🌐 mariPOC User manual.5.5.20

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mariPOC® RTI combi+ test plate mariPOC® RTI combi test plate mariPOC® Respi+ test plate mariPOC® Respi test plate mariPOC® Pharyn test plate mariPOC® Quick combi+ test plate

USER'S MANUAL

mariPOC® Quick combi test plate mariPOC® Gastro test plate mariPOC® Gastro CDI combi test plate mariPOC® Analyser AD7-020 mariPOC® Software (ArcDiagnoser™ version 20.01 or later)

mariPOC® is an automated multianalyte rapid test system for detection of acute infection pathogens from patientsamples

mariPOC® test plates are intended for use together with the computer controlled mariPOC® analyser

New samples can be added to the mariPOC® test system while the analysis of the previous samples is still in progress (i.e., so-called random accessoperation)

mariPOC®+ mode of the measuring program is intended primarily for laboratories. It enables result interpretation and use of multiple test plates on the sameanalyser.

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1 Intended Use

The mariPOC® test system is designed to be used for detection of pathogens from patients with acute infections. The mariPOC® test system enables the analysis of different pathogen combinations from patient samples (**Figure 1**, **Figure 2** and **Figure 3**). The combination is selected according to the clinical picture, clinical symptoms, and the age of the patient if appropriate. The product is intended for *in vitro* diagnostic professional use. Test system equipped with mariPOC®+ measuring program is intended primarily for laboratories. The manufacturer or manufacturer's representative will familiarise the user organisation with the test system.

1.1 mariPOC® Respi+, Respi and Pharyn Tests

The multianalyte mariPOC® Respi+, Respi and Pharyn tests are designed to be used for detection of acute respiratory tract infection pathogens from nasopharyngeal or throat samples depending on the test (**Figure 1**). Sampling for the detection of viral pathogens should be done during viremia within 6 days from the onset of symptoms, preferably within 5 days. Viral loads decrease over time and virus antigens are not usually detectable after 6 to 7 days from the onset of symptoms.

The Pharyn test is intended to be used when there is clinical suspicion of pharyngitis. The group A streptococci method of the Pharyn test can be used for the detection of the pathogen in perianal streptococcal dermatitis. The Respi+ and Respi tests are intended to be used for other lower and upper respiratory tract infections. In the Respi+ and Respi tests, the analyte to be tested depend on the patient's age. Pneumococcus is not measured in small children due to the high frequency of asymptomatic carriers (the Respi < 7 years old test). Test selection is patient-specific and is made with the measuring program.

Depending on the indication, the sample is collected either from the nasopharynx using a swab, aspirate or wash procedures, or from the pharynx or the perianal area using a swab procedure. Suitable flocked swabs are defined in **Table 7**.

Figure 1. Pathogens covered by the mariPOC® Respi+, Respi and Pharyn tests.

1.2 mariPOC® Quick Flu+, Quick Flu/RSV and Quick StrepA Tests

The mariPOC® Quick Flu+, Quick Flu/RSV and Quick StrepA (**Figure 2**) rapid tests are intended to be used for the detection of acute respiratory tract infection pathogens. The mariPOC® Quick Flu/RSV test detects influenza A and B viruses and respiratory syncytial virus and in addition to these the mariPOC® Quick Flu+ detects SARS coronavirus 2 from nasopharyngeal samples in 20 minutes. The mariPOC® Quick StrepA test detects group A streptococci from throat sample in 15 minutes. The Quick StrepA test may be used for the detection of the pathogen in perianal streptococcal dermatitis.

Sample collection is similar to Respi and Pharyn tests. The Quick tests can be selected from Combi+ and Combi tests plate (**Table 4**) only if the Quick feature is enabled in the measuring program.

Figure 2. Pathogens covered by the mariPOC® Quick Flu+, Quick Flu/RSV and Quick StrepA tests.

1.3 mariPOC® SARS-CoV-2 Test

The mariPOC® SARS-CoV-2 test is intended to be used for the detection of the virus when there is a clinical suspicion of acute coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The SARS-CoV-2 test detects SARS-CoV-1 and SARS-CoV-2. The sample collection is similar to Respitest.

1.4 mariPOC® Gastro and CDI Tests

The mariPOC® Gastro and CDI tests (**Figure 3**) are intended to be used for the detection of pathogens, causing gastroenteritis, from stool samples. The samples should be obtained from patients with symptoms of acute gastrointestinal infection, e.g. diarrhoea and/or vomiting.

Sampling for the detection of viral pathogens from a stool sample should be done within few days from the onset of symptoms. Viral loads decrease over time and virus antigens are not usually detectable after a week. Bacteria are more probable findings than viruses from a stool samples when the symptoms are prolonged.

The Gastro test enables the analysis of five different pathogens that cause similar symptoms at the onset of the gastrointestinal infection. The CDI test is intended to be used mainly when there is clinical suspicion of *Clostridium difficile* infection (CDI). The CDI test enables the analysis of CDI by detecting the presence of *C. difficile* GDH (*C. difficile* specific surface protein glutamate dehydrogenase) and *C. difficile* toxins A and B.

Figure 3. Pathogens and/or analytes covered by the mariPOC® Gastro and CDI tests.

2 Test System Features

2.1 Test System Order Details

The mariPOC® test system consists of an analyser package (**Table 1**) and consumables (**Table 2** and **Table 3**).

Table 1. The content of the analyser package.

REF	Product name
AD7-020	mariPOC® Analyser
A-21	Analyser power supply
A-22	Computer
A-9	Waste container (2.5 L)
A-12	Label printer
A-14	Bottletop dispenser (dispensing volume 1.3 ml)
A-29	Bottletop dispenser stand
A-16	Vortex mixer (minimum speed 2700 rpm and orbit 6 mm)
A-18	Sample tube rack
A-30	Sample tube box
A-31	Sample tube cap box
A-33	USB flash drive
A-36	2 Ethernet cables
A-37	Ethernet switch
A-28	Uninterruptible power supply (UPS), optional
A-43	Test plate storage rack
AD1-S	mariPOC® Software (ArcDiagnoser™ measuring program)
-	User's manual
-	Rapid instructions
-	Safety data sheets (SDS)

Table 2. Test system consumable's product numbers (REF), names and package sizes. If a consumable is marked with X, it is necessary to order with that mariPOC® test plate product for respiratory tract infections.

REF	Product name and package size	1194M mariPOC® RTI combi+ test plate	1164M mariPOC® RTI combi test plate	1184M mariPOC® Respi+ test plate	1154M mariPOC® Respi test plate	1124M mariPOC® Pharyn test plate	1214M mariPOC® Quick combi+ test plate	1174M mariPOC® Quick combi test plate	1204S mariPOC® SARS-CoV-2 test plate
1104MC	mariPOC® RTI control samples (includes 1 negative and 1 positive control sample)	X	X	X	X	X	X	X	
1124MC	mariPOC® Pharyn control samples (includes 1 negative and 1 positive control sample)					X			

REF	Product name and package size								
1204SC	mariPOC® SARS-2 control samples (includes 1 negative and 1 positive sample)								X
B02	mariPOC® RTI sample buffer (0.5 L)	X	X	X	X	X	X	X	X
B03A	mariPOC® Extraction solution A for Pharyn and Quick StrepA tests (15 ml)	X	X			X	X	X	
B03B	mariPOC® Extraction solution B for Pharyn and Quick StrepA tests (15 ml)	X	X			X	X	X	
B04	mariPOC® Wash solution (2.0 L)	X	X	X	X	X	X	X	X
B05	mariPOC® System solution (1.0 L)	X	X	X	X	X	X	X	X
A-1	mariPOC® Sample tubes (100 pcs)	X	X	X	X	X	X	X	X
A-2	mariPOC® Sample tube caps (100 pcs)	X	X	X	X	X	X	X	X
A-13	Label tape (1 pcs)	X	X	X	X	X	X	X	X

Table 3. Test system consumable's product numbers (REF), names and package sizes. If a consumable is marked with X, it is necessary to order with that mariPOC® test plate product for gastrointestinal infections.

REF	Product name and package size	2017M mariPOC® Gastro test plate	2027M mariPOC® Gastro CDI combi test plate	2037M mariPOC® CDI test plate
2017MC	mariPOC® Gastro control samples (includes 1 negative and 1 positive control sample)	X	X	X
B04	mariPOC® Wash solution (2.0 L)	X	X	X
B05	mariPOC® System solution (1.0 L)	X	X	X
B06	mariPOC® Gastro sample buffer (0.5 L)	X	X	X
A-1	mariPOC® Sample tubes (100 pcs)	X	X	X
A-2	mariPOC® Sample tube caps (100 pcs)	X	X	X
A-13	Label tape (1 pcs)	X	X	X
A-45	Syringe (5 ml, 100 pcs)	X	X	X
A-46	Filter (150 pcs)	X	X	X

| A-47 | Pasteur pipette (250 pcs), optional | X | X | X |
| A-48 | Swab in transport tube (100 pcs) | X | X | X |

See more information about mariPOC® test plates in **Table 4**, **Table 5** and **Table 6**.

Table 4. mariPOC® test plates and amount of tests in them.

REF	Test plate name	Test type	Tests/plate
1194M	mariPOC® RTI combi+ test plate	Respi+, Quick Flu+ or Quick Flu/RSV Pharyn or Quick StrepA	22 22
1164M	mariPOC® RTI combi test plate	Respi or Quick Flu/RSV Pharyn or Quick StrepA	22 22
1184M	mariPOC® Respi+ test plate	Respi+, Quick Flu+ or Quick Flu/RSV	22
1154M	mariPOC® Respi test plate	Respi or Quick Flu/RSV	22
1124M	mariPOC® Pharyn test plate	Pharyn or Quick StrepA	66
1214M	mariPOC® Quick combi+ test plate	Quick Flu+ Quick StrepA	22 22
1174M	mariPOC® Quick combi test plate	Quick Flu/RSV Quick StrepA	22 22
1204S	mariPOC® SARS-CoV-2 test plate	SARS-CoV-2	308
2017M	mariPOC® Gastro test plate	Gastro	44
2027M	mariPOC® Gastro CDI combi test plate	Gastro CDI	44 44
2037M	mariPOC® CDI test plate	CDI	44

Table 5. Target pathogen coverage of the mariPOC® test plates for respiratory tract infections.
mariPOC® test plate name and REF

Test type and pathogen coverage	RTI combi+	RTI combi	Respi+	Respi	Pharyn	Quick combi+	Quick combi	SARS-CoV-2	
1194M	**1164M**	**1184M**	**1154M**	**1124M**	**1214M**	**1174M**	**1204S**		
Respi+, Respi, Quick Flu+, Quick Flu/RSV or SARS-CoV-2	Influenza A virus	+	+	+	+	-	+	+	-
Influenza B virus	+	+	+	+	-	+	+	-	
Respiratory syncytial virus	+	+	+	+	-	+	+	-	
Human metapneumovirus	+	+	+	+	-	-	-	-	
Human bocavirus	-	+	-	+	-	-	-	-	
SARS coronavirus 2	+	-	+	-	-	+	-	+	
Human coronavirus OC43	+	+	+	+	-	-	-	-	
Parainfluenza 1 virus	+	+	+	+	-	-	-	-	

Parainfluenza 2 virus	+	+	+	+	-	-	-	-	
Parainfluenza 3 virus	+	+	+	+	-	-	-	-	
Adenovirus	+	+	+	+	-	-	-	-	
S. pneumoniae	+	+	+	+	-	-	-	-	
Pharyn or Quick StrepA	Group A streptococci	+	+	-	-	+	+	+	-
Adenovirus	+	+	-	-	+	-	-	-	

Table 6. Target pathogen coverage of the mariPOC® test plates for gastrointestinal infection.
mariPOC® test plate name and REF

Test type and pathogen coverage		Gastro 2017M	Gastro CDI combi 2027M	CDI 2037M	
Gastro	Norovirus GII.4	+	+	-	
Norovirus GI	+	+	-		
Rotavirus	+	+	-		
Adenovirus	+	+	-		
Campylobacter spp.	+	+	-		
CDI	*C. difficile* GDH	-	+	+	
C. difficile Toxin A/B	-	+	+		

Other mandatory equipment:
Use only flocked swabs for swab sampling. So far Copan flocked swabs are the only ones that have been clinically validated to be used in combination with the mariPOC® Respi+, Respi, Pharyn, Quick Flu+, Quick Flu/RSV and Quick StrepA tests. The following Medical Wire's (Puritan) flocked swabs havebeenshowntobetechnicallycompatiblewiththemariPOC®Respi+,Respi,Pharyn,QuickFlu+, Quick Flu/RSV and Quick StrepA tests, while their performance in clinical diagnostics has not yet been studiedextensively.

Table 7. Recommended flocked swabs for sampling.

Size	Description	Manufacturer	REF
Small	Pediatric flocked swab, nylon tip (shaft break point 100 mm), sterile	Copan	516CS01
Medium	Minitip flocked swab, nylon tip (shaft break point 80 mm), sterile	Copan	501CS01

Flexible nasopharyngeal flocked swab, nylon tip (shaft break point 100 mm), sterile	Copan	503CS01	
PurFlock® Ultra Mini Tip Flexible Peel Pouch	Medical Wire	MW812	
PurFlock® Ultra Ultrafine Flexible Peel Pouch	Medical Wire	MW813	
HydraFlock® Ultrafine Flexible Peel Pouch	Medical Wire	MW819	
Large	Regular flocked swab, nylon tip (shaft break point 80 mm), sterile	Copan	502CS01
Regular flocked swab, nylon tip (shaft break point 100 mm), sterile	Copan	519CS01	
Regular flocked swab, nylon tip (shaft break point 30 mm), sterile	Copan	520CS01	
PurFlock® Ultra Standard Tapered Peel Pouch	Medical Wire	MW810	
PurFlock® Ultra Standard Flexible Peel Pouch	Medical Wire	MW811	
HydraFlock® Standard Flexible Peel Pouch	Medical Wire	MW817	

When handling a swab sample the following items are required that is not included in the test system:

Scissors

Disinfectant (70% ethanol orsimilar)

The nasopharyngeal aspirate or wash sampling procedures and the sample treatment require part of the following laboratory equipment that is not included in the test system:

Nasopharyngeal aspirate collectionkit

Nasopharyngeal wash collection kit

Pipette and tips (0.3 ml and 0.6 ml dispensingvolume)

Centrifuge (1000 g speed requirement) with a suitable adapter for the sample tubes (diameter 11 mm and height 65mm)

Centrifuge (14000 g speed requirement) and high force centrifugation tubes (minimum volume 1 ml)

Filtrationunitrack(REFA-44,**Figure 31**)isrequiredwhenhandlingastoolsample.Pleasenote,that the stool sample collection container is not included in the mariPOC® Gastro and CDI test consumables.
The test results may be printed with the user's printer if necessary.

2.2 Description of Test System Components
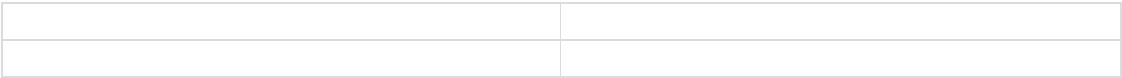
Figure 4. Analyser, computer, label printer, bottletop dispenser with stand and other components.
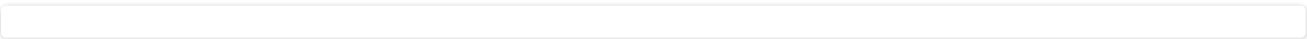
Figure 5. Front view of analyser showing components.
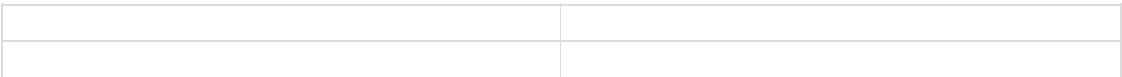
Figure 6. Back view of the analyser.

3 Precautions and Safety Instructions
The mariPOC® test system is intended for *in vitro* diagnostic use by health care professionals. The users are advised to carefully read this User's manual to be able to correctly use the mariPOC® test system.
The following cautions are used throughout this User's manual:
-*Safety!* For safetyinstructions
-*Note!* For other important instructions for the correct use of thedevice
Handle all samples and waste materials as if they were capable of transmitting infectious agents. The detailed waste disposal instructions are described in chapter "8 Cleaning and Waste Disposal".
Detailedsafetyinformationoftheproductsarefoundinseparate,productspecificsafetydatasheets (SDS).
The test system uses a strong laser light (Class 1 laser product EN 60825-1:2014, Third Edition; specificationsin**Table 8**)andmechanicalmovementforanalysingsamples.Forthisreasonnoforeign
bodiesorbodypartsmaybeinsertedintotheanalyser.Theanalysercasing,otherthanthetestplate hatch and the plate carriage and the sample hatch, must not be opened. User exposure to laser radiation in normal use is negligible. Analyser does not have user serviceable partsinside.
Table 8. Laser radiation characteristics.

Maximum accessible power	< 1.95 mW
Pulse duration	0.5 ns
Emitted wavelength	1064 nm

Figure 7. Laser class label mounted on the back of the analyser.

4 Operating Conditions, Storage and Maintenance

The operating temperature range of the test system is +21±5°C. The expiration dates of the consumables are printed on the packages.

The analyser must be stored on a flat platform with the sample and test plate hatches closed. The analyser must not be exposed to dust, high temperatures, strong vibrations, strong magnetic fields, chemicals or chemical vapours. The analyser heatsink must not be covered. The waste container and the System and Wash solution bottles must be placed so that there is at least 1 cm of free space around the heatsink. Liquids must not be sprayed directly inside or on the analyser! See the analyser cleaning instructions in chapter 8. The preventative maintenance interval of the analyser is 6 months. Only a person authorized by the manufacturer may carry out installation, maintenance or moving of the analyser.

