are placed by the Observation Reviewer, a successful reply from the Order Receiver should also specify the Accession Number of the order in MSA-3. This positive Acknowledgment must indicate that BOTH the Order and the Result was successfully processed – i.e. the Order Receiver should never create an open Order without a Result.)

For success:

<ACK>

MSH|^~\&|SQ|FLEXILAB|RALS|RALS-LIS|20000610010400||ACK^R01|20000610010400AA|P|2.3|||AL|NE|<CR>

MSA|AA|20000610010355:023|<CR>

<FS><CR>

Otherwise, for an error:

<ACK>

MSH|^~\&|SQ|FLEXILAB|RALS|RALS-LIS|20000610010400||ACK^R01|20000610010400AE|P|2.3|||AL|NE|<CR>

MSA|AE|20000610010355:023|INVALID PATIENT ID|||5634<CR>

<FS><CR>

Finally, RALS-LIS will send a Communication Level ACK message for the LIS ACK Message:

<ACK>

MSH|^~\&|RALS|RALS-G|VQ|VQ/LAB|20000502010401||ACK|20000610010401CA|P|2.3|||NE|NE|<CR>

MSA|CA|20000610010400AA|||<CR>

<FS><CR>

## 6.3.5.2 HL7 v2.3.x Equivalent (XML Syntax)

The following XML documents illustrate the communication of a Simple Test Result Message ('STR') between a Result Verifier (RALS-LIS) and a Result Recipient (Sunquest Flexilab). This exchange is based on the HL7 v2.3.1 DTDs.

Note that the document type used for the primary message is a 'STR' ("Simple Test Result") type. The basis for this message organization is an ORU message, however, the CIC has specified different field optionality for this message. So, the novel name (STR) distinguishes this message type from the standard ORU message.

```
<!DOCTYPE STR SYSTEM "hl7_v231.dtd">
<STR>
<MSH>
        <MSH.1>|</MSH.1>                                <!-- Field seperator -->
        <MSH.2>^~\&amp;amp;</MSH.2>                     <!-- Encoding characters -->
        <MSH.3><HD.1>RALS</HD.1></MSH.3>                <!—Sending Application -->
        <MSH.4><HD.1>RALS-LIS<HD.1></MSH.4>             <!—Sending Facility -->
        <MSH.5><HD.1>SQ<HD.1></MSH.5>                   <!—Receiving Application -->
        <MSH.6><HD.1>Flexilab<HD.1></MSH.6>             <!—Receiving Facility -->
        <MSH.7>20000610010355</MSH.7>                   <!-- Date/Time of message -->
        <MSH.9>                                         <!--Message type -->
                <CM_MSG_TYPE.1>STR</CM_MSG_TYPE.1>
                <CM_MSG_TYPE.2>R01</CM_MSG_TYPE.2>
        </MSH.9>
        <MSH.10>20000610010355:023</MSH.10>             <!--Message control ID -->
        <MSH.11><PT.1>P</PT.1></MSH.11>                 <!--Processing ID (Train/Debug/Prod)-->
        <MSH.12><VID.1>2.3.1</VID.1></MSH.12>           <!--Version ID -->
        <MSH.15>AL</MSH.15>                             <!--Accept Acknowledgement type -->
        <MSH.16>AL</MSH.16>                             <!--Application Acknowledgement type -->
</MSH>
<PID>
        <PID.3>12345678</PID.3>                         <!--Patient ID (internal) -->
</PID>
<ORC>
        <ORC.1>RE</ORC.1>                               <!--Order control (RE=obsv follows) -->
</ORC>
<OBR>
        <OBR.2>A24680</OBR.2>                           <!--Placer order number -->
        <OBR.4>                                         <!--Universal service ID -->
                <CE.1>GLU</CE.1>
                <CE.2>GLUCOSE</CE.2>
        </OBR.4>
</OBR>
<OBX>
        <OBX.2><CE.1>ST</CE.1></OBX.2>                  <!--Value type (ST=string) -->
        <OBX.3><CE.1>GLU^GLUCOSE</CE.1></OBX.3>         <!--Observation ID -->
        <OBX.5>120</OBX.5>                              <!--Observation value -->
        <OBX.6><CE.1>mg/dl</CE.1></OBX.6>               <!--Observation units -->
        <OBX.11>F</OBX.11>                              <!--Observation result status (F=final)-->
        <OBX.14>20000609102135</OBX.14>                 <!--Observation time (from device) -->
        <OBX.15><CE.1>1A2B3</CE.1></OBX.15>             <!--Producer ID (device GUID) -->
        <OBX.16><XCN.1>9876</XCN.1></OBX.16>            <!--Responsible observer (user id) -->
</OBX>
<NTE>
        <NTE.3>Stat~Physician notified</NTE.3>          <!--Notes and comments -->
</NTE>
```

```
</STR>
```

