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celltracks analyzer II®

CELLTRACKS ANALYZER II®
Laboratory Information System (LIS) Guide

IVD

CE

CellSearch®
Circulating Tumor Cell Test

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CONTENTS

1. INTRODUCTION

1.1 Purpose

This document defines the communications interface between the CELLTRACKS ANALYZER II® and a Laboratory Information System (LIS) or a Laboratory Information Management System (LIMS). This document also explains the supporting requirements for the configuration of this interface.

1.2 Audience

This document serves as a reference for Information Technology personnel who are responsible for creating and maintaining the communication between the CELLTRACKS ANALYZER II® and the Laboratory Information System (LIS) or Laboratory Information Management System (LIMS) in their facility.

1.3 Revision History

Version	Section Number & Title	Revision Details
2016-07-01	Title page Copyright page	• Changed LBL50923 to DS-SPE-25122 • Changed Company Name for Belgium address and removed MAGNEST®
2014-05-06	6.2 *Test Protocols* 6.5 *Observation IDs* 9 *Access Levels & Privileges* 10 *Appendix: Report and Message Examples*	• Removed IUO and IVD from **Regulatory Status** column for *user-defined protocols* • Added **Reviewed Events** to table and provided a definition. • Removed access levels 5 and 6 to match access levels displayed in *CELLTRACKS ANALYZER II® User's Guide* • Updated images of **Research Report** and **Control Report**. • Removed *Veridex* references and replaced with *Janssen Diagnostics, LLC* in **Example: Patient Message**, **Example: Control Message**, and **Example: No Result Message**.
2014-01-01	All	Janssen Diagnostics, LLC
2013-03-22	All	Initial Release

1.4 Definitions

[ ]	Brackets. In message formats, brackets indicate that the enclosed group of records/segments is optional.

{ }	Braces. In message formats, braces indicate that the enclosed group of records/segments may repeat.
LIS	Laboratory Information System. In relation to the CELLTRACKS ANALYZER II®, the LIS is a computer system in the laboratory responsible for tracking sample orders and results.
LIMS	Laboratory Information Management System. Similar to an LIS, the LIMS is typically used in a research lab as opposed to a clinical lab.
HL7	Health Level Seven. Standards development organization responsible for creating several protocols for the exchange of health care related information. This document uses HL7 to mean the v2.x protocol developed by the HL7 organization.
MLLP	Minimal Lower Layer Protocol. Low level communications protocol recommended by the HL7 organization.
IHE	Integrating the Healthcare Enterprise. IHE defines a technical framework for the implementation of established interoperability standards to achieve specific clinical goals (http://www.ihe.net)
Unassigned Event	An event that is determined by the user to be negative.
Primary Counts	Each field defined in the test definition (Test Result Fields) that satisfy any of the following criteria: "Order" column is 1 "Marker Field?" column is YES "Field Name" is the complement of a marker field; matches the name of maker with the exception the last character, for example, CTC+/Her2-is the complement of CTC+/Her2+.
Secondary Counts	Each field defined in the test definition (Test Result Fields) that does not satisfy any of the Primary Counts criteria.

1.5 References

[1]	HL7 2.5 Specifications
[2]	HL7 2.3.1 Implementation Guide
[3]	IHE Laboratory Technical Framework – Volume 1 – Profiles, LAB TF-1
[4]	IHE Laboratory Technical Framework – Volume 2 – Transactions, LAB TF-2

2. GENERAL DESCRIPTION

The Laboratory Information System (LIS) interface is used to communicate between the CELLTRACKS ANALYZER II® and a LIS or a Laboratory Information Management System (LIMS).

2.1 Functions

Provide a method to send patient results, quality control results, and patient demographics to another system.

Configure the parameters related to the LIS interface.

Provide a mechanism to display the LIS connection status.

Provide a means to display logs of communication traffic.

2.2 Operational Overview

The user interface (UI) provides a mechanism to release the completed results to the LIS. This causes the results to be sent to the LIS and the result is changed to the "Released" state.

Modifications to the result can be made while the result is in the "Released" state. This includes cell assignment and adding comments. Results can be resent to the LIS, when sending a result to the LIS in the "Released" state; the *Result Correction* status code will be applied to the results.

2.3 Design Constraints

Conform to the Lab Device Automation (LDA) integration profile defined by IHE.

Easily allow for updates to the interface to support order download in the future.

Easily allow for additional protocols to be added in the future.

Allow for future upload of images.

Support only a connection over an Ethernet connection (not support a serial connection).

2.4 Assumptions and Dependencies

Only one LIS will be connected to the system.

The LIS provider complies with this specification.

The security of the network is the responsibility of the customer.

3. COMMUNICATIONS SPECIFICATIONS

This section provides specifications related to transporting messages between the system and the LIS. The content of these messages is not relevant for these layers, which are only in charge of ensuring that messages are transferred in an error-free manner between systems.

3.1 HL7 MLLP Protocol

The HL7 MLLP protocol is defined in the HL7 2.3.1 Implementation. MLLP is essentially a half-duplex protocol, where a new message is sent only after receiving the acknowledgement for the previous message. The protocol assumes communications are layered on top of a circuit based reliable transport protocol (like TCP/IP).

A connection is used by the system to send messages to the LIS. This same connection is used by the LIS to send replies to the message (ex. acknowledgments). In this connection, the system acts as a client and the LIS acts as a server.

3.1.1 Connection Establishment

The system establishes a TCP/IP connection to the LIS at a configured IP address and port.

The system attempts to establish a connection:

a. at system startup

b. on an attempt to transmit a message to the LIS

c. on a configuration change

d. at the explicit request of a user

The system waits 30 seconds for the LIS to accept a connection request.

The system makes 5 attempts to connect to the LIS before stopping the attempts.

The system waits 0 seconds between connection attempts.

The system leaves the connection open between message transmissions.

3.1.2 Block Format

Every HL7 message is enclosed by special characters to form a block formatted as <SB>dddd<EB><CR>

where:

<SB> = Start Block character (1 byte), ASCII <VT> = 0x0B

dddd = Data (variable number of bytes). This is the HL7 data content of the block. The data can contain any single-byte values greater than 0x1F and the ASCII carriage return character, <CR>.

<EB> = End Block character (1 byte), ASCII <FS> = 0x1C

<CR> = Carriage Return (1 byte) = 0x0D

Messages received with incorrect delimitation characters are ignored.

4. PROCESSING SPECIFICATIONS

4.1 HL7 Message Acknowledgments

Unless otherwise stated, all messages are acknowledged using a general acknowledgment message defined in section 5.2.1.

Acknowledgement messages that are not expected are ignored.

The system waits for 30 second for the LIS to acknowledge the sent message.

The system makes 5 attempts to transmit a message to the LIS before stopping the attempts.

The system waits 0 seconds between attempts to transmit a message.

The system waits for a transmitted message to be acknowledged before sending another message.

4.2 Uploading Results

The system provides a mechanism for the user to initiate the transmission of results to the LIS.

Note: Results may only be sent to the LIS if they are in the "Complete", "Archive", or "Released" state.