The test plate, delivered in a foil bag, must be stored at +2 to +8°C. After the foil bag is opened, the test plate must immediately be placed inside the analyser. The test plate may be handled only by grasping it on its outer edges, and it must not be placed on a dusty surface. Touching the base of the test plate is strictly prohibited (**Figure 8**)! The test plates used for sample analysis is carefully traceable (see chapter "7.3.6 Reading and Reporting of the Results"; "mariPOC results"). The test plate is valid for 30 days from the opening of the foil bag and its insertion into the analyser. The measuring program will report automatically if the test plate is out-of-date. If the test plate is not stored inside the analyser, it must be placed in a special storage rack (see chapter 7.5). The test plate storage rack must not be exposed to temperatures over 60°C.
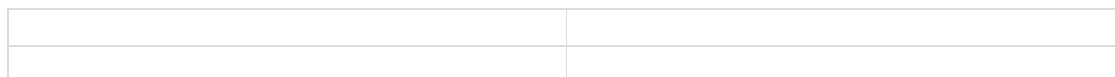
Figure 8. The right and wrong way to handle the test plate.

The control samples (comprising one positive and one negative control sample in a foil bag) must be stored unopened at +2 to +8°C. Once opened, control samples must be used within 5 hours. Once diluted in the test specific sample buffer, they must be used within 2 hours. The control samples may be used only once.

The RTI sample buffer must be stored at +2 to +25°C and protected from direct sunlight. It is important to handle the RTI sample buffer carefully and avoid direct skin contact. RTI sample buffer contains less than 0.1% microbicide sodium azide. When dispensing the buffer into a sample tube, care must be taken not to contaminate the dispensing head. For example, the sample tube must not touch the dispensing head of the bottletop dispenser. Use of the buffer must cease immediately if contamination is suspected, the buffer is cloudy or if there is sediment at the bottom of the bottle. In this case, the bottletop dispenser must be cleaned carefully before introducing a new solution bottle. See the cleaning instructions in chapter 10.3.

The Gastro sample buffer must be stored at +2 to +25°C and protected from direct sunlight. It is important to handle the Gastro sample buffer carefully and avoid direct skin contact. Gastro sample buffer contains less than 0.1% microbicide sodium azide. When dispensing the buffer, care must be taken not to contaminate the dispensing head. For example, the tube containing sample must not touch the dispensing head of the bottletop dispenser. Use of the buffer must cease immediately if contamination is suspected, the buffer is cloudy or if there is sediment at the bottom of the bottle. In this case, the bottletop dispenser must be cleaned carefully before introducing a new solution bottle. See the cleaning instructions in chapter 10.3. Please note, that the Gastro sample buffer may contain small amount of floating floccule that do not sediment at the bottom of the bottle. These floccules do not affect the use of the Gastro sample buffer.

The Wash solution must be stored at +2 to +25°C. The Wash solution contains harmful substances (alkaline) that may irritate the eyes and skin, and therefore it is important to handle it carefully and avoid direct skin contact. Protective gloves must be used. Special care should be taken that the solution does not come into contact with the eyes. If this occurs, wash them immediately with water and seek medical attention. See safety data sheet for more information.

The System solution must be stored at +2 to +25°C and protected from direct sunlight. It is important to handle the System solution carefully and avoid direct skin contact because it contains microbicide, sodium azide (less than 0.1%). Use protective gloves. See safety data sheet for more information.

The Extraction solutions A and B that are used in the Pharyn and QuickStrepA tests must be stored at +2 to +25°C and protected from direct sunlight. The Extraction solutions are valid for 3 months from the opening of the bottles. The Extraction solution A contains sodium nitrite which is harmful if swallowed. The solution may be irritant, and therefore it is important to handle it carefully and avoid direct skin contact. Use appropriate protective equipment if there is a risk of being exposed to product or spills. Special care should be taken that

the solution does not come into contact with the eyes. If this occurs, wash them immediately with water and seek medical attention. See safety data sheet for more information.

Flockedswab andunusedflockedswabintransporttubemustbestoredinaccordancewith the swab manufacturer's instructions.

Plasticconsumables mustbestoredappropriatelytoprotectthemfromdustandwithinthe temperature limits of the test system unless otherwise instructed by theirmanufacturers.

The bottletop dispenser must be checked and calibrated when needed, at least every 3 monthsorinaccordancewiththemanufacturer'sinstructions.Thesetvolumeis1.3ml.The average volume of 10 dosages must be 1.225−1.375 ml. The precision (coefficient of variation;CV)of10dosagesmustbe≤2.0%.ThedensityofRTIandGastrosamplebufferis 1.0 g/ml.

The filtration unit rack must be stored within the temperature limits of the test system. Filtration unit rack can be cleaned mechanically by brushing with a detergent solution. The rack can be disinfected with chlorine solution (e.g. 1000 ppm) and/or Ultraviolet C (UV-C) light.Aftercleaning,remembertoproperlyrinsetherackwithwateror/and70%ethanol(or similar). Please note, that the filtration unit rack's material does not tolerate temperatures over 60°C such as in dishwasher orautoclave.

5 Test Principle

Performing mariPOC® tests consists of the following steps: sampling, entering the patient's information into the user interface, sample pretreatment, inserting the sample into the analyser, andautomaticanalysisisatoneortwotimepoints.PreliminaryresultsarereportedforRespi+,Respi, Gastro and CDI tests at 20 minutes and final results at 2 hours. Preliminary results are reported for SARS-CoV-2 test at 20 minutes and final results at 95 minutes. Preliminary results are reported for Pharyn test at 15 minutes and final results at 55 minutes. Preliminary results of Respi+, Respi and Pharyn tests can be omitted from the start-up settings by the manufacturer or field service. At the preliminary results, the test identifies and reports strong and moderately positive samples. At the finalresults,thetestidentifiesandreportslowpositivesamplesandnegativetestresults.Theresults are reported at one time point, including positive and negative results, for Quick StrepA test at 15 minutes and for Quick Flu+ and Quick Flu/RSV tests at 20minutes. Analyte specific identification reactions are based on specific identification of viral or bacterial antigens with monoclonal or affinity purified polyclonal antibodies (immunometric detection). The fluorescence signal measured by the test system from an analyte specific reaction correlates positivelywiththeantigencontentofthesample.Thetestsystemcomparesthesignalreceivedfrom the test to the cut off values set by the manufacturer for positive test results. Based on this comparison,thesampleisreportedaspositive(+)ornegative(-).For *S. pneumoniae* apositiveresult is reported semi-quantitatively as + (very low), ++ (low), +++ (medium), or ++++ (high). For group A streptococci in the Pharyn test a positive result is reported semi-quantitatively as + (very low), ++ (low),or+++(high)at55minutetimepoint.At15minutetimepointonlyhighpositive(+++)results arereported.InQuickStrepAtestapositive(+)oranegative(-)resultisreportedat15minutetime point. For detailed guidance, see chapter "7.3.6 Reading and Reporting of the Results".

The test system is equipped with an internal autoverification system, which estimates the technical quality and success of the analysis. If the criteria for a reliable test result are not met, the result is not reported (i.e., the analysis is failed). A failed measurement is indicated in red on the patient informationlist.Inthiscase,thesamplecanbereanalysedoranewpatientsamplecanbecollected. Internal test result verification of the measuring program utilizes predetermined parameters. This ensures the reliability of aresult.

6 TestPerformance

In the mariPOC® test system, several pathogens are measured from one patient sample using separate immunochemical identification reactions. The imprecision of the assay signal (coefficient ofvariation)is5−10%forRespi+,Respi,SARS-CoV-2andPharyntestmethodsand3−22%forGastro and CDI test methods, according to the quantitative tests carried out by themanufacturer.

6.1mariPOC®Respi+,Respi,SARS-CoV-2,Pharyn,QuickFlu+,QuickFlu/RSVandQuickStrepA Tests

Table 9. Analytical sensitivities of the mariPOC® Respi+, Respi, SARS-CoV-2 and Pharyn tests for standard samples. Analytical sensitivity marked with a star (*) depends on the applied reporting sensitivity level (see **Table 12** and chapter "7.3.6 Reading and Reporting of the Results").

Analyte	Analytical sensitivity

Influenza A virus	2 ng/ml purified inactivated virus H1N1 (A/New Caledonia/20/99)
Influenza B virus	15 ng/ml purified inactivated virus (B/Qingdao/102/91)
Respiratory syncytial virus	200 ng/ml purified inactivated virus
Human metapneumovirus	250 ng/L purified antigen
Human bocavirus	10 ng/ml recombinant antigen
SARS coronavirus 2	2 ng/ml recombinant antigen
Human coronavirus OC43	4 ng/ml recombinant antigen
Parainfluenza 1 virus	150 ng/ml purified inactivated virus (Sendai)
Parainfluenza 2 virus	200 ng/ml (according to the preparation) purified inactivated virus
Parainfluenza 3 virus	1000 ng/ml (according to the preparation) purified inactivated virus
S. pneumoniae	30 ng/L purified antigen, 400 CFU/ml
Adenovirus	10 pM purified antigen
Group A streptococci	*3000−9900 bacteria/ml, 200−600 CFU/ml

Table 10. Analytical sensitivities of the mariPOC® Quick Flu+, Quick Flu/RSV and Quick StrepA tests for standard samples.

Analyte	Analytical sensitivity
Influenza A virus	11 ng/ml purified inactivated virus H1N1 (A/New Caledonia/20/99)
Influenza B virus	130 ng/ml purified inactivated virus (B/Qingdao/102/91)
Respiratory syncytial virus	3 µg/ml purified inactivated virus
SARS coronavirus 2	6 ng/ml recombinant antigen
Group A streptococci	9900 bacteria/ml, 600 CFU/ml

Table 11. Clinical performance of the mariPOC® Respi+, Respi, SARS-CoV-2 and Pharyn tests comparedtolaboratorymethods.Thesensitivitiesofthetestsmarkedwithastar(*)aredefinedby antigendilutionseriesinthereferencestudy(TR-FIA).Thisisbecauseofthelowincidenceofpositive clinical samples for those pathogens. See chapter "14 Literature". Clinical sensitivity marked with two stars (**) depends on the applied reporting sensitivity level (see **Table 12** and chapter "7.3.6Reading and Reporting of the Results").

Analyte	Sensitivity	Specificity	N	Reference test
Influenza A virus	92.3%	99.8%	899	PCR
Influenza B virus	88%	100%	192	PCR
Respiratory syncytial virus	89%	100%	158	PCR
Human metapneumovirus	78%	100%	74	PCR
Human bocavirus	76.5%	100%	632	mRNA PCR
SARS coronavirus 2	88%	100%	134	PCR
Human coronavirus OC43	NA	99.4%	160	PCR
Parainfluenza 1 virus	Similar*	100%	55	TR-FIA
Parainfluenza 2 virus	Similar*	99%	55	TR-FIA
Parainfluenza 3 virus	Similar*	100%	55	TR-FIA
S. pneumoniae	Similar	No cross-reactions	NA	Binax Now® rapid test

Adenovirus	92%	100%	95	TR-FIA
Group A streptococci	100−150%	~100%	328	Culture

The analytical specificity of mariPOC® multianalyte tests in preliminary result reporting phase is ≥99.977% compared to final results.

Table 12. Results reported for group A streptococci in the Pharyn test and corresponding clinical sensitivities compared to culture.

Results	Wording	Explanation	Sensitivity compared to culture
+++	High positive	Likely culture positive	~100%
++	Low positive	Likely culture negative	~120%
+	Very low positive	Very likely culture negative but analytically true positive	~150%

Table 13. Clinical performance of the mariPOC® Quick Flu+, Quick Flu/RSV and Quick StrepA tests compared to other laboratory methods.

Analyte	Sensitivity	Specificity	N	Reference test for sensitivity
Influenza A virus	>100%	100%	198	Lateral flow test
Influenza B virus	100%	100%	122	Lateral flow test
Respiratory syncytial virus	100%	99.9%	198	Lateral flow test
SARS coronavirus 2	71%	100%	134	mariPOC® Respi+ or mariPOC® SARS-CoV-2
Group A streptococci	100%	~100%	193	Culture

Table 14. Cross-reaction and recognition spectrum data. The analysed microbial strains and pathogen preparations are listed on the left and the analyte specific tests against which the sample has been analysed are listed on the right. A positive result is indicated by + (identifies/cross-reacts); a negative result is indicated by - (does not identify/cross-react); and NA signifies a combination that has not been studied.

Test method

	Influenza A virus	Influenza B virus	Respiratory syncytial virus	Human metapneumo virus	Human bocavirus	SARS corona virus 2	Human corona virus OC43	Parainfluenza 1 virus	Parainfluenza 2 virus	Parainfluenza 3 virus	*Streptococcus pneumoniae*	Adeno virus	Group A streptococci
Analysed sample													

Analysed sample	Influenza A virus	Influenza B virus	Respiratory syncytial virus	Human metapneumovirus	Human bocavirus	SARS coronavirus 2	Human coronavirus OC43	Parainfluenza 1 virus	Parainfluenza 2 virus	Parainfluenza 3 virus	*Streptococcus pneumoniae*	Adenovirus	Group A streptococci
Influenza A virus (purified virus preparation): H1N1: A/New Caledonia/20/99 H3N2: A/Panama/2007/99 H3N2: A/Victoria/361/11 H3N2: A/Texas/50/12	+	-	-	-	-	-	-	-	-	-	-	-	-
Influenza A virus (purified virus preparation): H3N2: seasonal 2011-2012, Finland H3N2: A/New York/55/04	NA	-	-	NA	NA	NA	NA	-	-	-	-	-	NA
Influenza A virus (purified virus preparation): H7N3: A/Mallard/Netherlands/12/00	+	-	-	-	-	NA	-	-	-	-	-	-	NA
Influenza A virus (crude allantoic fluid): H7N9: A/Shanghai/2/2013	+	-	-	-	NA	NA	NA	-	-	-	-	-	NA
Influenza A virus (purified virus preparation): H1N1: A/California/07/09pdm H2N2: A/Singapore/1/57 H3N2: A/Hongkong/1/68/164 H9N2: A/Hongkong/1093/99	+	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Influenza A virus (so-called avian flu, supernatant of virus culture): H5N1: A/rg/duck/HUMAN/795/02	+	-	-	-	-	NA	-	-	-	-	-	-	NA
Influenza A virus (so-called avian flu, supernatant of virus culture): H5N1: A/Vietnam/1194/2004 "NIBRG-14"	+	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Influenza A virus (so-called swine flu, supernatant of virus culture): H1N1v: A/FIN/554/09	+	-	-	-	-	-	-	-	-	-	-	-	-
Influenza B virus (purified virus preparation): B/Hong Kong 5/72 B/Victoria/504/00	-	+	-	-	-	NA	-	-	-	-	-	-	-

Test method

Analysed sample	Influenza A virus	Influenza B virus	Respiratory syncytial virus	Human metapneumovirus	Human bocavirus	SARS coronavirus 2	Human coronavirus OC43	Parainfluenza 1 virus	Parainfluenza 2 virus	Parainfluenza 3 virus	*Streptococcus pneumoniae*	Adenovirus	Group A streptococci

Influenza B virus (purified virus preparation): B/Qingdao/102/91	NA	+	-	NA	NA	NA	NA	-	-	-	-	-	NA
Influenza B virus (purified virus preparation): B/Florida/04/06	NA	+	-	-	NA	NA	NA	-	-	-	-	-	NA
Influenza B virus (purified virus preparation): Phuket/3073/2013	-	+	-	-	-	-	-	-	-	-	-	-	NA
Respiratory syncytial virus (purified virus preparation): Type A / Long	-	-	+	-	-	-	-	-	-	-	-	-	-
Respiratory syncytial virus (purified virus preparation): Type B / clinical strain (Labquality round 1, 2017)	-	-	+	-	-	-	-	-	-	-	-	-	-
Human metapneumovirus A and B (supernatant of virus culture)	NA	-	-	+	NA	NA	NA	-	-	-	-	-	NA
Human metapneumovirus (supernatant of virus culture)	-	-	-	+	-	-	-	-	-	-	-	-	-
Human bocavirus (recombinant VP2 antigen)	-	-	-	-	+	-	-	-	-	-	-	-	-
Human bocavirus (clinical specimen)	-	-	-	-	+	-	-	-	-	-	-	-	-
SARS coronavirus 2 (clinical specimen)	-	-	-	-	NA	+	-	-	-	-	-	-	NA
SARS coronavirus 2 (recombinant nucleoprotein)	-	-	-	-	-	+	-	-	-	-	-	-	NA
SARS coronavirus 1 (recombinant nucleoprotein)	-	-	-	-	-	+	-	-	-	-	-	-	NA
Human coronavirus OC43 (purified virus preparation or clinical sample)	-	-	-	-	-	-	+	-	-	-	-	-	-
MERS coronavirus (recombinant nucleoprotein)	-	-	-	-	-	-	-	-	-	-	-	-	NA
Human coronavirus strains 229E and NL63 (purified virus preparation), HKU1 (recombinant nucleoprotein)	NA	NA	NA	NA	NA	-	-	NA	NA	NA	NA	NA	NA
Parainfluenza 1 virus (purified virus preparation): Sendai	-	-	-	-	-	-	-	+	-	-	-	-	-
Parainfluenza 2 virus (purified virus preparation)	-	-	-	-	-	-	-	-	+	-	-	-	-

Test method

08/28/2020

Analysed sample	Influenza A virus	Influenza B virus	Respiratory syncytial virus	Human metapneumovirus	Human bocavirus	SARS coronavirus 2	Human coronavirus OC43	Parainfluenza 1 virus	Parainfluenza 2 virus	Parainfluenza 3 virus	*Streptococcus pneumoniae*	Adenovirus	Group A streptococci
Parainfluenza 3 virus (purified virus preparation): Washington/1957 C243	-	-	-	-	-	-	-	-	-	+	-	-	-
Streptococcus pneumoniae (purified antigen preparation)	-	-	-	-	-	NA	-	-	-	-	+	-	-
Streptococcus pneumoniae strain 4 (bacterial culture suspension inactivated by heating)	-	-	-	-	-	-	-	-	-	-	+	-	-
Streptococcus pneumoniae strains 1, 3, 6B, 7F, 9V, 14, 15, 18C, 19A, 19F, 23F (bacterial culture suspension inactivated by heating)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	+	NA	NA
Adenovirus antigen preparation (hexon protein)	-	-	-	-	-	NA	-	-	-	-	-	+	-
Adenovirus strains 1-8, 14, 19, 21 (inactivated cell culture suspension or clinical sample)	NA	-	-	NA	NA	NA	NA	-	-	-	-	+	NA
Adenovirus strain 6 (inactivated cell culture suspension)	-	-	-	-	-	-	-	-	-	-	-	+	-
Adenovirus strain 40 (inactivated cell culture suspension)	NA	-	-	NA	-	NA	NA	-	-	-	-	+	NA
Group A streptococci / *S. pyogenes* (inactivated and enriched bacterial preparation)	-	-	-	-	-	NA	-	-	-	-	-	-	+
Group A streptococci / *S. pyogenes* (bacterial culture suspension inactivated by heating): ATCC 19615	-	-	-	-	-	-	-	-	-	-	-	-	+
Group C streptococci (bacterial culture suspension)	-	-	-	-	-	NA	-	-	-	-	-	-	-
Group G streptococci (bacterial culture suspension)	-	-	-	-	-	NA	-	-	-	-	-	-	-
Staph. aureus (bacterial culture suspension inactivated by heating): ATCC 29213	-	-	-	-	-	-	-	-	-	-	-	-	-

