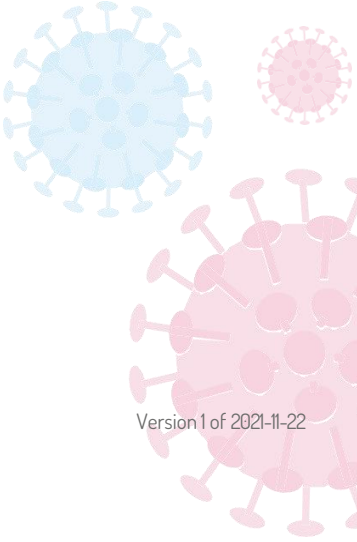
GENEME

SAVD+
by GENEME

SARS-CoV-2
Detection KIT

IFU – Instructions for Use



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Purpose and description

The SAVD+ by GeneMe is a SARS-CoV-2 direct rapid RT-PCR test designed for the rapid and accurate *in vitro* identification of two genes of SARS-CoV-2 coronavirus and human gene as internal control in a single reaction. The presence of the innovative and patented *Taq* polymerase and specific primers and probes made it possible to create a highly specific and sensitive test. The individually designed primers are 100% compatible with the SARS-CoV-2 genomic RNA sequence of the *ORF1ab* and *N* gene as deposited in the NCBI database and *human RNase P gene*. Amplification of target nucleic acids is observed by increasing the fluorescence signal during the reaction.

SAVD+ is compatible with the GeneMe Sample Collection Kits (CoVi19 TEST Sample Collection Kit and CoVi19 TEST Saliva Collection Kit). The kits vary depending on the sample being analyzed – throat swab, nasopharyngeal swab or saliva sample (see below).

Please read this manual carefully before performing the test.

SAVD+ Detection Kit components

ITEM	QUANTITY	STORAGE CONDITIONS
8-well SAVD+ Strip (with freeze-dried reagents)	4 pieces	+ 5 to + 12°C
Positive Control Tube	4 pieces	+ 5 to + 12°C
Control Buffer Tube	4 pieces	+ 5 to + 24°C
Normalization Buffer Tube	32 pieces	+ 5 to + 24°C

CoVi19 TEST Sample Collection Kit components (packed individually and delivered on request with SAVD+ Detection Kit)

ITEM	QUANTITY	STORAGE CONDITIONS
Single use Sterile Swab (throat or nasopharyngeal)	1 piece	+ 2 to + 30°C
Sample Collection Buffer Tube	1 piece	+ 5 to + 24°C

CoVi19 TEST Saliva Collection Kit components
(packed individually and delivered on request with SAVD+ Detection Kit)

ITEM	QUANTITY	STORAGE CONDITIONS
Sterile Funnel	1 piece	+ 5 to + 24°C
Sterile Collection Tube	1 piece	+ 5 to + 24°C
Sterile Saline	1 piece	+ 5 to + 24°C
Sample Collection Buffer Tube	1 piece	+ 5 to + 24°C

Additional storage information: The product should be kept in a dry place and hidden from direct sunlight.

Expiration date

8-well SAVD+ Strip - 6 months from the production date
Positive Control Tube - 6 months from the production date
Control Buffer Tube - 6 months from the production date
Normalization Buffer Tube - 6 months from the production date

Sterile Swab - 3 years from the production date
Sample Collection Buffer Tube - 6 months from the production date

Sterile Funnel - 3 years from the production date
Sterile Collection Tube - 3 years from the production date
Sterile Saline – 3 years from the production date
Sample Collection Buffer Tube – 6 months from the production date

General information

When pure SARS-CoV-2 RNA is used as a template in the above test it is very important to use RNase-free tools and reagents. In addition, it is recommended that the analysis is performed in nuclease-free areas and that only pipettes with filter tips are used. The SAVD+ test cannot be used as a method of analyzing SARS-CoV-2 virus directly collected from a cell line.

It is the distributor's and/or professional user responsibility to carry out an appropriate validation process for any component not indicated in this IFU, e.g., thermocycler, swabs, buffers, etc.

Kit compatibility with thermocyclers

PRODUCT / PARAMETER	SAVD+	
THERMOCYCLERS	BIORAD CFX96TOUCH	BIORAD CFXOPUS 96
SOFTWARE SUPPORT	CFX MaestroSoftware	CFX MaestroSoftware
OPERATING SYSTEM	Windows 7 (64-bit) Windows 10 (64-bit) macOS Mojave 10.14(for analysis only)	Windows 10 IoT
TYPE OF THERMOCYCLER	Real-time PCR	Real-time PCR
NUMBER OFCHANNELS	6	6
RANGE OF EXCITATION/ EMISSION WAVELENGTHS	450-730 nm	450-730 nm
FLUORESCENCE DYE	FAM/HEX/ Texas Red	FAM/HEX/ Texas Red
TAGGED GENES	ORF1ab/N/RP	ORF1ab/N/RP
RNA EXTRACTION REQUIRED	No	No
LOD (LIMIT OFDETECTION)	200 copies/mL	200 copies/mL

Please note that SAVD+ Detection Kit is validated on specific thermocyclers. If you are not using hardware listed above, make sure you validate the product on your own hardware to compare the results with the manufacturer's results (according to the IFU guideline).

