ANCHOR

C. difficile PCR Kit

Instructions for Use

Anchor C. difficile PCR Kit

CE

Qualitative Real-Time PCR Kit

for *in vitro* diagnostic use

IVD	For *in vitro* diagnostic use
REF	A0200
Σ	100
HB	A0210-UK – 25.05.2022
QG	A0211-UK – 25.05.2022
	-30°C to -15°C
	ANCHOR Diagnostics GmbH Grandweg 64 D-22529 Hamburg

compatible with

LightCycler 480 II (Roche)

cobas z 480 Analyzer (Roche)

CFX96 (Bio-Rad)

Rotor-Gene Q (QIAGEN)

QuantStudio 5 (Applied Biosystems)

Mic qPCR (Bio Molecular Systems)

1 Contents

2 Intended Use

The Anchor C. difficile PCR Kit is an *in vitro* nucleic acid amplification test based on Real Time PCR technology for the qualitative detection of toxigenic *Clostridium difficile* DNA, isolated from human stool or stool suspensions.
The product is intended to be used by professional users, such as laboratory technicians and physicians who are trained in molecular biological techniques.

3 Product Description

The Anchor C. difficile PCR Kit is a Real-Time PCR technology-based test for the amplification and detection of toxigenic *C. difficile* specific nucleic acids. The Master Mixes contain reagents for the amplification and differentiation of Toxin A *(tcdA)* and Toxin B *(tcdB)* specific DNA of *C. difficile*.
In addition, a heterologous amplification system (Internal Control) is included to supervise the success of the sample extraction procedure and to identify possible inhibition of the amplification reaction.
The *C. difficile* Toxin A *(tcdA)* / Toxin B *(tcdB)* specific nucleic acids and the Internal Control are parallel detected in two corresponding detector channels of the Real-Time PCR instrument using fluorescently labelled probes with distinguishable fluorescent dyes.
A combined *C. difficile* Toxin A and Toxin B Positive Control and a Negative Control are monitoring the integrity of the analyte-specific reagents of the kit and the proper performance of the reaction.

4 Kit Components

The Anchor C. difficile PCR Kit is a ready-to-use system.
Master A and Master B reagents contain all necessary components to allow PCR mediated amplification and target detection of *C. difficile* of Toxin A and Toxin B specific DNA and Internal Control in one reaction setup.
PC (Positive Control) C. difficile Tox A/B and NC (Negative Control) DNA are supplied with the IC (Internal Control) DNA already incorporated (see also section 9.2.1 Master Mix Set-Up).
The reagents provided with the kit allow the preparation of 100 reactions.

Master A C. difficile	Master B C. difficile	IC DNA 2	! PC C. difficile Tox A/B	! NC DNA 2
A0201	A0202	A0022	A0203	A0032
4 Vials	4 Vials	1 Vial	1 Vial	1 Vial
4x 125 µL	4x 125µL	1000 µL	200 µL	200 µL
Contains: Buffer, Bovine Serum Albumin, Polymerase	Contains: Buffer, Salt, Nucleotides, Target- and IC-specific Oligonucleotides	Contains: Buffer, IC-specific synthetic Polynucleotide	Contains: Buffer substance, Target-specific synthetic Polynucleotide	Contains: Buffer substance, IC-specific synthetic Polynucleotide

! INTERNAL CONTROL INSIDE !

5 Storage and Stability

- The Anchor C. difficile Kit is shipped on dry ice and should be stored at -30 to -15 C upon receipt.
- The components are stable until the expiration date stated on the label.
- Do not use components of the kit that have passed their expiration date.
- Store *C.difficile* DNA-positive and/or potentially positive material separated from the kit.
- Repeated thawing and freezing of the Master reagents of > 3x should be avoided, as this may reduce the assay performance.
- Due to the components used it might be possible that Master vials do not always freeze completely after initial thawing. This is not a matter of concern and does not influence the stability or performance of the assay.
- If the reagents are to be used only intermittently, they should be frozen in aliquots. Label aliquots clear and unambiguously to avoid a mix-up of reagents.
- During PCR set up the reagents should be kept cooled at +2 to +8°C – use cooling block.
- Do not store Master A and Master B C. difficile more than 3 h at +2 to +8°C.
- Protect all reagents from extensive light exposure.