The Result Observer (e.g. SQ) must reply immediately with either a Commit ACK specifying CA, CE, or CR. The Result Observer generates its own Message Control ID and uses the Message Control ID field from the received message for MSA.2. For success:

```
<!DOCTYPE STR SYSTEM "hl7_v231.dtd">
<ACK>
<MSH>
        <MSH.1>|</MSH.1>                                <!-- Field seperator -->
        <MSH.2>^~\&amp;</MSH.2>                         <!-- Encoding characters -->
        <MSH.3><HD.1>SQ</HD.1></MSH.3>                  <!—Sending Application -->
        <MSH.4><HD.1>Flexilab<HD.1></MSH.4>             <!—Sending Facility -->
        <MSH.5><HD.1>RALS<HD.1></MSH.5>                 <!—Receiving Application -->
        <MSH.6><HD.1>RALS-LIS<HD.1></MSH.6>             <!—Receiving Facility -->
        <MSH.7>20000610010356</MSH.7>                   <!-- Date/Time of message -->
        <MSH.9>                                         <!--Message type -->
                <CM_MSG_TYPE.1>STR</CM_MSG_TYPE.1>
                <CM_MSG_TYPE.2>R01</CM_MSG_TYPE.2>
        </MSH.9>
        <MSH.10>20000610010356CA</MSH.10>               <!--Message control ID -->
        <MSH.11><PT.1>P</PT.1></MSH.11>                 <!--Processing ID (Train/Debug/Prod)-->
        <MSH.12><VID.1>2.3.1</VID.1></MSH.12>           <!--Version ID -->
        <MSH.15>NE</MSH.15>                             <!--Accept Acknowledgement type -->
        <MSH.16>NE</MSH.16>                             <!--Application Acknowledgement type -->
</MSH>
<MSA>
        <MSA.1>CA</MSA.1>                               <!--Ack code (CA=commit accept) -->
        <MSA.2>20000610010355:023</MSA.2>               <!--Msg control ID (from MSH.10) -->
</MSA>
</ACK>
```

Otherwise, for a Commit error, the Result Observer would send a “Commit Error” message acknowledgement:

```
<!DOCTYPE STR SYSTEM "hl7_v231.dtd">
<ACK>
<MSH>
        <MSH.1>|</MSH.1>                                <!-- Field seperator -->
        <MSH.2>^~\&amp;</MSH.2>                         <!-- Encoding characters -->
        <MSH.3><HD.1>SQ</HD.1></MSH.3>                  <!—Sending Application -->
        <MSH.4><HD.1>Flexilab</HD.1></MSH.4>            <!—Sending Facility -->
        <MSH.5><HD.1>RALS</HD.1></MSH.5>                <!—Receiving Application -->
        <MSH.6><HD.1>RALS-LIS</HD.1></MSH.6>            <!—Receiving Facility -->
        <MSH.7>20000610010356</MSH.7>                   <!-- Date/Time of message -->
        <MSH.9>                                         <!--Message type -->
                <CM_MSG_TYPE.1>STR</CM_MSG_TYPE.1>
                <CM_MSG_TYPE.2>R01</CM_MSG_TYPE.2>
        </MSH.9>
        <MSH.10>20000610010356CE</MSH.10>               <!--Message control ID -->
        <MSH.11><PT.1>P</PT.1></MSH.11>                 <!--Processing ID (Train/Debug/Prod)-->
        <MSH.12><VID.1>2.3.1</VID.1></MSH.12>           <!--Version ID -->
        <MSH.15>NE</MSH.15>                             <!--Accept Acknowledgement type -->
        <MSH.16>NE</MSH.16>                             <!--Application Acknowledgement type -->
</MSH>
<MSA>
```

```
        <MSA.1>CE</MSA.1>                          <!--Ack code (CE=commit error) -->
        <MSA.2>20000610010355:023</MSA.2>          <!--Msg control ID (from MSH.10) -->
        <MSA.3>Invalid HL7 Message<MSA.3>          <!--Error text message -->
        <MSA.6><CE.1>3214<CE.1><MSA.6>             <!--Error condition -->
</MSA>
</ACK>
```

If this were Original Acknowledgment Mode (specified in ORU Message MSH-16), this would be the end of the transfer communication.

