# CELL-DYN EMERALD SYSTEM LABORATORY INFORMATION SYSTEM INTERFACE SPECIFICATION

LIST NO. 09H40-04 REVISION C

ABBOTT DIAGNOSTICS DIVISION Abbott Laboratories Abbott Park, IL 60064

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#### 1. OBJECTIVE

This document describes the data transmission format protocol between CELL-DYN Emerald and a host Laboratory Information System (LIS).

The functionality must match the software specifications of the Emerald.

## 2. APPROVAL AND HISTORY

| Version | Date     | Author                  | Reason and Type of Change                                   |
|---------|----------|-------------------------|---|
| А       | 14/10/08 | O. Genet/M.<br>Hepp     | Document creation   |
| В       | 13/02/09 | O. Genet/M.<br>Hosseini | Updated to align with CD-Emerald Operator's Manual changes. |
| С       | 11/06/10 | E. Ayala                | Updated to align with Software Version 2.1.0.               |

#### 3. SCOPE

This document applies to the CELL-DYN Emerald instrument. It specifies the messages and behaviors of the initial version of the CELL-DYN Emerald Host Computer Interface.

#### 4. TERMINOLOGY AND ABBREVIATIONS

Handshake: bi-directional communication using acknowledgement

LIS: Laboratory Information System, i.e. a HOST system

Host: external computer or data collection system

CRC: Cyclic Redundancy Code

#### 5. SYSTEM OVERVIEW

This document describes the interface characteristics of the CELL-DYN EMERALD automated hematology analyzer when attached to a Host.

## 6. GENERAL SPECIFICATIONS

The Host Interface for the CELL-DYN EMERALD System is a specific format designed to transfer data to an external system. The system does not use the ASTM or CLSI (LIS-x) standards for communications with a host system.

The format is text-oriented and is compatible with the CSV format used by various Microsoft Office applications.

The Supervisor level password (default password is 123) is necessary to access the COMMUNICATION menu. When LIS customization is completed, it is imperative that the user returns the instrument to general user login (no password).

# **NOTES**

## 1.1 Physical Interface

#### 1.1.1 RS232 connector

The CELL-DYN EMERALD provides a standard DB-9 female connector, labelled RS232C, mounted on the rear of the instrument.



RS232 Label

Pins on the DB-9 connector: (standard RS-232 9-pin assignments)

Pin 1: Data Carrier Detect (DCD input)

Pin 2: (output) CELL-DYN Emerald Data to Host (LIS, results)

Pin 3: (input) Host Data to CELL-DYN EMERALD

Pin 4: (output) Data Terminal Ready (DTR)

Pin 5: Signal Ground

Pin 6: Data Set Ready (DSR)

Pin 7: (input) Clear to Send (CTS input) (not enabled by CELL-DYN Emerald Software)

Pin 8: (output) Request to Send (RTS output) (not enabled by CELL-DYN Emerald

Software)

Pin 9: (not connected)

#### 1.1.2 Ethernet connector

The CELL-DYN EMERALD provides an RJ 45 connector 10/100Base, labelled with the symbol below, mounted on the rear of the instrument.



#### 1.2 Data Interface

The system can be configured to use either TCP/IP or UDP/IP over Ethernet or RS232 in the COMMUNICATION menu by selecting HOST SERIAL (for RS 232) or HOST NET (for TCP/IP or UDP). The default setting is no host.

## 1.2.1 Host serial configuration

The system can be configured for data transmission on the RS232 channel by using the COMMUNICATION/SERIAL PARAM. Menu. The configurable transmission parameters include data bits, stop bits, parity and baud rate.

- The asynchronous method of data transmission (serial by bit) is used.
- All information transmitted is in character form and is represented by 8-bit or ASCII.
- Transmitted characters consist of one (1) start bit, eight (8) data bits (least significant first), odd, even or no parity bit, and one (1) or two (2) stop bits.
- Parity may be selected as none, odd, or even. Default parity is None.
- The transmission speed may be selected from 1200, 9600, 19200, 57600 or 115200 bits per second (bps).
- The Default setting is 115200 bits per second.
- The number of bits per character is eight bits.

## 1.2.2 Host net configuration

- The system can be configured for data transmission via TCP/IP or UDP/IP over Ethernet by using the COMMUNICATION/NET. PARAM. Menu.
- The configurable transmission parameters include protocol, host IP address, host port, Emerald IP address, Emerald mask address, and Gateway address.
- The protocol may be set to TCP/IP in this menu. The default setting is "UDP/IP".
- The host default IP address is 192.168.0.103. Its port is default set to 1200. Its mask is 255.255.255.0.
- The Emerald default IP address is 192.168.0.200. The gateway default address is 192.168.0.1.
- The Emerald port is set to 3000.

#### 1.3 Communication Protocol

The following is available with RS232 only.

- Transmission control is provided in one way: XOFF/XON protocol in which the Host transmits an XOFF character (hex 13) to stop transmission from the System and an XON character (hex 11) to re-start transmission.
- This is optional and not default-enabled. The option is available in COMMUNICATION/SERIAL PARAM. Menu with the FLOW setting.
- The CTS/RTS pinouts are not used.

# 1.3.1 Invoking Host Transmission

The following assumes that the HOST mode is selected in the COMMUNICATION menu.

#### 1.3.1.1 RUN SAMPLE Menu Automatic Transmit Mode

The user is able to manually send the current results displayed in the RUN SAMPLE menu by selecting the SEND button available in the TOOLS menu.

## 1.3.1.2 QC RUN AND RESULTS Menu Automatic Transmit Mode

The user is able to manually send all selected QC runs by selecting the SEND button available in the TOOLS menu.

## 1.3.1.3 CALIBRATION Menu Automatic Transmit Mode

The user is able to manually send all selected calibration runs by selecting the SEND button available in the TOOLS menu.

#### 1.3.1.4 DATALOG Menu Transmit Mode

The user is able to manually send a range of selected results viewable in the DATALOG menu or the DATE menu by selecting the SEND button available in the TOOLS menu.

## 1.3.2 Transmission Control

## 1.3.2.1 Response from Host

The following assumes that the HOST mode with handshake mode is selected in the COMMUNICATION menu.

There is no automatic re-transmission following a transmission error.

## 1.3.2.2 No response from the host

The instrument displays an error message "HOST: TIME OUT".

## 1.3.2.3 Non valid Acknowledgement

If the acknowledgement message from the host is not the one expected, the instrument displays an error message "HOST: SYNCHRO ERROR"

## 1.3.2.4 Acknowledgement with error

The host acknowledges the message with an error.

The instrument displays an error message "HOST: ACK ERROR".

#### 1.3.3 Frame Format

Each frame sent by the instrument consists of the following elements:

FRAME HEADER FRAME ID

DATA SEGMENT

Each frame sent by the host consists of the following elements:

FRAME ID

DATA SEGMENT

DATA SEGMENT is optional according to the type of frame described in section 7.5.

The following subsections describe these constructs in detail.

#### 1.3.3.1 Frame header

The Emerald always begins its frame with the following header, named frame header:

INSTRUMENT TYPE; INSTRUMENT NUMBER; INSTRUMENT SERIAL NUMBER; USER LOGIN[CR]

The semicolon ';' is the field separator. [CR] is the carriage-return.

## 1.3.3.1.1 Field 1—Instrument Type

The Instrument Type is an alphanumeric field of seven (7) characters: enclosed in double quotation marks. The string for the CELL-DYN EMERALD is sent as ""EMERALD"".

#### 1.3.3.1.2 Field 2—Instrument Number

The Instrument Number is a numeric field of up to two (2) characters ranging from 0 to 99.

This number is set in the COMMUNICATION menu. The default value is 1.

#### 1.3.3.1.3 Field 3—Instrument Serial Number

The Instrument Serial Number is an alphanumeric field of thirteen (13) characters including the dash (-) character.

## 1.3.3.1.4 Field 4—User Login

The User Login is a field of up to ten (10) characters UTF8 encoded.

# 1.3.3.2 Frame ID

The frame ID allows to distinguish the type of information transmitted.

| FRAME ID         |            | SENDER                        | INFORMATION   |
|------------------|------------|-------------------------------|---|
|                  | INSTRUMENT | HOST (with handshake enabled) |   |
| CONNECT          | X          | X                             | Connection test request                             |
| ACK_CONNECT      |            | Х                             | Connection acknowledged                             |
| NAK_CONNECT      |            | Х                             | Connection acknowledged with failed status          |
| RESULT_READY     | Х          |                               | Instrument ready to send result data                |
| RESULT           | Х          |                               | Result data being sent                              |
| ACK_RESULT_READY |            | X                             | Host acknowledge: ready for result data             |
| ACK_RESULT       |            | Х                             | Host acknowledge: end of result data receipt        |
| CALIBRATION      | Х          |                               | Calibration report being sent                       |
| ACK_CALI         |            | Х                             | Host acknowledge: end of calibration report receipt |

## 1.3.3.3 Frame length

The length is variable.