6 Material Required but Not Provided

- Nucleic acid purification system
- Real-Time PCR instrument
- Appropriate PCR reaction vessels and related accessories
- Cooling block (for reaction setup)
- Benchtop centrifuge (rotor holding 2 mL reaction tubes)
- Vortex mixer
- Pipettes (variable volume)
- Single-use pipette filter tips
- 1.5 mL or 2 mL reaction tubes (for Master mix set-up)
- Single-use gloves (powder-free)

Use all materials and equipment according to the manufacturer's instructions. Maintain and calibrate the equipment as recommended.

7 Limitations

- Strict compliance with the user manual is required for optimal PCR results.
- Any diagnostic results generated must be interpreted in conjunction with other clinical and/or laboratory findings.
- The presence of PCR inhibitors may cause invalid results.
- Occurrence of mutations within the target region might result into a reduced sensitivity or a complete detection failure.
- Following good laboratory practices is crucial for the successful usage of the product.
- Appropriate handling of the reagents is essential to avoid contaminations or impurities.

8 Warnings and Precautions

- For *in vitro* diagnostic use.
- Use of this product is limited to personnel specially instructed and trained in the techniques of Real-Time PCR and *in vitro* diagnostic procedures.
- Specimens should always be treated as potentially infectious and/or biohazardous material in accordance with safe laboratory procedures.
- The Anchor Master A C. difficile contains a bovine sourced potentially infectious component (albumin). The bovine plasma is sourced from New Zealand or USA, which are recognized by the world organization for animal health Office International des Epizooties (OIE, Paris) as having a negligible BSE risk.
- Wear protective single-use gloves, a laboratory coat and eye protection when handling specimens or kit components.
- Avoid microbial and nuclease (DNase/RNase) contamination of the specimen and the components of the kit.
- Always use DNase/RNase-free single-use pipette tips with aerosol barriers.
- Use separated working areas for (1) specimen preparation, (2) PCR reaction set-up and (3) amplification/detection activities.
- Dedicate supplies and equipment to the separate working areas and do not move them from one area to another.
- Do not open the reaction tubes/plates post amplification, to avoid contamination with amplicons.
- Additional controls may be tested according to guidelines or requirements of local, state and/or federal regulations or accrediting organizations.
- Discard sample and assay waste according to your local safety regulations.

9 Workflow

9.1 Sample Preparation

9.1.1 Sample Matrix

The recommended patient sample matrix for sample preparation input is:

- human stool
- stool suspensions

Storage recommendations:
Storage recommendations for stool are dependent on the downstream testing algorithm. For nucleic acid amplification test-based detection systems, the storage of samples for 48 hours at +15 to +30 °C following 5 days at +2 to +8 °C did not show a negative impact on the detectability of the *C. difficile* DNA or the reproducibility of results obtained from fresh samples. This was confirmed for samples stored for additional 32 days at -20 °C or 5 months at -70 °C.

9.1.2 Sample Preparation

Purified DNA is the sample input material for the Anchor C. difficile PCR Kit. It has to be ensured that the chosen nucleic acid purification method is compatible with Real-Time PCR technology. The extraction has to be executed according to the manufacturer's instructions. The diagnostic applicability of the Anchor C. difficile PCR Kit has been shown using the following sample preparation systems:

Sample Preparation Systems
NucliSENS® easyMag® System (bioMérieux)
EMAG® (bioMérieux)
EZ1 Advanced XL / EZ2 Connect (QIAGEN)
QIAcube Connect (QIAGEN)
QIAsymphony® SP (QIAGEN)
MagNA Pure 96 System (Roche)
MagNA Pure Compact (Roche)
Maxwell® 16 / RSC Instrument (Promega)
KingFisher Systems (Thermo Fisher Scientific)
SEEPREP32™ (Seegene)
GenoXtract® (Hain Lifescience)

If sample eluates are not directly used for PCR analysis, store eluates at -30 to -15 °C. In case of using eluates repeatedly, avoid frequent thaw/freeze cycles (no more than 3 cycles).

Eluates should be labelled clearly and unambiguously to avoid a mix-up of samples.

9.1.3 Internal Control

The Internal Control DNA 2 provided with the Anchor C. difficile PCR Kit should be co-purified with the nucleic acid of interest to monitor sample preparation efficiency and quality and PCR inhibition.

The Internal Control DNA 2 MUST NOT be added directly to the clinical sample.

Always add the Internal Control DNA 2 after lysis buffer has been added to the sample.
The required volume of Internal Control DNA 2 per sample purification is defined by the chosen elution buffer volume.