For Enhanced Acknowledge Mode (as is specified in ORU Message MSH-16) the following exchanges apply:

Later, the LIS must send an ACK message as an Application Acknowledgment. This message is created similar to the Commit Acknowledgment except that the Message Type is ACK^R01 rather than ACK and the ACK code is AA, AE, or AR.

For success:

```
<!DOCTYPE STR SYSTEM "hl7_v231.dtd">
<ACK>
<MSH>
        <MSH.1>|</MSH.1>                           <!-- Field seperator -->
        <MSH.2>^~\&amp;amp;</MSH.2>                <!-- Encoding characters -->
        <MSH.3><HD.1>SQ</HD.1></MSH.3>             <!—Sending Application -->
        <MSH.4><HD.1>Flexilab</HD.1></MSH.4>       <!—Sending Facility -->
        <MSH.5><HD.1>RALS</HD.1></MSH.5>           <!—Receiving Application -->
        <MSH.6><HD.1>RALS-LIS</HD.1></MSH.6>       <!—Receiving Facility -->
        <MSH.7>20000502010400</MSH.7>              <!-- Date/Time of message -->
        <MSH.9>                                    <!--Message type -->
                <CM_MSG_TYPE.1>STR</CM_MSG_TYPE.1>
                <CM_MSG_TYPE.2>R01</CM_MSG_TYPE.2>
        </MSH.9>
        <MSH.10>20000502010400AA</MSH.10>          <!--Message control ID -->
        <MSH.11><PT.1>P</PT.1></MSH.11>            <!--Processing ID (Train/Debug/Prod)-->
        <MSH.12><VID.1>2.3.1</VID.1></MSH.12>      <!--Version ID -->
        <MSH.15>NE</MSH.15>                        <!--Accept Acknowledgement type -->
        <MSH.16>NE</MSH.16>                        <!--Application Acknowledgement type -->
</MSH>
<MSA>
        <MSA.1>AA</MSA.1>                          <!--Ack code (AA=app-level ack) -->
        <MSA.2>20000610010355:023</MSA.2>          <!--Msg control ID (from MSH.10) -->
</MSA>
</ACK>
```

Otherwise, for an error:

```
<!DOCTYPE STR SYSTEM "hl7_v231.dtd">
<ACK>
<MSH>
        <MSH.1>|</MSH.1>                           <!-- Field seperator -->
        <MSH.2>^~\&amp;amp;</MSH.2>                <!-- Encoding characters -->
        <MSH.3><HD.1>SQ</HD.1></MSH.3>             <!—Sending Application -->
        <MSH.4><HD.1>Flexilab</HD.1></MSH.4>       <!—Sending Facility -->
        <MSH.5><HD.1>RALS</HD.1></MSH.5>           <!—Receiving Application -->
        <MSH.6><HD.1>RALS-LIS</HD.1></MSH.6>       <!—Receiving Facility -->
        <MSH.7>20000502010400</MSH.7>              <!-- Date/Time of message -->
```

```
        <MSH.9>                                          <!--Message type -->
                <CM_MSG_TYPE.1>ACK</CM_MSG_TYPE.1>
                <CM_MSG_TYPE.2>R01</CM_MSG_TYPE.2>
        </MSH.9>
        <MSH.10>20000502010400AE</MSH.10>                <!--Message control ID -->
        <MSH.11><PT.1>P</PT.1></MSH.11>                  <!--Processing ID (Train/Debug/Prod)-->
        <MSH.12><VID.1>2.3.1</VID.1></MSH.12>            <!--Version ID -->
        <MSH.15>AL</MSH.15>                              <!--Accept Acknowledgement type -->
        <MSH.16>NE</MSH.16>                              <!--Application Acknowledgement type -->
</MSH>
<MSA>
        <MSA.1>AE</MSA.1>                                <!--Ack code (AE= app-level ack error) -->
        <MSA.2>20000610010355:023</MSA.2>                <!--Msg control ID (from MSH.10) -->
        <MSA.3>Invalid Patient ID</MSA.3>                <!--Error text -->
        <MSA.6><CE.1>5634</CE.1></MSA.6>                 <!--Error code -->
</MSA>
</ACK>
```