The system sends results to the LIS using the OUL – Unsolicited Specimen Oriented Observation Message-(Event R22) defined in section 5.2.2.

The system tracks whether a result record has been transmitted to the LIS.

The result state of successfully uploaded results is set to "Released" unless in the "Archived" state.

5. MESSAGE SPECIFICATIONS

This section provides specifications related to the messages exchanged between the system and an LIS.

5.1 Internationalization

The system supports the following character encodings to transmit and receive data streams:

a. UTF-8

b. ISO 8859-1

When translating text to the configured encoding, the system replaces unmappable characters with a question mark (?).

Note: Not all UTF-8 characters can be mapped to the ISO 8859-1 character set.

5.2 HL7 Messages

5.2.1 Acknowledgment Message

The system uses the message structure defined in Table 1 for general acknowledgements.

Table 1: Message ACK

Segment	Meaning	Card.	HL7 Chapter	Notes
MSH	Message Header	[1..1]	2	
MSA	Message Acknowledgement	[1..1]	2	
[ERR]	Error Details	[0..1]	2	

5.2.2 OUL – Unsolicited Specimen Oriented Observation Message – (Event R22)

The system uses the message structure defined in Table 2 for result messages.

Table 2: Message OUL^R22

Segment	Meaning	Card.	HL7 Chapter	Notes
MSH	Message Header	[1..1]	2	
[PID]	Patient Identification	[0..1]	3	Contains patient information
SPM	Specimen Information	[1..1]	7	
SAC	Sample Container Information	[1..1]	7	
[INV]	Detailed Substance Information	[0..1]	13	Applies to QC samples only
OBR	Observation Order	[1..1]	7	
{	--- RESULT Begin	[1..*]		
OBX	Observation Result	[1..1]	7	
[{SID}]	Substance Identifier	[0..*]	13	Reagents used for testing
[{NTE}]	Notes and Comments	[0..*]	2	
}	--- RESULT End			

5.3 HL7 Message Segments

The following section defines the HL7 message segments that are used. All segments are terminated with a Carriage Return <CR> (0x0D); this is not configurable.

The delimiter values are given in MSH-1 and MSH-2 and used throughout the message. Applications must use agreed upon delimiters to parse the message segments. The recommended delimiters for laboratory messages are listed in the first two fields of the MSH segment. The system employs these delimiters for all upload message segments; this is not configurable.

Escape sequences for field separator, component separator, subcomponent separator, repetition separator, and escape character are also valid within a data field. No escape sequence may contain a nested escape sequence.

The following escape sequences are used in the system:

\F\ field separator

\S\ component separator

\T\ subcomponent separator

\R\ repetition separator

\E\ escape character

\Xdddd...\ Hexadecimal data

The system transmits null values for any field listed as Unused.

The following message segments are used for HL7 messages. In the tables that show the field sequences, shaded rows indicate fields that are not supported by the system. The Table 3: Segment Column Descriptions can be used as a key for the values in these columns.

Table 3: Segment Column Descriptions

Column	Description
Seq	Field Sequence Number
Name	Name of Field
Usage	Optionality when uploading from system: R = Required RE = Required, but may be empty C = Conditional CE = Conditional, but may be empty X = Not supported O = optional

Column	Description
Card.	Cardinality of the field Specifies the number of repetitions of a field, [min..max]
Len	Length of a single repetition of a field
Type	Data type of the column. Refer to Chapter 2A of the HL7 2.5 Specification for a detailed description of each data type.
Notes	Description of contents of the field. Unless otherwise noted, this indicates the values the analyzer will send.

5.3.1 ERR Segment

The system supports the fields defined in Table 4 for the ERR segment.

Table 4: ERR Segment

Seq	Name	Usage	Card.	Len	Type	Notes
1	Error Code and Location	X	[0..0]	493	ELD	*Unused*
2	Error Location	RE	[0..*]	18	ERL	
3	HL7 Error Code	R	[1..1]	705	CWE	Refer to HL7 Table 0357 - Message error condition codes in reference [2], HL7 2.5 Specifications.
4	Severity	R	[1..1]	2	ID	W = Warning I = Information E = Error
5	Application Error Code	O	[0..1]	705	CWE	*Unused*
6	Application Error Parameter	O	[0..10]	80	ST	*Unused*
7	Diagnostic Information	O	[0..1]	2048	TX	More detailed information on error if available.
8	User Message	O	[0..1]	250	TX	*Unused*
9	Inform Person Indicator	O	[0..*]	20	IS	*Unused*
10	Override Type	O	[0..1]	705	CWE	*Unused*
11	Override Reason Code	O	[0..*]	705	CWE	*Unused*
12	Help Desk Contact Point	O	[0..*]	652	XTN	*Unused*

5.3.2 INV Segment

The system supports the fields defined in Table 5 for the INV segment.

Table 5: INV Segment

Seq	Name	Usage	Card.	Len	Type	Notes
1	Substance Identifier	R	[1..1]	250	CE	See Table 18: Control IDs Format: Control ID^^L Example: CTC CONTROL^^L
2	Substance Status	R	[1..*]	250	CE	OK = OK Status
3	Substance Type	O	[0..1]	250	CE	*Unused*
4	Inventory Container Identifier	O	[0..1]	250	CE	*Unused*
5	Container Carrier Identifier	O	[0..1]	250	CE	*Unused*
6	Position on Carrier	O	[0..1]	250	CE	*Unused*
7	Position on Carrier	O	[0..1]	20	NM	*Unused*
8	Current Quantity	O	[0..1]	20	NM	*Unused*
9	Available Quantity	O	[0..1]	20	NM	*Unused*
10	Consumption Quantity	O	[0..1]	20	NM	*Unused*
11	Quantity Units	O	[0..1]	250	CE	*Unused*
12	Expiration Date/Time	O	[0..1]	26	TS	Expiration Date
13	First Used Date/Time	O	[0..1]	26	TS	*Unused*
14	On Board Stability Duration	X	[0..0]	200	TQ	*Unused*
15	Test/Fluid Identifier(s)	O	[0..*]	250	CE	*Unused*
16	Manufacturer Lot Number	O	[0..1]	200	ST	Lot number
17	Manufacturer Identifier	O	[0..1]	250	CE	*Unused*
18	Supplier Identifier	O	[0..1]	250	CE	*Unused*
19	On Board Stability Time	O	[0..1]	20	CQ	*Unused*
20	Target Value	O	[0..1]	20	CQ	*Unused*

5.3.3 MSA Segment

The system supports the fields defined in Table 6 for the MSA segment.

Table 6: MSA Segment

Seq	Name	Usage	Card.	Len	Type	Notes
1	Acknowledgment Code	R	[1..1]	2	ID	AA = Message Accepted AE = Message Contains Errors AR = Message Rejected
2	Message Control ID	R	[1..1]	20	ST	Message control ID of message being acknowledged
3	Text Message	X	[0..0]	80	ST	*Unused*
4	Expected Sequence Number	O	[0..1]	15	NM	*Unused*
5	Delayed Acknowledgment Type	X	[0..0]			*Unused*
6	Error Condition	X	[0..0]	250	CE	*Unused*

5.3.4 MSH Segment

The system supports the fields defined in Table 7 for the MSH segment.