Ten percent of the elution buffer volume used should be added to the sample/lysis mixture.

Examples:

- Elution buffer per sample: 200 µL -> IC DNA 2 volume: 20 µL
- Elution buffer per sample: 60 µL -> IC DNA 2 volume: 6 µL

Secure the elimination of residual ethanol before elution of nucleic acids. Ethanol may inhibit the amplification process.

If no co-purification of the Internal Control is planned, the IC DNA 2 is used only as an inhibition control of the PCR reaction, but not as a control for efficient sample preparation. For this, either the amount of IC related to the used elution volume could be added to each eluate or 1.5 µL of the IC DNA 2 / per reaction should be added to the master mix (see section 9.2.1 Master Mix Set-Up).

9.2 PCR Preparation

9.2.1 Master Mix Set-Up

ⓘ Consider configuring the run settings of the PCR cycler software to have the instrument ready before starting the PCR reaction preparation (Refer to section 9.3 PCR Cycler Configuration).

Prepare the Master Mix step by step:

- Thoroughly thaw Master components A and B.
- Mix Master A and B by gentle pipetting or short pulse-vortexing.
- Spin Master A and B shortly with a benchtop centrifuge to remove residual droplets from tube lids.
- According to your preferred workflow follow one of the pipette schemes below to mix Master A and B using a 1.5 mL or 2 mL reaction tube:

IC DNA 2 present in sample eluates – NO IC DNA 2 added to Master Mix preparation:

Number of reactions	1	10(+1)*	N**
Master A C. difficile	5 µL (x)	55 µL	Y µL
Master B C. difficile	5 µL (x)	55 µL	Y µL
Volume Master Mix	10 µL	110 µL	Z µL

*10 reactions + 10%
** See formula next page

IC DNA 2 to be used as PCR inhibition control only – IC DNA 2 added to Master Mix preparation:

Number of reactions	1	10(+1)*	N**
Master A C. difficile	5 µL (x)	55 µL	Y µL
Master B C. difficile	5 µL (x)	55 µL	Y µL
IC DNA 2	1.5 µL (x)	16.5 µL	Y µL
Volume Master Mix	11.5 µL	126.5 µL	Z µL

*10 reactions + 10%
** See formula next page

ⓘ We recommend calculating for an additional volume of at least 10% to compensate potential loss during pipetting. The needed volume will be calculated by using the following formula:

** N×XµLx1.1=Y

N = Number of reactions
X = Volume of component per reaction
Y = Total volume of component
Z = Total volume of Master Mix

- Mix prepared Master Mix by gentle and short pulse-vortexing.
- Spin Master Mix shortly with a benchtop centrifuge to remove residual droplets from tube lids.

ⓘ It is recommended to test the Positive Control and the Negative Control at least once in each PCR run.

ⓘ Positive Control C. difficile Tox A/B and the Negative Control DNA 2 already contain the IC DNA 2 in a ready-to-use concentration. No addition of IC necessary!

If you want to use a Master Mix preparation with added IC DNA 2 (as inhibition control) in combination with PC and NC DNA 2, be aware that the IC signal of the controls will slightly shift towards a lower CT value in comparison to the IC signal of the controls using a Master mix without additional IC.

9.2.2 PCR Reaction Set-Up

ⓘ Always use a cooling block for the preparation of the PCR reaction mix.

Prepare the Reaction Mix step by step:

- If previously stored frozen, thaw eluates containing nucleic acid (and IC DNA 2) thoroughly.
- Mix eluates by gentle pipetting or brief pulse-vortexing.
- Spin eluates shortly with a benchtop centrifuge to remove residual droplets from tube lids.
- Pipette **10 µL of Master Mix** (see section 9.2.1 Master Mix Set-Up) into suitable reaction vessels for PCR analysis. This is also valid for Master Mix spiked with IC DNA 2.
- Add **15 µL of eluate** or control (Positive Control *C. difficile* Tox A/B or Negative Control DNA 2). **Mix well by repeated up and down pipetting.**
- Close reaction vessels securely with the appropriate sealing system.
- Immediately transfer closed and ready-to-use reaction vessels to the Real Time PCR instrument. Avoid any delays!

ⓘ **Carefully handle reaction vessels during transfer to avoid mix up of samples.**

ⓘ **Complete mixing of Master Mix reagents with a sample or control during reaction set up should be unconditionally secured by repeated up and down pipetting!**
This is essential to achieve an optimum amplification curve performance!!!