# 1.3.3.4 Control sum

A CRC 16 is provided according to the type of frame and may be optionally processed by the host to verify correct transmission.

Details of this algorithm are available in section 7.6.1.

## 1.3.3.5 Data representation

Numeric data are transmitted in fields of variable length. A data segment is made of several data fields.

## 1.3.3.5.1 Data field

Each data sent by the instrument consists of the following elements:

FIELD ID FIELD SEPARATOR DATA VALUE [CR]

According to the type of field, several data values, semicolon separated, may follow a field ID:

- The decimal separator is the dot '.'.
- The fields separator is the semicolon ';'.
- The lines separator and the end of frame indicator are the carriage return [CR].
- All field IDs must be transmitted. If no data value is available, the data value field is empty.
- There are two exceptions mentioned in the analysis result concerning the PDW and PCT values.

All Identifier key words (frame, parameter) are in upper case.

The following fields are UTF8 encoded: SID, PID, ID, blood type (specimen), operator, lot numbers.

#### 1.4 FRAMES

## 1.4.1 Connection (HOST)

The Connection frame is used to determine if the connection between the CELL-DYN Emerald and the host computer is operational.

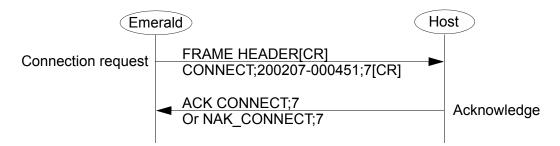
This frame is not mandatory to establish an operational connection with the host.

This transaction may be initiated either by the instrument or the host.

## 1.4.1.1 Connection request

## 1.4.1.1.1 Initiated by the Emerald

The Emerald sends this request when a user logs in.



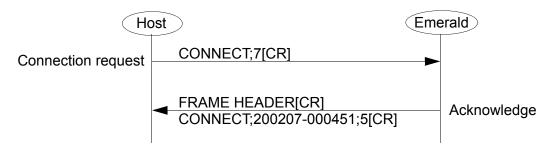
FRAME HEADER[CR]

CONNECT; instrument serial number; format version[CR]

Please refer to section 1.3.3.1 for details.

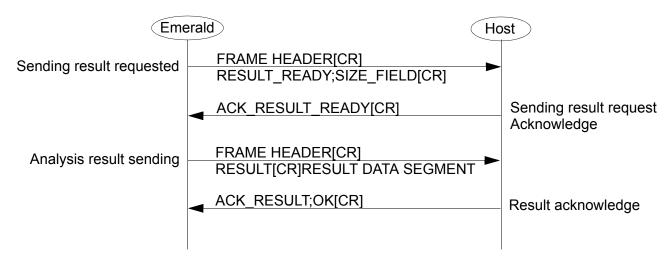
The current format version is number 7.

## 1.4.1.1.2 Initiated by the Host



#### 1.4.2 SENDING RESULTS

The Emerald sends results after the Host acknowledgement occurs, in order to avoid sending a data stream when there is no host connected.



## 1.4.2.1 Sending result request

FRAME HEADER[CR]
RESULT\_READY;Size\_field[CR]

#### 1.4.2.1.1 Field 1—Size

The size is a numeric field that is the size of the data segment to be sent by the instrument with a value ranging from 0 to 4294967295(2^32-1).

# 1.4.2.2 Sending result request acknowledgement

ACK\_RESULT\_READY[CR]

## 1.4.2.3 Sending analysis result

FRAME HEADER[CR]
RESULT[CR]

## 1.4.2.3.1 Result data segment

The following fields are described based upon their rank order in the data segment.

## 1.4.2.3.1.1 Field 1 - Date

The Specimen Date, giving the date on which the specimen was run, is an alphanumeric field of ten (10) characters. The date format is DD/MM/YYYY.

| Field ID | Field ID length | Data Format | Length |
|----------|-----------------|-------------|--------|
| DATE     | 4               | DD/MM/YYYY  | 10     |

## 1.4.2.3.1.2 Field 2 - Time

The Specimen Time is an alphanumeric field of eight (8) characters. It gives the time at which the specimen was run in standard 24-hour format.

| Field ID | Field ID length | Data Format | Length |
|----------|-----------------|-------------|--------|
| TIME     | 4               | HH:MM:SS    | 8      |

#### 1.4.2.3.1.3 Field 3 - Mode

The mode field is an alphanumeric field of up to thirteen (13) characters. It gives the analysis mode: standard analysis run, QC run, precision run, calibration run, linearity run or startup run.

| Field ID | Field ID length | Data format | Length   |
|----------|-----------------|-------------|----------|
| MODE     | 4               | NORMAL      | Variable |

#### 1.4.2.3.1.4 Field 4 - Unit

The unit code is a numeric field of one (1) character with a value ranging from 1 to 3.

The parameters reported by the instrument may be represented in any of three different sets of measurement units as follows:

| Unit code value | Unit system    |
|-----------------|----------------|
| 1               | USA = standard |
| 2               | S.I.           |
| 3               | S.I. MOD       |

| Field ID | Field ID length | Data format     | Length |
|----------|-----------------|-----------------|--------|
| UNIT     | 4               | Unit code value | 1      |

## Following are the unit labels according to the selected unit set:

|            | UNITS                     |                           |                           |  |
|------------|---------------------------|---------------------------|---------------------------|--|
| Parameters | USA(standard)             | SI                        | SI MOD                    |  |
| WBC        | XXX.X 10 <sup>3</sup> /µL | XXX.X 10 <sup>9</sup> /L  | XXX.X 10 <sup>9</sup> /L  |  |
| RBC        | XX.XX 10 <sup>6</sup> /µL | XX.XX 10 <sup>12</sup> /L | XX.XX 10 <sup>12</sup> /L |  |
| HGB        | XX.X g/dL                 | XXX g/L                   | XX.XX mmol/L              |  |
| НСТ        | XX.X %                    | X.XXX L/L                 | X.XXX L/L                 |  |
| MCV        | xxx.x fL                  | XXX.X fL                  | XXX.X fL                  |  |
| MCH        | XX.X pg                   | XX.X pg                   | X.XX fmol                 |  |
| MCHC       | XX.X g/dL                 | XXX g/L                   | XX.XX mmol/L              |  |
| RDW        | XX.X %                    | xx.x %CV                  | XX.X %CV                  |  |
| PLT        | XXXX 10 <sup>3</sup> /µL  | XXXX 10 <sup>9</sup> /L   | XXXX 10 <sup>9</sup> /L   |  |
| MPV        | XX.X fL                   | XX.X fL                   | XX.X fL                   |  |
| PCT*       | X.XXX %                   | x.xxx mL/L                | x.xxx mL/L                |  |
| PDW*       | XX.X %                    | XX.X %                    | XX.X %                    |  |

# 1.4.2.3.1.5 Field 5 - Seq

The sequence number is a numeric field of four (4) characters with values ranging from 1 to 9999.

| Field ID | Field ID length | Data format | Length    |
|----------|-----------------|-------------|-----------|
| SEQ      | 4               | Integer     | 1 up to 4 |

## 1.4.2.3.1.6 Field 6 - SID

The Sample ID is an alphanumeric field of up to sixteen (16) characters, UTF8 encoded. A SID is mandatory to run an analysis run.

| Field ID | Field ID length | Data format                | Length     |
|----------|-----------------|----------------------------|------------|
| SID      | 3               | Alphanumeric, UTF8 encoded | 1 up to 16 |

# 1.4.2.3.1.7 Field 7 - PID

The Patient ID is an alphanumeric field of up to sixteen (16) characters, UTF8 encoded.

| Field ID | Field ID length | Data format                | Length     |
|----------|-----------------|----------------------------|------------|
| PID      | 3               | Alphanumeric, UTF8 encoded | 0 up to 16 |

<sup>\*</sup> Clinical significance has not been established for these parameters; therefore they are not reportable in the U.S. These options may only be selected outside of the U.S.