Table 7: MSH Segment

Seq	Name	Usage	Card.	Len	Type	Notes
1	Field Separator	R	[1..1]	1	ST	"|"
2	Encoding Characters	R	[1..1]	4	ST	"^" = component separator "~" = repetition separator "\" = escape separator "&" = sub-component separator
3	Sending Application	R	[1..1]	227	HD	Format: <CellTracks Instrument Serial Number> *CellTracks Instrument Serial Number is for the instrument that sent the result message to the LIS, not the instrument that performed the scan.
4	Sending Facility	R	[1..1]	227	HD	Facility
5	Receiving Application	R	[1..1]	227	HD	LIS ID
6	Receiving Facility	R	[1..1]	227	HD	LIS Facility
7	Date/Time of Message	R	[1..1]	26	TS	Analyzer will send to millisecond precision.
8	Security	X	[0..0]	40	ST	*Unused*
9	Message Type	R	[1..1]	15	MSG	<Message Code> ^ <Trigger Event> ^ <Message Structure> For OUL messages, "OUL^R22^OUL_R22". For acknowledgements, "ACK^OUL^ACK_OUL".
10	Message Control Id	R	[1..1]	20	ST	Unique ID
11	Processing Id	R	[1..1]	3	PT	"P" Indicates this is a "production" message.
12	Version ID	R	[1..1]	60	VID	"2.5" HL7 major release version.
13	Sequence Number	O	[0..1]	15	NM	*Unused*
14	Continuation Pointer	X	[0..0]	180	ST	*Unused*

Seq	Name	Usage	Card.	Len	Type	Notes
15	Accept Acknowledgment Type	X	[0..0]	2	ID	*Unused*
16	Application Acknowledgment Type	X	[0..0]	2	ID	*Unused*
17	Country Code	RE	[0..1]	3	ID	*Unused*
18	Character Set	C	[0..1]	16	ID	The system will accept: 8859/1 = ISO 8859-1 (Western European) UNICODE UTF-8 = UTF-8 The system will transmit in the configured character encoding.
19	Principal Language Of Message	RE	[0..1]	250	CE	*Unused*
20	Alternate Character Set Handling Scheme	C	[0..1]	20	ID	*Unused*
21	Message Profile Identifier	RE	[0..*]	427	EI	*Unused*

5.3.5 NTE Segment

The system supports the fields defined in Table 8 for the NTE segment.

Table 8: NTE Segment

Seq	Name	Usage	Card.	Len	Type	Notes
1	Set ID – NTE	R	[1..1]	4	SI	"1"
2	Source of Comment	RE	[0..1]	8	ID	"A"
3	Comment	RE	[0..1]	65536	FT	Concatenation of all comment text. CELLTRACKS® AUTOPREP® System comments, CELLTRACKS ANALYZER II® operator comments, and flags (maximum recordable event limit reached and AUTOPREP temperature out of range).
4	Comment Type	RE	[0..1]	250	CE	*Unused*

5.3.6 OBR Segment

The system supports the fields defined in Table 9 for the OBR segment.

Table 9: OBR Segment

Seq	Name	Usage	Card.	Len	Type	Notes
1	Set ID – OBR	O	[0..1]	4	SI	"1"
2	Placer Order Number	C	[0..1]	22	EI	*Unused*
3	Filler Order Number	C	[0..1]	22	EI	Result Record ID
4	Universal Service Identifier	R	[1..1]	250	CE	Use local codes for this since no LOINC codes exist. See Table 16: Test Protocols Format: <Test Protocol> ^ <Regulatory Status>^L Example: CTC HER-2/neu^RUO^L
5	Priority – OBR	X	[0..0]	2	ID	*Unused*
6	Requested Date/Time	X	[0..0]	26	TS	*Unused*
7	Observation Date/Time	C	[0..1]	26	TS	Specimen Collection time
8	Observation End Date/Time	O	[0..1]	26	TS	*Unused*
9	Collection Volume	O	[0..1]	20	CQ	*Unused*
10	Collector Identifier	O	[0..*]	250	XCN	*Unused*
11	Specimen Action Code	O	[0..1]	1	ID	*Unused*
12	Danger Code	O	[0..1]	250	CE	*Unused*
13	Relevant Clinical Information	O	[0..1]	300	ST	*null* *or* "Cancer Type: *type"*
14	Specimen Received Date/Time	X	[0..0]	26	TS	*Unused*
15	Specimen Source	X	[0..0]	300	SPS	*Unused*
16	Ordering Provider	O	[0..*]	250	XCN	Physician Name Format: <ID#> ^ Last Name ^ First Name Note: ID# is always null.

Seq	Name	Usage	Card.	Len	Type	Notes
17	Order Callback Phone Number	O	[0..2]	250	XTN	*Unused*
18	Placer Field 1	O	[0..1]	60	ST	*Unused*
19	Placer Field 2	O	[0..1]	60	ST	*Unused*
20	Filler Field 1	O	[0..1]	60	ST	*Unused*
21	Filler Field 2	O	[0..1]	60	ST	*Unused*
22	Results Rpt/Status Chng - Date/Time	C	[0..1]	26	TS	*Unused*
23	Charge to Practice	O	[0..1]	40	MOC	*Unused*
24	Diagnostic Serv Sect ID	O	[0..1]	10	ID	*Unused*
25	Result Status	O	[0..1]	1	ID	F = Final results C = Corrected results
26	Parent Result	O	[0..1]	400	PRL	*Unused*
27	Quantity/Timing	X	[0..*]	200	TQ	*Unused*
28	Result Copies To	O	[0..*]	250	XCN	*Unused*
29	Parent	O	[0..1]	200	EIP	*Unused*
30	Transportation Mode	O	[0..1]	20	ID	*Unused*
31	Reason for Study	O	[0..*]	250	CE	*Unused*
32	Principal Result Interpreter	O	[0..1]	200	NDL	<Releasing operator> ^ <Release Time>
33	Assistant Result Interpreter	O	[0..*]	200	NDL	Repeated for each review: Repetition 1 - <first review operator> ^ <first review time Repetition 2 - <second review operator> ^ <second review time> . . . Repetition N - <Nth review operator> ^ <Nth review time> Repetitions separated by ~

Seq	Name	Usage	Card.	Len	Type	Notes
34	Technician	O	[0..*]	200	NDL	Repetition 1 - Scan: <operator> ^ <scantime> Repetition 2 - AUTOPREP: <operator> ^ <preptime> (may be blank) Repetitions separated by ~
35	Transcriptionist	O	[0..*]	200	NDL	*Unused*
36	Scheduled Date/Time	O	[0..1]	26	TS	*Unused*
37	Number of Sample Containers	O	[0..1]	4	NM	*Unused*
38	Transport Logistics of Collected Sample	O	[0..*]	250	CE	*Unused*
39	Collector's Comment	O	[0..*]	250	CE	*Unused*
40	Transport Arrangement Responsibility	O	[0..1]	250	CE	*Unused*
41	Transport Arranged	O	[0..1]	30	ID	*Unused*
42	Escort Required	O	[0..1]	1	ID	*Unused*
43	Planned Patient Transport Comment	O	[0..*]	250	CE	*Unused*
44	Procedure Code	O	[0..1]	250	CE	*Unused*
45	Procedure Code Modifier	O	[0..*]	250	CE	*Unused*
46	Placer Supplemental Service Information	O	[0..*]	250	CE	*Unused*
47	Filler Supplemental Service Information	O	[0..*]	250	CE	*Unused*
48	Medically Necessary Duplicate Procedure Reason	C	[0..1]	250	CWE	*Unused*
49	Result Handling	O	[0..1]	2	IS	*Unused*

5.3.7 OBX Segment

The system supports the fields defined in Table 10 for the OBX segment.