Master Mix	+	Eluate / Control	=	Reaction Mix
10 µL		15 µL		25 µL

9.3 PCR Cycler Configuration

The Anchor C. difficile PCR Kit has been evaluated in combination with the following different PCR Cycler platforms:

PCR Cycler Platform	Run Time
LightCycler 480 II (Roche)	≈ 30 min.
cobas z 480 (Roche)	≈ 30 min.
CFX96 (Bio-Rad)	≈ 33 min.
Rotor-Gene Q (QIAGEN)	≈ 39 min.
QuantStudio 5 (Applied Biosystems)	≈ 28 min.
Mic qPCR Cycler (Bio Molecular Systems)	≈ 33 min.

The listed run times for the different instruments are effectively measured durations and can differ from what is displayed on the graphical user interface of the individual instrument software. For basic information concerning set-up and programming of the respective Real-Time PCR instrument, refer to the instrument-specific manual.

9.3.1 General PCR Cycler Settings

Temperature cycling profile for **QuantStudio 5, LightCycler 480 II, Cobas z 480 Analyzer, CFX96 and Rotor-Gene Q**:

Cycling	95°C	1 sec	x 40
	65°C *	2 sec	
	72°C	1 sec	

***** Fluorescence acquisition for toxigenic *C. difficile* and IC

Temperature cycling profile for **Mic qPCR**:

Cycling	95°C	1 sec	x 40
	63°C *	2 sec	
	72°C	1 sec	

* Fluorescence acquisition for toxigenic *C. difficile* and IC

Reaction Volume: 25 µL

9.3.2 Specific PCR Cycler Settings

The following table contains PCR cycler-specific recommendations for the basic configuration of the run settings.
For additional information regarding the cycler settings recommended plastics, colour compensation, gain optimisation settings, etc. do not hesitate to contact us directly (see section 12 Technical Assistance & Contact Information).

Instrument	Target	Detection channel	Recommendations / Requirements
LightCycler® 480 II (cobas z 480)	Tox A/B	465/510	**Run Settings:** ▪ Block size: 96 ▪ If clear plates are used, the sensor of the LightCycler® has to be disabled by selecting the Clear Plates option in the software before the run is started. **Consumables:** ▪ LC480 Multiwell Plate 96, white (Roche Mat. No. 04729692001) ▪ LC480 Multiwell Plate 96, clear (Roche Mat. No. 05102413001) ▪ LC480 Sealing Foil (Roche Mat. No. 04729757001)
	IC	533/580 (540/580)	
Bio-Rad CFX96	Tox A/B	FAM	**Consumables:** ▪ Hard Shell 96-well PCR Plate, white (Mat. No. HSP9655) ▪ Optical flat 8 Cap Strip for 0.2ml (Mat. No. TCS0803) ▪ 0.2 ml 8-Tube PCR Strips without Caps, low profile, white (Bio-Rad Mat. No. TLS 0851) ▪ 8-strip optical clear flat caps (Sarstedt Mat. No. 65.1998.400)
	IC	HEX	
Rotor-Gene Q	Tox A/B	Green	**Run Settings:** ▪ Use 72-Well Rotor ▪ Perform Auto-Gain optimisation before 1st acquisition. **Consumables:** ▪ Strip Tubes and Caps, 0.1 ml (QIAGEN Mat. No 981103)
	IC	Yellow	

Instrument	Target	Detection channel	Recommendations / Requirements
QuantStudio™ 5	Tox A/B	FAM	**Run Settings:** ▪ Block Type: 96-Well 0.1-mL Block ▪ Experiment Type: Standard Curve Chemistry: TaqMan® Reagents ▪ Run Mode: Fast ▪ Plate attributes: Passive Reference - None **Consumables:** ▪ 96-Well Fast Thermal Cycling Plates (Life Technologies Mat.No. 4346907) ▪ MicroAmp™ Optical Adhesive Film (Life Technologies Mat. No. 4311971) or ▪ 96-Well-PCR-Plate, Skirted, „Low Profile“, white (Starlab Mat. No. E1403-5209) ▪ Xtra-Clear Advanced Polyolefin StarSeal (qPCR) (Starlab Mat. No. E2796-9795)
	IC	HEX	
Mic qPCR Cycler	Tox A/B	Green	**Run Settings:** ▪ Temperature Control: Standard TAQ **Consumables:** ▪ MIC Tubes and Caps (Mat. No. 68MIC-60653) or similar product.
	IC	Yellow	

9.4 Data Analysis

The following table contains cycler-specific references for the configuration of analysis settings. They could serve as an initial orientation. Depending on local cycler- and workflow-related differences adaptations might be necessary.
For additional information concerning data analysis, refer to the instrument-specific manual of the respective Real-Time PCR instrument or contact us (see section 12 Technical Assistance & Contact Information).