## 1.4.2.3.1.8 Field 8 - ID

The ID is an alphanumeric field of up to twenty (20) characters, UTF8 encoded. It is the patient name. In Linearity mode, this field is forced to Linearity.

| Field ID | Field ID length | Data format                | Length     |
|----------|-----------------|----------------------------|------------|
| ID       | 2               | Alphanumeric, UTF8 encoded | 0 up to 20 |

# 1.4.2.3.1.9 Field 9 - Type

The Type is an alphanumeric field of up to ten (10) characters, UTF8 encoded. It is the specimen name.

| Field ID | Field ID length | Data format                | Length     |
|----------|-----------------|----------------------------|------------|
| TYPE     | 3               | Alphanumeric, UTF8 encoded | 1 up to 10 |

There are 20 specimen types that can be defined in the instrument software. The first (default) one, named STANDARD, cannot be modified.

## 1.4.2.3.1.10 Field 10 - Test

Test is an alphanumeric field of three (3) characters. It is set to LMG for the type of tests runs on this instrument.

| Field ID | Field ID length | Data format | Length |
|----------|-----------------|-------------|--------|
| TEST     | 4               | LMG         | 3      |

## 1.4.2.3.1.11 Field 11 - Operator

The Operator is an alphanumeric field of up to ten (10) characters.

If no Operator ID is specified, the field is empty.

| Field ID | Field ID length | Data format                | Length     |
|----------|-----------------|----------------------------|------------|
| OPERATOR | 8               | Alphanumeric, UTF8 encoded | 0 up to 10 |

#### 1.4.2.3.1.12 Field 12 - WBC

#### NOTE:

- To better understand flagging fields, refer to Section 3-9 in the CELL-DYN Emerald System Operator's Manual.
- The count values are transmitted to the host in the selected unit.
- For Rank 3: '\*' is used for L1 and/or L5 WBC flags and 's' is used for L2 and/or L3 WBC flags. If both flags are generated simultaneously, '\*' will supercede 's'.

| Rank | Data values                     | Data format                                 | Length   |
|------|---------------------------------|---|--|
| 1    | Field ID                        | WBC   | 3  |
| 2    | Count value                     | Numeric<br>+++++                            | Variable (refer to the units table). Maximum 5 5 5 |
| 3    | Suspect flag                    | Empty, 's' or '*'                           | Up to 1 character                                  |
| 4    | Flag: over-range or panic flags | Empty or 'D' or 'L'<br>or 'l' or 'h' or 'H' | Up to 1 character                                  |
| 5    | Low Panic value                 | Numeric                                     | Variable (refer to the units table)                |
| 6    | Low value                       | Numeric                                     | Variable (refer to the units table)                |
| 7    | High value                      | Numeric                                     | Variable (refer to the units table)                |
| 8    | High panic value                | Numeric                                     | Variable (refer to the units table)                |

For the data values at rank 2, 5, 6, 7 and 8, please refer to the following table to determine the maximum length:

|            |               | UNITS |        |
|------------|---------------|-------|--------|
| Parameters | USA(standard) | SI    | SI MOD |
| WBC        | XXX.X         | XXX.X | XXX.X  |
| RBC        | XX.XX         | XX.XX | XX.XX  |
| HGB        | XX.X          | XXX   | XX.XX  |
| НСТ        | XX.X          | X.XXX | X.XXX  |
| MCV        | XXX.X         | XXX.X | XXX.X  |
| MCH        | XX.X          | XX.X  | X.XX   |
| MCHC       | XX.X          | XXX   | XX.XX  |
| RDW        | XX.X          | XX.X  | XX.X   |
| PLT        | xxxx          | XXXX  | xxxx   |
| MPV        | XX.X          | XX.X  | XX.X   |
| PCT*       | X.XXX         | X.XXX | X.XXX  |
| PDW*       | XX.X          | XX.X  | XX.X   |

<sup>\*</sup> Clinical significance has not been established for these parameters; therefore they are not reportable in the U.S. These options may only be selected outside of the U.S.

1.4.2.3.1.13 Field 13 - RBC

Please refer to the WBC field description for details. The field ID is RBC.

1.4.2.3.1.14 Field 14 - HGB

Please refer to the WBC field description for details. The field ID is HGB.

1.4.2.3.1.15 Field 15 - HCT

Please refer to the WBC field description for details. The field ID is HCT.

1.4.2.3.1.16 Field 16 - MCV

Please refer to the WBC field description for details. The field ID is MCV.

1.4.2.3.1.17 Field 17 - MCH

Please refer to the WBC field description for details. The field ID is MCH.

1.4.2.3.1.18 Field 18 - MCHC

Please refer to the WBC field description for details. The field ID is MCHC.

1.4.2.3.1.19 Field 19 - RDW

Please refer to the WBC field description for details. The field ID is RDW.

1.4.2.3.1.20 Field 20 - PLT

Please refer to the WBC field description for details. The field ID is PLT.

1.4.2.3.1.21 Field 21 - MPV

Please refer to the WBC field description for details. The field ID is MPV.

1.4.2.3.1.22 Field 22 - PCT\*

Please refer to the WBC field description for details. The field ID is PCT.

1.4.2.3.1.23 Field 23 - PDW\*

Please refer to the WBC field description for details. The field is PDW.

1.4.2.3.1.24 Field 24 - LYM%

Please refer to the WBC field description for details. The field is LYM%.

<sup>\*</sup>Clinical significance has not been established for these parameters; therefore they are not reportable in the U.S. These options may only be selected outside of the U.S.

1.4.2.3.1.25 Field 25 - MID%

Please refer to the WBC field description for details. The field is MID%.

1.4.2.3.1.26 Field 26 - GRA%

Please refer to the WBC field description for details. The field is GRA%.

1.4.2.3.1.27 Field 27 - LYM

Please refer to the WBC field description for details. The field is LYM.

1.4.2.3.1.28 Field 28 - MID

Please refer to the WBC field description for details. The field is MID.

1.4.2.3.1.29 Field 29 - GRA

Please refer to the WBC field description for details. The field is GRA.

1.4.2.3.1.30 Field 30 - WBC channel data

Following the field ID, there are 128 values. Each value is followed by a ';' separator and with a value ranging from 0 to 255.

| Field ID  | Field ID length | Data format     | Length   |
|-----------|-----------------|-----------------|----------|
| WBC CURVE | 9               | Numeric integer | Variable |

#### 1.4.2.3.1.31 Field 31 - WBC thresholds

This field gives the two WBC thresholds M1 and M2 set on the system. Each is a value ranging from 0 to 255.

| Rank | Data values            | Data format    | Length                                  |
|------|------------------------|----------------|---|
| 1    | Field ID               | WBC THRESHOLDS | 14                                      |
| 2    | Threshold M1           | Numeric        | Variable. Integer ranging from 0 to 255 |
| 3    | 3 Threshold M2 Numeric |                | Variable. Integer ranging from 0 to 255 |
| 4    | Not used               | 0              | 1 character                             |

## 1.4.2.3.1.32 Field 32 - RBC channel data

Following the field ID, there are 128 values. Each value is followed by a ';' separator and with a value ranging from 0 to 255.

| Field ID  | Field ID length | Data Format     | Length   |
|-----------|-----------------|-----------------|----------|
| RBC CURVE | 9               | Numeric integer | Variable |

## 1.4.2.3.1.33 Field 33 - RBC thresholds

This field gives both RBC thresholds that are unused on the Emerald. So, these values have no meaning on the system.

| Rank | Data values  | Data Format    | Length |
|------|--------------|----------------|--------|
| 1    | Field ID     | RBC THRESHOLDS | 14     |
| 2    | Threshold M1 | 32             | 2      |
| 3    | Threshold M2 | 55             | 2      |

## 1.4.2.3.1.34 Field 34 - PLT channel data

Following the field ID, there are 128 values. Each value is followed by a ';' separator and with a value ranging from 0 to 255.

## 1.4.2.3.1.35 Field 35 - PLT thresholds

This field gives the PLT thresholds set on the system. It is a value ranging from 0 to 255.

| Rank | Data values | Data Format    | Length   |
|------|-------------|----------------|----------|
| 1    | Field ID    | PLT THRESHOLDS | 14       |
| 2    | Threshold P | Numeric        | Variable |

#### 1.4.2.3.1.36 Field 36 - Alarms

This field lists the instrument alarms, operational alerts and measurand data flags applied on a result.

NOTE: To better understand Flagging fields, refer to Section 3-9 in the CELL-DYN Emerald System Operator's Manual.

Each flag is present in the list only if the flag is set. It means that the according data values are available if the according alarm flag is set. So, the number of data values depends on the number of flags set.