Analysed sample	Influenza A virus	Influenza B virus	Respiratory syncytial virus	Human metapneumovirus	Human bocavirus	SARS coronavirus 2	Human coronavirus OC43	Parainfluenza 1 virus	Parainfluenza 2 virus	Parainfluenza 3 virus	*Streptococcus pneumoniae*	Adenovirus	Group A streptococci
Staph. epidermidis (bacterial culture suspension inactivated by heating)	-	-	-	-	-	-	-	-	-	-	-	-	-
S. mitis (bacterial culture suspension inactivated by heating)	-	-	-	-	-	NA	-	-	-	-	-	-	-
S. mutans (bacterial culture suspension inactivated by heating): ATCC 25175	-	-	-	-	-	NA	-	-	-	-	-	-	-

Test method

Analysed sample	Influenza A virus	Influenza B virus	Respiratory syncytial virus	Human metapneumovirus	Human bocavirus	SARS coronavirus 2	Human coronavirus OC43	Parainfluenza 1 virus	Parainfluenza 2 virus	Parainfluenza 3 virus	*Streptococcus pneumoniae*	Adenovirus	Group A streptococci
S. agalactiae (bacterial culture suspension inactivated by heating): ATCC 13813	-	-	-	-	-	NA	-	-	-	-	-	-	-
S. bovis (bacterial culture suspension inactivated by heating): ATCC 9809	-	-	-	-	-	NA	-	-	-	-	-	-	-
S. sanguinis (bacterial culture suspension inactivated by heating)	-	-	-	-	-	NA	-	-	-	-	-	-	-
S. anginosus species: *S. anginosus* (1019, 3113, 3387, 4015, 5011, 7561, 7765, 8073), *S. constellatus* (3792, 5691) and *S. intermedius* (5380, 5643, 6194, 6418, 7404) (bacterial culture suspension inactivated by heating)	NA	-	-	-	NA	NA	NA	-	-	-	-	-	-
S. anginosus species: *S. anginosus* (209), *S. constellatus* (5690) and *S. intermedius* (1343) (bacterial culture suspension inactivated by heating)	-	-	-	-	-	-	-	-	-	-	-	-	-
H. influenzae (bacterial culture suspension inactivated by heating): ATCC 33391	-	-	-	-	-	-	-	-	-	-	-	-	-

H. parainfluenzae (bacterial culture suspension inactivated by heating): ATCC 33392	-	-	-	-	-	-	-	-	-	-	-	-

According to the literature, about 5% of isolates of the *Streptococcus anginosus* species express Lancefield group A surface antigen, which is measured in the antigen detection test for *Streptococcus pyogenes*. Consequently, a sample containing *S. anginosus* bacterium may occasionally give false positive results in a test for group A streptococci. The frequency of *S. anginosus* carriage in respiratory epithelia is not reported in the literature. This, however rarely results in a false clinical diagnosis.

6.2 mariPOC® Gastro and CDI Tests

Table 15. Analytical sensitivities of the mariPOC® Gastro and CDI tests for standard samples.

Analyte	Analytical sensitivity
Norovirus GII.4	5 ng/ml recombinant antigen
Norovirus GI	6 ng/ml recombinant antigen
Rotavirus	0.5 ng/ml recombinant antigen
Adenovirus	7 ng/ml purified antigen
Campylobacter spp.	0.3 ng/ml purified antigen
C. difficile GDH	0.7 ng/ml recombinant antigen
C. difficile Toxin A	0.1 ng/ml purified toxin A when *C. difficile* GDH test is positive 1.5 ng/ml purified toxin A when *C. difficile* GDH test is negative
C. difficile Toxin B	0.1 ng/ml purified toxoid B when *C. difficile* GDH test is positive 1.2 ng/ml purified toxoid B when *C. difficile* GDH test is negative

Note! The analytical sensitivity of C. difficile Toxin A/B test is depended on the result in C. difficile GDH test.

Table 16. Clinical performance of the mariPOC® Gastro and CDI tests with stool samples compared to other laboratory methods. PCR was used to resolve discrepant results.

Analyte	Sensitivity	Specificity	N	Reference test for sensitivity
Norovirus GII.4	100%	99.5%	428	Lateral flow test
Norovirus GI	NA	99.5%	428	Lateral flow test
Rotavirus	100%	99.8%	651	Lateral flow test
Adenovirus	100%	99.5%	651	Lateral flow test
Campylobacter spp.	>100% to LF 91% to culture	97.5%	352	Lateral flow (LF) test and culture
C. difficile GDH	100%	98.8%	188	Membrane enzyme immunoassay
C. difficile Toxin A/B	>100%	100%	188	Membrane enzyme immunoassay

Table 17. Cross-reaction and recognition spectrum data. The analysed microbial strains and pathogen preparations are listed on the left and the analyte specific tests against which the sample has been analysed are listed on the right. A positive result is indicated by + (identifies/cross-reacts); a negative result is indicated by - (does not identify/cross-react); and NA signifies a combination that has not been studied.

Test method

Analysed sample	Norovirus GII.4	Norovirus GI	Rotavirus	Adenovirus	Campylobacter spp.	*C. difficile* GDH	*C. difficile* Toxin A/B
Norovirus GII.4 (stool sample)	+	-	-	-	-	-	-
Norovirus GI.1 (recombinant virus-like particle)	-	+	-	-	-	NA	NA
Norovirus GI.3 (stool sample)	-	+	NA	NA	-	NA	NA
Norovirus GI.4 (stool sample)	NA	+	NA	NA	NA	NA	NA
Norovirus GI.6 (stool sample)	-	+	-	-	-	NA	NA
Rotavirus A, serotype G1, G2, G4 and G9 (stool samples)	-	-	+	-	-	NA	NA
Rotavirus A, serotype G3 (stool samples)	-	-	+	-	-	-	-
Adenovirus (stool sample)	-	-	-	+	-	-	-
Campylobacter coli (cultured bacterial suspension)	-	-	-	-	+	-	-
Campylobacter hyoilei (cultured bacterial suspension)	-	-	-	-	+	-	-
Campylobacter jejuni (cultured bacterial suspension)	-	-	-	-	+	-	-
Campylobacter upsaliensis (cultured bacterial suspension)	-	-	-	-	+	NA	NA
Clostridium difficile (cultured bacterial suspension) Toxin production: Negative or only binary toxin Ribotype: 010, 033	-	-	-	-	-	+	-
Clostridium difficile (cultured bacterial suspension) Toxin production: Toxin A and/or B Ribotype: 016, 017, 019, 023, 027, 053, 056, 078, 107, 126, 176, 251	NA	NA	NA	NA	NA	+	+
Clostridium sordellii (cultured bacterial suspension)	NA	NA	NA	NA	NA	-	+
Astrovirus type 1 (inactivated cell lysate)	-	-	-	-	-	NA	NA
Aeromonas hydrophila (cultured bacterial suspension)	-	-	-	-	-	-	-
Bacillus cereus (cultured bacterial suspension)	-	-	-	-	-	-	-

	Norovirus GII.4	Norovirus GI	Rotavirus	Adenovirus	Campylobacter spp.	*C. difficile* GDH	*C. difficile* Toxin A/B
Bacillus subtilis (cultured bacterial suspension)	-	-	-	-	-	NA	NA

Test method

Analysed sample	Norovirus GII.4	Norovirus GI	Rotavirus	Adenovirus	Campylobacter spp.	*C. difficile* GDH	*C. difficile* Toxin A/B
Campylobacter fetus ss. fetus (cultured bacterial suspension)	-	-	-	-	-	-	-
Campylobacter lari (cultured bacterial suspension)	-	-	-	-	-	-	-
Clostridium bifermentans (cultured bacterial suspension)	NA	NA	NA	NA	NA	-	-
Clostridium clostridioforme (cultured bacterial suspension)	-	-	-	-	-	-	-
Clostridium innocuum (cultured bacterial suspension)	NA	NA	NA	NA	NA	-	-
Clostridium novyi type A (cultured bacterial suspension)	NA	NA	NA	NA	NA	-	-
Clostridium perfringens (cultured bacterial suspension)	-	-	-	-	-	-	-
Clostridium orbiscindens / Flavonifractor plautii (cultured bacterial suspension)	-	-	-	-	-	-	-
Clostridium septicum (cultured bacterial suspension)	NA	NA	NA	NA	NA	-	-
Clostridium sporogenes (cultured bacterial suspension)	NA	NA	NA	NA	NA	-	-
Escherichia coli (cultured bacterial suspension)	-	-	-	-	-	-	-
Helicobacter pylori (cultured bacterial suspension, stool sample)	-	-	-	-	-	-	-

Salmonella enteritidis (cultured bacterial suspension)	-	-	-	-	-	-	-
Salmonella group B (cultured bacterial suspension)	-	-	-	-	-	-	-
Salmonella group C (cultured bacterial suspension)	-	-	-	-	-	-	-
Salmonella typhi (cultured bacterial suspension)	-	-	-	-	-	-	-
Salmonella typhimurium (cultured bacterial suspension)	-	-	-	-	-	-	-
Shigella dysenteriae (cultured bacterial suspension)	-	-	-	-	-	-	-
Staphylococcus aureus (cultured bacterial suspension)	-	-	-	-	-	-	-
Staphylococcus epidermidis (cultured bacterial suspension)	-	-	-	-	-	-	-
Streptococcus agalactiae (cultured bacterial suspension)	-	-	-	-	-	-	-
Streptococcus anginosus (cultured bacterial suspension)	-	-	-	-	-	-	-
Streptococcus bovis (cultured bacterial suspension)	-	-	-	-	-	-	-
Streptococcus constellatus (cultured bacterial suspension)	-	-	-	-	-	-	-

Test method

Analysed sample	Norovirus GII.4	Norovirus GI	Rotavirus	Adenovirus	Campylobacter spp.	*C. difficile* GDH	*C. difficile* Toxin A/B
Streptococcus intermedius (cultured bacterial suspension)	-	-	-	-	-	-	-
Streptococcus mitis (cultured bacterial suspension)	-	-	-	-	-	-	-

Streptococcus mutans (cultured bacterial suspension)	-	-	-	-	-	-	-
Streptococcus pyogenes (cultured bacterial suspension)	-	-	-	-	-	-	-
Streptococcus sanguinis (cultured bacterial suspension)	-	-	-	-	-	-	-
Yersinia enterocolitica avirul. (cultured bacterial suspension)	-	-	-	-	-	-	-
Yersinia enterocolitica O:3 (cultured bacterial suspension)	-	-	-	-	-	-	-

Clostridium sordellii produces haemorrhagic toxin (HT) and lethal toxin (LT) which have a high homology with *Clostridium difficile* toxin A and toxin B, respectively. *C. sordellii* is a bacterium which may cause infections with a very high mortality rate. *C. sordellii* infections (caused by HT and LT) are rare but may occur after an injury, surgical procedure, drug injection, childbirth or medically induced abortions. Symptoms of *C. sordellii* infection are pain, nausea, vomiting and diarrhoea. Cross- reaction with *C. sordellii* toxins is a known property of the mariPOC® toxin A/B test and some other commercially available *C. difficile* toxin tests. However, mariPOC® GDH test does not detect *C. sordellii*. Both the mariPOC® GDH and the Toxin A/B tests must be positive to confirm the positivity for CDI. See chapters 7.3.6 and 10.3 for more information about the results.

7 Using the Test System
7.1 Deployment of the Test System
The installation of the test system is carried out by the manufacturer's representative. The test system and the measuring program must be kept switched on to enable automatic rinsing.

7.2 mariPOC® Software (ArcDiagnoser™ Measuring Program)
The main window of the mariPOC® Software (ArcDiagnoser™ measuring program i.e. the user interface) is explained in **Figure 9**. Letters in the image indicate the main features of the main window. The measuring program is divided into the patient information section and the report section. The function buttons (**A, B** and **C**) and a drop-down menu (**D**) are along the top of the measuring program's left pane. Below these the patient information lines, which may be selected one at a time, are displayed. The selected line is indicated by a blue highlight (**E**) whereas the unselected lines are light-coloured (**F**). If a patient information line is bold, its results have not yet been viewed. The results for the selected patient are shown in the report section (right pane). The test status which is shown in the patient information line is explained in **Table 18**.
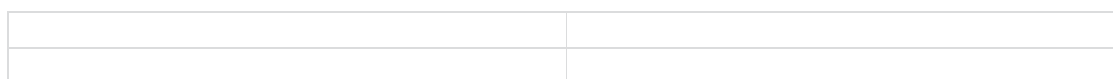
Figure 9. Main window of the mariPOC® Software (ArcDiagnoser™ mariPOC®+ measuring program) with its features marked by letters (example from mariPOC® RTI combi test plate in use).

The new sample button (**A**) is pressed to open the "Patient information" window for entry of a new patient's information (**Figure 10**). In order to identify the patient, at least one of the following fields must be filled: "First name", "Last name", or "ID code". The identification code field is free-form. The test type is selected from the "Test type" drop-down menu. The test types to be selected in the mariPOC® RTI combi test plates are described in **Figure 10**. The mariPOC® Software shows only those tests that can be selected from the test plate in use. The "Rapid instruction" drop-down menu allows the selection of the rapid instruction displayed on-screen. This selection, however, is only instructional and does not affect the analysis. If not selected, the default setting is without rapid instruction display. Additional information such as symptoms may be entered in the "Other information" field. The information is shown only in the printed results report and when the patient information line is double clicked to open "Patient information" window.

The "Read code" button is active only when the test system has been connected to a laboratory information system (LIS). In a test system connected to a LIS, patient information and the type of test ordered will be automatically filled once the sample referral bar code has been read with a separate reader.
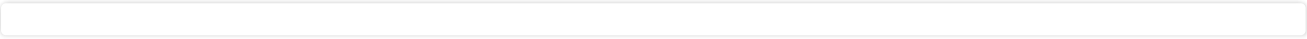
Figure 10. "Patient information" window that opens when the new sample button is clicked (example from mariPOC® RTI combi test plate in use). The shown test types are depended on the test plate in use. "External quality assessment sample" selection is available only if the mariPOC® test system is connected to mariCloud™ online service. When available, the selection should be used when an external quality assessment (EQA) sample is analysed. "Read code" is used when the mariPOC® test system is connected to Laboratory or Hospital Information System (HIS/LIS).

Newly entered patient information can be deleted by clicking the "Cancel" button. When the patient information has been entered, an individual bar code label is printed by clicking the "Print" button. A new patient information line is then created in the bottom of the patient information section of the mariPOC® Software. When the new patient information line has been selected a rapid instruction appears on the right side of the measuring program.

Information on control samples does not need to be entered separately because their factory installed bar code labels are read automatically once inserted into the analyser. The information is automatically transferred to the measuring program.

"External quality assessment sample" selection is available only if the mariPOC® test system is connected to mariCloud™ online service (**Figure 10**). When available, the selection should be used when an external quality assessment (EQA) sample is analysed. If not selected, the default setting is a "Patient sample" and the result may distort the real-time epidemiological surveillance data. The selection of "External quality assurance sample" does not affect the sample analysis or result reporting to mariPOC® Software.

When the Test type has been selected (**Figure 10**) the pathogens detected with the selected test type are visualised on the right side (the report section) of the mariPOC® Software until the results are reported (**Figure 11**).

Figure 11. Main window of the mariPOC® Software (ArcDiagnoser™ measuring program) when the Test type is selected in "Patient information" window (example from mariPOC® RTI combi test plate in use).

Table 18. Terms and explanations illustrating analysis (test) status shown in the measuring program.

Test status	Explanation
Insert sample	The sample information has been entered and the bar code label printed. The sample treatment protocol is shown in the report section. The analyser is waiting for a sample tube.
Processing	The analyser is dispensing a new sample or is waiting for the result from the first time point.

Pending	Dispensing has not started yet because either several patient samples were inserted at the same time, and/or the test plate is full, and there is not enough space for all the samples on the same test plate.
Preliminary	The preliminary analysis (first measurement) result is ready. Only the positive results are reported.
Finished	The analysis is complete. Negative results are also reported if the analysis is allowed to continue until the final results.
"Preliminary" or "Finished" text in red	Analysis has failed. There has been a failure during one of the phases of the analysis, which hinders reporting of the results for one or more analytes.

There are three time bars on the bottom of the patient information section (**Figure 9**). The time remaining for inserting next sample(s) is indicated in the "Ready for new sample in" time bar (**G**). This time bar changes into "Ready for new test plate in" when there is an opportunity to change the test plate. The time remaining before the results are ready can be seen for each patient by selecting the patient line in question. Then the "Preliminary result in" time bar (**H**) on the bottom of the measuring program's main window indicates the remaining time for the completion of the preliminary results and, correspondingly, the "Final result in" time bar (**I**) indicates the remaining time for the final results. The top part of the report section (on the right) shows the number of remaining multianalyte tests on the current test plate (**J**).

Note! Quick Flu/RSV (or Quick Flu+) test consumes Respi (or Respi+) tests and Quick StrepA test consumes Pharyn tests when a mariPOC® RTI combi (or combi+) test plate is in use.