Table 10: OBX Segment

Seq	Name	Usage	Card.	Len	Type	Notes
1	Set ID – OBX	R	[1..1]	4	SI	Sequence number of the OBX
2	Value Type	C	[0..1]	2	ID	"NM" Indicates observation values are numeric.
3	Observation Identifier	R	[1..1]	250	CE	Use local codes for test results; there are no LOINC descriptors for CTC. See Table 19: Observation IDs. Format: <Test Result>^^L Example: CTC+/Her2-^^L
4	Observation Sub-ID	C	[0..1]	20	ST	*Unused*
5	Observation Value	C	[0..1]	n/a	Varies	Cell counts When result is "No Result", cell count is null and Observation Result Status=X.
6	Units	C	[0..1]	250	CE	"**/***vol* mL" where *vol* is the primary sample volume
7	References Range	RE	[0..1]	60	ST	For patient samples: *null* For control samples: "low - high"
8	Abnormal Flags	RE	[0..1]	5	IS	For patient samples: *null* For control samples: L = below low limit H = above high limit *null* = within range
9	Probability	X	[0..0]	5	NM	*Unused*
10	Nature of Abnormal Test	X	[0..0]	2	ID	*Unused*

Seq	Name	Usage	Card.	Len	Type	Notes
11	Observation Result Status	R	[1..1]	1	ID	X = Results cannot be obtained (Used when result is "No Result") F = Final results C = Correction to final result (Used when result resent to LIS)
12	Effective Date of Reference Range	X	[0..0]	26	TS	*Unused*
13	User Defined Access Checks	C	[0..1]	20	ST	*Unused*
14	Date/Time of the Observation	RE	[0..1]	26	TS	Review time
15	Producer's ID	RE	[0..1]	250	CE	*Unused*
16	Responsible Observer	RE	[0..1]	250	XCN	Releasing operator ID
17	Observation Method	C	[0..1]	250	CE	*Unused*
18	Equipment Instance Identifier	O	[0..1]	22	EI	<CTA Serial #> ~ <AP Serial #> CTA Serial # is the for the instrument that scanned the sample. AP Serial # will be null if not known.
19	Date/Time of the Analysis	RE	[0..1]	26	TS	Scan time
20	Reserved by HL7 for future use					
21	Reserved by HL7 for future use					
22	Reserved by HL7 for future use					
23	Performing Organization Name	C	[0..1]	567	XON	*Unused*
24	Performing Organization Address	O	[0..1]	631	XAD	*Unused*
25	Performing Organization Director Name	O	[0..1]	3002	XCN	*Unused*

5.3.8 PID Segment

The system supports the fields defined in Table 11 for the PID segment.

Table 11: PID Segment

Seq	Name	Usage	Card.	Len	Type	Notes
1	Set ID – PID	R	[1..1]	4	SI	"1"
2	Patient ID	X	[0..0]	20	CX	*Unused*
3	Patient Identifier List	R	[1..*]	250	CX	Patient ID
4	Alternate Patient ID	X	[0..0]	20	CX	*Unused*
5	Patient Name	R	[0..1]	250	XPN	Patient Name <Last Name>^<Fist Name>
6	Mother's Maiden Name	O	[0..1]	250	XPN	*Unused*
7	Date/Time Birth	RE	[0..1]	26	TS	Patient Birth Date
8	Administrative Sex	R	[1..1]	1	IS	F = Female M = Male U = Unknown
9	Patient Alias	X	[0..0]	250	XPN	*Unused*
10	Race	RE	[0..1]	250	CE	1002-5 = American Indian or Alaska Native 2028-9 = Asian 2054-5 = Black or African American 2076-8 = Native Hawaiian or Other Pacific Islander 2106-3 = White 2131-1 = Other Race
11	Patient Address	RE	[0..*]	250	XAD	*Unused*
12	Country Code	X	[0..0]	4	IS	*Unused*
13	Phone Number – Home	O	[0..*]	250	XTN	*Unused*
14	Phone Number – Business	O	[0..*]	250	XTN	*Unused*
15	Primary Language	O	[0..1]	250	CE	*Unused*
16	Marital Status	O	[0..1]	250	CE	*Unused*

Seq	Name	Usage	Card.	Len	Type	Notes
17	Religion	O	[0..1]	250	CE	*Unused*
18	Patient Account Number	RE	[0..1]	250	CX	*Unused*
19	Patient SSN	X	[0..0]	16	ST	*Unused*
20	Patient DLN	X	[0..0]	25	DLN	*Unused*
21	Mother's Identifier	O	[0..1]	250	CX	*Unused*
22	Ethnic Group	O	[0..1]	250	CE	*Unused*
23	Birth Place	O	[0..1]	250	ST	*Unused*
24	Multiple Birth Indicator	O	[0..1]	1	ID	*Unused*
25	Birth Order	O	[0..1]	2	NM	*Unused*
26	Citizenship	O	[0..1]	250	CE	*Unused*
27	Veterans Military Status	O	[0..1]	250	CE	*Unused*
28	Nationality	X	[0..0]	250	CE	*Unused*
29	Patient Death Date and Time	O	[0..1]	26	TS	*Unused*
30	Patient Death Indicator	O	[0..1]	1	ID	*Unused*
31	Identity Unknown Indicator	RE	[0..1]	1	ID	*Unused*
32	Identity Reliability Code	RE	[0..1]	20	IS	*Unused*
33	Last Update Date/Time	O	[0..1]	26	TS	*Unused*
34	Last Update Facility	O	[0..1]	241	HD	*Unused*
35	Species Code	C	[0..1]	250	CE	*Unused*
36	Breed Code	C	[0..1]	250	CE	*Unused*
37	Strain	O	[0..1]	80	ST	*Unused*
38	Production Class Code	O	[0..1]	250	CE	*Unused*
39	Tribal Citizenship	O	[0..1]	250	CWE	*Unused*

5.3.9 SAC Segment

The system supports the fields defined in Table 12 for the SAC segment.