.

| Rank | Data values            | Data Format   | Length |
|------|------------------------|---------------|--------|
| 1    | Field ID               | ALARMS        | 6      |
| 2    | L1                     | L1            | 2      |
| 3    | L2                     | L2            | 2      |
| 4    | L3                     | L3            | 2      |
| 5    | L5                     | L5            | 2      |
| 6    | P1                     | P1            | 2      |
| 7    | P2                     | P2            | 2      |
| 8    | P3                     | P3            | 2      |
| 9    | Startup not done       | S-UP NOT DONE | 13     |
| 10   | Startup failed         | S-UP FAIL     | 9      |
| 11   | QC not done            | QC NOT DONE   | 11     |
| 12   | QC failed              | QC FAIL       | 7      |
| 13   | Temperature alert      | INS-T         | 5      |
| 14   | Pressure alert         | INS-P         | 5      |
| 15   | HGB channel saturation | INS-H         | 5      |
| 16   | WBC clog               | W_CL          | 4      |
| 17   | RBC clog               | R_CL          | 4      |

1.4.2.3.1.37 Field 37 - WBC interpretive result

This field lists the WBC interpretive result.

NOTE: To better understand WBC interpretive results, refer to Section 3-19 in the CELL-DYN Emerald System Operator's Manual.

Each WBC interpretive result is present in the list only if it is set. This means that the according data values are available if the according interpretive flag is set. So, the number of data values depends on the number of interpretive flags set.

| rank | Data values         | Data Format       | Length |
|------|---------------------|-------------------|--------|
| 1    | Field ID            | INTERPRETIV_WBC   | 16     |
| 2    | Leukocytosis        | LEU>              | 4      |
| 3    | Leukopenia          | LEU<              | 4      |
| 4    | Lymphocytosis       | LYM>              | 4      |
| 5    | Lymphopenia         | LYM<              | 4      |
| 6    | Granulocytosis      | GRA>              | 4      |
| 7    | Granulocytopenia    | GRA<              | 4      |
| 8    | Unable to interpret | NO_INTERPRETATION | 17     |

1.4.2.3.1.38 Field 38 - RBC interpretive result
This field lists RBC interpretive results.

NOTE: To better understand RBC interpretive results, refer to Section 3-19 in the CELL-DYN Emerald System Operator's Manual.

Each RBC interpretive result is present in the list only if it is set. This means that the according data values are available if the according interpretive flag is set. So, the number of data values depends on the number of interpretive flags set.

| Rank | Data values         | Data Format       | Length |
|------|---------------------|-------------------|--------|
| 1    | Field ID            | INTERPRETIV_RBC   | 16     |
| 2    | Anemia              | ANE               | 3      |
| 3    | Erythrocytosis      | ERY>              | 4      |
| 4    | Macrocytosis        | MACRO             | 5      |
| 5    | Microcytosis        | MICRO             | 5      |
| 6    | Unable to interpret | NO_INTERPRETATION | 17     |

1.4.2.3.1.39 Field 39 - PLT interpretive result
This field lists PLT interpretive results.

NOTE: To better understand PLT interpretive results, refer to Section 3-19 in the CELL-DYN Emerald System Operator's Manual.

Each PLT interpretive result is present in the list only if it is set. This means that the according data values are available if the according interpretive flag is set. So, the number of data values depends on the number of interpretive flags set.

| Rank | Data values         | Data Format       | Length |
|------|---------------------|-------------------|--------|
| 1    | Field ID            | INTERPRETIV_PLT   | 16     |
| 2    | Thrombocytosis      | ANE               | 3      |
| 3    | Thrombocytopenia    | ERY>              | 4      |
| 4    | Giant platelets     | MACRO             | 5      |
| 5    | Cell debris         | CELLD             | 5      |
| 6    | Cold agglutinin     | PLTAGGR           | 7      |
| 7    | Unable to interpret | NO_INTERPRETATION | 17     |

## 1.4.2.3.1.40 Field 40 - COMMENT

This field is filled with text if IUO\*\* mode and US\*\* mode are enabled. Both options are default disabled.

| Field ID | Field ID length | Data Format                     | Length |
|----------|-----------------|---------------------------------|--------|
| COMMENT  | 7               | PCT* and PDW* are for Info Only | 29     |

## 1.4.2.3.1.41 Field 41 - END RESULT

This field is populated with the CRC value computed on the transmitted buffer and is the end marker of the result transmission.

The Algorithm is described in section 1.5.

| Field ID   | Field ID length | Data Format | Length   |
|------------|-----------------|-------------|----------|
| END RESULT | 10              | Integer     | Variable |

<sup>\*</sup> Clinical significance has not been established for these parameters; therefore they are not reportable in the U.S.

<sup>\*\*</sup> These Options may only be selected outside of the U.S.

## 1.4.2.3.2 Result data segment example

```
DATE; 06/06/2008 [CR]
TIME; 13:41:29 [CR]
MODE; NORMAL [CR]
UNIT; 1 [CR]
SEQ; 31; 0 [CR] SID; No ID Entered [CR]
PID; [CR]
ID; [CR]
TYPE; STANDARD [CR]
TEST; LMG [CR]
OPERATOR; OG[CR]
WBC;12.0;;H;0.0;0.0;0.0;0.0
                                  [CR]
RBC; 5.20 ;; H; 0.00 ; 0.00 ; 0.00 ; 0.00 [CR]
HGB;11.9;;H;0.0;0.0;0.0;0.0 [CR]
HCT; 40.9;; H; 0.0; 0.0; 0.0; 0.0 [CR]
MCV;78.7 ;;H;0.0 ;0.0 ;0.0 ;0.0
                                  [CR]
MCH; 22.9 ;; H; 0.0 ; 0.0 ; 0.0 ; 0.0
                                  [CR]
MCHC;29.1 ;;H;0.0 ;0.0 ;0.0 ;0.0
                                   [CR]
RDW; 17.7 ;; H; 0.0 ; 0.0 ; 0.0 ; 0.0
                                  [CR]
PLT;220 ;;H;0
                 ; 0
                            ; 0
                       ; 0
                                  [CR]
MPV; 7.6 ;; H; 0.0 ; 0.0 ; 0.0 ; 0.0
                                  [CR]
LYM%;22.5;;H;0.0;0.0;0.0;0.0 [CR]
MID%; 23.7;; H; 0.0; 0.0; 0.0; 0.0 [CR]
GRA%;53.8;;H;0.0;0.0;0.0;0.0 [CR]
LYM; 2.7 ;; H; 0.0 ; 0.0 ; 0.0 ; 0.0
                                  [CR]
MID; 2.8 ;; H; 0.0 ; 0.0 ; 0.0 ; 0.0
                                  [CR]
GRA; 6.5 ;; H; 0.0 ; 0.0 ; 0.0 ; 0.0
                                  [CR]
WBC
CURVE; 0; 0; 0; 0; 0; 0; 0; 0; 1; 5; 13; 25; 40; 56; 73; 91; 109; 128;
146; 165; 184; 202; 220; 235; 244; 245; 240; 229; 215; 199; 182;
164;145;127;108;89;71;54;40;31;25;21;18;17;17;17;17;
17;17;18;20;23;25;27;29;32;35;37;39;41;44;47;49;51;
53;56;59;61;63;65;68;71;73;75;77;79;82;84;86;88;91;
94;96;98;98;98;97;95;94;92;89;87;85;83;81;78;75;73;
71;69;66;63;61;59;57;54;51;49;47;45;42;39;37;35;33;
30;27;23;17;11;6;2;0;0;0;0;0;0;[CR]
WBC THRESHOLDS; 25; 37; 0; [CR]
RBC
0;0;0;0;0;1;3;6;12;20;30;42;56;70;86;102;119;136;
153;170;186;201;213;221;225;225;221;214;204;192;178;
163;147;130;113;96;80;64;50;37;27;19;13;8;5;3;1;0;0;
0;0;0;0;[CR]
```

RBC THRESHOLDS; 32; 55 [CR]PLT CURVE; 0; 0; 0; 0; 0; 0; 1; 2; 4; 7; 10; 14; 19; 23; 29; 34; 40; 46; 52;58;64;70;77;83;89;95;100;104;108;110;112;113;114; 113;113;112;111;109;107;105;103;101;98;96;94;91;89; 86;83;81;78;75;73;70;68;65;63;60;57;55;52;49;47;44; 41;39;36;33;31;28;25;23;20;17;15;12;10;8;6;5;4;3;2; PLT THRESHOLDS; 100 [CR] ALARMS; QC FAIL; INS-T; [CR] INTERPRETIVE\_WBC; LEU>; LYM>; GRA>; [CR] INTERPRETIVE\_RBC; ERY>; MACRO; [CR] INTERPRETIVE\_PLT; THR>; GIANTP; [CR] COMMENT;; [CR] END RESULT; 7774 [CR]

## 1.4.2.4 Result acknowledgement

## ACK\_RESULT;A;B[CR]

Where A: OK or error code, B: Nothing.