The analysis status and identity information of the selected patient's (marked with a blue line in the patient information section) is indicated by a yellow or green bar (**K**). Yellow indicates Preliminary results and green Final results. The analysis results are shown below. The analytes tested are listed in the column **L**. If the analysis qualitative result in column **M** is positive, it is shown first. After obtaining the final results, a red exclamation mark (!) can appear next to the negative result in the column **M**. It indicates that a positive preliminary result has changed into a negative final result.

However, a positive preliminary result rarely changes into a negative final result (approximately one sample per 400 samples). The column Ψ (psi, indicated with **N** in **Figure 9**) provides additional quantitative information about the pathogen levels in the sample (see chapter 7.3.6). Ψ feature is optional. The last column (**O**) displays the result of the internal quality controls (autoverification) indicating the technical success of the analysis (OK/Failed). The analysis report for the selected patient (**E**; indicated with blue background) can be printed on an external printer by clicking the print results button (**B**). The report for customer support (**C**), created in case of malfunction or for invoicing, includes anonymized results, the system log file, the full results of failed samples and control samples from the last 60 days, and the amount of tests performed.

In the patient information section (left pane) under the "More options" drop-down menu (**D**) are the following options: Maintenance wizard, Control data, Reports, About mariPOC and Change test plate. The "Maintenance wizard" guides the maintenance operations by giving instructions on how to empty the waste container, to change the Wash and System solution container and to shut down the analyser. The "Control data" report allows monitoring results from single analytes in the positive and negative control samples. The report will be shown automatically in the web browser. The purpose of the report is to demonstrate the performance of the analyser and the tests in order to track possible trends. A blue dot means that the measurement has been successful. A red dot indicates either an unsuccessful measurement or a result that is contrary to the expected value (+ or -). The quantitative results (Y-axis, signal) of the control samples are plotted in the order of analysis (X-axis, date or week). "Reports" opens a report creation pop-up window where Epidemiological report, Tests day by day and/or mariPOC results (summary reports) can be created. The selected report will be shown automatically in the web browser. See chapter 7.3.6 for more information about the reports. "About mariPOC" includes information about the manufacturer. "Change test plate" allows test plate change at any time (see chapter 7.5).

The test system is equipped with a self-diagnostic error-reporting system. Thus, the system automatically reports most of the possible errors to the screen. The report may contain a possible reason for failure and possible actions for restoring the function of the test system. It is recommended to always notify customer support about any errors.

7.3 Performing the Test and Reading the Results

The clinical suspicion (indication) determines the sampling location, the selected test type, and the pretreatment of the sample. The test plate in use determines the target pathogen coverage of the test (see **Table 4**, **Table 5** and **Table 6**).

7.3.1 Sampling

For the **Respi+**, **Respi**, **Respi < 7 years old**, **Quick Flu+**, **Quick Flu/RSV** and **SARS-CoV-2 tests**, the sample is taken from the mucosa of the respiratory tract nasopharynx by rubbing with a swab or collecting a standard nasopharyngeal aspirate. The swab sampling must be done using flocked swabs defined in the User's manual (see

Table 7). It is beneficial to use as large a swab as possible, considering patient size, because the sample volume directly affects test performance. Nasopharyngeal wash samples are not recommended because they are dilute. The manufacturer disclaims any responsibility if any other sample materials are used in the mariPOC® test system.

For the **Pharyn** and **Quick Strep A tests**, the sample is typically taken from the throat or the perianal area depending on the symptoms. The sampling must be done using flocked swabs defined in the User's manual (see **Table 7**). A rigid large swab is recommended to be used for sampling because the sampling volume has a direct effect on test performance.

For the **Gastro** and **CDI tests**, the sample material is stool (faeces) from patients with symptoms of acute gastroenteritis. Stool sample should be collected to a clean container.

7.3.2 Storage of Samples

Refrigerated storage of the samples for several days, or freeze-thaw cycles, are known to have a deleterious effect on the sensitivity of all antigen detection tests. It is recommended, therefore, that the sample is analysed as soon as possible following sampling. See **Table 19** for manufacturer's recommendations for storage temperatures and times. Before analysis, nasopharyngeal and throat swab samples can be stored in RTI sample buffer. However, swab samples are preferred to be stored without the sample buffer. The mariPOC® Sample tube must be frozen in upright position with parafilm sealing the cap to prevent any leakage. Thaw the frozen sample totally before pretreatment.

Table 19. Storage temperatures and times of samples.

Phase	Storage
Transport	Refrigerated
Before analysis	+2 to +8°C up to 2 days/ -20 to -80°C over 2 days
Leftover samples	+2 to +8°C up to 2 days/ -20 to -80°C over 2 days

Note! Samples should not be stored in any kind of transport or storage media or buffers. The preferred way of storing the samples is in their naïve form. Transport and storage media and buffers can affect adversely to the stability of the sample and the performance of the test.

7.3.3 Respi+, Respi, Respi < 7 Years Old, Quick Flu+, Quick Flu/RSV and SARS-CoV-2 Tests

The pretreatment of the swab, aspirate and wash samples differs and in this manual they are referred to as A (swab), B (aspirate), C (wash, concentration protocol) and D (wash). Each sample type's pretreatment procedures are described separately in this chapter in between printing the sample bar code and inserting the pretreated sample into the analyser.

Printing Bar Code

Click the new sample button in the top left corner of the mariPOC® Software. The "Patient information" pop-up window (**Figure 12**) opens. Enter patient information into at least one of the following fields: First name, Last name, and ID code (identifier). Depending on the test plate in use, select the test type Respi+, Respi, Respi < 7 years old, Quick Flu+, Quick Flu/RSV or SARS-CoV-2 from the "Test type" drop-down menu. The pathogens detected with the selected test type are visualised to the right side (the report section) of the mariPOC® Software until the results are reported (**Figure 11**).

Respi+ and Respi tests detect 11 pathogens and reports the preliminary results in 20 minutes and final results in 2 hours. Respi+ test includes a test method for SARS-CoV-2. Because of the high frequency of Pneumococcus carriage in children under 7 years, the manufacturer recommends selecting the Respi < 7 years old test for young children. This is a Respi+ or Respi test without Pneumococcus.

Quick Flu+ and Quick Flu/RSV rapid tests reports influenza A virus, influenza B virus and respiratory syncytial virus (RSV) in 20 minutes. Quick Flu+ test also includes a test method for SARS-CoV-2. The Quick Flu+ and Quick Flu/RSV tests can be selected from the Combi+ or Combi test plates, respectively, only if the Quick feature is enabled.

The SARS-CoV-2 test method in Respi+, Quick Flu+ and SARS-CoV-2 tests detects SARS-CoV-1 and SARS-CoV-2. SARS-CoV-2 test can be selected only if the mariPOC® SARS-CoV-2 test plate (REF 1204S) is in use. The SARS-CoV-2 test reports the preliminary results in 20 minutes and final results in 95 minutes.

The user may select the rapid instruction appearing on-screen in the "Rapid instruction" drop-down menu (informative selection, no effect on analysis) and enter any notes or symptoms in the separate "Other information" field. Both fields are for information only and do not affect the test.

"External quality assessment sample" selection is available only if the mariPOC® test system is connected to mariCloud™ online service. When available, the selection should be used when an externalqualityassessment(EQA)sampleisanalysed.Ifnotselected,thedefaultsettingisa"Patient sample"andtheresultmaydistortthereal-timeepidemiologicalsurveillancedata.Theselectionof "External quality assurance sample" does not affect the sample analysis or result reporting to mariPOC® Software.

Figure 12. "Patient information" pop-up window before and after entering patient information (example from mariPOC® Respi+ test plate in use).

Printthebarcodelabelfor thesampletubebyclickingthe"Print"button.Attach thebarcodelabel tothemiddleofthesampletubesothatthetextonthebarcodelabelisparallelwiththelengthof the sample tube (**Figure 13**).

Figure 13. Photograph showing how bar code labels may be attached to a sample tube.

Anewlineforanewpatient'sinformationhasbeencreated.Theprogressofthetestforeachpatient canbefollowedinthe"Test status"section.Theteststatusisnowinthe"Insertsample"phase.

Note! The patient information cannot be changed after the bar code label is printed. If there is a problem in attaching theprintedbarcodelabeltothesampletube,forexampleifthelabeliswrinkledordefacedinsomeway,anewbarcodelabel may be printed by double-clicking the patient information line and then clicking the "Print"button.

A.Swab Sample Collection andPretreatment

Totakeanasopharyngealswabsample(**Figure 14**),insertaswabtoadepthofabout8–12cmin adults and 4–8 cm in children inside the nostril (according to the patient age and size) and rub the nasopharyngeal mucosa with a rotational motion so that cells from the mucosa adhere to the swab. It is recommended that the patient blow their nose before the nasopharyngeal swab is collected. More information about the nasopharyngeal swab sampling is in the Sampling Guide.

Figure 14. Swab sampling.

*Note! Always use the swabs defined in the User's manual (**Table 7**).*

Note!Iftwoswabsamplescollectedfromthepatient,onefromthenasopharynxandonefromthethroat,aretobe run in a single test, the samples must be collected using two swabs, and only a single swab may be a large throat swab. Inserting two large swabs into a single sample tube may lead to analysermalfunction.

Cuttheswabshaftwithscissorsatabout1–2cmfromthenylonfibreheadoftheshaftintothe mariPOC® Sample tube as shown in **Figure 15**. Ensure that the patient information on the bar code label of the sample tube is for the correctpatient.

Figure 15. Cutting off a swab into a sample tube.

Safety!Cleanthescissorscarefullybetweeneachsamplingusing70%ethanolorsimilar.Wipethemwithdisposable paper.

Place diagonally the bottom of the sample tube to the bottletop dispenser's stand below of the dispensingheadandpushthetubebetweenclips.Add1.3mlofRTIsamplebuffertothesample tubebyliftingthebottletopdispensertopupanddownonce(**Figure16**).Afterdispensing,draw the tube horizontally away from the stand's clips. Seal the sample tube with acap.

Figure 16. Dispensing with the bottletop dispenser.

Note! The bottletop dispenser's stand is provided to minimize the contamination of the dispensing head and for ease of use. The sample tube should not be lifted upwards when using the stand.

Note! If the bottletop dispenser has not been used for a long time or its protective cap has been left open, dispense into a waste container a few times to expel the air from the dispensing head.

*Safety! The RTI sample buffer can be dispensed to the sample tube (**Figure 16**) before sampling (**Figure 14**) and cutting the swab into the tube (**Figure 15**). This eliminates aerosol formation and release during sample pretreatment.*

Safety! Avoid touching the dispensing head with the sample tube or spilling any solution on bare skin, eyes, or mucous membranes (see the cleaning instructions for the dispensing head in chapter 10.3). If any solution spills on the skin or eyes, wash with plenty of water and consult a doctor if necessary. Take the User's manual and SDSs with you.

Mix the sample tube with a vortex mixer for about 10–15 seconds (**Figure 17**).

Figure 17. Mixing the sample tube.

*Note! Press firmly on the top of the sample tube cap during mixing (**Figure 17**) so that a vortex forms inside the sample tube. The purpose of mixing is to release the sample from the swab or mucus into the sample solution. Mixing that does not last long enough or is not strong enough (i.e., no vortex forms) leads to an incomplete release of the sample from the swab or mucus and thus less sensitive test results.*

B. Aspirate Sample Collection and Pretreatment

The tubing of the aspirate collection system (for example syringe with tubing) is inserted through the nose into the nasopharynx and mucus is aspirated from both nostrils.

Dispense approximately 0.3 ml of the native nasopharyngeal aspirate (i.e., untreated) into the mariPOC® Sample tube.

Place diagonally the bottom of the sample tube to the bottletop dispenser's stand below of the dispensing head and push the tube between clips. Add 1.3 ml of RTI sample buffer to the sample tube by lifting the bottletop dispenser top up and down once (**Figure 16**). After dispensing, draw the tube horizontally away from the stand's clips. Seal the sample tube with a cap.

Mix the sample tube with a vortex mixer for about 30 seconds (**Figure 17**). Let the sample settle for 2–10 minutes.

Mix the sample tube with a vortex mixer again for about 10 seconds. Centrifuge the sample tube at 1000 g for 5 minutes. Do not allow the pellet to be mixed or swayed again in order to avoid the dispenser needle aspirating the pelleted mucus.
Safety! The mariPOC® Sample tube does not withstand higher g-forces than 1000 g.

C. Wash Sample Collection and Pretreatment with Concentration Protocol
Nasopharyngeal wash sample is not preferred sample material. It should only be used for patients who can be sampled within 5 days from the onset of respiratory infection symptoms. For wash sample pretreatment use the concentration protocol (C) if possible. The performance specifications stated by the manufacturer in terms of analytical and clinical sensitivity are valid for samples obtained using flocked swabs or by aspiration without saline. If the observed performance with nasopharyngeal wash samples does not match with the specifications of the manufacturer or the results reported in the literature, please use nasopharyngeal swabs and/or aspirates (no saline addition), which are primarily

recommended by themanufacturer.

The tubing of the wash collection system (for example syringe with tubing) is inserted through the nose into the nasopharynx. Use preferably about 1–2 ml of saline to collect the sample. No viraltransportmediaisallowed.Aspiratemucusfrombothnostrilsanddispensethesampleinto a high force centrifugationtube.

Centrifugeentirewashsample(minimumof0.6ml)for5min14000ginhighforcecentrifugation tube. Discard supernatant so that approximately 0.3–0.4 ml of the sample isleft.
Safety! The mariPOC® Sample tube does not withstand higher g-forces than 1000 g.

Add1.3mlofRTIsamplebufferdiagonallytothesampletubebyliftingthebottletopdispenser top up and down once (**Figure 16**). Be careful not to contaminate the dispensinghead.

Mix the sample tube with a vortex mixer for about 30 seconds (**Figure 17**). Transfer the sample toamariPOC®Sampletube.Sealthesampletubewithacap.Letthesamplesettlefor2–10min.

Mixthesampletubewithavortexmixeragainforabout10seconds.Centrifugethesampletube at 1000 g for 5 minutes. Do not allow the pellet to be mixed or swayed again in order to avoid the dispenser needle aspirating the pelletedmucus.

D.Wash Sample Collection andPretreatment
Nasopharyngeal wash sample is not preferred sample material. It should only be used for patients who can be sampled within 5 days from the onset of respiratory infection symptoms. For wash samplepretreatmentusetheconcentrationprotocol(C)ifpossible.Theperformancespecifications stated by the manufacturer in terms of analytical and clinical sensitivity are valid for samples obtained using flocked swabs or by aspiration without saline. If the observed performance with nasopharyngeal wash samples does not match with the specifications of the manufacturer or the results reported in the literature, please use nasopharyngeal swabs and/or aspirates (no saline addition), which are primarily recommended by themanufacturer.

The tubing of the wash collection system (for example syringe with tubing) is inserted through the nose into the nasopharynx. Use preferably about 1–2 ml of saline to collect the sample. No viraltransportmediaisallowed.Aspiratemucusfrombothnostrilsanddispensethesampleinto atube.

Dispense approximately 0.6 ml of the nasopharyngeal wash sample into the mariPOC® Sample tube.

Place diagonally the bottom of the sample tube to the bottletop dispenser's stand below of the dispensingheadandpushthetubebetweenclips.Add1.3mlofRTIsamplebuffertothesample tubebyliftingthebottletopdispensertopupanddownonce(**Figure16**).Afterdispensing,draw the tube horizontally away from the stand's clips. Seal the sample tube with acap.

Mixthesampletubewithavortexmixerforabout30seconds(**Figure 17**).Letthesamplesettle for 2–10minutes.

Mixthesampletubewithavortexmixeragainforabout10seconds.Centrifugethesampletube at 1000 g for 5 minutes. Do not allow the pellet to be mixed or swayed again in order to avoid the dispenser needle aspirating the pelletedmucus.
Safety! The mariPOC® Sample tube does not withstand higher g-forces than 1000 g.

Inserting Sample into Analyser
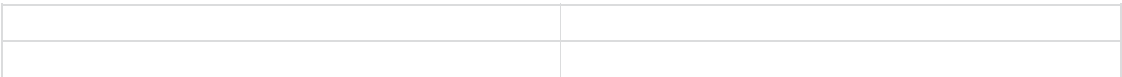
 Whenthesamplehatch'sLEDlightisgreen,theanalyserisreadyforanewsample.Openthesample hatch, remove the old sample tubes, and insert a new sample tube into the rack. The patient information on the bar code label should face the user (**Figure 18**) so that the analyser is able to read the bar code from behind. The analyser automatically starts processing the sample after the sample hatch is closed. The hatch becomes locked for a few minutes per sample while dispensing. Already dispensed samples can be removed before the analysis results are ready. If required, samples can be stored according to instructions in chapter "7.3.2 Storage of Samples".
Figure 18. Proper position of the sample tube in the sample tube rack.

Note! In most cases the sample hatch locks immediately after the hatch is closed. If, however, the analyser is in the process of measuring a sample, there can be a delay of about 30 seconds before the hatch locks.

Note! The sample tube rack can hold 1–6 sample tubes at a time. Old samples that have been already processed do not need to be removed each time the sample hatch is opened. However, the measuring program notifies that position of the sample tube rack where there already is a dispensed sample. Position number 1 is on the left edge of the rack.

7.3.4 Pharyn and Quick StrepA Tests

The swab sample can be collected either from the throat or perianal area depending on the indication. The collection procedures for both sample types are described later in this chapter. Printing the bar code and the pretreatment are the same for both sample types.

Printing Bar Code

Click the new sample button in the top left corner of the mariPOC® Software. The "Patient information" pop-up window (**Figure 19**) opens. Enter patient information into at least one of the following fields; First name, Last name, and ID code (identifier). Select the Pharyn or Quick StrepA test. The pathogens detected with the selected test type are visualised on the right side (the report section) of the mariPOC® Software until the results are reported.

The Quick StrepA test identifies only group A streptococci and the results are reported in 15 minutes. Instead, Pharyn test reports preliminary results in 15 minutes and final results in 55 minutes.

The user may select the rapid instruction appearing on-screen in the "Rapid instruction" drop-down menu and enter any notes or symptoms in the separate "Other information" field. Both fields are for information only and do not affect the test.

