Technical File - qPCR

FRIZ Biochem GmbH

Exportiert am 12. August 2026

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1.1. 1 Meta Information

Document type	REC
Version	16
Status	● Approved
Last release date	Wed 22 Jul 2026, 14:37
Page ID	1341751450
Last change to the document	Initial creation and approval.

1.1.1. 1 Purpose

This Summary of Safety and Performance (SSP) is intended to provide public access to an up-to-date summary of the main aspects of the safety and performance of the IVD medical device Helicobacter *direct* PCR.

The SSP is not intended to replace the Instructions For Use (IFU) as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users.

The information in the next section is intended for professional users.

1.2. 2 Summary of Safety and Performance (SSP) for professional users

1.2.1. Device identification and general information

Parameter	Value
Device trade name(s)	Helicobacter *direct* PCR
Device reference number	FBC116
Manufacturer´s name and address	FRIZ Biochem GmbH Floriansbogen 2-4 82061 Neuried Germany
Manufacturer´s single registration number (SRN)	DE-MF-000017533
Basic UDI-DI	426075389fbc116U7
European Medical Device Nomenclature (EMDN)	• EMDN W0105: infectious diseases (derived based on W010507 multiple parameters) • IVP 3011: In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)
Risk class of the device	Class C
Indication whether it is a device for near-patient testing and/or a companion diagnostic	☐ Device for near-patient testing ☐ Companion Diagnostic (CDx) ☑ n.a.
Year when the first certificate was issued under Regulation (EU) 2017/746 covering the device	the device has not been certified under IVDR yet
Authorized representative, if applicable; name and the SRN	n.a.
NB's name (the NB that will validate the SSP) and NB's single identification number	Name of NB that will validate the SSP: TÜV Süd Product Service GmbH NB's single identification number: NB 0123

SSP reference number	FBC1161341751450

1.2.2. Intended use of the device

1.2.2.1. Intended purpose

DI Intended Purpose IVD FBC116

The Helicobacter *direct* PCR is an assay for *in vitro* examination of bacterial DNA in biopsy or culture samples to provide information to aid in the diagnosis of patients under suspicion for *Helicobacter pylori* infection and its resistance to levofloxacin and/or clarithromycin. Resistance to levofloxacin is identified by mutations C261A/G, G271A/T and A272G in the gyrA gene and resistance to clarithromycin is identified by mutations A2142G/C and A2143G in the 23S rDNA gene.

The IVD medical device detects the DNA of the aforementioned pathogen by qualitative measurements based on qPCR and is intended for use in medical laboratories or health institutions by laboratory personnel specifically trained in qPCR and *in vitro* diagnostic techniques. It has to be used in combination with conventional nucleic acid extraction systems for DNA extraction and qPCR cyclers for detection and analysis.

1.2.2.2. Indication(s) and target population(s)

The Helicobacter *direct* PCR test may be applied for symptomatic or asymptomatic patients under suspicion of *Helicobacter pylori* infection. Symptoms may include nausea, vomiting, belly pain, and bloating. The most important therapeutic measure is antibiotic treatment. While initial infection of *Helicobacter pylori* often occurs in childhood, prevalence rises with age, with a high incidence in older adults.

1.2.2.3. Limitation(s) and/or contra-indication(s)

There are no known contraindications or limitations to the target patient group. For detailed limitations and/or contra indications arising from associated interferences, cross-reactions, etc. see Instructions for Use IFU FBC116 Helicobacter direct PCR V1.0.

1.2.3. Device description

1.2.3.1. Description of the device

DI Intended Purpose IVD FBC116

The Helicobacter *direct* PCR is a multiplex qPCR test for the detection of *Helicobacter pylori* and its resistance to levofloxacin and clarithromycin.

A separate Internal Control (IC) is added to each sample prior to DNA extraction and serves as a control for nucleic acid isolation from the biological specimen as well as for amplification.

The nucleic acid eluate is added to the ready-to-use reaction solution that contains all reagents necessary for qPCR. The analysis can be performed on various qPCR cyclers.

The Helicobacter *direct* PCR contains primers and probes specific for the targets listed in Table 1 as well as the Internal Control. The probes are each labelled with fluorescent reporter dyes and a second dye that serves as a quencher and suppresses the fluorescence signals of intact probes.