Regardless of the error code transmitted by the host, the CELL-DYN Emerald does not interpret the error code, so if A is different from OK, the instrument generates an error such as described in section.1.3.2.4.

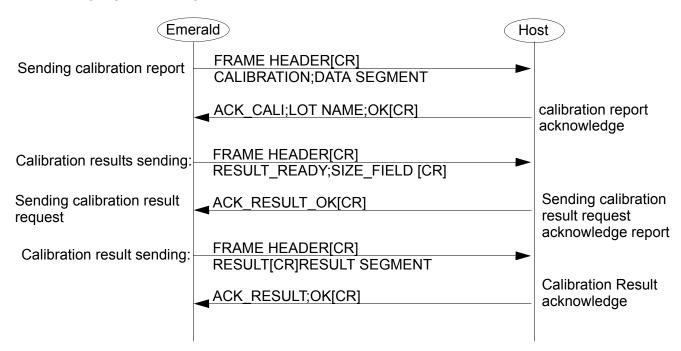
## 1.4.2.5 Error handling in handshake mode

In handshake mode, each result is tagged as sent if no error is generated in the acknowledgement process. If an error is ever generated then the result is not tagged as sent.

At next login, the CELL-DYN Emerald prompts the user to automatically transmit the results not sent. The user then has the ability to accept, to postpone or ignore (in this case the results are flagged as sent).

In non handshake mode, the CELL-DYN Emerald assumes that all frames were correctly sent and so marks all samples as 'transmitted'.

## 1.4.3 CALIBRATION



## 1.4.3.1 Sending a calibration report

FRAME HEADER[CR]

CALIBRATION; CALIBRATION DATA SEGMENT

The following fields are described based on their rank order in the calibration data segment.

1.4.3.1.1 Field 1 - Calibration field ID - data segment

| Rank | Data values            | Data Format  | Length                            |
|------|------------------------|--------------|-----------------------------------|
| 1    | Field ID               | CALIBRATION  | 11                                |
| 2    | User login             | Alphanumeric | Up to 10 characters. UTF8 encoded |
| 3    | Calibration Date       | DD/MM/YYYY   | 10                                |
| 4    | Calibration Time       | HH:MM:SS     | 8                                 |
| 5    | Lot Name               | Alphanumeric | Up to 10 characters. UTF8 encoded |
| 6    | Expiry Date            | DD/MM/YYYY   | 10                                |
| 7    | Creation Date          | DD/MM/YYYY   | 10                                |
| 8    | Creation Time          | HH:MM:SS     | 8                                 |
| 10   | WBC calibration factor | numeric      | Float ranging from 0.5 to 2.0     |
| 11   | RBC calibration factor | numeric      | Float ranging from 0.5 to 2.0     |
| 12   | HGB calibration factor | numeric      | Float ranging from 0.5 to 2.0     |
| 13   | MCV calibration factor | numeric      | Float ranging from 0.5 to 2.0     |
| 14   | PLT calibration factor | numeric      | Float ranging from 0.5 to 2.0     |
| 15   | Number of result       | numeric      | Integer ranging from 0 to 10      |

## 1.4.3.1.1.1 User Login

The User Login, which identifies the operator that performed the calibration, is an alphanumeric field of up to ten (10) characters. It is UTF8 encoded.

#### 1.4.3.1.1.2 Calibration Date

The Calibration Date, the date on which the calibration was done, is an alphanumeric field of ten (10) characters. The default format of the date is DD/MM/YYYY.

#### 1.4.3.1.1.3 Calibration Time

The Calibration Time is an alphanumeric field of eight (8) characters. It gives the time at which the Calibration was done in standard 24-hour format.

#### 1.4.3.1.1.4 Lot name

The Calibration Lot is an alphanumeric field of up to eight (8) characters.

## 1.4.3.1.1.5 Expiry Date

The Expiry Date, the expiration date of the calibrator lot, is an alphanumeric field of ten (10) characters. The default format of the date is DD/MM/YYYY.

#### 1.4.3.1.1.6 Creation Date

The Creation Date, the date on which the calibration was done, is an alphanumeric field of ten (10) characters. The default format of the date is DD/MM/YYYY.

## 1.4.3.1.1.7 Creation Time Field

The Creation Time is an alphanumeric field of eight (8) characters. It gives the time at which the Calibration was done in standard 24-hour format.

## 1.4.3.1.1.8 WBC calibration factor

The WBC calibration factor is a numeric field filled out with the computed calibration factor. It ranges from 0.5 to 2.0.

#### 1.4.3.1.1.9 RBC calibration factor

The RBC calibration factor is a numeric field filled out with the computed calibration factor. It ranges from 0.5 to 2.0.

#### 1.4.3.1.1.10 HGB calibration factor

The HGB calibration factor is a numeric field filled out with the computed calibration factor. It ranges from 0.5 to 2.0.

## 1.4.3.1.1.11 MCV calibration factor

The MCV calibration factor is a numeric field filled out with the computed calibration factor. It ranges from 0.5 to 2.0.

## 1.4.3.1.1.12 PLT calibration factor

The PLT calibration factor is a numeric field filled out with the computed calibration factor. It ranges from 0.5 to 2.0.

## 1.4.3.1.1.13 Number of result

When a manual calibration is performed, the number of results is set to 0.

## 1.4.3.1.2 Field 2 - WBC target assay / limit

This field lists the assay value and limits input from the calibrator's assay sheet for the WBC parameter.

| Rank | Data values     | Data Format | Length |
|------|-----------------|-------------|--------|
| 1    | Field ID        | WBC         | 3      |
| 2    | WBC assay value | Numeric     | Float  |
|      | WBC limit       | Numeric     | Float  |

## 1.4.3.1.3 Field 3 - RBC target value /limits

This field lists the assay value and limits input from the calibrator's assay sheet for the RBC parameter.

| Rank | Data values     | Data Format | Length |
|------|-----------------|-------------|--------|
| 1    | Field ID        | RBC         | 3      |
| 2    | RBC assay value | Numeric     | Float  |
| 3    | RBC limit       | Numeric     | Float  |

# 1.4.3.1.4 Field 4 - HGB target value / limits

This field lists the assay value and limits input from the calibrator's assay sheet for the HGB parameter.

| Rank | Data values     | Data Format | Length |
|------|-----------------|-------------|--------|
| 1    | Field ID        | HGB         | 3      |
| 2    | HGB assay value | Numeric     | Float  |
| 3    | HGB limit       | Numeric     | Float  |

## 1.4.3.1.5 Field 5 - MCV target value / limits

This field lists the assay value and limits input from the calibrator's assay sheet for the MCV parameter.

| Rank | Data values     | Data Format | Length |
|------|-----------------|-------------|--------|
| 1    | Field ID        | MCV         | 3      |
| 2    | MCV assay value | Numeric     | Float  |
| 3    | MCV limit       | Numeric     | Float  |

## 1.4.3.1.6 Field 6 - PLT target value / limits

This field lists the assay value and limits input from the calibrator's assay sheet for the PLT parameter.

| Rank | Data values     | Data Format | Length |
|------|-----------------|-------------|--------|
| 1    | Field ID        | PLT         | 3      |
| 2    | PLT assay value | Numeric     | Float  |
| 3    | PLT limit       | Numeric     | Float  |

#### 1.4.3.1.7 Field 7 - END CALI

This field is populated with the CRC value computed on the transmitted buffer and is the end marker of the calibration report transmission.

The Algorithm is described in section 1.5

| Field ID | Field ID length | Data Format | Length   |
|----------|-----------------|-------------|----------|
| END CALI | 8               | Integer     | Variable |

## 1.4.3.1.8 Calibration data segment example

CALIBRATION; OG; 20/06/2008; 15:02:08; CALI; 01/01/2009; 20/06/
2008; 14:54:30; OG; 0.556000; 1.000000; 1.000000; 0.922000; 1.000000; 2[CR]
WBC; 5.0; 2.0[CR]
RBC; 6.00; 2.00[CR]
HGB; 25.0; 5.0[CR]
MCV; 80.0; 20.0[CR]
PLT; 150; 10[CR]
END CALI; 8333[CR] ...

# 1.4.3.2 Calibration report acknowledgement

Calibration acknowledgement by the host is done by the following frame:

ACK\_CALI;Calibration Lot;A[CR]

Where A: OK or Error code.