Table 12: SAC Segment

Seq	Name	Usage	Card.	Len	Type	Notes
1	External Accession Identifier	O	[0..1]	80	EI	*Unused*
2	Accession Identifier	O	[0..1]	80	EI	*Unused*
3	Container Identifier	R	[1..1]	80	EI	Cartridge ID
4	Primary (parent) Container Identifier	C	[0..1]	80	EI	Sample ID
5	Equipment Container Identifier	O	[0..1]	80	EI	*Unused*
6	Specimen Source	X	[0..0]	300	SPS	*Unused*
7	Registration Date/Time	O	[0..1]	26	TS	*Unused*
8	Container Status	O	[0..1]	250	CE	*Unused*
9	Carrier Type	O	[0..1]	250	CE	*Unused*
10	Carrier Identifier	O	[0..1]	80	EI	*Unused*
11	Position in Carrier	O	[0..1]	80	NA	Sample Position
12	Tray Type – SAC	O	[0..1]	250	CE	*Unused*
13	Tray Identifier	O	[0..1]	80	EI	*Unused*
14	Position in Tray	O	[0..1]	80	NA	*Unused*
15	Location	O	[0..*]	250	CE	*Unused*
16	Container Height	O	[0..1]	20	NM	*Unused*
17	Container Diameter	O	[0..1]	20	NM	*Unused*
18	Barrier Delta	O	[0..1]	20	NM	*Unused*
19	Bottom Delta	O	[0..1]	20	NM	*Unused*
20	Container Height/Diameter/Delta Units	O	[0..1]	250	CE	*Unused*
21	Container Volume	O	[0..1]	20	NM	*Unused*
22	Available Specimen Volume	O	[0..1]	20	NM	*Unused*

Seq	Name	Usage	Card.	Len	Type	Notes
23	Initial Specimen Volume	O	[0..1]	20	NM	*Unused*
24	Volume Units	O	[0..1]	250	CE	*Unused*
25	Separator Type	O	[0..1]	250	CE	*Unused*
26	Cap Type	O	[0..1]	250	CE	*Unused*
27	Additive	O	[0..*]	250	CWE	*Unused*
28	Specimen Component	O	[0..1]	250	CE	*Unused*
29	Dilution Factor	O	[0..1]	20	SN	*Unused*
30	Treatment	O	[0..1]	250	CE	*Unused*
31	Temperature	O	[0..1]	20	SN	*Unused*
32	Hemolysis Index	O	[0..1]	20	NM	*Unused*
33	Hemolysis Index Units	O	[0..1]	250	CE	*Unused*
34	Lipemia Index	O	[0..1]	20	NM	*Unused*
35	Lipemia Index Units	O	[0..1]	250	CE	*Unused*
36	Icterus Index	O	[0..1]	20	NM	*Unused*
37	Icterus Index Units	O	[0..1]	250	CE	*Unused*
38	Fibrin Index	O	[0..1]	20	NM	*Unused*
39	Fibrin Index Units	O	[0..1]	250	CE	*Unused*
40	System Induced Contaminants	O	[0..*]	250	CE	*Unused*
41	Drug Interference	O	[0..*]	250	CE	*Unused*
42	Artificial Blood	O	[0..1]	250	CE	*Unused*
43	Special Handling Code	O	[0..*]	250	CWE	*Unused*
44	Other Environmental Factors	O	[0..*]	250	CE	*Unused*

5.3.10 SID Segment

The system supports the fields defined in Table 13 for the SID segment.

Table 13: SID Segment

Seq	Name	Usage	Card.	Len	Type	Notes
1	Application / Method Identifier	C	[0..1]	250	CE	Use local codes for this since no LOINC codes exist. See Table 15: Test Kits and Table 17: Marker IDs. Format: <Test ID>^<Test (Kit)Name>^L Example: CTC^CellSearch CTC^L Format: <Marker ID>^^L Example: HER-2/neu^^L
2	Substance Lot Number	C	[0..1]	20	ST	Lot number
3	Substance Container Identifier	C	[0..1]	200	ST	*Unused*
4	Substance Manufacturer Identifier	C	[0..1]	250	CE	*Unused*

5.3.11 SPM Segment

The system supports the fields defined in Table 14 for the SPM segment.

Table 14: SPM Segment

Seq	Name	Usage	Card.	Len	Type	Notes
1	Set ID – SPM	R	[1..1]	4	SI	"1"
2	Specimen ID	R	[1..1]	80	EIP	Sample ID (Controls use the Control ID.)
3	Specimen Parent IDs	RE	[0..1]	80	EIP	*Unused*
4	Specimen Type	R	[1..1]	250	CWE	"BLD"
5	Specimen Type Modifier	X	[0..0]	250	CWE	*Unused*
6	Specimen Additives	O	[0..1]	250	CWE	*Unused*
7	Specimen Collection Method	RE	[0..1]	250	CWE	*Unused*
8	Specimen Source Site	C	[0..1]	250	CWE	*Unused*
9	Specimen Source Site Modifier	C	[0..1]	250	CWE	*Unused*
10	Specimen Collection Site	O	[0..1]	250	CWE	*Unused*
11	Specimen Role	RE	[0..1]	250	CWE	"P" = Patient "Q" = Control
12	Specimen Collection Amount	X	[0..0]	20	CQ	*Unused*
13	Grouped Specimen Count	X	[0..0]	6	NM	*Unused*
14	Specimen Description	O	[0..1]	250	ST	*Unused*
15	Specimen Handling Code	O	[0..*]	250	CWE	*Unused*
16	Specimen Risk Code	RE	[0..1]	250	CWE	*Unused*
17	Specimen Collection Date/Time	RE	[0..1]	26	DR	Draw Date/Time (from AUTOPREP data)
18	Specimen Received Date/Time	C	[0..1]	26	TS	*Unused*

Seq	Name	Usage	Card.	Len	Type	Notes
19	Specimen Expiration Date/Time	O	[0..1]	26	TS	*Unused*
20	Specimen Availability	C	[0..1]	1	ID	*Unused*
21	Specimen Reject Reason	C	[0..*]	250	CWE	*Unused*
22	Specimen Quality	O	[0..1]	250	CWE	*Unused*
23	Specimen Appropriateness	O	[0..1]	250	CWE	*Unused*
24	Specimen Condition	C	[0..*]	250	CWE	*Unused*
25	Specimen Current Quantity	O	[0..1]	20	CQ	*Unused*
26	Number of Specimen Containers	RE	[0..1]	4	NM	*Unused*
27	Container Type	O	[0..1]	250	CWE	*Unused*
28	Container Condition	O	[0..1]	250	CWE	*Unused*
29	Specimen Child Role	O	[0..1]	250	CWE	*Unused*

6. CODE TABLES

The following tables provide code information used in various segments above.

6.1 Test Kits

These are the test definition kit names.

Table 15: Test Kits

Test ID	Test (Kit) Name
CTC	CellSearch CTC
CEC	Endothelial Cell
CXC	CellSearch CXC
CMC	CellTracks CMC

6.2 Test Protocols

Table 16: Test Protocols

Protocols	Regulatory Status
CEC Control	RUO
CEC Research	RUO
CEC Sample	RUO
CMC Control	RUO
CMC Research	RUO
CMC Sample	RUO
CTC Control	IVD
CTC EGFr	RUO
CTC HER-2/neu	RUO
CTC Research	RUO
CTC Sample	IVD
CXC Control	RUO
CXC IGF-1R	RUO
CXC Research	RUO
CXC Sample	RUO
*User defined protocols are allowed. This can be any unique string defined by the user.	User defined: RUO

6.3 Marker Reagent

These are the Marker IDs associated with a Test Protocol.