Table 2: Analytes and target genes of Helicobacter direct PCR

ANALYTE	GENE
Helicobacter pylori	16S rDNA
Levofloxacin resistance	C261A/G, G271A/T and A272G in the gyrA gene
Clarithromycin resistance	A2142G/C and A2143G mutations in the 23S rDNA

The analysis is performed by determining Ct (cycle threshold) values. The Ct value describes the cycle in which the signal rises above a certain threshold for the first time. The more target copies are present in the sample, the lower the Ct value.

1.2.3.2. Description of the components

Each kit contains the following vials which are sufficient for 96 reactions (see Table 1).

Table 1: Package content of Helicobacter direct PCR

Material	Lid Colour	#Vials;Volume	#rxns	Comment
Solution A	green	1x; 1050 µL	96	Reaction mix (buffer, enzymes, primer and probes)
Internal Control	blue	1x; 400 µL	96	Internal Control (artificial nucleic acid target)
Positive Control	red	1x; 50 µL	4	Plasmid DNA of target gene regions

1.2.3.3. Previous generation(s) or variants

There are no previous generations of the IVD medical device.

The Helicobacter *direct* PCR shall be available in the following variants:

Table 2: Helicobacter direct PCR configurations

Article number	Configuration	Channel of Internal Control	UDI-DI (GTIN)

FBC116-Ax	suitable for use on a qPCR instrument with at least 5 detection channels (Cyan500/FAM/HEX/Red610/Cy5)	Cyan500	4260753890297
FBC116-Bx	suitable for use on a qPCR instrument with at least 5 detection channels (FAM/HEX/Red610/Cy5/Cy5.5)	Cy5.5	4260753890471

1.2.3.4. Accessories

Additional components required that are not provided with the kit:

- qPCR cycler (with at least 5 detection channels)
- Disposable protective gloves, powder-free
- PCR reaction tubes/microtiter plate plus lids/adhesive optical film
- Pipettes
- sterile filter-tips for PCR testing (DNA/RNA-free)
- Table centrifuge
- DNA extraction kit (IVD-1049 chemagic™ Pathogen NA gDNA Kit H96 by PerkinElmer chemagen Technologie GmbH, MagNA Pure 96 DNA and Viral NA Small Volume Kit by Roche Life Science, or similar devices)
- Negative Control (no-template control, molecular grade water, or any other negative control according to the laboratory´s standard procedure)

1.2.3.5. Other devices and products to be used in combination

The Helicobacter *direct* PCR is intended to be used in combination with conventional nucleic acid extraction systems for DNA extraction and qPCR cyclers for detection and analysis.

1.2.4. List of harmonized standards applied

Standard	**Title**
BS EN ISO 23640:2015	In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents
BS EN ISO 17511:2021	In vitro diagnostic medical devices. Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples
BS EN ISO 14971:2019+A11:2021	Medical devices. Application of risk management to medical devices
BS EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer — General requirements
BS EN ISO 13485:2016+A11:2021	Medical devices. Quality management systems. Requirements for regulatory purposes

Standard	Title
BS EN ISO 20916:2024	In vitro diagnostic medical devices. Clinical performance studies using specimens from human subjects. Good study practice

1.2.5. Risks and warnings

1.2.5.1. Residual risks and undesirable effects

We successfully applied risk mitigation strategies. These measures reduced the probability category by at least one level without introducing new risks, thus we positively affected the benefit-risk ratio. After measure implementation all individual residual risks are accepted and consequently the overall residual risk is acceptable.

The Helicobacter *direct* PCR fulfils the following parameters:

- compliance with the applicable general safety and performance requirements
- acceptable performance claims according to the state of the art and available diagnostic alternatives
- suitability of the device and its IFU for the intended users and use environment, including usability aspects

The residual risks are unlikely/moderate (probability/severity) or less.

Based on the clinical evidence and in alignment with the state of the art and the common specifications, Helicobacter *direct* PCR achieves a clinical benefit by accurately detecting and differentiating DNA of *Helicobacter pylori* and its resistance to clarithromycin and levofloxacin in human clinical specimens (i.e., biopsy samples and culture samples) and supporting diagnostic decision-making, taking into account additional clinical and laboratory information.