## 1.4.3.3 Calibration results

The runs used for the calibration are sent after the calibration report. The number of calibration results is given in the calibration field.

The calibration result segment is a subset of the fields described in the analysis result segment with some specific details listed below.

## 1.4.3.3.1 Calibration result segment

#### 1.4.3.3.1.1 Field 1 - Date

The Date, the date on which the calibration run was done, is an alphanumeric field of ten (10) characters. The default format of the date is DD/MM/YYYY.

| Field ID | Field ID length | Data Format | Length |
|----------|-----------------|-------------|--------|
| DATE     | 4               | DD/MM/YYYY  | 10     |

#### 1.4.3.3.1.2 Field 2 - Time

The Time is an alphanumeric field of eight (8) characters. It gives the time at which the calibration run was done in standard 24-hour format.

| Field ID | Field ID length | Data Format | Length |
|----------|-----------------|-------------|--------|
| TIME     | 4               | HH:MM:SS    | 8      |

#### 1.4.3.3.1.3 Field 3 - Mode

The mode field is an alphanumeric field of up to thirteen (13) characters. It gives the analysis mode, which is here CALIBRATION.

| Field ID | Field ID length | Data Format | Length |
|----------|-----------------|-------------|--------|
| MODE     | 4               | CALIBRATION | 11     |

1.4.3.3.1.4 Field 4 - Unit
Please refer to Section 1.4.2.3.1.4

1.4.3.3.1.5 Field 5 - Seq
Please refer to Section 1.4.2.3.1.5

1.4.3.3.1.6 Field 6 - Test
Please refer to Section 1.4.2.3.1.10

1.4.3.3.1.7 Field 7 - Operator
Please refer to Section 1.4.2.3.1.11

1.4.3.3.1.8 Field 8 - WBC

NOTE: To better understand Flagging fields, refer to Section 3-9 in the CELL-DYN Emerald System Operator's Manual.

- The count values transmitted to the host are sent in the selected units.
- For Rank 3: '\*' is used for L1 and/or L5 WBC flags and 's' is used for L2 and/or L3 WBC flags. If both flags are generated simultaneously, '\*' will supercede 's'.

| Rank | Data values                     | Data Format                                    | Length  |
|------|---------------------------------|--|---|
| 1    | Field ID                        | WBC  | 3   |
| 2    | Count value                     | Numeric<br>+++++                               | Variable (look at the units table). Maximum 5 5 |
| 3    | Suspect flag                    | Empty, 's' or '*'                              | Up to 1 character                               |
| 4    | Flag: over range or panic flags | Empty or 'D' or<br>'L' or 'l' or 'h' or<br>'H' | Up to 1 character                               |
| 5    | Low Panic value                 | Empty  | 0   |
| 6    | Low value                       | Empty  | 0   |
| 7    | High value                      | Empty  | 0   |
| 8    | High panic value                | Empty  | 0   |

1.4.3.3.1.9 Field 9 - RBC

Please refer to the WBC field description for details. The field ID is "RBC".

1.4.3.3.1.10 Field 10 - HGB

Please refer to the WBC field description for details. The field ID is "HGB".

1.4.3.3.1.11 Field 11 - MCV

Please refer to the WBC field description for details. The field ID is "MCV".

1.4.3.3.1.12 Field 12 - PLT

Please refer to the WBC field description for details. The field ID is "PLT".

1.4.3.3.1.13 Field 13 - END RESULT

Please refer to Section 1.4.2.3.1.41

# 1.4.3.3.2 Calibration result segment example

RESULT[CR]
DATE;20/06/2008[CR]
TIME;15:00:24[CR]

MODE; CALIBRATION[CR]
UNIT; 1[CR]

SEQ;1;0[CR]

TEST; LMG[CR]

OPERATOR; OG[CR]

WBC;7.0 ;;;;;;[CR] RBC;4.70 ;;;;;;[CR]

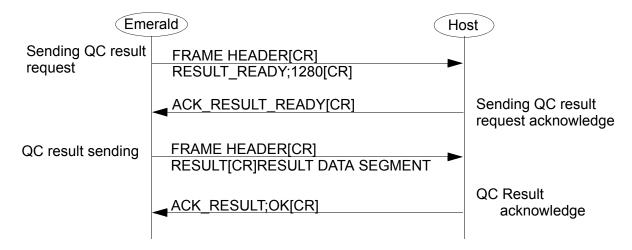
HGB;11.4;;L;;;[CR]

MCV;86.0 ;;;;; [CR]

PLT;120 ;;L;;;;[CR]

END\_RESULT;11687[CR] ..

## 1.4.4 QC



## 1.4.4.1 QC Result

The QC result segment is a subset of the fields described in the analysis result segment with some specific details listed below.

## 1.4.4.1.1 QC Result segment

#### 1.4.4.1.1.1 Field 1 - Date

The Date, the date on which the QC run was done, is an alphanumeric field of ten (10) characters. The default format of the date is DD/MM/YYYY.

| Field ID | Field ID length | Data Format | Length |
|----------|-----------------|-------------|--------|
| DATE     | 4               | DD/MM/YYYY  | 10     |

## 1.4.4.1.1.2 Field 2 - Time

The Time is an alphanumeric field of eight (8) characters. It gives the time at which the QC run was done in standard 24-hour format.

| Field ID | Field ID length | Data Format | Length |
|----------|-----------------|-------------|--------|
| TIME     | 4               | HH:MM:SS    | 8      |

## 1.4.4.1.1.3 Field 3 - Mode

The mode field is an alphanumeric field of up to thirteen (13) characters. It gives the analysis mode: here QC.

| Field ID | Field ID length | Data Format | Length |
|----------|-----------------|-------------|--------|
| MODE     | 4               | QC          | 2      |

1.4.4.1.1.4 Field 4 - Unit

Please refer to Section 1.4.2.3.1.4

1.4.4.1.1.5 Field 5 - Seq

Please refer to Section 1.4.2.3.1.5

Note that in this case the SEQ field is filled out with the sequence number initialized by the CELL-DYN Emerald when the QC run is requested.

If the QC results are sent later, then the sequence number becomes a rank number from 0 to n.

#### 1.4.4.1.1.6 Field 6 - Lot Name

The Lot Name giving the name of the QC lot is an alphanumeric field of up to eight (8) characters, UTF8 encoded.

| Field ID | Field ID length | Data Format  | Length         |
|----------|-----------------|--------------|----------------|
| LOT      | 3               | Alphanumeric | From 1 up to 8 |

#### 1.4.4.1.1.7 Field 7 - Level

The Lot Level, giving the level of the QC, is an alphanumeric field of one (1) character.

| Field ID | Field ID length | Data Format | Length |
|----------|-----------------|-------------|--------|
| LEVEL    | 5               | H or L or N | 1      |

H for High Level

L for Low Level

N for Normal Level

#### 1.4.4.1.1.8 Field 8 - Lot Date

The Lot Date, giving the date and time on which the QC lot was created.

| rank | Fields        | Data Format | Length |
|------|---------------|-------------|--------|
| 1    | Field ID      | LOT DATE    | 8      |
| 2    | Creation date | DD/MM/YYYY  | 10     |
| 3    | Creation time | HH:MM:SS    | 8      |

## 1.4.4.1.1.9 Field 9 - Expiry DateType

The Expiry Date, the expiration date of the QC lot, is an alphanumeric field of ten (10) characters. The default format of the date is DD/MM/YYYY

| Field ID    | Field ID length | Data Format | Length |
|-------------|-----------------|-------------|--------|
| EXPIRY DATE | 11              | DD/MM/YYYY  | 10     |

## 1.4.4.1.1.10 Field 10 - User

The User, the operator who created the QC lot, is an alphanumeric field of up to ten (10) characters. It is UTF8 encoded.

| Field ID | Field ID length | Data Format  | Length                  |
|----------|-----------------|--------------|-------------------------|
| USER     | 4               | Alphanumeric | Up to 10. UTF8 encoded. |

## 1.4.4.1.1.11 Field 11 - Test

Please refer to Section 1.4.2.3.1.10

## 1.4.4.1.1.12 Field 12 - Operator

Please refer to Section 1.4.2.3.1.11

## 1.4.4.1.1.13 Field 13 - WBC

NOTE: To better understand Flagging fields, refer to Section 3-9 in the CELL-DYN Emerald System Operator's Manual.

