SYMBOL GLOSSARY

Explanation of symbols used in Quidel device labeling.

Symbol	Symbol Title	Explanatory Text	Standard Reference
CE	CE marking Conformité Européene Notified Body Reference no. ###	The requirements for accreditation and market surveillance relating to the marketing of products	MDD 93/42/EEC IVDD 98/79/EC Article 16.2
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1:2016 Reference no. 5.1.1
EC REP	Authorized representative in the European Community	Indicates the authorized representative in the European Community	ISO 15223-1:2016 Reference no. 5.1.2
	Date of manufacture	Indicates the date when the medical device was manufactured	ISO 15223-1:2016 Reference no. 5.1.3 ISO 7000:2014 Reference no. 2497
	Use by	Indicates the date after which the medical device is not to be used	ISO 15223-1:2016 Reference no. 5.1.4 ISO 7000:2014 Reference no. 2607
LOT	Batch code	Indicates the manufacturer's batch code to identify the batch or lot	ISO 15223-1:2016 Reference no. 5.1.5 ISO 7000:2014 Reference no. 2492
REF	Catalog number	Indicates the manufacturer's catalogue number to identify the medical device	ISO 15223-1:2016 Reference no. 5.1.6 ISO 7000:2014 Reference no. 2493
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified	ISO 15223-1:2016 Reference no. 5.1.7 ISO 7000:2014 Reference no. 2498
STERILE	Sterile	Indicates a medical device that has been subjected to a sterilization process	ISO 15223-1:2016 Reference no. 5.2.1 EU IVDD 98/79/EC, ANNEX I.B.(2.3) EU IVDR 2017/746 20.2(I) ISO 7000:2014 Reference no. 2499

SYMBOL GLOSSARY

Explanation of symbols used in Quidel device labeling.

Symbol	Symbol Title	Explanatory Text	Standard Reference
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1:2016 Reference no. 5.2.3 ISO 7000:2014 Reference no. 2501
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation	ISO 15223-1:2016 Reference no. 5.2.4 ISO 7000:2014 Reference no. 2501
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully	ISO 15223-1:2016 Reference no. 5.3.1 ISO 7000:2014 Reference no. 0621
	Keep away from sunlight	Indicates a medical device that needs protection from light sources	ISO 15223-1:2016 Reference no. 5.3.2 ISO 7000:2014 Reference no. 0624
	Keep dry	Indicates a medical device that needs protection from moisture	ISO 15223-1:2016 Reference no. 5.3.4 ISO 7000:2014 Reference no. 0626
	Lower limit of temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed	ISO 15223-1:2016 Reference no. 5.3.5 ISO 7000:2014 Reference no. 0534
	Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed	ISO 15223-1:2016 Reference no. 5.3.6 ISO 7000:2014 Reference no. 0533
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed	ISO 15223-1:2016 Reference no. 5.3.7 ISO 7000:2014 Reference no. 0632
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed	ISO 15223-1:2016 Reference no. 5.3.8 ISO 7000:2014 Reference no. 2620

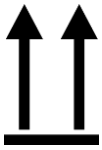
SYMBOL GLOSSARY

Explanation of symbols used in Quidel device labeling.

Symbol	Symbol Title	Explanatory Text	Standard Reference
	Recycable	Indicates that an item can be recycled	ISO 7000 Reference no. 1135
	Biological risks	Indicates that there are potential biological risks associated with the medical device	ISO 15223-1:2016 Reference no. 5.4.1 ISO 7000:2014 Reference no. 0659
	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure	ISO 15223-1:2016 Reference no. 5.4.2 ISO 7000:2014 Reference no. 1051
	Consult instructions for use	Indicates the need for the user to consult the instructions for use	ISO 15223-1:2016 Reference no. 5.4.3 ISO 7000:2014 Reference no.1641
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information	ISO 15223-1:2016 Reference no. 5.4.4 ISO 7000:2014 Reference no. 0434
	*In vitro* diagnostic medical device	Indicates a medical device that is intended to be used as an *in vitro* diagnostic medical device	ISO 15223-1:2016 Reference no. 5.5.1
	Control	Indicates a control material that is intended to verify the performance characteristics of another medical device	ISO 15223-1:2016 Reference no. 5.5.2 ISO 7000:2014 Reference no. 2494
	Negative control	Indicates a control material that is intended to verify the results in the expected negative range	ISO 15223-1:2016 Reference no. 5.5.3 ISO 7000:2014 Reference no. 2495
	Positive control	Indicates a control material that is intended to verify the results in the expected positive range	ISO 15223-1:2016 Reference no. 5.5.4 ISO 7000:2014 Reference no. 2496

SYMBOL GLOSSARY

Explanation of symbols used in Quidel device labeling.