The clinical benefit is, to provide physicians with useful information with respect to patient management and therapy decisions, if applicable. This may help separate infected people from uninfected people and to isolate them from the rest of the population especially for high-risk patients.

The overall residual risk is in line with the risk policy and acceptable.

1.2.5.2. Warnings and precautions

The Helicobacter *direct* PCR is intended for *in vitro* diagnostic use only. The test should only be performed by personnel trained in molecular diagnostic techniques. If the user makes substantial changes to the product or the application instructions, results may not correlate with the intended purpose.

- Before performing the test, read the entire instructions for use and follow them carefully. Deviations from the given test protocols can lead to invalid results.
- All patient samples must be treated as potentially infectious material.
- Discard sample and assay waste that was in contact with patient material according to your local, regional, or national safety regulations.
- Do not use the test beyond the expiration date.
- Do not use the test with opened or damaged packaging.
- Protect reagents from heat, moisture, and light.
- Do not replace or mix the reagents with reagents from other batches or other chemicals.
- Avoid contamination of the test by microorganisms and nucleases (DNases and RNases).
- Any carry-over of samples during handling and processing of the test may result in false positive test results.
- Use separated and segregated working areas for (1) sample preparation, (2) reaction setup and (3) amplification/detection activities. The workflow in the laboratory should proceed in unidirectional manner.
- Always wear disposable gloves in each area and change them before entering a different area.

- The test kits are intended for single use and must not be reused after performing qPCR reaction.
- If contamination of the qPCR cycler is suspected, cleaning and maintenance must be carried out according to the system´s manual.
- In the event of failure of the controls, the test result cannot be evaluated, and a repeat run should be considered.
- Safety Data Sheets (SDS) are available for download via https://frizbiochem.de/downloads/
- Pending EUDAMED entry, the Safety and Performance Summary (SSP) can be downloaded via http://www.frizbiochem.de

1.2.5.3. Other relevant aspects of safety

The chapter is not applicable as no field safety corrective actions (FSCA) and field safety notices (FSN) have been taken.

1.2.6. Summary of performance evaluation and post-market performance follow-up (PMPF)

1.2.6.1. Summary of scientific validity

To demonstrate the scientific validity of the Helicobacter *direct* PCR, the following data sources were used:

- information (e.g., IFU) about the scientific validity of similar devices according to the State-of-the-Art report
- scientific (peer-reviewed) literature

We selected PubMed (MEDLINE database) as the source for the literature search.

A combined literature search covering all analytes was performed considering the last 20 years (2005 – 2026).

We defined the following exclusion criteria:

- The target organisms and/or analytes not related to Helicobacter *direct* PCR
- The respective target gene was not considered.
- The publication focuses on food safety.
- The publication investigates only samples from animals.
- The publication does not focus on real-time PCR based detection.
- The publication focuses on the prevalence/characterization of strains and/or antibiotic resistances.

The following table provides an overview of how many publications were excluded after abstract screening and how many publications were considered for demonstration of scientific validity.

Table 3: Results of the literature searches

Search time frame	Literature search results	Excluded after abstract screening	Considered for scientific validity
2005-2010	20	16	4
2011-2016	35	31	4
2017-2022	35	27	8
2023-2026	21	14	7

In summary, it could be shown that qPCR is a powerful method for a fast and comprehensive diagnosis of *Helicobacter pylori* infection. In general, rapid PCR assays show a sensitivity and specificity equivalent to established reference methods, including culture and/or histology-based diagnostics.

Moreover, it could be shown in this report that the chosen target genes underlying the Helicobacter *direct* PCR are appropriate targets for the detection of *H. pylori* (wild-type, wt *H. pylori*) as well as clinically relevant resistance-associated mutations. In particular, the *gyrA* gene is a well-established marker for fluoroquinolone resistance, including levofloxacin resistance, and mutations in the 23S rDNA are strongly associated with macrolide resistance, including clarithromycin resistance. These targets are well described in the literature and are also used in comparable molecular diagnostic assays.