- •The count values transmitted to the host are sent in the selected unit.
- •For Rank 3: '\*' is used for L1 and/or L5 WBC flags and 's' is used for L2 and/or L3 WBC flags. If both flags are generated simultaneously, '\*' will supercede 's'.

| rank | Data values                     | Data Format                                 | Length   |
|------|---------------------------------|---|--|
| 1    | Field ID                        | WBC   | 3  |
| 2    | Count value                     | Numeric<br>+++++                            | Variable (refer to the units table). Maximum 5 5 5                                       |
| 3    | Suspect flag                    | Empty, 's' or '*'                           | Up to 1 character  |
| 4    | Flag: over range or panic flags | Empty or 'D' or 'L'<br>or 'l' or 'h' or 'H' | Up to 1 character  |
| 5    | Low Panic value                 | Numeric                                     | Variable (refer to the units table) In QC, the value here is the low limit assay value.  |
| 6    | Low value                       | Empty                                       | 0  |
| 7    | High value                      | Empty                                       | 0  |
| 8    | High panic value                | Numeric                                     | Variable (refer to the units table) In QC, the value here is the high limit assay value. |

## 1.4.4.1.1.14 Field 14 - RBC

Please refer to the WBC field description for details. The field ID is RBC.

#### 1.4.4.1.1.15 Field 15 - HGB

Please refer to the WBC field description for details. The field ID is HGB.

#### 1.4.4.1.1.16 Field 16 - HCT

Please refer to the WBC field description for details. The field ID is HCT.

#### 1.4.4.1.1.17 Field 17 - MCV

Please refer to the WBC field description for details. The field ID is MCV.

## 1.4.4.1.1.18 Field 18 - MCH

Please refer to the WBC field description for details. The field ID is MCH.

1.4.4.1.1.19 Field 19 - MCHC Please refer to the WBC field description for details. The Field 20 - RDW 1.4.4.1.1.20 Please refer to the WBC field description for details. The field ID is RDW. Field 21 - PLT 1.4.4.1.1.21 Please refer to the WBC field description for details. The field ID is PLT. 1.4.4.1.1.22 Field 22 - MPV Please refer to the WBC field description for details. The field ID is MPV. Field 23 - PCT\* 1.4.4.1.1.23 Please refer to the WBC field description for details. The field ID is PCT. 1.4.4.1.1.24 Field 24 - PDW\* Please refer to the WBC field description for details. The field ID is PDW. 1.4.4.1.1.25 Field 25 - LYM% Please refer to the WBC field description for details. The field ID is LYM%. 1.4.4.1.1.26 Field 26 - MID% Please refer to the WBC field description for details. The field ID is MID%. 1.4.4.1.1.27 Field 27 - GRA% Please refer to the WBC field description for details. The field ID is GRA%. 1.4.4.1.1.28 Field 28 - LYM Please refer to the WBC field description for details. The field ID is LYM. 1.4.4.1.1.29 Field 29 - MID Please refer to the WBC field description for details. The field ID is MID. 1.4.4.1.1.30 Field 30 - GRA Please refer to the WBC field description for details. The field ID is GRA. Field 31 - END RESULT

Please refer to Section 1.4.2.3.1.41

1.4.4.1.1.31

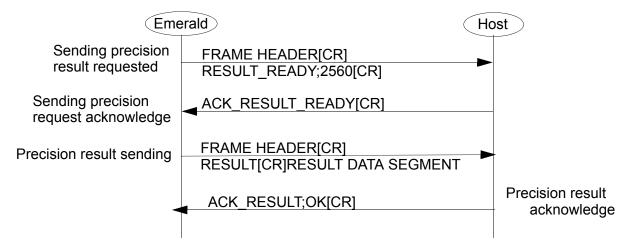
<sup>\*</sup>Clinical significance has not been established for these parameters; therefore they are not reportable in the U.S. These options may only be selected outside of the U.S.

## 1.4.4.1.2 QC Result example

RESULT[CR] DATE; 21/06/2008 [CR] TIME; 10:08:25 [CR] MODE; QC [CR] UNIT; 1 [CR] SEQ;1;0[CR] LOT; 16961CD[CR] LEVEL; L[CR] LOT DATE; 21/06/2008; 10:07:59 [CR] EXPIRY DATE; 07/06/2009 [CR] USER; OG[CR] TEST; LMG[CR] OPERATOR; OG[CR] WBC; 8.0 ;; L; 15.0 ;;; 20.0 [CR] RBC;4.80 ;;;4.68 ;;;5.28 [CR] HGB; 11.5;; L; 14.4;;; 15.8 [CR] HCT; 40.5;;; 37.8;;; 44.8[CR] MCV;84.4 ;;;79.0 ;;;87.0 [CR] MCH;24.0 ;;L;27.8 ;;;32.8 [CR] MCHC; 28.4 ;; L; 33.2 ;;; 39.8 [CR] RDW;16.6 ;;;0.0 ;;;99.8 [CR] PLT;220 ;;L;407 ;;;527 [CR] MPV;15.8 ;;;0.0 ;;;99.8 [CR] \*PCT; 0.580;; H; 0.000;;; 0.000[CR] \*PDW;12.2 ;;H;0.0 ;;;0.0 [CR] LYM%;28.1;;L;46.8;;;56.8[CR] MID%;29.5;;H;6.2 ;;;12.2[CR] GRA%;42.4;;;34.0;;;44.0[CR] LYM; 2.2 ;; L; 6.8 ;;; 11.4 [CR] MID; 2.4 ;;; 0.8 ;;; 2.4 [CR] GRA; 3.4 ;; L; 4.8 ;;; 8.8 [CR] END\_RESULT;29885[CR] ...

<sup>\*</sup> Clinical significance has not been established for these parameters; therefore they are not reportable in the U.S. These options may only be selected outside of the U.S.

#### 1.4.5 Precision



#### 1.4.5.1 Precision Result

The Precision result segment is a subset of the fields described in the analysis result segment with some specific details listed below.

# 1.4.5.1.1 Precision result data segment

#### 1.4.5.1.1.1 Field 1 - Date Field

The Date, the date on which the precision run was done, is an alphanumeric field of ten (10) characters. The default format of the date is DD/MM/YYYY.

| Field ID | Field ID length | Data Format | Length |
|----------|-----------------|-------------|--------|
| DATE     | 4               | DD/MM/YYYY  | 10     |

#### 1.4.5.1.1.2 Field 2 - Time Field

The Time is an alphanumeric field of eight (8) characters. It gives the time at which the precision run was done in standard 24-hour format.

| Field ID | Field ID length | Data Format | Length |
|----------|-----------------|-------------|--------|
| TIME     | 4               | HH:MM:SS    | 8      |

#### 1.4.5.1.1.3 Field 3 - Mode

The mode field is an alphanumeric field of up to thirteen (13) characters. It gives the analysis mode: here REPEATABILITY.

| Field ID | Field ID length | Data Format   | Length |
|----------|-----------------|---------------|--------|
| MODE     | 4               | REPEATABILITY | 13     |

1.4.5.1.1.4 Field 4 - Unit

Please refer to Section 1.4.2.3.1.4

1.4.5.1.1.5 Field 5 - Seq

Please refer to Section 1.4.2.3.1.5

1.4.5.1.1.6 Field 6 - Test

Please refer to Section 1.4.2.3.1.10

1.4.5.1.1.7 Field 7 - Operator

Please refer to Section 1.4.2.3.1.11

1.4.5.1.1.8 Field 8 - WBC

NOTE: To better understand Flagging fields, refer to Section 3-9 in the CELL-DYN Emerald System Operator's Manual.

- •The count values transmitted to the host are sent in the selected unit.
- •For Rank 3: '\*' is used for L1 and/or L5 WBC flags and 's' is used for L2 and/or L3 WBC flags. If both flags are generated simultaneously, '\*' will supercede 's'.

| rank | Data values                   | Data Format                                 | Length   |
|------|-------------------------------|---|--|
| 1    | Field ID                      | WBC   | 3  |
| 2    | Count value                   | Numeric<br>+++++                            | Variable (refer to the units table). Maximum 5 5 5 |
| 3    | Suspicion flag                | Empty, 's' or '*'                           | Up to 1 character                                  |
| 4    | Flag: overange or panic flags | Empty or 'D' or 'L'<br>or 'l' or 'h' or 'H' | Up to 1 character                                  |
| 5    | Low Panic value               | Empty                                       | 0  |
| 6    | Low value                     | Empty                                       | 0  |
| 7    | High value                    | Empty                                       | 0  |
| 8    | High panic value              | Empty                                       | 0  |

1.4.5.1.1.9 RBC- Field 9

Please refer to the WBC field description for details. The field ID is RBC.

1.4.5.1.1.10 HGB- Field 10

Please refer to the WBC field description for details. The field ID is HGB.