Instrument	Recommendations
LightCycler® 480 II (cobas z 480)	**Analysis Settings:** ▪ Abs Quant/2nd Derivative Max ▪ Color Comp (off) ▪ Mean ▪ High Confidence
Bio-Rad CFX96	**Analysis Settings (all channels):** ▪ Baseline Substracted Curve Fit ▪ C(t) Determination Mode: Single Threshold ▪ Baseline Threshold: - Baseline Cycles: Auto Calculated - Single Threshold - FAM: 1000 - HEX: 250
Rotor-Gene Q	**Analysis Settings (all channels):** ▪ Quantitation ▪ Linear Scale ▪ Dynamic Tube ON ▪ Threshold: - Green: 0.04 - Yellow: 0.08
QuantStudio™ 5	**Analysis Settings (all channels):** ▪ Plot Type: ΔRn vs Cycle ▪ Graph Type: Linear ▪ Baseline Start/End: 3/15 ▪ Threshold: - FAM 600,000 - HEX 100,000
Mic qPCR Cycler	**Analysis Settings: (all channels):** ▪ Graph Type: Linear ▪ Method: Dynamic ▪ Ignore Cycles Before: 3 ▪ Threshold Start: 1 ▪ Exclusion: None ▪ Threshold Level: - Green: 0.12 - Yellow: 1.5

9.4.1 Qualitative Analysis

For a valid run and as a prerequisite for the interpretation of the individual clinical sample results, the following requirements have to be met by the included kit controls:

Channel/Target	Tox A/B	IC
PC C.difficile Tox A/B	+	+
NC DNA 2	-	+

If one of the conditions has failed, result interpretation of clinical sample results might be flawed. In case of kit control failure, it is recommended to repeat the PCR run.

In case of a valid run, the following result interpretation can be made:

Qualitative result	Tox A/B	IC
Toxigenic *C. difficile* DNA positive	+	+/-
Toxigenic *C. difficile* DNA negative	-	+
Invalid	-	-

A positive result in the target specific channel does not necessarily require a positive signal for the IC since high concentrations of the respective target nucleic acid can result in a competitive inhibition of the IC amplification.

An invalid result for a clinical sample can be due to PCR inhibition or a failure during the nucleic acid isolation procedure. In such cases, it is recommended to dilute the nucleic acid extract 1:10 (recommended to be done in elution buffer, if possible) for a PCR retest or to repeat the nucleic acid isolation procedure. Note that the dilution of the nucleic acid extract might also lead to a reduction of the target nucleic acid concentration below the limit of detection of the Anchor C. difficile PCR Kit.

10 Performance Data

10.1 Analytical Performance

10.1.1 Sensitivity

The LOD for the Anchor C. difficile PCR Kit was determined by undertaking a probit analysis on the Rotor-Gene Q platform. A dilution series of different concentration levels for *C. difficile* strain 630 DNA (ATCC / LGC Mat # 1382DQ) was used. Each dilution level was tested with overall 24 replicates using 3 different PCR reagent lots across 3 different days, executed by 2 different persons on 2 different instruments.
The LOD value determined on the Rotor-Gene was then confirmed or re-evaluated on the other 4 instruments.

Instrument	LOD	Unit
Rotor-Gene Q	0.3	copies/ul
QuantStudio 5	0.6	copies/ul
LightCycler 480 II (cobas z 480 Analyzer)	0.3	copies/ul
CFX96	0.3	copies/ul
Mic qPCR	0.3	copies/ul

10.1.2 Specificity

Triplicates of different clinical isolates which have been independently characterized with regards to their ribotype affiliation, were tested at a concentration near the 3x LOD of the Anchor C. difficile PCR Kit.