Finally, the scientific validity for the Helicobacter *direct* PCR was demonstrated since the detection of *H. pylori* DNA and clinically relevant antibiotic resistance-associated mutations (gyrA and 23S rDNA) is verifiably associated with the infection of the respective pathogen.

1.2.6.2. Summary of performance data from equivalent device(s)

The chapter is not applicable as evidence of the underlying IVD medical device is not based on data from devices claimed to be equivalent to the device.

1.2.6.3. Summary of performance data from conducted studies prior to CE-marking

The chapter is not applicable as no performance studies have been conducted according to IVDR, Annex I, section 9 prior to CE-marking.

1.2.6.4. Summary of performance data from other sources

The chapter is not applicable as clinical evidence of the underlying IVD medical device is not based on data from other sources e.g., published experience gained by routine diagnostic testing.

1.2.6.5. Overall summary of the performance and safety

1.2.6.5.1. 1 Analytical performance

Helicobacter *direct* PCR test shows analytical specificity, analytical sensitivity, and precision that are similar to competitor devices. All analytical performance claims were able to be proven (*Table 4*).

Table 4: Overview of all applicable analytical performance parameters and the intended claims in comparison to the achieved results.

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Analytical performance parameter	Claim	Result/s	Requirement fulfilled

Specimen collection, handling and stability	In general, specimen collection, handling, and stability are applicable for the Helicobacte *direct* PCR which is performed with nucleic acid that has been extracted from biopsy and culture specimen. Quality and yield of DNA is highly dependent on the DNA extraction method used. The analytical performance is evaluated based solely on extracted DNA and thus independent of specimen collection, handling and stability.	N/A	☒ yes ☐ no
Analytical sensitivity	see Limit of detection		☒ yes ☐ no
Analytical specificity	See Cross-reactivities, Endogenous and exogenous interference, Inclusivity, Competitive interference and Physical Interaction of primers and probes		☒ yes ☐ no
Cross-reactivities	Cross-reactivity is tested with in silico analysis as well as with wet-lab testing. For the in silico analysis, the following acceptance criteria are applied: • The homology between the cross-reactive microorganism and at least one primer sequence is < 80%. • If both primer show a homology of ≥ 80%, the probe should show a homology of < 80%. • If neither of the above conditions is met, the respective organism should be wet-lab tested. For wet-lab testing the following acceptance criteria are applied: • No false positive test results for tests with negative samples regarding the test analytes. • No false negative test results for tests with positive samples regarding the test analytes.	Wet-lab testing showed that *Campylobacter* species cross-react with the 23S rDNA channel. However, this does not lead to diagnostic error, as it is accompanied by a negative 16S rDNA signal, allowing the two to be distinguished. Separately, *in-silico* sequence analysis indicates that due to high homology in the 16S/23S rDNA primer-probe regions, the assay cannot completely exclude misdetection of non-*H. pylori Helicobacter* species such as H. heilmannii, H. felis, or H. suis, though these represent rare clinical scenarios compared to *H. pylori* infection.	☒ yes ☐ no (Note in the IFU about cross-reactivity)

Endogenous and exogenous interferences	Both positive and negative samples regarding the test analytes are tested with the spiked interfering substance. The following acceptance criteria are applied: • No false positive test results for tests with negative samples regarding the test analytes. • No false negative test results for tests with positive samples regarding the test analytes.	Tested substances at relevant concentrations did not interfere with the performance. There were no false positive nor false negative test results.	☒ yes ☐ no
Inclusivity	For inclusivity analysis, an in silico analysis is performed. The following acceptance criterion is applied: • Frequency of sequences with exact match: minimum 90% of the target sequences Otherwise, the respective isolate is wet-lab tested.	The primer and probe sequences are suitable to detect the test analytes.	☒ yes ☐ no
Competitive interference	To analyse competitive interference, one test analyte is applied in a high concentration (e.g., 10^5 copies/mL), whereas the other test analytes are applied in a low concentration (3x LoD). The following acceptance criterion is applied: In standard sample solution (3x LoD) • All targets present in the standard sample solutions should be positive • The Internal Control should be positive In spiked sample solution (100 DNA copies/µl) • All targets should be positive • The Internal Control should be positive • The predominant allele in the tested sample should be correctly identifies.	The device reliably identifies the predominant allele in a sample, including cases of predominant resistance mutations or suspected heteroresistance. However, when wild-type is predominant and a resistant mutant is present as a minority subpopulation, the assay may report antibiotic susceptibility.	☒ yes ☐ no (Note in the IFU about competitive interference)