"External quality assessment sample" selection is available only if the mariPOC® test system is connected to mariCloud™ online service. When available, the selection should be used when an external quality assessment (EQA) sample is analysed. If not selected, the default setting is a "Patient sample" and the result may distort the real-time epidemiological surveillance data. The selection of "External quality assurance sample" does not affect the sample analysis or result reporting to mariPOC® Software.

Figure 19. "Patient information" pop-up window: before and after entering patient information (example from mariPOC® Pharyn test plate in use).

Print the barcode label for the sample tube by clicking the "Print" button. Attach the barcode label for the sample on the middle of the sample tube so that the text on the bar code label is parallel with the sample tube (**Figure 20**).

Figure 20. Photograph showing how bar code labels may be attached to a sample tube.

A new line for a new patient's information has been created. The progress of the test for each patient can be followed in the "Test status" section. The test status is now in the "Insert sample" phase.

Note! The patient information cannot be changed after the bar code label is printed. If there is a problem in attaching the printed barcode label to the sample tube, for example if the label is wrinkled or defaced in some way, a new barcode label may be printed by double-clicking the patient information line and then clicking the "Print" button.

A. Throat Swab Collection

The patient's tongue is pressed downwards with a spatula or held with fingers and gauze. Vigorously rub the tonsils and the posterior wall with a swab so that cells are collected on the swab (**Figure 21**). Avoid contacting the mucous of the cheek or the tongue in order to collect as much sample from the throat as possible.

Figure 21. Throat sampling.

Note! Eating and drinking just before sampling may reduce the sensitivity of the analysis. Accordingly, it is recommended that the patient does not drink for at least one hour before the throat swab is collected. In addition, the use of antiseptic throat tablets and mouthwashes for relieving the symptoms of mouth and throat inflammation should be avoided before sampling.

*Note! Always use the swabs specified in the User's manual (**Table 7**).*

Note! Always use large swabs for adults. If two swab samples collected from the patient, one from the nasopharynx and one from the throat, are to be run in a single test, the samples must be collected using two swabs and only a single swab may be large throat swab. Inserting two large swabs into a single sample tube may lead to analyser malfunction.

B. Perianal Swab Collection

The perianal swab sample is collected with similar large and stiff flocked (dry) swab (**Table 7**) as the throat sample by rubbing carefully the surroundings of the anus. A swab sample containing visible traces of stool should be discarded and a new sample taken after cleaning the sampling area.
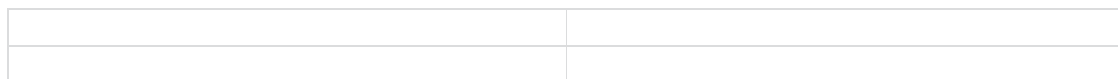
Pretreatment
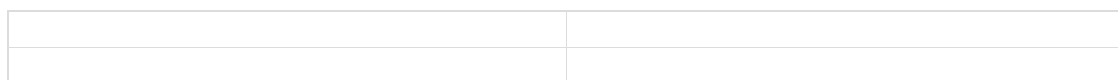
Cut the swab shaft with scissors at about 1–2 cm from the nylon fibre head of the shaft into the mariPOC® Sample tube as shown in **Figure 22**.

Figure 22. Cutting off a swab into a sample tube.

Safety! Clean the scissors carefully between samples using 70% ethanol or similar. Wipe them with disposable paper.


Add 6 drops of the two mariPOC® Extraction solutions, A and B, to the sample tube (**Figure 23**). Seal the sample tube with a cap.

Figure 23. Adding the Extraction solutions.

Note! Do not combine the Extraction solutions A and B beforehand. Note! Extraction solution A is light sensitive. Safety! Avoid spilling any solution on bare skin, eyes, or mucous membranes. If any solution spills on the skin or eyes, wash with plenty of water and consult a doctor if necessary. Take the User's manual and SDSs with you.

Mix the sample tube with the vortex mixer for about 10–15 seconds (**Figure 24**). Let the tube stand for 2–10 minutes for the extraction to take place.
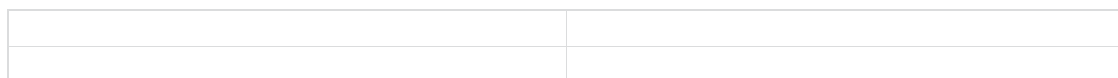
Figure 24. Mixing the sample tube.

*Note! Press firmly on the top of the sample tube cap during mixing (**Figure 24**) so that a vortex forms inside the sample tube. The purpose of mixing is to release the sample from the swab into the Extraction solution. Mixing that does not last long enough or is not strong enough (i.e., no vortex forms) leads to an incomplete release of the sample from the swab and incomplete extraction and thus less sensitive test results.*

Note! The maximum standing time under the influence of the Extraction solution is 30 minutes. Adding the RTI sample buffer terminates the extraction reaction.

Remove the cap and place diagonally the bottom of the sample tube to the bottletop dispenser's stand below of the dispensing head and push the tube between clips. Add 1.3 ml of RTI sample buffer to the sample tube by lifting the bottletop dispenser top up and down once (**Figure 25**). After dispensing, draw the tube horizontally away from the stand's clips. Seal the sample tube with a cap.

Figure 25. Dispensing with the bottletop dispenser.

Note! The bottletop dispenser's stand is provided to minimize the contamination of the dispensing head and for ease of use. The sample tube should not be lifted upwards when using the stand.

Note! If the bottletop dispenser has not been used for a long time or its protective cap has been left open, dispense into a waste container a few times to expel the air from the dispensing head.

Safety! Avoid touching the dispensing head with the sample tube or spilling any solution on bare skin, eyes, or mucous membranes (see the cleaning instructions for the dispensing head in chapter 10.3). If any solution spills on the skin or eyes, wash with plenty of water and consult a doctor if necessary. Take the User's manual and SDSs with you.

Mix the sample tube with the vortex mixer for about 10–15 seconds (**Figure 24**).
Note! Press firmly on the top of the sample tube cap during mixing so that a vortex forms inside the sample tube.

Inserting Sample into Analyser

When the sample hatch's LED light is green, the analyser is ready for a new sample. Open the sample hatch, remove the old sample tubes, and insert a new sample tube into the rack. The patient information on the bar code label should face the user (**Figure 26**) so that the analyser is able to read the bar code from behind. The analyser automatically starts processing the sample after the sample hatch is closed. The hatch becomes locked for few minutes per sample while dispensing. Already dispensed samples can be removed before the analysis results are ready. If required, samples can be stored according to instructions in chapter "7.3.2 Storage of Samples".

Figure 26. Proper orientation of the sample tubes in the sample tube rack.

Note! In most cases the sample hatch locks immediately after the hatch is closed. If, however, the analyser is in the process of measuring a sample, there can be a delay of about 30 seconds before the hatch locks.

Note! The sample tube rack can hold 1–6 sample tubes at a time. Old samples that have been already processed do not need to be removed each time the sample hatch is opened. However, the measuring program notifies that position of the sample tube rack where there already is a dispensed sample. Position number 1 is on the left edge of the rack.

7.3.5 Gastro and CDI Tests Printing BarCode

Click the new sample button in the top left corner of the mariPOC® Software. The "Patient information" pop-up window opens (**Figure 27**). Enter patient information into at least one of the following fields; First name, Last name, and/or ID code (identifier). Select the test type (describe in **Figure 3** and **Table 6**) from the "Test type" drop-down menu. The pathogens detected with the selected test type are visualised on the right side (the report section) of the mariPOC® Software until the results are reported.

Gastro or GastroVir (without Campylobacter spp.) are available for mariPOC® Gastro test plate (2017M), Gastro+CDI, GastroVir+CDI, Gastro, GastroVir or CDI for mariPOC® GastroCDI combitest plate (2027M) and CDI for mariPOC® CDI test plate (2037M). The preliminary results are reported in 20 minutes and final results in 2 hours. The user may select the rapid instruction to appear on-screen from the "Rapid instruction" drop-down menu and enter any notes in the separate "Other information" field. The last two fields are for information only and do not affect the test.

"External quality assessment sample" selection is available only if the mariPOC® test system is connected to mariCloud™ online service. When available, the selection should be used when an externalqualityassessment(EQA)sampleisanalysed.Ifnotselected,thedefaultsettingisa"Patient sample"andtheresultmaydistortthereal-timeepidemiologicalsurveillancedata.Theselectionof "External quality assurance sample" does not affect the sample analysis or result reporting to mariPOC® Software.

Figure 27. "Patient information" pop-up window before and after entering patient information (example from mariPOC® Gastro CDI combi test plate inuse).

Printthebarcodelabelforthesampletubebyclickingthe"Print"button.Attachthebarcodelabel tothemiddleofthesampletubesothatthetextonthebarcodelabelisparallelwiththelengthof the sample tube (**Figure 28**). Seal the sample tube with acap.

Figure 28. Photograph showing how bar code labels may be attached to a sample tube.

Anewlinefornewsample'sinformationhasbeencreated.Theprogressofthetestforeachsample canbefollowedinthe"Teststatus"section.Theteststatusisnowinthe"Insertsample"phase.

Note! The patient information cannot be changed after the bar code label is printed. If there is a problem in attaching theprintedbarcodelabeltothesampletube,forexampleifthelabeliswrinkledordefacedinsomeway,anewbarcode label may be printed by double-clicking the patient information line and then clicking the "Print"button.

Sample Collection and Pretreatment

Remove flocked swab from transport tube. Add two (2) volumes of Gastro sample buffer to the transport tube by lifting the bottletop dispenser top up and down twice (**Figure 29**). The total volume is 2.6ml.

Figure 29. Dispensing with the bottletop dispenser.

Note! If the swab already contains stool sample, be careful not to contaminate the dispensing head of the bottletop dispenser and proceed directly to the step 3.

Safety! Wear sufficient protective clothing and gloves when handling stool samples.

Safety!Avoidspillinganysolutiononbareskin,eyes,ormucousmembranes.Ifanysolutionspillsontheskinoreyes, wash with plenty of water and consult a doctor if necessary. Take the User's manual and SDSs withyou.

Dip the dry flocked swab into the stool and move it rigorously for 5–10 seconds (**Figure30**).

Figure 30. Optimum amount of stool in the swab.

Note! Typically, the stool samples that are tested for the presence of gastrointestinal pathogens should take the shape of a container. If the sample is not watery diarrhoea swirl the swab in 4 different spots of the firm stool in order to have a representative sample.

Insert the swab with sample to the transport tube with Gastro sample buffer and close. Vortex the transport tube for 10–15 seconds to release the sample from the swab into the sample solution.

Note! Mixing that does not last long enough leads to an incomplete release of the sample from the swab and thus less sensitive test results.

Assemble the filtration unit (**Figure 31**). Remove the piston from the syringe. Attach the filter to the syringe. Attach the bar coded mariPOC® Sample tube with a cap to the filter's other end. Place the filtration unit to the rack.
Figure 31. Assembly of the filtration unit.

Remove the swab from the transport tube. Transfer the supernatant of the sample (appr. 2.3 ml) with a Pasteur pipette to the syringe (**Figure 32**). Avoid disturbing the pellet of solid material if such has formed by settling. Alternatively, connect the syringe to the transport tube and pour the sample (**Figure 33**). Pouring may result more often in filter becoming blocked by the solids of the sample.

Figure 32. Pipetting the sample to the syringe.
Figure 33. Pouring the sample to the syringe.
Note! When the swab is removed from the transport tube, the mouth of the transport tube can be pressed to drain the swab. This will maximize the amount of sample and reduces the possibility of contaminating the workstation.
Note! Sample transfer with Pasteur pipette can be done in two phases. In this way the sufficient sample volume is easier to obtain and it is less likely to disturb the pellet and transfer solids to the filtration unit.

Attach the piston to the syringe and filter the sample to the mariPOC® Sample tube. The solution level should meet the 1.3 ml minimum volume mark in the filtration unit rack (**Figure 34**).

Figure 34. Filtration and minimum volume mark in the filtration unit rack.
Safety! In case of foam forming on top of filtrated sample, stop the filtering as soon as the minimum volume mark is met. If the volume mark is not met, wait for the foam to settle and continue filtration carefully in order to prevent foam extruding from the sample tube through the cap.
Safety! After filtering, the piston can be lifted upwards to avoid contaminating the sample tube or workspace with drops leaking from the filter.

Remove the filtration unit carefully from the rack and detach the mariPOC® Sample tube.

Inserting Sample into Analyser

When the sample hatch's LED light is green, the analyser is ready for a new sample. Open the sample hatch, remove the old sample tubes, and insert a new sample tube into the rack. The patient information on the bar code label should face the user (**Figure 35**) so that the analyser is able to read the bar code from behind. The analyser automatically starts processing the sample after the sample hatch is closed. The hatch becomes locked for few minutes per sample while dispensing. Already dispensed samples can be removed before the analysis results are ready. If required, samples can be stored according to instructions in chapter "7.3.2 Storage of Samples".

Figure 35. Proper orientation of the sample tubes in the sample tube rack.

Note! In most cases the sample hatch locks immediately after the hatch is closed. If, however, the analyser is in the process of measuring a sample, there can be a delay of about 30 seconds before the hatch locks.

Note! The sample tube rack can hold 1–6 sample tubes at a time. Old samples that have been already processed do not need to be removed each time the sample hatch is opened. However, the measuring program notifies that position of the sample tube rack where there already is a dispensed sample. Position number 1 is on the left edge of the rack.

7.3.6 Reading and Reporting of the Results

The test reactions are automatically measured at one or two time points (**Table 20**) unless the preliminary time point has been omitted. At the preliminary results, the test identifies and reports strong and moderately positive samples. At the final results, the test identifies and reports low positive samples and negative test results. The result is reported with a positive (+) or negative (-) symbol.

For *S. pneumoniae* a positive result is reported semi-quantitatively as + (very low), ++ (low), +++ (medium), or ++++ (high). In the Pharyn test, group A streptococci positive result is reported semi- quantitatively as + (very low), ++ (low), or +++ (high) (see chapter "6 Test Performance"; **Table 12**). Optionally, reporting of + (very low) can be selected out when the test system is installed. The sensitivity of the Quick StrepA test and the preliminary result phase of group A streptococci test in the Pharyn test correspond approximately standard culture.

A red exclamation mark (!) next to the negative result in the column is indicating that a positive preliminary result has changed into a negative final result. A sound signal is played from the computer when preliminary results or Quick test results become available. The sound can be muted from computer sound settings. Additional quantitative information (see instructions from **Table 22**) about the pathogen levels in the sample can be provided next to the qualitative result in column Ψ, psi in the measuring program. Ψ feature is optional. Samples obtained from mucosa are by their nature semi-quantitative and are subject to variability in sampling. However, in some cases the result quantification may still be useful in clinical practice. If reporting of Ψ values is in use, the preliminary phase identifies strong and moderately positive samples and reports them with a positive (+) symbol or with a borderline (+/-) symbol in case the assay signal is slightly below the cutoff. The final result is reported with a positive (+), borderline (+/-) or negative (-) symbol. Borderline result (+/-) should always be considered by default as negative unless result interpretation is used (see **Table 22**). For *S. pneumoniae* the borderline (+/-) result is reported only with the preliminary result. For group A streptococci, Gastro and CDI tests borderline (+/-) results are not reported. Qualitative reporting of the results is summarized in **Table 20**.

Table 20. Qualitative result reporting.

Test	Preliminary results	Final results
Respi+ or Respi test viruses	20 min: (+/-,) +	2 h: -, (+/-,) +
Respi+ or Respi test *S. pneumoniae*	20 min: (+/-,) +, ++, +++, ++++	2 h: -, +, ++, +++, ++++
SARS-CoV-2 test	20 min: +	95 min: -, +
Quick Flu+ or Quick Flu/RSV test		20 min: -, +
Pharyn test adenovirus	15 min: (+/-,) +	55 min: -, (+/-,) +
Pharyn test group A streptococci	15 min: +++	55 min: -, (+,) ++, +++
Quick StrepA test		15 min: -, +
Gastro test	20 min: +	2 h: -, +

CDI test	20 min: +	2 h: -, +

In the mariPOC® CDI test, GDH and Toxin A/B test results form together the result for presence or absenceofCDI(**Table 21**).GDHpositivityindicatesthepresenceof*C.difficile*bacteriainthesample. Simultaneous Toxin A/B positivity indicates the presence of *C. difficile* toxins causing thedisease.

Table 21. Interpretation of the results in CDI test.

GDH test	Toxin A/B test	Interpretation of the results
-	-	*C. difficile* or its toxins A and/or B are not present in the sample. The disease is very unlikely caused by *C. difficile.*
+	+	Toxins A and/or B producing *C. difficile* is present in the sample. The disease is likely caused by *C. difficile.*
+	-	Non-toxigenic *C. difficile* strain is present in the sample or the amount of produced toxins A and/or B is below the detection limit of the assay. The disease is unlikely caused by *C. difficile.* Optionally, molecular testing of toxin gene (e.g., PCR) or toxigenic culture can be used to determine the toxigenicity of the *C. difficile* strain.
-	+	Invalid result. The sample should be reanalysed from the naïve stool sample. If the results persist after retesting, consider using other methods to confirm the results. In rare cases, the infection may be caused by highly pathogenic *C. sordellii* (see chapters 6.2 and 10.3).

Table 22. Qualitative analysis results and their interpretation using additional quantitative information (Ψ, psi) combined with clinical evidence.

Result	Consider as	Situation and/or prerequisite
-	Negative (-)	The analysis signal is well below the cut off value of the test. No Ψ (psi) value is reported.
+/-	Negative (-)	The analysis signal is slightly below the cut off value of the test and there is no other evidence to support the positivity.
+/-	Positive (+)	The analysis signal is slightly below the cut off value of the test but the Ψ (psi) value which describes probability (%) of an analytically true positive finding is high and there is significant other clinical, laboratory and/or epidemiological information supporting the change of the default value (-).

+	Positive (+)	The analysis signal is above the cut off value. The Ψ (psi) value is a signal multiple to cut off.

Quantification for the positive (+) and borderline (+/-) results is presented in different units because the probability of a true positive result around the cut off changes non-linearly.