Symbol	Symbol Title	Explanatory Text	Standard Reference
	Contains sufficient for <n> tests	Indicates the total number of IVD tests that can be performed with the IVD	ISO 15223-1:2016 Reference no. 5.5.5 ISO 7000:2014 Reference no. 0518
	Patient number	Indicates a unique number associated with an individual patient	ISO 15223-1:2016 Reference no. 5.7.1 ISO 7000:2014 Reference no. 2610
	This way up	Indicates correct upright position of the transport package	ISO 780 ISO 7000 Reference no. 0623
	Expiration date	Indicates the date after which the medical device is not to be used	Quidel generated symbol per EDMA
	Use-by/ expiration date	Indicates the date after which the medical device is not to be used	Quidel generated symbol
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed and must be kept in the dark until use	Quidel generated symbol per EDMA
	Intended use	Indicates the general purpose of a device	Quidel generated symbol
	Prescription use only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner	21 CFR 801.109
	Consult e-labeling instructions for use	Indicates the instructions for use may be accessed from the Quidel website	Quidel generated symbol per EDMA

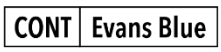
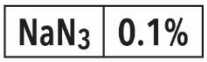
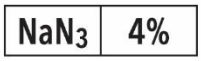
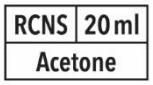
SYMBOL GLOSSARY

Explanation of symbols used in Quidel device labeling.

Symbol	Symbol Title	Explanatory Text	Standard Reference
RUO	Research use only	Indicates a medical device is intended for research use in the laboratory research phase of development; not for therapeutic or *in vitro* diagnostic use	Quidel generated symbol per EDMA 21 CFR 809.10(c)(2)(I)
GPR	General purpose reagent	Indicates a chemical reagent that has general laboratory application; used to collect, prepare, and examine specimen from the human body for diagnostic purposes	Quidel generated symbol per EDMA 21 CFR 864.4010
	Flammable	Indicates a potential of fire	US: 29 CFR 1910:1200 (HCS) EU: Regulation 1272/2008/EC GHS 02
	Oxidizer	May intensify fire	US: 29 CFR 1910:1200 (HCS) EU: Regulation 1272/2008/EC GHS 03
	Corrosive	Indicates a potential of corrosion	US: 29 CFR 1910:1200 (HCS) EU: Regulation 1272/2008/EC GHS 05
	Toxic	Toxic if swallowed, inhaled, or contact with skin	US: 29 CFR 1910:1200 (HCS) EU: Regulation 1272/2008/EC GHS 06
	Health hazards	Indicates a potential for health risk to the user of the medical device	US: 29 CFR 1910:1200 (HCS) EU: Regulation 1272/2008/EC GHS 07
	Serious health hazards	Indicates a potential for serious health risk to the user of the medical device	US: 29 CFR 1910:1200 (HCS) EU: Regulation 1272/2008/EC GHS 08
	Environmental or aquatic toxicity	Indicates a potential of environmental or aquatic toxicity	US: 29 CFR 1910:1200 (HCS) EU: Regulation 1272/2008/EC GHS 09

SYMBOL GLOSSARY

Explanation of symbols used in Quidel device labeling.

Symbol	Symbol Title	Explanatory Text	Standard Reference
	Contains/Contents	Indicates the components of a particular medical device	EDMA Symbols for IVD Reagents and Components
	Contains DMSO	Contains dimethyl sulfoxide, toxic hazard addressed in the SDS document	Quidel generated symbol per EDMA EDMA Symbols for IVD Reagents and Components
	Contains Evans Blue	Contains Evans Blue, toxic hazard addressed in the SDS document	EDMA Symbols for IVD Reagents and Components
	Contains Tween 20	Contains Tween 20, toxic hazard addressed in the SDS document	EDMA Symbols for IVD Reagents and Components
	Contains sodium azide	Contains sodium azide, toxic hazard addressed in the SDS document	EDMA Symbols for IVD Reagents and Components
	Contains 1% sodium azide	Contains 0.1% sodium azide, toxic hazard addressed in the SDS document	EDMA Symbols for IVD Reagents and Components
	Contains 4% sodium azide	Contains 4% sodium azide, toxic hazard addressed in the SDS document.	EDMA Symbols for IVD Reagents and Components
	Reconstitute with	Instructs the end-user that the contents of the package requires dilution; directs end-user to refer to product insert for additional information, e.g., dilution medium and volume.	EDMA Symbols for IVD Reagents and Components
	Reconstitute with 20-mL of Acetone	Instructs the end-user that the contents of the package requires dilution; directs end-user to refer to product insert for additional information, e.g., dilution medium (Acetone) and volume (20-mL)	EDMA Symbols for IVD Reagents and Components

SYMBOL GLOSSARY

Explanation of symbols used in Quidel device labeling.