Physical Interaction of primers and probes	The physical interaction of the different assay primers and probes are investigated with an in silico analysis. The following acceptance criteria are applied: • ΔG (kcal/mol) shall be > -9.0 and > -6.0 at 3´ complementary base pairs.	Potential dimers that do not fulfil the acceptance criteria were identified. Other parameters of the analytical performance studies show that potential dimers do not have an effect on the performance of the Helicobacter *direct* PCR.	☒ yes ☐ no
Accuracy	see trueness and precision		☒ yes ☐ no
Trueness (bias)	No certified reference materials or reference measurement procedures are available. Thus, the comparison to the current clinical standard practice is addressed within the clinical performance evaluation.	N/A	☒ yes ☐ no
Precision	see repeatability and reproducibility		☒ yes ☐ no
Repeatability	Due to the same technological principle and the highly comparable workflow, reagent composition, amplification chemistry, instrumentation and cycling conditions, the impact of variation factors such as reagent lots, instruments, operators, days and runs on assay precision is considered comparable between the previously evaluated assays (res4plex *direct* RT-PCR, GastroBac *direct* PCR, res1plex *direct* PCR, res2plex *direct* PCR, res3plex *direct* PCR, res5plex *direct* RT-PCR and res6plex *direct* RT-PCR) and the Helicobacter *direct* PCR assay. Therefore, additional dedicated precision studies for the Helicobacter *direct* PCR are not considered necessary.	The previously evaluated assays differed from each other primarily in their target-specific oligonucleotide sequences while sharing the same overall assay design. Despite these sequence differences, all assays met the predefined precision acceptance criteria. The Helicobacter *direct* PCR assay differs from the previously evaluated assays in the same manner, i.e. primarily with respect to the target-specific oligonucleotide sequences. Therefore, the impact of the relevant sources of variation on repeatability or reproducibility is considered comparable.	☒ yes ☐ no
Reproducibility			☒ yes ☐ no

Carryover/Cross-contamination	The potential for carryover and cross-contamination has previously been evaluated for the res4plex *direct* RT-PCR and GastroBac *direct* PCR assays. As carryover and cross-contamination are primarily associated with sample processing, pipetting procedures and workflow conditions, and as the Helicobacter *direct* PCR assay employs the same workflow, reagent composition, instrumentation, plate format and processing conditions as the previously evaluated assays, the potential for carryover and cross-contamination is considered comparable. Therefore, additional dedicated carryover/cross-contamination study for the Helicobacter *direct* PCR assay is not considered necessary.	Carryover and cross-contamination are primarily associated with sample processing, pipetting procedures, plate handling and workflow conditions rather than assay-specific oligonucleotide sequences. The Helicobacter *direct* PCR assay employs the same workflow, reagent composition, instrumentation, plate format and processing conditions as the previously evaluated assays. Therefore, the potential for carryover and cross-contamination is considered comparable between the assays and no relevant carryover or cross-contamination was observed in the previously evaluated assays.	☒ yes ☐ no
Measuring range, Linearity	As the Helicobacter *direct* PCR delivers a qualitative result (“detected” or “not detected”), the measuring range and linearity are not assessed.	N/A	N/A