Table 17: Marker IDs

Marker ID
EGFr
HER-2/neu
IGF-1R
*User defined markers are allowed for the Marker ID. This can be any string defined by the user.

6.4 Control IDs

This table lists the Control IDs used for controls.

Table 18: Control IDs

Value
CEC Control
CMC Control
CTC Control
CXC Control

6.5 Observation IDs

These are the test result strings.

Table 19: Observation IDs

Value
CD105-PE+/CD45-APC+
CEC
CEC+
CEC+/<UDA>+
CEC+/<UDA>-
CK-FLU+/CD45-APC+
CK-PE+/CD45-APC+
CMC
CMC+
CMC+/<UDA>+
CMC+/<UDA>-
CTC
CTC+
CTC+/EGFr+
CTC+/EGFr-
CTC+/Her2+
CTC+/Her2-
CTC+/<UDA>+
CTC+/<UDA>-
CXC
CXC+
CXC+/IGF-1R+
CXC+/IGF-1R-
CXC+/<UDA>+
CXC+/<UDA>-

High Control
Low Control
MEL-PE/CD45/CD34-APC
Total Events
Unassigned Events
Reviewed Events

The system reports the observations (results) based upon the following:

1. Primary Counts – Always included.
2. Secondary Counts – Included according to LIS configuration settings
3. Unassigned (events not selected) – Included according to LIS Report configuration settings. Sent as result in OBX.
4. Total (total count of events) – Included according to LIS Report configuration settings. Sent as result in OBX.
5. Reviewed Events – Included if a Partial Review was performed for this sample.

7. CONFIGURATION SPECIFICATIONS

This section contains specifications related to the configuring of the LIS interface.

The system allows the LIS interface to be enabled and disabled without affecting other LIS configuration parameters.

The system allows the user to configure the LIS interface to use one of the following protocols:

a. HL7

The system allows the user to configure the LIS interface to use one of the following character encodings:

a. UTF-8 [default]

b. ISO 8859-1

The system allows the user to configure the LIS server IP address.

The system allows the user to configure the LIS server port.

Note: Valid port numbers are: 1 to 65535

The system allows the user to configure the LIS facility string; length 30, default blank.

The system allows the user to configure the LIS ID string; length 30, default blank.

LIS Report Configuration. Allows the user to select results types to be sent to the LIS.

1. Unassigned Events (default: do not include)
2. Total Events (default: do not include)
3. Secondary Counts (default: do not include)

8. DIAGNOSTICS SPECIFICATIONS

This section contains specifications related to the troubleshooting issues with the LIS interface.

The system provides an indication of the following LIS connection states:

a. Disabled

b. Connected

c. Not Connected

d. Transferring

Note: Transferring can refer to either transmitting or receiving.

The system sends all LIS communications to a log file.

The system provides a mechanism to manually initiate a connection with the LIS.

The system provides a mechanism to view the logged LIS communications.

The system provides a mechanism to print the logged LIS communications.

The system provides a mechanism to export the logged LIS communications.

9. ACCESS LEVELS & PRIVILEGES

The system uses the access levels listed in Table 20 to determine if a user can perform a specific action related to the LIS interface.

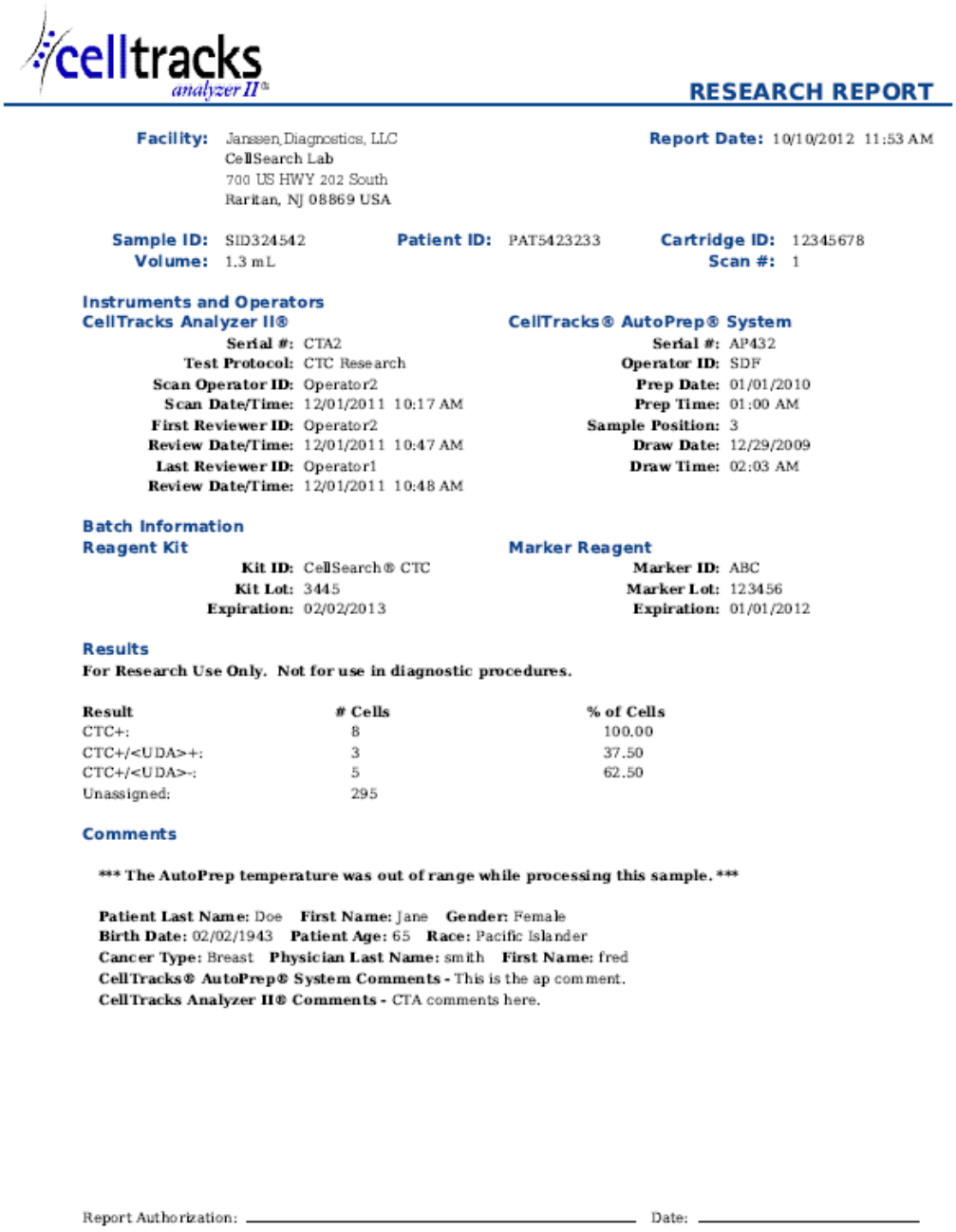
Table 20: Access Level Privileges

	Level 1	Level 2	Level 3	Level 4
Enable/Disable LIS interface		X	X	X
Configure all other LIS interface settings				X
Manually initiate LIS connection		X	X	X
View/Print/Export LIS logs		X	X	X
Send result to LIS		X	X	X