C. difficile Ribotype	*C. difficile* Tox A/B
Ribotype 001	+
Ribotype 002	+
Ribotype 005	+
Ribotype 014	+
Ribotype 015	+
Ribotype 017	+
Ribotype 020	+
Ribotype 027	+
Ribotype 078	+

Nucleic acid of selected pathogens with a concentration of ≈5.00E+03 copies/µL (alternative units CFU/µl or TCID50/µL) was added to the PCR reaction and tested in triplicates in the absence or presence of *C. difficile* DNA at its 3x LOD and 3x LOQ concentration on the Rotor-Gene Q.

Pathogen	- *C.difficile*	3x LOD *C. difficile*
*C. difficile Ribotype 010**	-	Not tested
*C. difficile Ribotype 140**	-	Not tested
Clostridium sordellii	-	+
Clostridium perfringens	-	+
Norovirus GI.P4_GI4	-	+
Norovirus GII.P16_GII4_2012	-	+
Escherichia coli	-	+
Human Rotavirus	-	+
Salmonella enterica	-	+
Campylobacter coli	-	+
Entamoeba histolytica	-	+
Guardia intestinalis	-	+
Listeria monocytogenes	-	+
Candida albicans	-	+
Enterococcus faecium	-	+
Human Hepatitis A Virus	-	+

* concentration of non-toxigenic ribotypes was unknown, undiluted DNA was tested as provided

10.1.3 Precision

Precision testing was initially performed on the Rotor-Gene Q instrument. For intra-run variability, 3-6 replicates of each sample dilution were tested within one run using one instrument and reagent lot by one operator. For inter-run variability, 3-6 replicates of each sample dilution were tested within overall four runs using two instruments and one reagent lot by two operators across days. For inter-batch variability, 3-5 replicates of each sample dilution were tested within one run using one instrument and three reagent lots by one operator.

		PC C. difficile Tox A/B	
Variability	AVE (CT)	SD (CT)	CV (%)
Intra-Run	27.31	0.14	0.53
Inter-Run	27.74	0.37	1.32
Inter-Batch	27.32	0.15	0.55
Total	27.61	0.37	1.34
		IC DNA 2	
Variability	AVE (CT)	SD (CT)	CV (%)
Intra-Run	24.59	0.13	0.52
Inter-Run	25.00	0.30	1.20
Inter-Batch	24.86	0.28	1.14
Total	25.00	0.28	1.12
		ATCC C. difficile 3xLOD	
Variability	AVE (CT)	SD (CT)	CV (%)
Intra-Run	35.73	0.32	0.89
Inter-Run	36.07	0.60	1.68
Inter-Batch	36.07	0.60	1.68
Total	36.12	0.62	1.71

Precision of the Anchor C. difficile PCR Kit in combination with the other instruments was evaluated for intra- and inter-run variability.

10.2 Clinical Performance

The clinical performance of the Anchor C. difficile PCR Kit for the qualitative detection of toxigenic *C. difficile* DNA in human stool samples was evaluated comparatively at 2 different study sites against an established *C. difficile* routine diagnostic workflow using a CE-marked PCR-Assay as reference standard.
Prospectively collected and banked specimen were analysed with the Anchor *C. difficile* PCR Kit and with the comparator assays to determine their positive percent agreement (PPA) and negative percent agreement (NPA), respectively. Testing was done using the LightCycler 480II, Bio-Rad CFX96, and Rotor-Gene Q Cycler.

		Comparators	
	∑ 671	POS	NEG
Anchor	POS	281	22
C. difficile PCR Kit	NEG	2	366

PPA: 99.3 % NPA: 94.3 %

11 Quality Control

In accordance with the implemented ISO 13485-certified Quality Management System, each lot of the Anchor C. difficile PCR Kit is tested against predetermined specifications to ensure consistent product quality.

12 Technical Assistance & Contact Information

For any questions, a need for technical assistance or if you identify difficulties using our products do not hesitate to contact us:

phone: +49 40 520 14 830
email: support@anchor-diagnostics.com

13 Literature

(1) Chen S et al., Rapid detection of Clostridium difficile toxins and laboratory diagnosis of Clostridium difficile infections. Infection. 2017 Jun;45(3):255-262

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14 Symbols

IVD For *in vitro* diagnostic use

REF Product - Catalogue number


Contains sufficient reagents for <N> tests


Instructions for Use - Catalogue number and version


Consult Instructions for Use

QG Quick Guide - Catalogue number and version


Temperature limits for storage


Use by

LOT Batch code


Important Note


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