Limit of detection	The limit of detection is determined for each analyte separately. The following acceptance criterion is applied: • The limit of detection is ≤ 30 copies/reaction for each analyte To verify the limit of detection on a LightCycler480 II instrument (Roche), 20 replicates of each target at 1x LoD are run on a LightCycler480 II instrument. The following acceptance criterion is applied: • At least 19/20 replicates shall be positive for each target analyte (≥ 95% agreement)	The limit of detection in copies/ reaction for the different analytes is: • pUC19-gyrA C261A: 22.95 (11.12 - 49.66) • pUC19-gyrA C261G: 15.78 (13.46 - 18.32) • pUC19-gyrA G271A: 13.76 (6.3-34.83) • pUC19-gyrA G271T: 15.32 (10.3-23.23) • pUC19-gyrA A272G: 21.06 (8.77-48.75) • *H.pylori* genomic DNA 16S rDNA: 5.87 (3.88-8.65) • pUC19-23S rDNA A2142C: 13.82 (8.45-30.20) • pUC19-23S rDNA A2142G: 19.19 (11.02-35.08) • pUC19-23S rDNA A2143G: 26.71 (9.25-74.3) Moreover, at least 19/20 replicates were positive for each target analyte, when the LoD was verified on a LightCycler480 II (Roche) cycler (≥ 95% agreement).	☒ yes ☐ no
Limit of quantitation	As the Helicobacter *direct* PCR delivers a qualitative result (“detected” or “not detected”), the limit of quantitation is not.	N/A	N/A
Assay cut-off	As the Helicobacter *direct* PCR delivers a qualitative result (“detected” or “not detected”), the assay cut-off is not assessed.	N/A	N/A
Metrological traceability of calibrator and control material values	The Helicobacter *direct* PCR kit contains an internal control which is based on an artificial sequence. No suitable reference materials or reference measurement procedures of higher metrological order are available.	N/A	N/A
Stability	See Transport stability, Shelf life, and In-use stability		☒ yes ☐ no

Transport stability	Before and after the transport simulation, negative and positive samples regarding the test analytes are tested. The following acceptance criteria are applied: • No false positive test results. • The agreement of the test results before and after the transport simulation is ≤ 10% for each test analyte and the Internal Control.	In accordance with the acceptance criteria, Ct values deviated ≤ 10% for each test analyte and the Internal Control after simulated transport.	☒ yes ☐ no
Shelf life	The Helicobacter *direct* PCR shall have a shelf life of 12 months when stored between temperatures from -25 °C to -18 °C. Within the shelf-life study, positive and negative samples regarding the test analytes as well as the Positive Control are tested every month until 13 months. The following acceptance criteria are applied: • No false positive test results. • The agreement (ΔCt) of the test results between t0 and a measurement test point is ≤ 10% for each test analyte and the Internal Control.	The shelf life study is still ongoing.	☒ yes ☐ no

In-use stability	The Helicobacter *direct* PCR should be able to be thawed and refrozen 6 times. The following acceptance criteria are applied: • No false positive test results • The agreement (ΔCt) of the test results between thawing cycle 1 and a later thawing cycle is ≤ 10% for each test analyte and the Internal Control. Moreover, the Helicobacter *direct* PCR shall have an in-use stability up to 8 hours in a temperature range from 2°C to 8°C. The following acceptance criteria are applied: • No false positive test results • The agreement (ΔCt) of the test results before and after storage at 4 °C is ≤ 10% for each test analyte and the Internal Control.	In accordance with the acceptance criteria, Ct values deviated ≤ 10% for each test analyte and the Internal Control after 6 times thawing and refreezing as well as after 8 hours of storage at 4 °C.	☒

1.2.6.5.2. 2 Clinical performance

For the evidence of clinical performance of the Helicobacter *direct* PCR, we evaluated the parameters according to Annex I, section 9.1 b) of the IVDR. Diagnostic sensitivity and specificity data of the Helicobacter *direct* PCR fulfill the acceptance criteria (*Table 5*). In conclusion, clinical performance data demonstrate clinical evidence of the Helicobacter *direct* PCR.

Table 5: Overview of applicable clinical performance parameters and the intended claims in comparison to the achieved results.

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Clinical Performance Parameter	Acceptance criteria	Results
Diagnostic sensitivity	For each analyte, the diagnostic sensitivity is ≥ 90%	For H. pylori yes/no the diagnostic sensitivity is 100.0% (89.4 – 100.0) For Levofloxacin-resistance the diagnostic sensitivity is 100.0% (29.2 – 100.0) For Clarithromycin-resistance the diagnostic sensitivity is 100.0% (73.5 – 100.0)
Diagnostic specificity	For each analyte, the diagnostic specificity is ≥ 95%	For Levofloxacin-resistance the diagnostic specificity is 100.0% (88.4 – 100.0) For Clarithromycin-resistance the diagnostic specificity is 100.0% (83.9 – 100.0)

1.2.6.6. Ongoing or planned post-market performance follow-up (PMPF)

We use a Post-Market Performance Follow-Up (PMPF) Plan to define PMPF measures to be taken for the Helicobacter *direct* PCR in order to keep the performance evaluation continually updated. The results of the PMPF activities are summarized and evaluated in the post-market performance follow-up report.