Finally, RALS-LIS will send a Communication Level ACK message for the LIS ACK Message:

```
<!DOCTYPE STR SYSTEM "hl7_v231.dtd">
<ACK>
<MSH>
        <MSH.1>|</MSH.1>                                 <!-- Field seperator -->
        <MSH.2>^~\&amp;amp;</MSH.2>                      <!-- Encoding characters -->
        <MSH.3><HD.1>RALS</HD.1></MSH.3>                 <!—Sending Application -->
        <MSH.4><HD.1>RALS-G</HD.1></MSH.4>               <!—Sending Facility -->
        <MSH.5><HD.1>VQ</HD.1></MSH.5>                   <!—Receiving Application -->
        <MSH.6><HD.1>VQ/LAB</HD.1></MSH.6>               <!—Receiving Facility -->
        <MSH.7>20000502010401</MSH.7>                    <!-- Date/Time of message -->
        <MSH.9>                                          <!--Message type -->
                <CM_MSG_TYPE.1>ACK</CM_MSG_TYPE.1>
        </MSH.9>
        <MSH.10>20000502010401CA</MSH.10>                <!--Message control ID -->
        <MSH.11><PT.1>P</PT.1></MSH.11>                  <!--Processing ID (Train/Debug/Prod)-->
        <MSH.12><VID.1>2.3.1</VID.1></MSH.12>            <!--Version ID -->
        <MSH.15>NE</MSH.15>                              <!--Accept Acknowledgement type -->
        <MSH.16>NE</MSH.16>                              <!--Application Acknowledgement type -->
</MSH>
<MSA>
        <MSA.1>CA</MSA.1>                                <!--Ack code (CA= commit acknowledge) -->
        <MSA.2>20000610010400AA </MSA.2>                 <!--Msg control ID (MSA.1 ‘AA’ message -->
</MSA>
</ACK>
```

# 7 Appendix A: Use Cases for Comment Field

Rick Lebo, Geisinger Healthcare, has provided the following use cases for the comment field.

| Comment | Use Cases | Function |
|---|---|---|
| Procedural Error | Used whenever the testing personnel feel the result should not be posted against the patients record | Stops the processing of the sample, interrupts autoverification without discarding the record |
| Venous | Used to identify the sample as an exception to the routine capillary sample | Amends the result to assist in subsequent interpretation |
| Correlation samples | Used when a test is performed to validate the meter readings against the central lab testing | Used primarily to remove charges from correlation testing. Useful in States with frequent correlation requirements (NJ) |
| Post Exercise | Added when activity level prior to testing may have influenced result | Amends the result to assist in subsequent interpretation |
| Pre or Post Meal | Used when dietary status may have influenced result | Amends the result to assist in subsequent interpretation |
| Results Rechecked | Used whenever protocol calls for a result to be repeated for verification | Used to identify a duplicate testing and eliminate duplicate charges |
| Pre Meds | Used when testing results precede a medication dose that may affect patient's glucose level | Amends the result to assist in subsequent interpretation |
| Post Meds | Used when testing results follows a medication dose that may affect patient's glucose level | Amends the result to assist in subsequent interpretation |
| Confirm to Lab | Used to indicate a sample has been sent to the central lab to confirm result (Usually when result exceed meter technical limits) | Used to identify a duplicate confirmation testing and eliminate duplicate charges without eliminating test record |
| Called to provider | Used to document the notification of the result to the responsible provider | Amends result to document notification |

# 8 References

## 8.1 CIC Standards

The most current information about the Connectivity Industry Consortium's organization, status and standards can be found on the CIC's website:

http://www.poccic.org

Consortium members may review standards proposals under development in the "Members Only" section of the website. This section is password protected.

## 8.2 HL7 Standards

Using XML as a Supplementary Messaging Syntax for HL7 Version2.3.1 21jan00

Information about the HL7 organization can be found at the following website:

http://www.hl7.org

The published HL7 standards may be purchased from this website.

## 8.3 IEEE 1073.3.2 Medical Information Bus (transport and physical layers)

**IEEE 1073.3.2** - 2000 Standard for Medical Device Communications - Transport Profile - IrDA Based - Cable Connected.

An 18-page tutorial is available from the IEEE at:

http://www.ieee-isto.org/mdcig/presentations.html

The complete standard is available for a modest fee at:

http://standards.ieee.org/catalog/olis/meddev.html

## 8.4 IrDA Standards

| | | |
|---|---|---|
| Serial Infrared Physical Layer Link Specification (IrPhys) | v1.2 | 10nov97 |
| Serial Infrared Link Access Protocol (IrLAP) | v1.1 | 16jun96 |
| Serial Infrared Link Management Protocol (IrLMP) | v1.1 | 23jan96 |
| 'Tiny TP': A Flow-Control Mechanism for use with IrLMP | v1.1 | 20oct96 |