Analysis result with a borderline symbol (+/-) should be reported by default as negative to ensure high specificity. In case the user has other significant evidence, such as other laboratory, epidemiological, and/or clinical information that strongly supports the decision to report the result as positive, the negative (-) default result may be considered to be changed to positive (+). Depending on the clinical need, samples with +/- result may be confirmed with an amplification based method to rule in the diagnostic result or the patient may be resampled after 12–24 hours in case the infection has just started and the microbial loads are still very low.

From quantitative value (a signal multiple to cut off) of a positive analysis result, the user may evaluate the accuracy of a positive finding in case of epidemiological situation, other laboratory test results, and/or clinical findings do not match. The user should take into account that the preset cut offs have been set so that the specificity of the assay (**Table 11**, **Table 13** and **Table 16**) is very high when using the default reporting. Depending on the method, cut offs may be different in preliminary and final result reporting phases. Therefore, i) sometimes (with certain antigen concentrations) the Ψ (psi) value obtained in preliminary phase can be higher than the psi value obtained in the final phase, and ii) Ψ (psi) values obtained in preliminary and final phases cannot always be compared quantitatively.

The sensitivity and specificity stated by the manufacturer are derived from the default positive and negative results, which are based on the preset cutoffs. The default results should only be changed upon joint decision of the laboratory and medical doctor responsible of the patient. Such decision shall be based on other significant evidence, such as other laboratory, epidemiological, and/or clinical information to increase the accuracy of the test result. Otherwise accuracy will suffer.

The "Test status" field for each patient reports the status of the analysis (see chapter "7.2 mariPOC® Software (ArcDiagnoser™ Measuring Program)"; **Table 18**). The selected patient information line is highlighted in blue and a line in bold letters indicates that the results have not been looked at. The patient information line remains bold for 3 seconds after its selection.

The test system includes internal quality control of results, i.e. autoverification, which estimates the reliability of the measurement and technical success of the analysis. When the measurement is unsuccessful, the test result is not stated. Instead, in such cases "Failed" appears in the result field and the test status in question is marked red in the patient information list. In that case a new patient sample can be collected or the old sample can be reanalysed (see chapter 10.3). Interfering matrix substances may rarely give falsely high fluorescent signals for negative samples despite the implemented result autoverification.

The test results of a single sample may be printed with the user's printer if necessary using the "Print" button. Report creation pop-up window (**Figure 36**) offers more possibilities for the result reporting: Epidemiological report, Tests day by day and mariPOC results (summary reports). The test types, pathogens or analytes and their abbreviations used in summary reports are explained in **Table 23**. Report creation is accessed from the More options pull-down menu by selecting Reports. Select the report type and then start and end dates if applicable. The report creation will take some time.

When completed, the selected report will be shown automatically in the web browser. The report in the web browser can be saved or printed with the user's printer.

Figure 36. Report creation pop-up window.

Table 23. The test types, pathogens and their abbreviations used in summary reports.

Test type	Pathogen or analyte	Abbreviation
Respi+ or Respi test	Influenza A virus	IAV
Influenza B virus	IBV	

Respiratory syncytial (RS) virus	RSV	
Human metapneumovirus	hMPV	
Parainfluenza virus 1	PIV1	
Parainfluenza virus 2	PIV2	
Parainfluenza virus 3	PIV3	
Human coronavirus OC43	hCoV	
SARS coronavirus 2	SARSCoV	
Human bocavirus	hBoV	
Adenovirus	AdV	
S. pneumoniae	Pnc	
Quick Flu+ or Quick Flu/RSV test	Influenza A virus	IAVQ
Influenza B virus	IBVQ	
Respiratory syncytial (RS) virus	RSVQ	
SARS coronavirus 2	SARSCoVQ	
SARS-CoV-2 test	SARS coronavirus 2	SARSCoVs
Pharyn test	Adenovirus	AdVp
Group A streptococci	StrAW	
Quick StrepA test	Group A streptococci	StrAQ
Gastro test	Norovirus GII.4	NoVGII
Norovirus GI	NoVGI	
Rotavirus	RoV	
Adenovirus	AdVg	
Campylobacter spp.	Camp	
CDI test	*C. difficile* GDH	GDH
C. difficile Toxin A/B	ToxAB	

"Epidemiological report" is automatically created for 6 month time period from the report creating dateandconsistsofresultsobtainedfromtheRespi+orRespitest(Figures1-4)andtheGastrotest (Figures 5-7). Figure 1 of the report is the weekly proportion (%) of positive samples from all tested Respi+ or Respi tests. The large variation between consecutive weeks may be due to small number of analysed samples. The intensity of epidemiological situation can be evaluated by comparing the graph with the number of weekly positive findings in report's Figures 2 and 3. In case of multiple positivefindingsareobtainedfromthesamesample,eachfindingistakenintoaccount.InFigure2, the positive findings of influenza A virus (IAV), influenza B virus (IBV) and respiratory syncytial virus (RSV), are shown. Other viruses of the Respi+ or Respi test are grouped together. In Figure 3 the other viruses (grouped in Figure 2; adenovirus (AdV), SARS coronavirus 2 (SARSCoV) or human bocavirus (hBoV), human coronavirus OC43 (hCoV), human metapneumovirus (hMPV), parainfluenza virus 1 (PIV1), parainfluenza virus 2 (PIV2) and parainfluenza virus 3 (PIV3)), and *S. pneumoniae* (Pnc) are shown. In report's Figure 4 the proportion of positive preliminary results of the Respi+ or Respi test compared to the final positive results is presented. During the epidemiological season over 50% (typically 60-80%) of virus positive samples are, on average, positive at the preliminary phase. However, this requires that the sample collection has been timed correctly and performed according to the instructions provided by the manufacturer. If the proportion of positive results in the preliminary reporting phase is continuously lower than 50%, it isrecommendedthatthesamplecollectionroutines,includingsamplingandtimefromtheonsetof symptoms,shouldbepaidattentionto.Figure5ofthereportistheweeklyproportion(%)ofpositive samples from all tested gastro tests. The large variation between consecutive weeks may be due to small number of analysed samples. The intensity of epidemiological situation can be evaluated by comparing the graph with the number of weekly positive findings in report's Figure 6. In case of multiplepositivefindingsareobtainedfromthesamesample,eachfindingistakenintoaccount.In report'sFigure7theproportionofpositivepreliminaryresultscomparedtothefinalpositiveresults of the Gastro test ispresented. "Tests daybyday"canbecreatedforanytimespanbyfreelyselectingthestartandenddates.The reportconsistsofthefollowingtables:successfultests,failedtestsandcustomersupporttests.The dailytestamountsaredividedbasedonthetestorcontrol types.Thesumofdailytestsisshownin the green column. The sum of tests per test type is shown in the greenrow.

"mariPOCresults"isasummaryreportofallperformedtestsincludingthecontrols.Itcanbecreated foranytimespanbyfreelyselectingthestartandenddates.Positivefindingsandpathogenspecific testswithfailedand/orchangedtestresults(betweenpreliminaryandfinalresultphases)arelisted in separate columns. The final column "Test plate" provides fully traceable information of the test plate used for sample analysis. The information includes test plate's name and its REF/Lot/Serial number. The report is available also in the computer's desktop (mariPOC.csv) and can be processed inaspreadsheetapplication(e.g.Excel).InformationinFirstname,LastnameandIDcodefieldsare repeatedassuch.Notethatanewreportwillautomaticallyreplacethepreviousoneonthedesktop.

7.4ControlSamples

The functioning and the use of the test system are also monitored by a weekly analysis of the multianalytecontrolsamplesprovidedbythemanufacturer(positiveandnegative).Controlsamples arenotusedtocalibratethesystem.Onecontrolsamplefoilbagincludesbothpositiveandnegative control samples dried in factory bar coded sample tubes. One positive control sample includes all analytes for the provided test plate type. The measuring program gives an automatic pop-up reminderwhenoneweekhaspassedsincethelastrunofcontrolsamplesforthecorrespondingtest plate type. The reminder includes instructions on handling a control sample (**Figure 37**). If the reminder has been closed without analysing the control samples, it will appear again until both controls arerun.
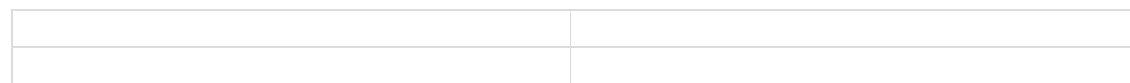
Figure 37. Control sample reminder.

*Note! Control samples are test plate specific. When measuring program gives an automated pop-up reminder, please check the test plate type and analyse the correct set of control samples (see **Table 2**).*

Analysing the Control Samples:

a.Open the control samples foil bag (including both the positive and the negative control sample tubes). Remove the caps of the control sample tubes. Add 1.3 ml of test specific sample buffer toeachtubebyliftingthebottletopdispensertopupanddownonce(**Figure 38**).Becarefulthat thepositivecontroldoesnotcontaminatethedispensinghead.Replacethecapsontheoriginal sample tubes. Be careful that the caps do not get mixed. The pink cap belongs to the positive control sample and the colourless cap to the negative controlsample.
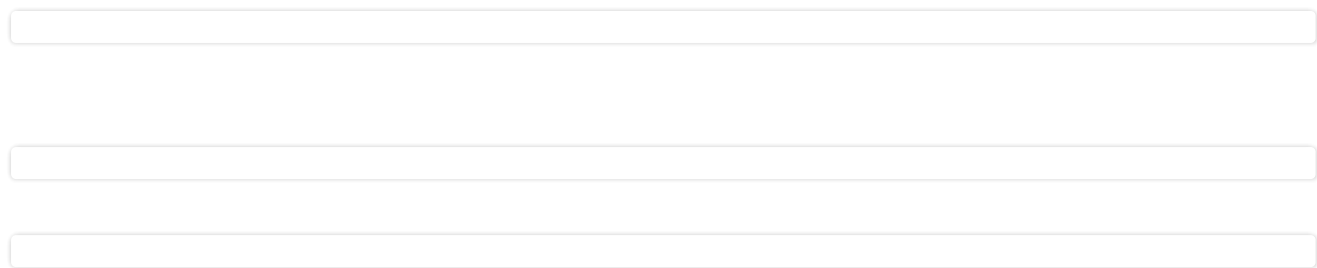
Figure 38. Adding the test specific sample buffer to the positive control sample tube.

Safety!Avoidtouchingthedispensingheadwiththecontroltubeorspillinganysolutiononbareskin,eyes,ormucous membranes (see the cleaning instructions for the dispensing head in chapter 10.3). If any solution spills on the skin or eyes, wash with plenty of water and consult a doctor if necessary. Take the User's manual and SDSs withyou.

b.Mix the control sample tubes separately with the vortex mixer for 10−15 seconds (**Figure 39**).

c.Letthecontrolsamplesdissolvebyleavingthemtostandatroomtemperaturefor2−10minutes (**Figure 39**).

Figure 39. Mixing and leaving to stand of control sample tubes.

d. Mix the control sample tubes again for 10–15 seconds with the vortex mixer.

e. Open the sample hatch, place the control sample tubes in the sample tube rack and close the sample hatch. The analyser begins to automatically process the control samples. The automatic pop-up reminder will close automatically when the control samples have been inserted to the testsystem.

Note! The dissolved control samples remain usable at room temperature for two hours.

Note! Controls prepared by other organisations than the manufacturer may not be technically suitable or optimal for the mariPOC® test system.

Safety! The positive control sample is potentially infectious so it must be handled and disposed of in the same way as clinical patient samples.

Reporting the Results:

The results for control samples are reported automatically in the same way as for clinical patient samples. When using mariPOC® RTI combi+ or combi test plates, the control sample results will be available for the all Respi+ or Respi and Pharyn test analytes. When using mariPOC® Quick combi+ or combi test plates, the control sample results will be available for the all Quick Flu+ or Quick Flu/RSV and Quick StrepA test analytes. When using mariPOC® Gastro CDI combi test plates, the control sample results will be available for the all Gastro and CDI test analytes.

The results for control samples are always reported in two time points regardless of the test plate type in use (preliminary results at 20 minutes and final results at 2 hours). The preliminary results for SARS-CoV-2 test plate's SARS-2 control samples are reported at 20 minutes and final results at 95 minutes. The results of the positive control sample analytes should all be positive at the preliminary results. The negative control sample should always give negative test results at the final result, however, at the preliminary result the results are not yet reported. It is recommended that the user observes the preliminary results for the control samples and reports any possible anomalies to customer support.

If the result given by the control sample is inconsistent with the control sample type (for example, the negative control sample gives a positive result) and the analysis was technically successful (OK), appears the Test status (Preliminary or Finished) in red in the measuring program's patient information list (see chapter "10 Possible Problem Situations and Potential Solutions" in the User's manual). If no result is reported for an analyte at the final results and "Failed" appears in the autoverification field, the test in question has failed for that analyte. The other analyses for this control sample have been technically successful if OK appears in the other autoverification fields.

The results of the control samples, their trends, and the functionality of the analyser can be followed in the "Control data" window that can be accessed from the "More options" drop-down menu. If there are several divergent results seen among the results, customer support should be contacted.

7.5 Running Out of Tests and Changing the Test Plate

The user can change the test plate at any time by selecting "Change test plate" in the "More options" drop-down menu. In this case, the results for unfinished samples will not be reported and the test status is changed to Finished. Otherwise the measuring program automatically guides the process of running out of tests and changing the test plate. When new samples have been inserted into the analyser, it automatically dispenses the samples to the test plate or prompts the user to change the test plate. If the user does not react to the measuring program's notification to change the test plate, the test system automatically continues to dispense samples after 5 minutes.

The user can monitor the number of remaining multianalyte tests from the top right corner of the measuring program. The user can monitor the valid test plates by selecting "List test plates" in the "More options" drop-down menu. In the new window, all test plates in use are listed and the test plate inside the analyser is highlighted. The listing includes product, lot and serial numbers, and the number of remaining tests and days to expiry for each plate.

The test plates must be stored in a special storage rack (**Figure 40**) if taken outside the analyser. If the test plate change notification is given after all final results have been reported, the user is able to change the test plate directly through the notification window. In combi plates where tests, e.g. Respi (or Quick Flu/RSV) and Pharyn (or Quick StrepA) or Gastro and CDI, are consumed independently, it is possible to continue using the test plate even if one of the test types has been used up. If the test plate is not changed and there is not enough tests left for all inserted samples, the test system begins to dispense all possible samples, typically from left to right. Remaining samples will stay as pending until the test plate has been changed.

Figure 40. Storage rack for the test plates and its use.

Deployment and Storage of the Test Plate

a.The mariPOC® Software will automatically prompt the user when the test plate is almost full, full, or out of date. Change the test plate from a notification on screen or at any time "Change test plate" in the "More options" drop-down menu. The measuring program will notify if any results would belost.

b.Openthetestplatehatchlocatedonthefrontsideoftheanalyserwhenthesignallightisgreen. Move the white button to the left to release the lock and simultaneously pull the plate carriage out (**Figure 42**). Remove the test plate from the analyser. Test plates in use must be stored in a specialstoragerack(**Figure40**)ordisposedofappropriately(seechapter"8 Cleaning and Waste Disposal").Thetestplatemustbeplaceddirectlytothestoragerackandpreferablyinsuchway that the bar code faces theuser.

c.Unused test plates should be stored in a refrigerator in their original foil bag. When taking out a new test plate for use, check that the test plate foil bag is undamaged. Cut the bag open with scissors.Removethetestplatefromthefoilbaggraspingitontheedgeswiththefingers(**Figure 41**). When removing the test plate from the storage rack, push the test plate to front from the gaponthebacksideoftherackandgraspitwiththefingersontheedges.Checkthattheplastic edges and the bottom of the test plate are undamaged. Avoid touching the bottom of the test plate. The test plate bottom should be dust free and unscratched. A test plate from a damaged bag or one that is broken or scratched must not beused.
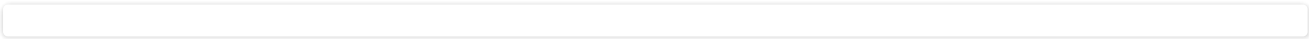
Figure 41. Removing the test plate from the foil bag.

d.

Placethetestplateatanangleintotheplatecarriage(backedgefirst,**Figure 42**).Notethatthe bar code side of the test plate faces up and the bar code label is on the right viewed from the front.Pushtheplatecarriageallthewaybackinsideandensurethattheplatecarriageislocked. Close the test platehatch.

Figure 42. Placing the test plate in the plate carriage.

Note! When the signal light is red the test plate hatch cannot be opened.

Note! The measuring program cannot read the bar code if the test plate hatch is still open or the test plate is placed in the plate carriage against the instructions.

e.The test system will recognize each test plate individually based on the bar code. The test plate is valid for 30 days from the opening of the foil bag and its insertion into theanalyser.

7.6 Changing and Emptying the Solution Containers

Monitoringoftheconsumptionofthetestsystem'sWashandSystemsolutionsandwastecontainer capacityisbasedonacalculationofthedispensingvolumes.Themeasuringprogramautomatically promptswhenasolutionbottleneedstobereplacedorthewastecontaineremptied.Itisofutmost importance that this measuring program notification is followed so that the solutions consumption levelcalculatorwillrecognizethecorrectsolutionlevels.Notfollowingthisnotificationwillresultin depletion of the Wash and/or System solution. This can cause the analysis to fail and/or result in erroneous results due to a failed wash. If the notification to empty is not followed, the waste container can become too full and overflow causing the fluid to flood inside the analyser. This may lead to analyser malfunction and contamination with potentially infectiouswaste.

Themeasuringprogramrememembersthecalculatedsolutionamounts,eveniftheanalyserhasbeen accidentallyswitchedoff.Accordingly,thesolutionamountsinthebottlesshouldnotbechanged.If needed,theWashandSystemsolutionbottlescanbereplacedandthe waste containeremptiedby using the "Maintenance wizard" accessed through the "More options" drop-down menu and selecting the desiredfunction.

a)**Emptying the waste container:** Always empty the waste container when notified by the

measuringprogram.Afterthenotification,themeasuringprogramgivesdetailedinstructionson how to empty the waste container. The waste container is located either on the left or the back of the analyser. The tube leading to the waste container is transparent and about 1 cm in diameter.Whenemptyingthewastecontainer,alwayswearprotectiveglovesbecauseitcontains both the System and Wash solution as well as patient samples. See safety data sheets for more information.