The following PMPF activities are planned:

- Research customer feedback, if applicable evaluate for trends and initiate action.
- Compile information from in-house quality control tests. If applicable, evaluate for trends and initiate action.
- Search for information on equivalent/comparative products and alternative procedures:
    - Review the scientific literature and other sources for relevant (clinical) performance and scientific data
    - Monitor relevant clinical guidelines from professional (medical) societies
    - Verify the performance data of equivalent and similar products, including searches in safety databases
- Search for changes in regulations, laws, initiate action if necessary
- Regular check of primer/probe sequences against sequence data bank entries
- Interlaboratory comparisons; further quality assurance programs

1.2.7. Metrological traceability of assigned values

The Helicobacter *direct* PCR kit contains an internal control which is based on an artificial sequence. No suitable reference materials or reference measurement procedures of higher metrological order are available.

1.2.7.1. Explanation of the unit of measurement

The chapter is not applicable as no suitable reference materials or reference measurement procedures of higher metrological order are available.

1.2.7.2. Applied reference materials and/or reference measurement procedures

The chapter is not applicable as no suitable reference materials or reference measurement procedures of higher metrological order are available.

1.2.8. Suggested profile and training for users

We define the following user groups:

Table 6: User Groups

No.	Name of the User Group	Short Description
1	Healthcare Professional	tertiary/indirect user: collects and handles specimen, uses the results to derive an organizational and/or patient management decision
2	Laboratory Personnel	primary user: uses the GastroBac *direct* PCR for in vitro diagnostic analysis in a medical laboratory.
3	Laboratory Specialist	primary user: responsible for evaluation and release of the results

Table 7: User Group 1 "Healthcare Professional" as tertiary user

User group:	**Healthcare Professional**
Typical job title(s):	Physician, nurse, caregiver, pharmacist, pharmaceutic-technical assistant
Demographic characteristics (age, sex, language, specific physical attributes):	no specific gender typical age: between 20 and 67 years not necessarily a native speaker, but knows the required technical terminology
Expected qualification (education, degree, training):	medical or pharmaceutical education
Expected job experience (related to the product, similar products or IT in general):	No specific job experience related to the product required
Typical work environment (physical and organizational/social):	clinical environment (e.g. reception area), doctors' office

Core tasks:	1. Register a patient/specimen
	2. Collect a specimen
	3. Ship the collected specimen
	4. Interpret results to make an organizational and/or patient management decision
Typical equipment (used during performance of the tasks):	Swab and transport medium for specimen collection
Expected product training (with regard to the medical device)	no training required

Table 8: User Group 2 "Laboratory Personnel" as primary user

User group:	**Laboratory Personnel**
Typical job title(s):	medical/biological-laboratory assistant, laboratory technician
Demographic characteristics (age, sex, language, specific physical attributes):	no specific gender typical age: between 20 and 67 years not necessarily a native speaker, but knows the required technical terminology
Expected qualification (education, degree, training):	education as medical/biological-laboratory assistant or laboratory technician
Expected job experience (related to the product, similar products or IT in general):	Experience in molecular diagnostic techniques, i.e. nucleic acid extraction and qPCR
Typical work environment (physical and organizational/social):	medical laboratory
Core tasks:	1. Receive the specimen
	2. Register the patient/specimen
	3. Perform nucleic acid extraction according to the laboratory's standard

	4. Perform the GastroBac *direct* PCR using a qPCR cycler
Typical equipment (used during performance of the tasks):	qPCR cycler disposable protective gloves PCR reaction tubes/microtiter plate plus lids/adhesive optical film Pipettes Pipette tips with filter (DNase/RNase-free) Table centrifuge DNA isolation kit
Expected product training (with regard to the medical device)	Training in qPCR and *in vitro* diagnostic techniques

