SIEMENS

Urgent Field Safety Notice

14-29

May 2014

syngo® Lab Data Manager

Custom Reference Range and Sample Report Issues

Our records indicate that your facility has or may have received the following product:

Table 1. *syngo* Lab Data Manager Affected Products

Product	Software Version	Siemens Material Number (SMN)
syngo Lab Data Manager	VA11B VA12A VA12B	10800057 10803189 10804573

Reason for Correction

Siemens Healthcare Diagnostics has received complaints regarding custom reference ranges and sample reports for the *syngo*® Lab Data Manager application software, versions VA11B, VA12A, and VA12B. Through internal investigation, Siemens has confirmed:

Custom Reference Ranges (VA12A and VA12B Only)

In the Assay Details screen, certain configuration parameters selected during configuration of reference ranges for assays may cause the reference ranges to not hold results as expected. This may cause the release of results to the Laboratory Information System (LIS) that should have been held for manual review.

IMPORTANT Please refrain from using the Assay Details page and contact a Siemens technical service representative if you need to delete unused reference ranges (recommended), make additions or edits to the assays, reference ranges, or units that are configured on your system.

Sample Reports

There are several limitations with the use of sample reports in the *syngo* Result Manager that have not previously been communicated in the Operator's Guide. The following limitations will apply to the sample report if it is viewed, printed, or exported:

All Software Versions

- Ignored or Held results (with a result status of "I" or "H") are included on the report.
- Results that have Null or Blank values will not be included on the report. This may include results that generated a "below assay range" flag on the instrument.
- Result status indication (e.g. Held, Ignored, Transmitted) will not be included on the report.

VA11B Only

- Please be aware that Comments/Flags derived from the instrument or manually entered by the user will not be included on the report.

Refer to Figure 1 in the Additional Information section for an example of a sample report and a description of its limitations and expected content.

Risk to Health

Siemens recommends discussing the contents of this letter with your Medical Director.

Depending on certain parameters selected when configuring custom reference ranges on the *syngo* Lab Data Manager, the system reporting and rules may not perform as intended. When this occurs, it may lead to the release of results that should be held for user action.

It is possible for operators of syngo Lab Data Manager to misinterpret the information contained in the sample report. The information provided in this letter is intended to help prevent inappropriate interpretation of, or action based on, the sample report.

A review of previously generated results is not required.

Actions to be Taken by the Customer

Please be aware that a Siemens technical support representative will contact you to implement the following changes to your *syngo* Lab Data Manager system for custom reference ranges:

- Review custom reference ranges that are currently in place.
- Remove units that appear to be duplicates from the units configuration screen.
- Edit custom reference ranges that have the improper configuration(s) for sample fluid type, units, or equipment model.

  NOTE After these changes have been implemented, Siemens recommends that customers retest reference ranges and associated rules that were modified.

  NOTE On the *syngo* system reference ranges are used to provide trim limits for patient statistics, populate the Sample Report, and as a reference for any rule that is based on reference ranges. Reference ranges do not update automatically so when they are changed on an instrument they should also be manually changed on the *syngo* system. Reference ranges defined on the *syngo* system are only applied to patient results; they are not applied to quality control results.

In addition, please perform the following:

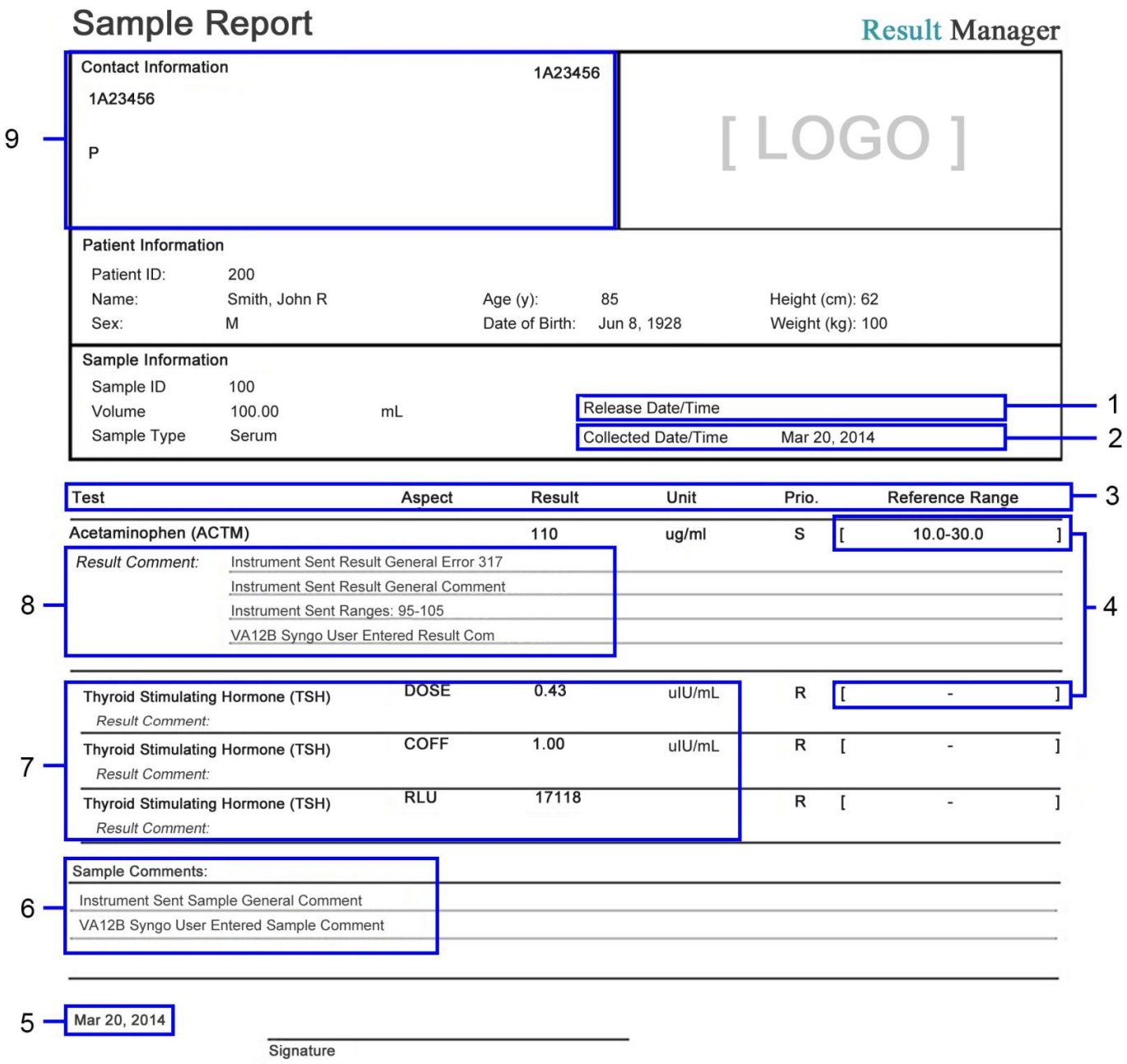
- **Refer to the Additional Information section for information about the contents of the sample report for your future reference.**
- **Complete and return the Field Correction Effectiveness Check attached to this letter within 30 days.**

Please retain this letter with your laboratory records, and forward this letter to those who may use this product.

We apologize for the inconvenience this situation has caused. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Additional Information

Figure 1. Sample Report Limitations and Expected Content



Limitations

1. The “Release Date/Time” field of the sample report will always be blank.
2. The “Collected Date/Time” field only displays the date. The time is not displayed.
3. The column header titles apply to the information displayed in the table.

NOTE The following information will be included on the report:

- Results, regardless of status, may be included on the report. This may include Ignored or Held results (with a result status of “I” or “H”).

NOTE The following information will **not** be included on the report:

- Results that have Null or Blank values will not be included on the report. This may include results that generated a “below assay range” flag on the instrument.
- Information not shown includes the status of the results (e.g. Held, Ignored, Transmitted), and the date and time of each result.

Expected Content

4. The reference range shown is:
   a. The range sent by the instrument, or
   b. The age-specific or gender-specific range configured on *syngo* Lab Data Manager.
5. The date the report was generated.
6. The “Sample Comments” field displays the comments that were entered manually from the Sample Review screen and general sample comments sent from the instrument.
7. Aspects display on separate lines of the report.
8. The “Result Comment” field displays manually entered comments, in addition to instrument generated comments, errors, and flags from the Sample Review screen.
9. Patient visit information displays from the LIS: Location and Location Kind.

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FIELD CORRECTION EFFECTIVENESS CHECK

Custom Reference Range and Sample Report Issues

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 14-29 dated May 2014 regarding Custom Reference Range and Sample Report Issues. Please read each question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax/email provided at the bottom of this page.

REF: ISW 14-06 [C/2767]

1. I confirm that I understand that if changes are required to the system that affect rules in the system I will need to revalidate the affected rules.	Yes ☐	No ☐
Signed:	Date:	
2. I have read and understood the Urgent Field Safety Notice instructions provided in this letter.	Yes ☐	No ☐

Name of person completing questionnaire:	
Title:	
Institution:	Instrument Serial Number:
Street:	
City:	Post Code:
Phone:	Email:

PLEASE FAX or EMAIL THIS COMPLETED FORM within 30 days of receipt to
FAX 0845 605 6800
EMAIL robert.davies@siemens.com

It is important that your organisation takes the actions detailed in the in the FSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to the FSN.

Your organisations reply is evidence which Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the FSN. Without your reply Siemens Healthcare Diagnostics cannot properly verify the completeness of the FSN and the MHRA may need to issue a Medical Device Alert.