Detach the rapid-connect fitting coupled to the waste container by pressing the metallic coupling. Wipe off any solution potentially dripping out from the tube using disposable paper.

Becausethereisriskofbackflow,liftthewastecontaineronlyafterdetachingthetube.Because the cap has an air hole, do not tilt the waste container to avoid spills. Unscrew the cap, empty the waste container and discard the contents appropriately. Avoid spilling any fluid on clothing, skin,eyes,orothersurfaces.Thewastecontainermustnotbeautoclavedbutitcanberinsedor washedwithdetergent.Screwthecapbackonandreturnthewastecontainertotheleftsideor backoftheanalyser.Coupletherapid-connectfittingbypressingthemouthpiecefirmlyagainst its counterpart until there is a "clicking"sound.

b)**ReplacingtheWashsolutionbottle:**AlwaysreplacetheWashsolutionbottle(2L)whennotified bythemeasuringprogram.Followingthenotification,themeasuringprogramwillgivedetailed instructions on how to replace the Wash solution bottle. The Wash solution bottle is located on rightsideofthebackoftheanalysernexttothe Systemsolutionbottle.Thetubeleadingtothe Washsolutionbottleisyellowishandabout5mmindiameter.Whenchangingthebottle,always useprotectiveglovesbecausetheWashsolutionisveryalkaline.Seesafetydatasheetsformore information.

To facilitate work, the Wash solution bottle can be moved nearer to the table edge as far as the tubelengthallows.RemovetheouterandinnercapsofthenewWashsolutionbottle.Openthe capoftheemptyWashsolutionbottleandliftitoutofthebottlewithitstubeandsupporttrack. Becarefulnottoallowthecap(orthetubeattachedtoit)totouchanypotentiallydirtysurfaces. Lift the nearly empty bottle out, and replace it with a full Wash solution bottle. Place the cap (with its tube carefully in place) on the bottle and close the cap. The remaining Wash solution can be poured into the drain, taking into account the relevant legislation. Ensure that the label onthenewWashsolutionbottlecorrespondstothelabelonthereplacedWashsolutionbottle.

c)**Replacing the System solution bottle:** Always replace the System solution bottle (1 L) when notifiedbythemeasuringprogram.Afterthenotification,themeasuringprogramgivesdetailed instructions on how to replace the System solution bottle. The System solution bottle is located on the right side of the back of the analyser next to the Wash solution bottle. The tube leading totheWashsolutionbottleisyellowishandabout5mmindiameter.Whenchangingthebottle, useprotectiveglovesbecausetheSystemsolutioncontainssurface-activesubstancesandalow concentration (< 0.1%) of sodium azide. See safety data sheets for moreinformation.

Tofacilitatework,theSystemsolutionbottlecanbemovednearertothetableedgeasfarasthe tube length allows. Remove the outer and inner caps of the new System solution bottle. Open thecapoftheemptySystemsolutionbottleandliftitoutofthebottlewithitstubeandsupport rack. Be careful not to allow the cap (or the tube attached to it) to touch any potentially dirty surfaces.Liftthenearlyemptybottleout,andreplaceitwithafullSystem solutionbottle.Place the cap (with its tube carefully in place) on the bottle and close the cap. The remaining System solution can be poured into the drain taking into account the relevant legislation. Ensure that the label of the new System solution bottle corresponds to the label of the replaced solution bottle.

7.7 Creating Customer Support Report

In case of a test system malfunction, a request from customer support or for invoicing purposes a customer support report should be created. The short-cut icon for creating the report is located between print results button and "More options" drop-down menu. The measuring program gives detailed instructions on how to do it. ArcDiaReport zip-folder will be created to the computer's desktop. Transfer the ArcDiaReport from the desktop to a USB flash drive (USB ports can be found from the behind or the side of the computer). Note that the previous report will automatically be replacedbyanewoneonthedesktopbutnotontheUSBflashdrive.SendtheArcDiaReporttothe customer support as an emailattachment.

7.8 Switching the Analyser Off and On

Both the analyser and the measuring program must be kept switched on because of the automatic rinsing of the test system. If the test system will not be used for long period of time (i.e., more than one week), it can be shut down in a controlled manner. This is done by selecting "Shutdown analyser"fromthe"Maintenancewizard",whichisaccessedthroughthe"Moreoptions"drop-down menu of the mariPOC® Software. Follow the instructions. Remember to empty the waste container and change both the Wash and the System solution bottles with caps (and tubes) into water bottles pre-filled with deionized or distilled water. Finally, the program instructs the analyser to switch off viathepowerswitchonitsbackpanel(topleftcorner).Afterthat,themeasuringprogramprompts the user to click the "Finish" button. The measuring program will then close automatically. The test plate can then be changed or removed from the analyser. Next, the label printer, the computer and the analyser should also be switched off. When the test system is used again first switch on the analyser and then the computer and label printer. Open the measuring program from the short-cut icon on the desktop (**Figure 43**) and follow the on-screen instructions. Note that the water bottles must to be replaced with new Wash and System solution bottles. Empty and store the used water bottles until their nextuse.

Figure 43. Analyser short-cut icon.

The analyser must never be switched off without a controlled shutdown (Maintenance wizard: Shutdown analyser) unless there is a serious failure. Only then should the analyser be switched off fromthepowerswitchonthetopleftcornerofthebackpanel.Aseriousfailuresuchasanoverflow orasimilareventcoulddamagetheanalyser.Ifthereisaseriousfailure,donotrestarttheanalyser; instead contact customer support. In any other case, wait approximately for 5 seconds before switching the power on again. The mariPOC® Software will give an error notification about a connection break within 30 seconds of analyser restart. After the notification, the computer and measuring program can be closed and then reopened. The measuring program will start by double clicking the short-cut icon on the desktop (**Figure 43**). Note that this switch off procedure is to be used only in error situations and, accordingly, the measuring program will not usually prompt the user how to restart the analyser. Further, the solution bottles should not bereplaced.
Clearing the computer and measuring program's memory, or deleting patient information, can only be done by the manufacturer or its representative.

8 Cleaning and WasteDisposal
Cleaning
If surfaces get contaminated with respiratory sample or test System solutions, the cover of the analyser and other surfaces can be wiped with a cloth moistened with water or a mild cleaning solution. The cover and other surfaces can be disinfected with a disposable cloth moistened with 70% ethanol or similar when needed.
If surfaces get contaminated with stool sample, wipe the visible stain with disposable paper and clean the area first with a disposable paper moistened with detergent. Then clean the area with chlorinesolution(preferably1000ppm)becauseseveralfaecalpathogens(e.g.norovirus,*C.difficile* spores) tolerate cleaning with ethanol. For the final cleaning use water or/and 70% ethanol (or similar) to remove chlorine residues. Additionally Ultraviolet C (UV-C) light can beused.
If solution from e.g. sample tube or wash station has leaked inside the analyser, please contact the customer support. Visible stains in the analyser inside or cover can be cleaned as instructed above. This cleaning recommendation applies also to the other electric devices (e.g. vortex) unless otherwise stated in their User's manual. Liquids must not be sprayed directly inside or on the analyser or other electric devices.
Filtration unit rack, required when handling a stool sample, and test plate storage rack can be cleaned mechanically by brushing with a detergent solution. The rack can be disinfected with chlorine solution (e.g. 1000 ppm) and/or Ultraviolet C (UV-C) light. Remember to properly rinse the rackaftercleaningwithwateror/and70%ethanol(orsimilar).Pleasenote,thatbothrack'smaterial does not tolerate temperatures over 60°C such as in dishwasher orautoclave.

Waste Disposal
The plastic consumables used to carry out tests, such as used test plates, sampling swabs, swabs in transport tube, syringe, filter, Pasteur pipette, sample tubes and caps may contain infectious materials.Theymustbedisposedofappropriately.Anunusedtestplatecanbedisposedwithnormal waste. The foil bag is suitable for metal recycling. The used or expired RTI or Gastro sample buffer, SystemandWashsolutions,ExtractionsolutionBandthecontentsofthewastecontainerandwater bottles can be poured into the drain taking into account the local legislation and the precautions mentionedintheUser'smanualandsafetydatasheets.TheWashsolutionisdesignedtoinactivate microbes. However, the waste should be considered potentially infectious and safety precautions should be followed when disposing thewaste.
When disposing the used or expired Extraction solution A, take into account local legislation and the precautions for the disposal of sodium nitrite. Empty storage containers (except the waterbottles), unused plastic components, silica gel bags, and protective wraps can be disposed with normal waste or recycled according to their material. The manufacturer is responsible for the appropriate disposal of the analyser components.

9 Remarks
The patient's clinical information must be taken into account when interpreting the results. The diagnosisofthepatient'sdiseasemustalwaysbedonebyahealthcareprofessionalwithasufficient level of education. The function of the

test is to assist the professional making the diagnosis by providing limited information on the microbiological content of the sample. Those samples that give a negative result may be verified using gene amplification tests (e.g., PCR). This is recommended especially for critically ill patients, and it is advised that also positive results from such are verified using an independent method. Those samples that give positive test results can be further typed using, for example, gene amplification tests or immunodiagnostic tests. The methodological suitability of using a leftover sample from the mariPOC® test system in another test, and the stability of the sample, must be validated appropriately. For swab sampling, only the swabs defined in the **Table 7** must be used. The nasopharyngeal aspirate and stool sample must be untreated (i.e., native or naïve). Nasopharyngeal wash sample is not a preferred sample material. The results are reliable only if the sampling and pretreatment have been appropriate and the test is used in accordance with the instructions given in this User's manual. Correct and careful sampling is of utmost importance for test success. Swab and aspirate sampling for the detection of viral pathogens should be done during viremia within 6 days from the onset of symptoms, preferably within 5 days. Nasopharyngeal wash sampling should be done during viremia within 5 days from the onset of symptoms. Viral loads decrease over time and virus antigens are not usually detectable after 6 to 7 days from the onset of symptoms.

Samples should not be stored in any kind of transport or storage media or buffers. The preferred way of storing the sample is in their naïve form. Transport and storage media and buffers can affect adversely to the stability of the sample and the performance of the test.

The performance specifications stated by the manufacturer in terms of analytical and clinical sensitivity are valid for samples obtained using flocked swabs or by aspiration without saline. If the observed performance with nasopharyngeal wash samples does not match with the specifications of the manufacturer or the results reported in the literature, please use nasopharyngeal swabs and/or aspirates (no saline addition), which are primarily recommended by the manufacturer.

Recently administered oral rotavirus vaccine may give a positive result in the rotavirus test.

mariPOC® toxin A/B method of the CDI test cross-reacts with toxins produced by *C. sordellii*. Cross- reaction with *C. sordellii* toxins is a known property of the mariPOC® toxin A/B test and some other commercially available *C. difficile* toxin A/B tests. However, mariPOC® GDH test does not cross-react with *C. sordellii*. See chapters 6.2 and 10.3 for more information.

mariPOC® + measuring program is primarily intended for laboratories. Along with qualitative results, it provides quantitative information about the microbe levels in the sample (indicated in the measuring program's results column Ψ, psi). Mucosal samples are by their nature semi-quantitative at best with respect to microbial load in the tissue. Therefore, the results are subject to variability in sampling. Optionally, reporting of Ψ values can be selected out when the test system is installed.

The sensitivity and specificity stated by the manufacturer are derived from the default positive and negative results, which are based on the preset cutoffs. The default results should only be changed upon joint decision of the laboratory and medical doctor responsible of the patient. Such decision shall be based on other significant evidence, such as other laboratory, epidemiological, and/or clinical information to increase the accuracy of the test result. Otherwise accuracy will suffer.

Analyser is basic electromagnetic equipment (class A; CISPR 11:2009, 5:3). The system is intended to be used in light-industrial locations such as laboratories.

The computer used with the mariPOC® test system should not be connected to an information network without manufacturer's authorization. The computer can be connected to a mobile network temporarily if instructed by the manufacturer or manufacturer's representative e.g. when problem situations are solved via remote access.

If more than one test system is being used in the same department, care must be taken not to mix the test plates and the sample tubes between the test systems. The analyser identifies the sample tube by its bar code label and does not allow it to be reused: i.e., the used bar codes are both analyser and measuring program-specific. A sample tube bar code created by another test system will not be recognized and thus the sample will not be analysed. Additionally, one analyser will not identify test plates partially or completely used by another analyser, so that inserting the used test plate in another analyser will with high probability give wrong results.

The manufacturer has designed the test system so that cross-contamination from one sample or test to another is rare. Carelessness in sample pretreatment can, however, lead to cross-contamination and therefore the interpretation of results must be carefully reviewed in relation to the patient information.

Each test marked as RUO is intended for research use only. Results from such tests with RUO status should not be used for clinical diagnostics. The manufacturer or its representative provides separately more information about RUO tests.

10 Possible Problem Situations and Potential Solutions
10.1 When to Contact Customer Support
The test system malfunction is typically indicated with an error notification in the dialogue window. Contact customer support immediately if the fault diagnosis and repair instructions presented in the chapters below do not result in a

functioning test system. Examples of issues requiring immediate customer supportare:

The analyser, or the measuring program, isunresponsive.

Recurrent failedresults.

Unexpected results for the controlsamples.

A flooded washing station caused, for example by a flooding waste container or a blockage in the washing station or itstube.

A bent or detached dispensingneedle.

Faulty operation of the sample tube rack, the sample hatch, the plate carriage or the test plate hatch.

Abnormal sounds.

Foreign bodies inside theanalyser.

10.2 Problems when Using the Test System

Problem: The analyser does not respond to the commands given in the measuring program. The results are not completed.

Reason for the problem	Solution / Action
The connection between the computer and the analyser is disturbed or has disconnected.	Check that the analyser power is switched on and that the Ethernet cables between the analyser and the computer are connected. Make sure the Ethernet switch is turned on. Try to close the measuring program by clicking on the cross in the top right corner of the main window. If the measuring program closes, start it again from the short-cut icon on the desktop. If the problem persists, contact customer support.

Problem: The bar code reader does not recognize a sample tube.

Reason for the problem	Solution / Action
The sample tube bar code is the wrong way round or is at the wrong height, or the bar code label has been attached diagonally or crosswise, or is wrinkled.	Rotate the sample tube so that the patient's name is visible through the gap in the sample tube rack and then close the sample hatch. If this does not help, double-click the patient information line to open the "Patient information" window and print a new bar code label. Insert the sample tube into the sample tube rack gently to prevent it from getting stuck.
Please note message: "Too old sample tube at pos." (i.e., bar code has been printed over 24 hours ago), or Warning messages: "Already dispensed sample tube at pos." (i.e. the sample has already been dispensed) or "Unknown sample tube at pos." (i.e., the bar code label is not recognized.	Re-enter the patient information and print a new bar code label. The old bar code label may need to be detached. Make sure that the sample solution has not expired (storage instructions are found in chapter 7.3.2). If the sample has expired, a new sample should be taken from the patient. Insert the sample tube gently into the sample tube rack to prevent it from getting stuck.
The operation of the bar code reader or measuring program has slowed down or ended. The bar code reader is broken.	Contact customer support.

Problem: The analyser does not accept the control samples.

Reason for the problem	Solution / Action
The control sample has expired or its processing in the analyser has not begun within two (2) hours of reading the bar code.	Make sure that the control sample expiry has not passed. In the case that the control sample has been pending for more than two (2) hours, for example due to a test plate change, the measuring program will automatically reject it. Repeat the test using new control samples.

Problem: Analyser does not accept the positive control.

Reason for the problem	Solution / Action
Control samples were inserted into the analyser but the positive control was rejected (notification prompted). Negative control was analysed.	Analyse new control samples and make sure the package is for correct test plate: REF 1104MC for mariPOC® Respi+, mariPOC® Respi, mariPOC® RTI combi+, mariPOC® RTI combi, mariPOC® Quick combi+ and mariPOC® Quick combi test plates, REF 1204SC for mariPOC® SARS-CoV-2 test plate, REF 1104MC or 1124MC for mariPOC® Pharyn test plate and REF 2017MC for mariPOC® Gastro, CDI and Gastro CDI combi test plates. Contact customer support if the problem continues.
Control samples were inserted into the analyser but the positive control was rejected without a notification. Negative control was analysed.	Rotate the positive control tube so that the text is visible through the gap in the sample tube rack and then close the sample hatch. Contact customer support if the problem continues.

Problem: The sample hatch will not lock.

Reason for the problem	Solution / Action
A measurement is in progress.	Wait 30 seconds. The sample hatch should lock after the measurement is finished.
The sample hatch has not been closed properly.	Open the sample hatch slightly and close it again. Make sure that the sample hatch is fully closed. Contact customer support if the problem persists.

Problem: The System solution has run out.

Reason for the problem	Solution / Measure Solution / Action

The notification to change System solution bottle has been ignored. The test performance may have impeded by Wash solution residues.	Change the System solution bottle in accordance with the "Change system solution container" instruction found on the "Maintenance wizard", which can be opened from the drop-down menu "More options".

Problem: The Wash solution has run out.

Reason for the problem	Solution / Measure Solution / Action
The notification to change Wash solution bottle has been ignored. Possible cross-contamination between samples.	Change the Wash solution bottle in accordance with the "Change wash solution container" instruction found on the "Maintenance wizard", which can be opened from the drop-down menu "More options". Interpret the results with caution.

Problem: The use of Extraction solutions in the Pharyn or Quick StrepA test has been forgotten.

Reason for the problem	Solution / Action
Sample processing contrary to the instructions.	If the Streptococcus group A analysis gives a negative result, this should be reported with caution. If necessary, take a new patient sample and process it in accordance with the instructions. The Extraction solutions significantly enhance the analytic sensitivity of the group A streptococci analysis.

Problem: There is white powder or dirt on the dispensing needle or the top surface of the washing station.

Reason for the problem	Solution / Action
Some solution components, such as salt or washing agent, have dried.	Carefully rub the material with a swab moistened with purified water. Avoid bending the dispensing needle. If this does not help, contact customer support.