The IrDA standards are available at no charge from the Infrared Data Association at::

http://www.irda.org

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Robinson, Lifescan, Inc. * Petrie Rainey, University of Washington * Dan Nowicki, GE Marquette Medical Systems * Joachim Koeninger, Agilent Technologies * Rodney Kugizaki, Lifescan, Inc. * Thomas Bluethner, Roche Diagnostics Corporation * Dominique Freeman, Agilent Technologies * Charles Schindler, POC Consultant * Jacqueline Baker, Roche Diagnostics Corporation * Ken Gary, Abbott Diagnostics * Mike Higgins, Agilent Technologies * Christopher Fetters, Medical Automation Systems, Inc. * Miguel Blanc, Motorola * Borzu Sohrab, Lifescan, Inc. * Stephen Kellett, Agilent Technologies * Christian Kargl, AVL Scientific * Ellis Jacobs, Mount Sinai Medical Center * Syrous Parsay, Lifescan, Inc. * Rick Hrabe, Medical Automation Systems, Inc. * Jon Kitahara, Lifescan, Inc. * Gerhard Pross, Agilent Technologies * Bryan Allen, Bayer Diagnostics * Matthias Essenpreis, Roche Diagnostics Corporation * Deepak Narsipur, Lifescan, Inc. * Billie Keller, Connectivity Industry Consortium * Jack Harrington, Agilent Technologies * Tom Braithwaite, Medical Automation Systems, Inc. * Stephen Lee, Medical Devices Agency * Dirk Boecker, Agilent Technologies * Paula Santrach, Mayo Medical Center * Wayne Mullins, Medical Automation Systems, Inc. * Bob Anders, Agilent Technologies * Andrew St. John, AVL Scientific * Roger D. Hughes, SCC Clinical Information Systems * Craig Robinson, SMS * Allan Soerensen, Radiometer Medical * Chris Melo, Agilent Technologies * Thomas Downey, Avocet Medical, Incorporated * Gerd Grenner, Roche Diagnostics Corporation * Daniel Trainor, Agilent Technologies * Steve Lundy, AVL Scientific * Michael Vock, IGEN International, Inc. * Paul Chirico, Avocet Medical, Incorporated * Rick Lebo, Geisinger Medical Center * Forrest Kneisel, Department of Defense Office of Clinical Laboratory Affairs * Mike Gavin, International Technidyne Corporation * Jared Monaco, AVL Scientific * Candi Barker, Citation Computer Systems, Inc. * Jim Macemon, VIA Medical Corp * Bruce Noon, Sunquest Information Systems * Suzanne Cross, Lifescan/OCD * Louis J. Dunka, Lifescan, Inc. * Wolfgang Janschitz, AVL Scientific * Heiko Ziervogel, Agilent Technologies * Kenneth Powell, BD * Stephanie Higgins, Kaiser-Permanente * Stephen Zweig, Avocet Medical, Incorporated * Paul Schluter, GE Marquette Medical Systems * Sharon Sampson, Agilent Technologies * Anwar Azer, Instrumentation Laboratory * John Quigley, Chiron Diagnostics Corporation * Robin Zimmerman, Kaiser-Permanente * Klaus Kjoller, Radiometer Medical * Kendra Whittier, Agilent Technologies * Joe Rodgers, i-STAT Corporation * Teresa Prego, Bayer Diagnostics * Dana Landry, Instrumentation Laboratory * Barry Willis, Agilent Technologies * Charles Balas, International Technidyne Corporation * Marcy Anderson, Medical Automation Systems, Inc. * Mary Audette, Medtronic * Charles Laughinghouse, AVL Scientific * Fabienne Sebire, FluorRX, Inc. * Nancy Newton, Mayo Medical Center * Robert Uleski, FluorRX, Inc. * Robert J. Knorr, Lifescan, Inc. * Daniel Cheek, Medtronic * Kamran Rastgooy, Roche Diagnostics Corporation * Jay B. Jones, Geisinger Medical Center * Kenneth Levy, Roche Diagnostics Corporation * Jason Ratcliffe, AVL Scientific * Mark Maund, i-STAT Corporation * Gerhard Krammer, Agilent Technologies * Brent Lowensohn, Kaiser-Permanente * Jim Lindauer, Agilent Technologies * Anne LeBlanc, Bayer Diagnostics * Paul Fernandes, CompuCyte Corporation * Tony Nugent, Cholestech Corp * Paul Fingerman, Kaiser-Permanente * Jim Nichols, Johns Hopkins Hospital Department of Pathology * Gert Fendesak, Roche Diagnostics Corporation * David Frey, Agilent Technologies * Mark Cederdahl, Telcor Inc. * Rick Pittaro, Agilent Technologies * Per Matsonn, Pharmacia & Upjohn * Gerd Grenner, Roche Diagnostics Corporation * William J. 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