Table 9: User Group 3 "Laboratory Specialist" as primary user

User group:	**Laboratory Specialist**
Typical job title(s):	specialist in laboratory medicine
Demographic characteristics (age, sex, language, specific physical attributes):	no specific gender typical age: between 30 and 67 years not necessarily a native speaker, but knows the required technical terminology
Expected qualification (education, degree, training):	university degree, specialist training for laboratory medicine
Expected job experience (related to the product, similar products or IT in general):	specialist training in infectious respiratory diseases
Typical work environment (physical and organizational/social):	medical laboratory
Core tasks:	Analyze and release the diagnostic report
Typical equipment (used during performance of the tasks):	qPCR cycler with corresponding software LIMS software

Expected product training (with regard to the medical device)	Analysis and interpretation of the results

1.3. 3 Annex

1.3.1. 1 Terms and Abbreviations

The following table lists document-specific abbreviations and definitions:

Term	Description	Reference
CDx	Companion diagnostic	n. a.
Companion diagnostic	Device which is essential for the safe and effective use of a corresponding medicinal product to: - identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or - identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product	IVDR, Art. 2
Contra-indication	Specific medical reasons for not using a particular IVD medical device in the usual way (e. g. a virus infection that interferes with the biomarker analysis, a urinary tract infection that affects the results of a urine test).	internal definition
DI	Device Identifier	n. a.
EMDN	European Medical Device Nomenclature	n.a.
EUDAMED	European Database on Medical Devices	n.a.

FSCA	Field Safety Corrective Action; Corrective action taken by a manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market	IVDR, Art. 2
FSN	Field Safety Notice; Communication sent by a manufacturer to users or customers in relation to a field safety corrective action	IVDR, Art. 2
IFU	Instructions For Use; Information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken	IVDR, Art. 2
Intended purpose	Use for which the IVD medical device is intended according to the data supplied by the manufacturer on the label, the IFU, or in promotional and sales materials and as specified by the performance evaluation.	IVDR, Art. 2
IVD	In Vitro Diagnostic	n. a.
IVDD	Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices	n. a.
IVDR	European Regulation 2017/476 on in vitro diagnostic medical devices	n. a.
Kit	Set of components that are packaged together and intended to be used to perform a specific in vitro diagnostic examination, or a part thereof	IVDR, Art. 2

Lay person	Individual who does not have formal education in a relevant field of healthcare or medical discipline	IVDR, Art. 2
Limitation	A situation/factor that (may) affect the results of an in-vitro diagnostic test (e.g. running a marathon before Ca^{2+}-measurement due to untypically high Ca^{2+}-level) or for which the test has not been clinically validated (e.g. usage for children, usage during pregnancy).	internal definition
MDSW	Medical device software	MDCG 2019-11
n. a.	not applicable	n. a.
NB	Notified Body; conformity assessment body designated in accordance with this Regulation	IVDR, Art. 2
Near-patient testing	Any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional	IVDR, Art. 2
PEP	Performance evaluation plan	n. a.
PER	Performance evaluation report	n. a.
Performance of a device	Ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable, the clinical performance supporting that intended purpose	IVDR, Art. 2
PMPF	Post-Market Performance Follow-up	n. a.

Scientific validity	Association of an analyte with a clinical condition or a physiological state	IVDR, Art. 2
Self-testing	Any device intended by the manufacturer to be used by lay persons, including devices used for testing services offered to lay persons by means of information society services	IVDR, Art. 2
SRN	Single Registration Number	n. a.
SSP	Summary of Safety and Performance	n. a.
SVR	Scientific validity report	n. a.
TD	Technical documentation	n. a.
UDI	Unique Device Identification; Series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market	IVDR, Art. 2

1.3.2. 2 Revision history

SSP revision number	Date issued	Change description	Revision validated by the Notified Body	
13	01.07.2026	Initial creation	☐	Yes Validation language: ENG
			☐	No (*see note)

*For class C devices, a draft SSP should be submitted to the NB involved in the conformity assessment as part of the application documents. The NB should validate the draft SSP. If the relevant certificate covers more than one device, at least one draft SSP should be validated by the NB against relevant documents in the technical

documentation during the initial conformity assessment before issuing the certificate. Any other draft SSPs that are not validated at the initial conformity assessment should be at least validated once during the period of validity of the certificate.