Symbol	Symbol Title	Explanatory Text	Standard Reference
CONTROL 1	Control 1	Indicates Control 1	ISO 15223-1:2016 Clause 5.2
CONTROL 2	Control 2	Indicates Control 2	ISO 15223-1:2016 Clause 5.2
CONTROL 3	Control 3	Indicates Control 3	ISO 15223-1:2016 Clause 5.2
CAL	Calibrator	Indicates Calibrator	EDMA Symbols for IVD Reagents and Components
CAL S0	Calibrator S0	Indicates Calibrator S0	EDMA Symbols for IVD Reagents and Components
CAL S1	Calibrator S1	Indicates Calibrator S1	EDMA Symbols for IVD Reagents and Components
CAL S2	Calibrator S2	Indicates Calibrator S2	EDMA Symbols for IVD Reagents and Components
CAL S3	Calibrator S3	Indicates Calibrator S3	EDMA Symbols for IVD Reagents and Components
CAL S4	Calibrator S4	Indicates Calibrator S4	EDMA Symbols for IVD Reagents and Components

SYMBOL GLOSSARY

Explanation of symbols used in Quidel device labeling.

Symbol	Symbol Title	Explanatory Text	Standard Reference
	Calibrator S5	Indicates Calibrator S5	EDMA Symbols for IVD Reagents and Components
	Reagent	Indicates a substance that causes chemical reactions; used in analysis	EDMA Symbols for IVD Reagents and Components
	Reagent 1a	Indicates Reagent level 1a	EDMA Symbols for IVD Reagents and Components
	Reagent 1b	Indicates Reagent level 1b	EDMA Symbols for IVD Reagents and Components
	Reagent 1c	Indicates Reagent level 1c	EDMA Symbols for IVD Reagents and Components
	Calibration Card	Indicates a Calibration Card	Quidel generated symbol
	Quality control card	Indicates a Quality Control Card	Quidel generated symbol
	Buffer	Indicates Buffer	EDMA Symbols for IVD Reagents and Components
	Antibody	Indicates Antibody BNP	EDMA Symbols for IVD Reagents and Components

SYMBOL GLOSSARY

Explanation of symbols used in Quidel device labeling.

Symbol	Symbol Title	Explanatory Text	Standard Reference
	Antibody	Indicates Antibody BNP – alkaline phosphatase conjugate	EDMA Symbols for IVD Reagents and Components
	Antigen	Indicates Antigen B-Type natriuretic peptide (BNP)	EDMA Symbols for IVD Reagents and Components
	Origin	Indicates origin as Mouse	EDMA Symbols for IVD Reagents and Components
	Origin	Indicates origin as Human	EDMA Symbols for IVD Reagents and Components
	Origin	Indicates origin as Goat	EDMA Symbols for IVD Reagents and Components
	Item number	Indicates the item number	Quidel generated symbol
	Part number	Indicates the part number of a component	Quidel generated symbol
	Test device	Hold the sample from the patient. Contains reagent zones that cause reactions to occur to determine analyte levels in the patient.	Quidel generated symbol
	Type	Indicates the type	Quidel generated symbol

SYMBOL GLOSSARY

Explanation of symbols used in Quidel device labeling.