10. Appendix: Report and Message Examples

Example: Patient Report

Shown below is an example patient report from the instrument. The LIS message and response for this patient is shown in the Patient Message.



celltracks analyzer II®

RESEARCH REPORT

Facility: Janssen Diagnostics, LLC
CellSearch Lab
700 US HWY 202 South
Raritan, NJ 08869 USA

Report Date: 10/10/2012 11:53 AM

Sample ID: SID324542 **Patient ID:** PAT5423233 **Cartridge ID:** 12345678
Volume: 1.3 mL **Scan #:** 1

Instruments and Operators

CellTracks Analyzer II®

Serial #: CTA2
Test Protocol: CTC Research
Scan Operator ID: Operator2
Scan Date/Time: 12/01/2011 10:17 AM
First Reviewer ID: Operator2
Review Date/Time: 12/01/2011 10:47 AM
Last Reviewer ID: Operator1
Review Date/Time: 12/01/2011 10:48 AM

CellTracks® AutoPrep® System

Serial #: AP432
Operator ID: SDF
Prep Date: 01/01/2010
Prep Time: 01:00 AM
Sample Position: 3
Draw Date: 12/29/2009
Draw Time: 02:03 AM

Batch Information

Reagent Kit

Kit ID: CellSearch® CTC
Kit Lot: 3445
Expiration: 02/02/2013

Marker Reagent

Marker ID: ABC
Marker Lot: 123456
Expiration: 01/01/2012

Results

For Research Use Only. Not for use in diagnostic procedures.

Result	# Cells	% of Cells
CTC+:	8	100.00
CTC+/<UDA>+:	3	37.50
CTC+/<UDA>-:	5	62.50
Unassigned:	295	

Comments

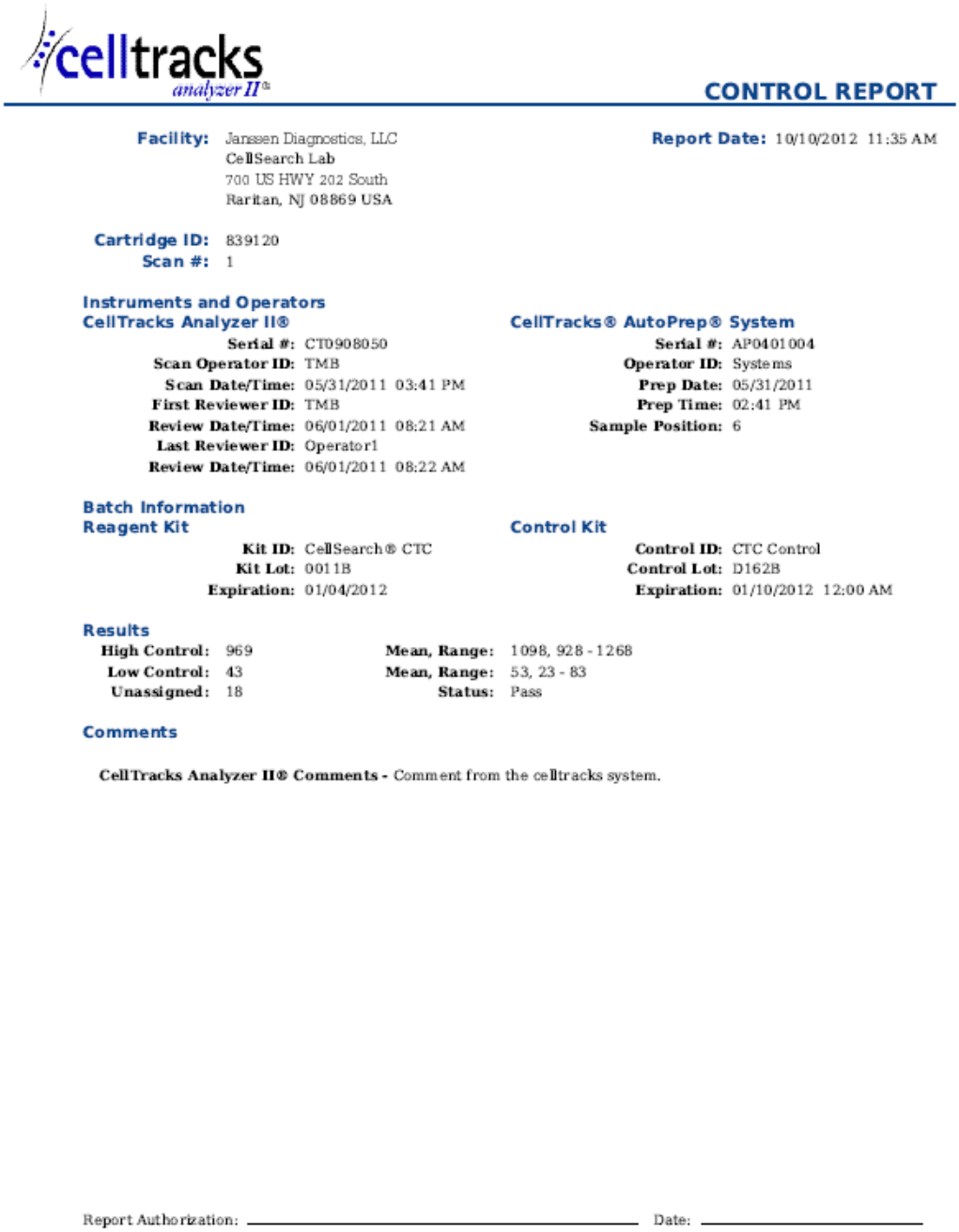
***** The AutoPrep temperature was out of range while processing this sample. *****

Patient Last Name: Doe **First Name:** Jane **Gender:** Female
Birth Date: 02/02/1943 **Patient Age:** 65 **Race:** Pacific Islander
Cancer Type: Breast **Physician Last Name:** smith **First Name:** fred
CellTracks® AutoPrep® System Comments - This is the ap comment.
CellTracks Analyzer II® Comments - CTA comments here.

Report Authorization: _____ Date: _____

Example: Control Report

Shown below is an example control report from the instrument. The LIS message and response for this patient is shown in the Control Message.



celltracks analyzer II®

CONTROL REPORT

Facility: Janssen Diagnostics, LLC
CellSearch Lab
700 US HWY 202 South
Raritan, NJ 08869 USA

Report Date: 10/10/2012 11:35 AM

Cartridge ID: 839120
Scan #: 1

Instruments and Operators

CellTracks Analyzer II®

Serial #:	CT0908050
Scan Operator ID:	TMB
Scan Date/Time:	05/31/2011 03:41 PM
First Reviewer ID:	TMB
Review Date/Time:	06/01/2011 08:21 AM
Last Reviewer ID:	Operator1
Review Date/Time:	06/01/2011 08:22 AM

CellTracks® AutoPrep® System

Serial #:	AP0401004
Operator ID:	Systems
Prep Date:	05/31/2011
Prep Time:	02:41 PM
Sample Position:	6

Batch Information

Reagent Kit

Kit ID:	CellSearch® CTC
Kit Lot:	0011B
Expiration:	01/04/2012

Control Kit

Control ID:	CTC Control
Control Lot:	D162B
Expiration:	01/10/2012 12:00 AM

Results

High Control:	969	**Mean, Range:**	1098, 928 - 1268
Low Control:	43	**Mean, Range:**	53, 23 - 83
Unassigned:	18	**Status:**	Pass

Comments

CellTracks Analyzer II® Comments - Comment from the celltracks system.