1.4.5.1.1.11 Field 11 - HCT

Please refer to the WBC field description for details. The field ID is HCT.

1.4.5.1.1.12 Field 12 - MCV

Please refer to the WBC field description for details. The field ID is MCV.

1.4.5.1.1.13 Field 13 - MCH

Please refer to the WBC field description for details. The field ID is MCH.

1.4.5.1.1.14 Field 14 - MCHC

Please refer to the WBC field description for details. The field ID is MCHC.

1.4.5.1.1.15 Field 15 - RDW Please refer to the WBC field description for details. The field ID is RDW. 1.4.5.1.1.16 Field 16 - PLT Please refer to the WBC field description for details. The field ID is PLT. 1.4.5.1.1.17 Field 17 - MPV Please refer to the WBC field description for details. The field ID is MPV. 1.4.5.1.1.18 Field 18 - PCT\* Please refer to the WBC field description for details. The field ID is PCT. Field 19 - PDW\* 1.4.5.1.1.19 Please refer to the WBC field description for details. The field is PDW. Field 20 - LYM% 1.4.5.1.1.20 Please refer to the WBC field description for details. The field is LYM%. 1.4.5.1.1.21 Field 21 - MID% Please refer to the WBC field description for details. The field is MID%. 1.4.5.1.1.22 Field 22 - GRA% Please refer to the WBC field description for details. The field is GRA%. 1.4.5.1.1.23 Field 23 - LYM Please refer to the WBC field description for details. The field is LYM. 1.4.5.1.1.24 Field 24 - MID Please refer to the WBC field description for details. The

field is MID.

1.4.5.1.1.25 Field 25 - GRA

> Please refer to the WBC field description for details. The field is GRA.

Field 26 - END RESULT 1.4.5.1.1.26

Please refer to section 1.4.2.3.1.41

<sup>\*</sup>Clinical significance has not been established for these parameters; therefore they are not reportable in the U.S. These options may only be selected outside of the U.S.

## 1.4.5.1.2 Precision result example

```
RESULT[CR]
DATE; 21/06/2008 [CR]
TIME; 10:23:09[CR]
MODE; REPEATABILITY [CR]
UNIT; 1 [CR]
SEQ; 2; 0 [CR]
TEST; LMG[CR]
OPERATOR; OG[CR]
WBC;12.0 ;;;;;[CR]
RBC; 4.70 ;;;;; [CR]
HGB;11.4;;;;;[CR]
HCT; 40.4;;;;; [CR]
MCV;86.0 ;;;;;[CR]
MCH;24.3 ;;;;;[CR]
MCHC; 28.2 ;;;;; [CR]
RDW;16.2 ;;;;;[CR]
PLT;220 ;;;;;[CR]
MPV;10.4 ;;;;; [CR]
*PCT; 0.380;;;;; [CR]
*PDW;12.0 ;;;;;[CR]
LYM%;9.3 ;;;;;[CR]
MID%; 9.7 ;;;;; [CR]
GRA%;81.0;;;;;[CR]
LYM; 1.1 ;;;;; [CR]
MID; 1.2
        ;;;;;[CR]
GRA; 9.7 ;;;;; [CR]
END_RESULT;59882[CR]
```

## 1.5 Control sum

The control sum is a CRC code: CRC-16.

#### 1.5.1 Algorithm

The source code used is below(C code). It allows generation of standard CRC-16.

This algorithm is mainly used in embedded systems (like a hard disk controller). For best performance, computation is done from a seek table with 16 values.

Here is the CRC computation:

```
CRC = 0xFFFF

For each nibble:

    Work on high weight nibble:
    Index = byte EXCLUSIVE OR CRC
    Index = Index AND 000F
    CRC = Table (Index) EXCLUSIVE OR (CRC divided by 16)

Index = byte divided by 16
    Index = Index EXCLUSIVE OR CRC
    Index = Index AND 000F
    CRC = Table (Index) EXCLUSIVE OR (CRC divided by 16)
```

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<sup>\*</sup> Clinical significance has not been established for these parameters; therefore they are not reportable in the U.S. These options may only be selected outside of the U.S.

## C language source example implementation:

```
Seek table declaration:
static const unsigned short ausCrcTab1[] =
 0x0000, 0xCC01,0xD801,0x1400,0xF001,0x3C00,0x2800,0xE401,
 0xA001,0x6C00,0x7800,0xB401,0x5000,0x9C01,0x8801,0x4400,
};
CRC computation:
unsigned short calc_crc(unsigned char *pucData, long lSize)
unsigned short usAcc1 = 0xFFFF;
while ( lSize > 0 )
          usAcc1 = ausCrcTab1[(*pucData ^ usAcc1) & 15] ^ (usAcc1 >> 4);
          usAcc1 = ausCrcTab1[((*pucData >> 4) ^ usAcc1) & 15] ^ (usAcc1 >>
4);
          pucData++;
          1Size--;
return(usAcc1);
}
^: EXCLUSIVE OR
>>: LOGICAL RIGHT SHIFT.
&: LOGICAL AND.
```

This CRC is computed from the beginning of the sent data until the end of the line ([CR] included) preceding the checksum line (Identifier + value).

#### 1.5.2 Example

The CRC is computed with all grey background data: EMERALD; INSTRUMENT NUMBER; INSTRUMENT SERIAL NUMBER; USER LOGIN[CR] RESULT[CR] DATE; 06/06/2008 [CR] TIME; 13:41:29 [CR] MODE; NORMAL [CR] UNIT; 1 [CR] SEQ; 31; 0 [CR] SID; No ID Entered [CR] PID; [CR] ID; [CR] TYPE; STANDARD [CR] TEST; LMG [CR] OPERATOR; OG[CR] WBC;12.0;;H;0.0;0.0;0.0;0.0 RBC; 5.20 ;; H; 0.00 ; 0.00 ; 0.00 ; 0.00 [CR] HGB;11.9;;H;0.0;0.0;0.0;0.0 [CR] HCT; 40.9;; H; 0.0; 0.0; 0.0; 0.0 [CR] MCV;78.7 ;;H;0.0 ;0.0 ;0.0 ;0.0 [CR] MCH; 22.9 ;; H; 0.0 ; 0.0 ; 0.0 ; 0.0 [CR] MCHC;29.1 ;;H;0.0 ;0.0 ;0.0 ;0.0 [CR] RDW; 17.7;; H; 0.0; 0.0; 0.0; 0.0 [CR] ;0 PLT;220 ;;H;0 ; 0 ; 0 [CR] MPV;7.6 ;;H;0.0 ;0.0 ;0.0 ;0.0 [CR] LYM%; 22.5;; H; 0.0; 0.0; 0.0; 0.0 [CR] MID%; 23.7;; H; 0.0; 0.0; 0.0; 0.0 [CR] GRA%;53.8;;H;0.0;0.0;0.0;0.0 [CR] LYM; 2.7 ;; H; 0.0 ; 0.0 ; 0.0 ; 0.0 [CR] MID; 2.8 ;; H; 0.0 ; 0.0 ; 0.0 ; 0.0 [CR] GRA; 6.5 ;; H; 0.0 ; 0.0 ; 0.0 ; 0.0 [CR] WBC CURVE; 0; 0; 0; 0; 0; 0; 0; 0; 1; 5; 13; 25; 40; 56; 73; 91; 109; 128; 146; 165; 184; 202; 220;235;244;245;240;229;215;199;182;164;145;127;108;89;71;54;40;31;25; 21;18;17;17;17;17;17;17;18;20;23;25;27;29;32;35;37;39;41;44;47;49;51; 53;56;59;61;63;65;68;71;73;75;77;79;82;84;86;88;91;94;96;98;98;98;97; 95;94;92;89;87;85;83;81;78;75;73;71;69;66;63;61;59;57;54;51;49;47;45; 42;39;37;35;33;30;27;23;17;11;6;2;0;0;0;0;0;0;0;[CR] WBC THRESHOLDS; 25; 37; 0; [CR] RBC 12;20;30;42;56;70;86;102;119;136;153;170;186;201;213;221;225;225;221; 214;204;192;178;163;147;130;113;96;80;64;50;37;27;19;13;8;5;3;1;0;0;0; 

RBC THRESHOLDS;32;55

[CR]PLT

PLT THRESHOLDS; 100 [CR]

ALARMS; QC FAIL; INS-T; [CR]

INTERPRETIVE\_WBC; LEU>; LYM>; GRA>; [CR]

INTERPRETIVE\_RBC; ERY>; MACRO; [CR]

INTERPRETIVE\_PLT; THR>; GIANTP; [CR]

COMMENT;; [CR]