Symbol	Symbol Title	Explanatory Text	Standard Reference
QTY	Quantity	Indicates the quantity	Quidel generated symbol
MDD	Medical Device Directive	European Union requirements for Medical Devices	Quidel generated symbol
CAL VER	Calibration verification	Materials used with a test device to verify the calibration of the test devices throughout the measurable range	EDMA Symbols for IVD Reagents and Components
EV	Expected values	Indicates expected values	Quidel generated symbol
	Waste stream disposal status	DO NOT throw this unit into a municipal trash bin when this unit has reached the end of its lifetime. To ensure utmost protection of the global environment and minimize pollution, please recycle this unit.	Directive 2012/19/EC on waste electrical and electronic equipment (WEEE)
	Warning!	Indicates a potential injury to the user of the medical device	ISO 7010 W001 Graphical symbols -- Safety colors and safety signs -- Part 2: Design principles for product safety labels
	Caution! Hot surface	Indicates a potential for burns to the user of the medical device	ISO 7010 W017 Graphical symbols -- Safety colors and safety signs -- Part 2: Design principles for product safety labels
	Ultraviolet radiation	Indicates a potential for ultraviolet radiation to the user of the medical device	ISO 7010 W027 Graphical symbols -- Safety colors and safety signs -- Part 2: Design principles for product safety labels
	Potential biohazard	Indicates a potential for health risk to the user of the medical device	ISO 7010 W009 Graphical symbols -- Safety colors and safety signs -- Part 2: Design principles for product safety labels

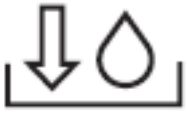
SYMBOL GLOSSARY

Explanation of symbols used in Quidel device labeling.

Symbol	Symbol Title	Explanatory Text	Standard Reference
	Radiation	Indicates a potential for radiation exposure to the user of the medical device	ISO 7010 W004 Graphical symbols -- Safety colors and safety signs -- Part 2: Design principles for product safety labels
	Important	Indicates important information being conveyed	Quidel generated symbol
	CD-Rom	Indicates that a CD containing instructions for use is included in a kit	Quidel generated symbol
	Information	Indicates information of particular importance	ISO 7000:2014 Reference no. 2760
	SD Card	Any of several kinds to SD cards bearing information to be downloaded into a medical device or saved from a medical device	Quidel generated symbol
	China RoHS	Indicates a device does not contain any hazardous substances exceeding concentration limits and is a green environmentally friendly product which can be recycled	China RoHS 2
	Thaw	Indicates that the product needs to remain between 19°C to 25°C for a designated amount of time	Quidel generated symbol
	Transfer pipette	Plastic tube with barrel at one end that is used to transfer sample liquid	Quidel generated graphic
	Mean	Indicates average number	ISO 3534-1:2006 Reference 1.15

SYMBOL GLOSSARY

Explanation of symbols used in Quidel device labeling.

Symbol	Symbol Title	Explanatory Text	Standard Reference
σ	Standard deviation	Indicates standard deviation	ISO 3534-1:2006 Reference 1.24
	CODE CHIP module	Any of several kinds to chips bearing information to be downloaded into a medical device	Quidel generated graphic
	Printer paper	Paper roll	Quidel generated symbol
	Peel open here	Indicates how to open	Quidel generated symbol
	Add sample here	Indicates where to add sample specimen	Quidel generated symbol
	Treated human urine matrix	Indicates the type of sample specimen to be used	Quidel generated symbol
	Use EDTA plasma sample only	Indicates that an EDTA plasma sample must be used	Quidel generated symbol
	Use urine sample only	Indicates that a urine sample must be used	Quidel generated symbol
	Use EDTA whole blood or plasma sample only	Indicates that an EDTA whole blood or plasma sample must be used	Quidel generated symbol

SYMBOL GLOSSARY

Explanation of symbols used in Quidel device labeling.

Symbol	Symbol Title	Explanatory Text	Standard Reference
	Add sample immediately after opening foil pouch	Steps for using a device	Quidel generated graphic

Standard Reference	Standard Title
MDD 93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
IVDD 98/79/EC	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
ISO 15223-1:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
ISO 7000:2014	Graphical symbols for use on equipment – registered symbols
ISO 7010:2011	Graphical Symbols – Safety Colours and Safety Signs – Registered safety signs
ISO 780:2015	Packaging – Distribution Packaging – Graphical symbols for handling and storage of packages
ISO 3534-1:2006	Statistics Vocabulary and Symbols Part 1: General statistical terms and terms used in probability
EDMA Symbols for IVD reagents and components	European Diagnostic Manufacturers Association guidance “EDMA Symbols” for IVD Reagents and Components, 2009
EDMA Symbols for IVD reagents and instruments	European Diagnostic Manufacturers Association guidance “IVD Symbols” for Reagents and Instruments, 2012
29 CFR 1910:1200 (HCS)	Code of Federal Regulations, Title 29 – Hazard Communication Standard
(EC) 1272/2008	Regulation on classification, labelling and packaging of substances and mixtures
Directive 2012/19/EC	Directive 2012/19/EC on waste electrical and electronic equipment (WEEE)
China RoHS 2	China Restriction of Hazardous Substances 2