Problem: The bar code label does not get printed.

Reason for the problem	Solution / Action

The label tape has run out.	Change to a new label tape cartridge. If the bar code label does not print automatically after the repair measures, double-click the patient information line to reopen the "Patient information" window. The bar code label can be printed again, but the information entered cannot be changed.
The computer is not communicating with the label printer.	Check whether the label printer power is on (indicated by a green light is on the front) and that it is connected to the computer with a cable. Turn the label printer back on again. If the bar code label does not print automatically after the repair measures, double-click the patient information line to reopen the "Patient information" window. The bar code label can be printed again, but the information entered cannot be changed.
Error notification: "Label printer does not recognize the label tape".	Switch the label printer off and turn it back on again. If this does not help, try to put the label tape cartridge back in the printer. The bar code label can be printed again by double-clicking the patient information line to open the "Patient information" window.

10.3Problems with Results

Problem: The status of the analysis (Test status) is indicated in red text. One or more analysis has failed (i.e. no result is obtained and the text "Failed" appears after the analyte in the results).

Reason for the problem	Solution / Action

The total sample volume is too small (pretreatment has failed); the analyser cannot aspirate enough of the sample in the dispensing system.	**The solution level should be about halfway of the sample tube height.** Reanalyse the sample. Re-enter the patient information and print a new bar code label. Remove the old bar code before attaching the new one. Check that the adjusted volume in the bottletop dispenser is 1.3 ml. Make sure that the bottletop dispenser piston is lifted to the top position. **Throat swab sample:** Make sure that RTI sample buffer, in addition to Extraction solutions A and B, has been added to the sample. If RTI sample buffer has been forgotten, add 1.3 ml of RTI sample buffer with the bottletop dispenser. If there is RTI sample buffer in the sample tube, add approximately 0.5 ml of the RTI sample buffer to the sample tube, and vortex for 10–15 seconds. **Nasopharyngeal swab sample:** Make sure that RTI sample buffer has been added to the sample. If RTI sample buffer has been forgotten, add 1.3 ml of RTI sample buffer with the bottletop dispenser. If there is RTI sample buffer in the sample tube, add approximately 0.5 ml of the RTI sample buffer to the sample tube, and vortex for 10–15 seconds. **Aspirate sample:** Sample to be reanalysed after addition of RTI sample buffer must be vortexed for 10–15 seconds and centrifuged before inserting it into the analyser. **Stool sample:** For a failed stool sample repeat the sample pretreatment. Check that the stool sample (flocked swab) was diluted into two volumes of the Gastro sample buffer (2x 1.3 ml) and that the pretreated sample solution volume in the Gastro sample tube is at or above the volume mark pointed in the filtration unit rack. If there is no naïve sample left, re- filter the pretreated sample. Before re-filtering, add Gastro sample buffer (if needed) until the total sample volume is approximately 2.3 ml to ensure enough (1.3 ml) flow-through after the second filtration. However, please note that dilution may have a negative effect on the test sensitivity.

Reason for the problem	Solution / Action
Dispensing has failed. Difficult sample material or the filter in stool sample pretreatment was faulty.	The sample solution may be too viscous (mucous) or contain particular material. Reanalyse the sample. Re-enter the patient information and print a new bar code label. Remove the old bar code before attaching the new one. **Throat/nasopharyngeal swab sample:** Add approximately 1 ml of the RTI sample buffer to the failed sample, and vortex for 10–15 seconds. The solution level should be over 2/3 of the sample tube height. **Aspirate sample:** Sample to be reanalysed after addition of RTI sample buffer must be vortexed for 10–15 sec and centrifuged before inserting it into the analyser. **Stool Sample:** Check that the stool sample was pretreated (filtered) as instructed. Make the pretreatment again from the naïve stool sample if there is sample left. If there is no naïve sample left, re-filter the pretreated sample. Before re-filtering, add Gastro sample buffer (if needed) until the total sample volume is approximately 2.3 ml to ensure enough (1.3 ml) flow-through after the second filtration. However, please note that dilution may have a negative effect on the test sensitivity.
The dilution of the Pharyn or Quick StrepA test (done automatically on the test plate) has failed because the System solution has run out.	Change to a new System solution bottle immediately using the Maintenance wizard. The sample must be reanalysed. Re-enter the patient information and print a new bar code label. Remove the old bar code before attaching the new one. Addition of RTI sample buffer to sample tube is not needed. Insert the sample tube into the sample tube rack gently to prevent it from getting stuck. Vortex the sample tube for 10–15 seconds. The measuring program calculates consumption of System solution and will not work correctly if a user changes the bottle before a notification is given by the measuring program or if a notification is ignored.
Control samples were inserted to the analyser without addition of test specific sample buffer and vortexing.	Analyse a new set of control samples and make the pretreatment as instructed in chapter 7.4.

Problem: The results give a reason to suspect that the samples are cross-contaminated. For example, a negative control sample gives a positive result or a borderline result (+/-) in two or more consecutive control runs.

Reason for the problem	Solution / Action
The RTI sample buffer or the dispensing head of the bottletop dispenser is contaminated (cross-contamination).	Clean the outside of the bottletop dispenser by wiping with 70% ethanol or similar. Dispense 10 times into the drain to rinse the dispensing head. Change to a new RTI sample buffer bottle and dispense 10 times into the drain again. If required, the bottletop dispenser can be autoclaved by following the manufacturer's instructions. Remember to recalibrate the dispenser after autoclaving.
The Gastro sample buffer or the dispensing head of the bottletop dispenser is contaminated (cross- contamination suspicion).	Clean the outside of the bottletop dispenser by wiping the visible stain with disposable paper and then with disposable paper moistened with detergent. Then clean the outside with chlorine solution (preferably 1000 ppm) because several faecal pathogens (e.g. norovirus, *C. difficile* spores) tolerate cleaning with ethanol. For the final cleaning use water or/and 70% ethanol (or similar) to remove chlorine residues from the dispensing head. Dispense 10 times into the drain to rinse the dispensing head. Additionally, Ultraviolet C (UV-C) light or autoclave can be used. Remember to follow the manufacturer's instructions and recalibrate the dispenser after autoclaving. Change to a new Gastro sample buffer bottle and dispense 10 times into the drain.
Between samples, the scissors have not been adequately cleaned.	Check the procedure for cleaning the scissors. Clean the scissors carefully between samples using 70% ethanol or similar and then wiping them with disposable paper.
The Wash solution has run out.	Change a new Wash solution bottle immediately. Select "Change wash solution container" from the "Maintenance wizard" that can be opened from the drop-down menu "More options". Interpret the results with caution. The measuring program calculates consumption of Wash solution and will not work correctly if a user changes the bottle before a notification is given by the measuring program or if a notification is ignored.

Problem: The result for a negative control sample is reported with a borderline symbol +/-.

Reason for the problem	Solution / Action

The analysis signal of negative samples or negative controls can occasionally be close to the cut off due to statistical reasons. Nevertheless, borderline result is lower than the clinical cut off set by the manufacturer for reporting of positive findings.	Result for a negative control with a borderline symbol (+/-) should be considered by default as negative.

Problem: The result for a positive control sample is negative.

Reason for the problem	Solution / Action
The test reagents or the control sample have been spoiled or the control sample treatment instructions, for example mixing and/or settling, have not been followed.	Make sure that the test plate or the control sample have not been stored contrary to the instructions and that the control sample pretreatment length has been in accordance with the instructions. The control sample must not be treated with the Extraction solutions intended for the Pharyn and Quick StrepA test methods. Repeat the test using a new control sample. If the negative result recurs, contact customer support.

Problem: 3 or more positive virus results from a single patient sample.

Reason for the problem	Solution / Action

HAMA (human anti-mouse antibody) response or other interfering agent causes unspecific binding in the antigen detection reaction. There are multiple pathogens (e.g. sewer water based illness).	Consider the results with caution and compare the results to existing clinical and epidemiological data. **Throat/nasopharyngeal swab sample:** If possible, resample the patient. Reanalysing the respiratory sample can reduce the amount of interference and increase the reliability of analysis. However, there is a risk that some false positives still remain and this complicates the use of the result in clinical decision-making. If you decide to reanalyse the sample, add approximately 1 ml of the RTI sample buffer to the failed sample, and vortex for 10–15 seconds. The solution level should be about 2/3 of the sample tube height. Re-enter the patient information and print a new bar code label. Remove the old bar code before attaching the new one. **Aspirate sample:** Sample to be reanalysed after addition of RTI sample buffer must be vortexed for 10–15 sec and centrifuged before inserting it into the analyser. **Stool sample:** Repeat the sample pretreatment or resample the patient if possible. Reanalysing the stool sample after freeze-thaw treatment may reduce the amount of interference and increase the reliability of analysis. However, there is a possibility that some false positives still remain and this complicates the use of the result in clinical decision-making. Consider using other methods to confirm the results. Note, however, that the interfering agent may also affect the reliability of other methods.

Problem: *C. difficile* GDH test gives a negative while Toxin A/B test gives a positive result.

Reason for the problem	Solution / Action

C. difficile GDH negative but Toxin A/B positive result might have been caused by cross-reaction with *C. sordellii* toxins.	Negative GDH but positive toxin A/B result should be considered invalid by default. Make the pretreatment again from the naïve stool sample if there is sample left. If there is no naïve sample left, re-filter the pretreated sample. Before re-filtering, add Gastro sample buffer (if needed) until the total sample volume is approximately 2.3 ml to ensure enough (1.3 ml) flow-through after the second filtration. However, please note that dilution may have a significant effect on the test sensitivity. Cross-reaction with *C. sordellii* toxins is a known property of the mariPOC® Toxin A/B test and some other commercially available *C. difficile* toxin tests. *C. sordellii* toxins are homologous to toxins produced by *C. difficile*. *C. sordellii* is a pathogen with clinical relevance. Therefore, if the results persist after re-analysis, *C. sordellii* should be suspected and further tested with other methods.

Problem: Not enough sample solution in the Gastro/CDI sample tube after filtration.

Reason for the problem	Solution / Action
Too little Gastro sample buffer was used to suspend the sample, filter was blocked, there was too much of stool in the swab or the stool was too firm.	Make the pretreatment again from the naïve stool sample if there is sample left. Pay attention to the Gastro sample buffer amount. If the sample volume is still not sufficient (≥1.3 ml) after filtration, combine the two pretreated samples. If there is no naïve sample left, re-filter the pretreated sample. Add Gastro sample buffer until the total sample volume is approximately 2.3 ml to ensure enough (1.3 ml) flow-through after the second filtration. However, please note that dilution may have a significant effect on the test sensitivity.

Problem: There is a red exclamation mark (!) next to the negative result.

Reason for the problem	Solution / Action
A positive preliminary result was changed into a negative result in the final analysis. Incorrect positive preliminary result may be due to an interfering substance present in the sample. The substance is most often inactivated during the incubation.	Report the result as a negative finding. The final result is more specific than the rapid preliminary result.

11 Test System Technical Data

Analyser

Dimensions: 41 x 50 x 41cm

Weight: 32kg

Serial and type numbers: see the type plate located on the backside theanalyser

Voltage: mains electricity supply 100–230 V, 50–60Hz

Input power: 25W

Accessories (application dependent): mariPOC® Software (ArcDiagnoser^{TM} measuring program), Ethernet switch and cables, power supply, computer with display, keyboard, mouse, label printer, label tape cartridge, bottletop dispenser with stand, vortex mixer, sample tube rack, sample tube box, sample tube cap box, filtration unit rack, test plate storage rack, User's manual, rapid instructions and safety datasheets

Plastic consumables (application dependent): sample tube, sample tube cap, swab in transport tube, syringe, filter and Pasteurpipette

Chemical Composition

Test plates: pathogen specific biochemical reagents (immunoglobulins) and buffercomponents (under 0.1% NaN3) dried on a test plate and coveredhermetically

Negative control samples: no notifiable chemicalcomponents

Positivecontrolsamples:inactivatedandpossiblyinfectiousviralandbacterialpreparations, recombinant proteins and buffer components (under 0.1% NaN3)

RTI sample buffer: buffer components, surface active agents, bovine serum albumin (BSA) and NaN3 (under0.1%)

Gastrosamplebuffer:buffercomponents,surfaceactiveagents,bovineserumalbumin(BSA) and NaN3 (under0.1%)

Wash solution: alkaline (pH 12) non-foaming washsolution

System solution: buffer components, surface active agents and NaN3 (under0.1%)

ExtractionsolutionA:sodiumnitrite(Warning:AcuteTox.4,Harmfulifswallowed.European Regulation (EC) No1272/2008)

Extraction solution B: buffer components, acidicsolution

For more information about chemical composition, H-statements and R-phrases, please see the safety data sheets (SDS).

12 Symbols Description

Figure 44. Description of the symbols in the User's manual and on labels.

13Warranty

The mariPOC® test system has a 12 month warranty. The warranty begins when installation is accepted by the User. The warranty does not cover damage caused by use contrary to the Manufacturer's instructions.

The warranty on the test's consumables only covers defects in manufacture process and damage during transportation. The Manufacturer guarantees the reliability of the tests until their use-by date,whichisstatedonpackage.TheUserisresponsibleforstoringeachcomponentinthecondition defined in the User'smanual.

Repairs, adjustments and other changes to the test system may only be performed by persons authorized by ArcDia International Oy Ltd. If you suspect that the test system is faulty contact the aforementioned entities immediately.

14Literature

Prospective Evaluation of the mariPOC® Test for the Detection of *Clostridioides difficile* GDH and Toxins A/B. Savolainen R, et al. J Clin Microbiol. (2019) 58(4). DOI: 10.1128/JCM.01872-19.

Evaluation of a Gastrointestinal Pathogen Panel Immunoassay in Stool Testing of Patients with Suspected *Clostridioides (Clostridium) difficile* Infection. Krutova M, et al. J Clin Microbiol. (2019) 57(10). DOI: 10.1128/JCM.00710-19.

Prospective evaluation of a new mariPOC respitest with improved sensitivity for influenza A virus. Thomas E, et al. 29th European Congress of Clinical Microbiology and Infectious Diseases 2019, Amsterdam, the Netherlands. Abstract #2977 and poster #P0114.

Microbial identification from feces and urine in one step by two-photon excitation assay technique. Koskinen, JM, et al. J Immunol Methods. (2018) 460:113-118.

Rapid detection and monitoring of human coronavirus infections. Bruning AH, et al. New Microbes New Infect. (2018) 24:52-55.

mariCloud™ on-line service for real-time and global epidemiological surveillance of acute infections. Koskinen JO, et al. International scientific WHO conference "Trends in influenza research" 2017, St. Petersburg, Russia. Plenary lecture. Abstract p. 26-27.

New QuickStrep A test of automated mariPOC® system provides culture sensitivity in 15 minutes. Antikainen P, et al. 34th annual meeting of NSCMID 2017, Tórshavn, Faroe Islands, Denmark. Abstract and poster #PP02.36.

Novel automated mariPOC® test for Clostridium difficile infection realises the updated ESCMID diagnostic guideline. Mäkilä J, et al. 27th European Congress of Clinical Microbiology and Infectious Diseases 2017, Vienna, Austria. Abstract #984 and poster #EV0169.

Automated mariPOC® platform enables highly sensitive and rapid antigen detection and subtyping of influenza viruses. Antikainen P, et al. International scientific WHO conference "Trends in Influenza Research 2017", St. Petersburg, Russia. Abstract O23, p. 71-73 and oral presentation.

Comprehensive Real-Time Epidemiological Data from Respiratory Infections in Finland Between 2010 and 2014 Obtained from an Automated and Multianalyte mariPOC® Respiratory Pathogen Test. Gunell M, et al. Eur J Clin Microbiol Infect Dis. (2016) 35(3):405-13.

Detection and monitoring of Human Bocavirus 1 infection by a new rapid antigen test. Bruning AH, et al. New Microbes New Infect. (2016) 11:17-9.

Comparison of mariPOC® gastro, a new multianalyte test for acute gastroenteritis, and five norovirus lateral flow tests. Koskinen JM, et al. 26th European Congress of Clinical Microbiology and Infectious Diseases 2016, Amsterdam, the Netherlands. Abstract and poster #EVLB60.

European Society of Clinical Microbiology and Infectious Diseases: update of the diagnostic guidance document for Clostridium difficile infection. Crobach MJT, et al. Clin Microbiol Infect. (2016) Suppl 4S:63-81.

Analytical performance of the automated multianalyte point-of-care mariPOC® for the detection of respiratory viruses. Sanbonmatsu-Gámez S, et al. Diagn Microbiol Infect Dis. (2015) 83(3):252-256.

Detection of Group A Streptococcus from Pharyngeal Swab Samples by Bacterial Culture is Challenged by a Novel mariPOC Point-of-Care Test. Vakkila J, et al. J Clin Microbiol. (2015) 53(7):2079-83.

Evaluation of the Automated Multianalyte Point-of-Care mariPOC® Test for the Detection of Influenza A Virus and Respiratory Syncytial Virus. Tuuminen T, et al. J. Med. Virol. (2013) 85(9):1598-1601.

Identification of Respiratory Viruses with a Novel Point-of-Care Multianalyte Antigen Detection Test in Children with Acute Respiratory Tract Infection. Ivaska L, et al. J Clin Virol. (2013) 57(2):136-140.

No Cross-Reactions Detected by mariPOC® Group A Streptococci Antigen Test with Streptococcus anginosus. Antikainen P, et al. GAS Infections 2013, Rome, Italy. Abstract and poster.

Performance Evaluation of Multianalyte mariPOC® Respiratory Infection Test for Adenovirus Types 1-8, 14, 19 and 21. Koskinen JO, et al. 22nd European Congress of Clinical Microbiology and Infectious Diseases 2012, London, UK. Abstract.

Rapid Method for Detection of Influenza A and B Virus Antigens by Use of a Two-Photon Excitation Assay Technique and Dry-Chemistry Reagents. Koskinen JO, et al. J Clin Microbiol. (2007) 45(11): 3581-8.

A New Microvolume Technique for Bioaffinity Assays Using Two-Photon Excitation. Hänninen P, et al. Nat Biotechnol. (2000) 18(5):548-50.

15 Manufacturer's Contact Details

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