COBAS® TaqMan® Analyzer

Addendum version 1.0
For use with the AMPLILINK Software

Roche

cobas®
Life needs answers

Publication information

Publication version	Revision date	Changes
1.0	September 2016	First version

Table 1 Revision history

Edition notice This addendum contains revisions to released COBAS® TaqMan® Analyzer publications.

General attention

To avoid serious or fatal injury, ensure that you are familiar with the system and safety information before you use the system.

- Pay particular attention to all safety precautions.
- Always follow the instructions in this publication.
- Do not use the instrument in a way that is not described in this publication.
- Store all publications in a safe and easily retrievable place.

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Feedback Every effort has been made to ensure that this publication fulfills the intended use. All feedback on any aspect of this publication is welcome and is considered during updates. Contact your Roche representative, should you have any such feedback.

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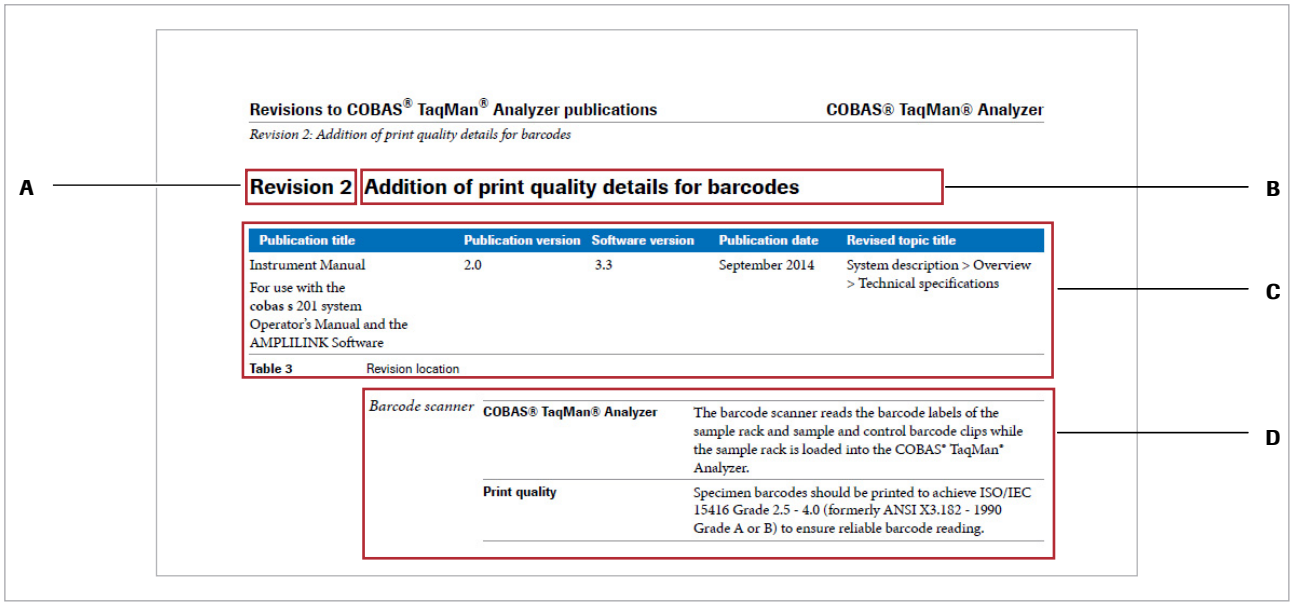
About the addendum content

Roche recommends that you familiarize yourself with the new and/or revised content provided in this addendum.

The following illustration explains how this content is presented in this document.



A Change ID

B Change summary

C Topic affected

D Changed element

Figure 1 Structure of a revision

If you print these pages, Roche recommends printing them single-sided. In this way, you can easily insert the new and/or revised content in its appropriate location(s) in the existing document.

Revisions to COBAS® TaqMan® Analyzer publications

Revision 1: Addition of RoHS directive and update of CE compliance

Publication title	Publication version	Software version	Publication date	Revised topic title
Instrument Manual For use with the **cobas s** 201 system Operator's Manual and the AMPLILINK Software	2.0	3.3	September 2014	Publication information
Instrument Manual For use with the AMPLILINK Software	2.0	3.3 and 3.4	June 2015	Publication information

Table 2 Revision location

Approvals

The COBAS® TaqMan® Analyzer meets the requirements laid down in:

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Compliance is provided by means of the Declaration of Conformity.

The following marks demonstrate compliance:

IVD	For *in vitro* diagnostic use.
CE	Complies with the provisions of the applicable EU directives.
c UL us	Issued by Underwriters Laboratories, Inc. (UL) for Canada and the US.

Revision 2: Addition of print quality details for barcodes

Publication title	Publication version	Software version	Publication date	Revised topic title
Instrument Manual For use with the **cobas s** 201 system Operator's Manual and the AMPLILINK Software	2.0	3.3	September 2014	System description > Overview > Technical specifications

Table 3 Revision location

Barcode scanner	**COBAS® TaqMan® Analyzer**	The barcode scanner reads the barcode labels of the sample rack and sample and control barcode clips while the sample rack is loaded into the COBAS® TaqMan® Analyzer.
	Print quality	Specimen barcodes should be printed to achieve ISO/IEC 15416 Grade 2.5 - 4.0 (formerly ANSI X3.182 - 1990 Grade A or B) to ensure reliable barcode reading.