Report Authorization: _____ Date: _____

Example: Patient Message

In the example, longer lines are split because they would not fit on the page. In the actual message, each line begins with a segment identifier like MSH and ends with a <CR>.

Message sent to LIS

MSH|^~\&|SERNUM123|Janssen<SP>Diagnostics,<SP>LLC|LIS123|LISFacility123|20121010112335.558||
OUL^R22^OUL_R22|20121010112335.558|P|2.5||||||UNICODE<SP>UTF-8<CR>

PID|1||PAT5423233||Doe^Jane||19430202|F||2076-8<CR>

SPM|1|SID324542||BLD|||||||P||||||20090101020300<CR>

SAC|||12345678|SID324542|||||||3<CR>

OBR|1||1|CTC<SP>Research^RUO^L|||20090101020300||||||Cancer<SP>Type:<SP>Breast|||^smith^fred|||||||||F|||||||
Operator1^20121010112334|Operator2^20111201104736~Operator2^20111201104834|Operator2^20111201101750~SDF^20100101010000<CR>

OBX|1|NM|CTC+^^L||8|/1.3<SP>mL|||||F|||20111201104834||Operator1||CTA2~AP432|20111201101750<CR>

SID|CTC^CellSearch<SP>CTC^L|3445<CR>

SID|ABC^^L|123456<CR>

NTE|1|A|This<SP>is<SP>the<SP>ap<SP>comment.\X0A\CTA<SP>comments<SP>here.\X0A***<SP>The<SP>AutoPrep<SP>temperature<SP>
was<SP>out<SP>of<SP>range<SP>while<SP>processing<SP>this<SP>sample.<SP>***<CR>

OBX|2|NM|CTC+/<UDA>+^^L||3|/1.3<SP>mL|||||F|||20111201104834||Operator1||CTA2~AP432|20111201101750<CR>

OBX|3|NM|CTC+/<UDA>-^^L||5|/1.3<SP>mL|||||F|||20111201104834||Operator1||CTA2~AP432|20111201101750<CR>

Response from LIS

MSH|^~\&|LIS123|LISFacility123|SERNUM123| Janssen Diagnostics LLC,<SP>LLC|20121010112055.643||
ACK^OUL^ACK_OUL|20121010112055.643|P|2.5||||||UNICODE<SP>UTF-8|||<CR>

MSA|AA|20121010112335.558||||<CR>

Example: Control Message

In the example, longer lines are split because they would not fit on the page. In the actual message, each line begins with a segment identifier like MSH and ends with a <CR>.

Message sent to LIS

MSH|^~\&|SERNUM123|Janssen<SP>Diagnostics,<SP>LLC|LIS123|LISFacility123|20121010113547.808||
OUL^R22^OUL_R22|20121010113547.808|P|2.5||||||UNICODE<SP>UTF-8<CR>

SPM|1|CTC<SP>Control||BLD|||||||Q||||||<CR>

SAC|||839120|CTC<SP>Control|||||||6<CR>

INV|CTC<SP>Control^^L|OK|||||||||20120110000000||||D162B<CR>

OBR|1||3|CTC<SP>Control^IVD^L|||||||||||||||||||||F|||||||
Operator1^20121010113547|TMB^20110601082144~TMB^20110601082208|TMB^20110531154117~Systems^20110531144132<CR>

OBX|1|NM|High<SP>Control^^L||969|/7.5<SP>mL|
928<SP>-<SP>1268||||F|||20110601082208||Operator1||CT0908050~AP0401004|20110531154117<CR>

SID|CTC^CellSearch<SP>CTC^L|0011B<CR>

NTE|1|A|Comment<SP>from<SP>the<SP>celltracks<SP>system.<CR>

OBX|2|NM|Low<SP>Control^^L||43|/7.5<SP>mL|
23<SP>-<SP>83||||F|||20110601082208||Operator1||CT0908050~AP0401004|20110531154117<CR>

Response from LIS

MSH|^~\&|LIS123|LISFacility123|SERNUM123|Janssen<SP>Diagnostics,<SP>LLC|20121010113311.953
||ACK^OUL^ACK_OUL|20121010113311.953|P|2.5||||||UNICODE<SP>UTF-8|||<CR>

MSA|AA|20121010113547.808||||<CR>

Example: No Result Message

This example shows how a sample with a no result is transmitted. In the example, longer lines are split because they would not fit on the page. In the actual message, each line begins with a segment identifier like MSH and ends with a <CR>.

Message sent to LIS

MSH|^~\&|SERNUM123|Janssen<SP>Diagnostics,<SP>LLC|LIS123|LISFacility123|20121010121750.730||OUL^R22^OUL_R22|20121010121750.730|P|2.5|||||UNICODE<SP>UTF-8<CR>

PID|1||PAT5423233||Doe^Jane||19430202|F||2076-8<CR>

SPM|1|SID324542||BLD|||||||P||||||20091229020300<CR>

SAC|||12345678|SID324542|||||||3<CR>

OBR|1||1|CTC<SP>Research^RUO^L|||20091229020300|||||Cancer<SP>Type:<SP>Breast|||^smith^fred|||||||||F|||||||Operator1^20121010121750|Operator2^20111201104736~Operator2^20111201104834~Operator1^20121010121719|Operator2^20111201101750~SDF^20100101010000<CR>

OBX|1|NM|CTC+^^L|||/1.3<SP>mL|||||X|||20121010121719||Operator1||CTA2~AP432|20111201101750<CR>

SID|CTC^CellSearch<SP>CTC^L|3445<CR>

SID|ABC^^L|123456<CR>

NTE|1|A|This<SP>is<SP>the<SP>ap<SP>comment.\X0A\Result<SP>could<SP>not<SP>be<SP>determined.\X0A***<SP>The<SP>AutoPrep<SP>temperature<SP>was<SP>out<SP>of<SP>range<SP>while<SP>processing<SP>this<SP>sample.<SP>***<CR>

OBX|2|NM|CTC+/<UDA>+^^L|||/1.3<SP>mL|||||X|||20121010121719||Operator1||CTA2~AP432|20111201101750<CR>

OBX|3|NM|CTC+/<UDA>-^^L|||/1.3<SP>mL|||||X|||20121010121719||Operator1||CTA2~AP432|20111201101750<CR>

Response from LIS

MSH|^~\&|LIS123|LISFacility123|SERNUM123|Janssen<SP>Diagnostics,<SP>LLC|20121010121513.338||ACK^OUL^ACK_OUL|20121010121513.338|P|2.5|||||UNICODE<SP>UTF-8|||<CR>

MSA|AA|20121010121750.730||||<CR>

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