Before you start

Required equipment

- Thermocycler
- Vortex mixer
- 8-well mini-centrifuge
- Single-channel adjustable volume pipette (required volume range: 10 - 50 µl) or single-channel fixed volume pipette 50 µl (direct samples only)
- Pipette tips with filters

Samples

The following procedure do not cover collecting the samples. Please prepare throat swab, nasopharyngeal swab, or saliva samples before, by using the instructions in the respective Sample Collection Kit. It is recommended to store the samples refrigerated (+4°C to +8°C). SAVD+ Detection Kit can be used both with *direct samples* and with *isolated RNA samples*. ***Make sure you are following the appropriate procedure for the type of sample.***

Prepare your workplace

- Remember to dress properly before performing the test. It is mandatory to wear closed-toe shoes, long pants which fully covers the legs. Hair and shoes shall be covered with the cap. It is necessary to wear a laboratory coat, face mask and gloves.
- Make sure your table, pipette and fresh gloves are sterile. Use appropriate disinfectants and paper towels. It is important that the workplace is dry before starting work.
- If possible, separate the workstation for working with the tests and samples from the workstation of the thermocycler and analysis of the results to prevent the spread of contamination.

Plan your work

- Determine the quantity of samples tested during a single run of thermocycler.
- Determine the appropriate number of SAVD+ Detection Kits you need. It is recommended to use ONE LOT for the entire run (each SAVD+ Detection Kit box has a LOT number assigned at the back).
- It is mandatory to use one positive and one negative control for each LOT used in a single run. ***Take this into account when calculating the number of samples and***

kits needed.

- Plan the positions of negative and positive controls in the thermocycler. These positions can be specified according to user's preference under the condition that the following rules are applied:

    1. There should be at least one negative and one positive control in each run of a thermocycler.
    2. If more than one LOT of SAVD+ Detection Kit is used in a single run – it is mandatory to use ONE positive and ONE negative control for each LOT used in a run.
    3. It is mandatory to follow the order when using the SAVD+ Detection Kit:
        a. preparation of all negative controls,
        b. preparation of all samples,
        c. preparation of all positive controls.

        Having this in mind it is recommended to use the first well of the first strip from a single LOT for negative control and the last well of the last strip of a single LOT for positive control. All remaining wells should be used for samples.

Precautions

- Holding the strips in your hand may reduce the sensitivity of the test.
- Avoid removing the strips from the rack whenever possible.
- **Make sure you <u>do not touch</u> anything with your bare hands.**
- If you have any doubts – please read this SAVD+ Detection Kit IFU again.

Procedure

Negative control wells preparation

1. Open SAVD+ Detection Kit box. Take the rack from the main box. Place one SAVD+ 8-well Strip in the rack.
2. Open the well that you intended for a negative control when planning work (please see *Before you start – Planning your work* section).

3. Open the Control Buffer Tube. Transfer 50 µl of Control Buffer to the open well. Do this by using a fresh sterile tip on an automatic pipette. **Pipette 5 times.**
4. Close the well and the tube.
5. **Repeat steps 1-4 for each negative control.**

Sample wells preparation

*NOTE: If you are working with **isolated RNA samples** continue with step **6.** If you are working with **direct samples** skip steps **6-13** and continue with step **14.***

Isolated RNA samples

6. Put your sample tubes (isolated RNA) on the table.
7. Open the first available well that you intended for a sample.
8. Open the Normalization Buffer Tube (these are the slightly larger tubes on the top row on the rack). Number on the rack should match the number of the first available well intended for sample (e.g., 1 match 1, 2 match 2 and so on).
9. Transfer 40 µl of normalization buffer to the open well. Do this by using a fresh sterile tip on an automatic pipette. **Pipette 5 times.**
10. Open the sample tube. Transfer 10 µl of the isolated RNA to the open well. Do this by using a fresh sterile tip on an automatic pipette.
11. Close the well and both tubes.
12. **Repeat steps 6-11 for each sample.**
13. When all sample wells are ready continue with step **24.**

Direct samples

14. Put your sample tubes (direct samples) on the table.
15. Open the Normalization Buffer Tube (these are the slightly larger tubes on the top row on the rack). Number on the rack should match the number of the first available well intended for sample (e.g., 1 match 1, 2 match 2 and so on).
16. Mix sample in the sample tube by rotating 5 times.
17. Open the sample tube. Transfer 50 µl of the mixture to the open Normalization Buffer Tube. Do this by using a fresh sterile tip on an automatic pipette. **Pipette 5 times.**

18. Close both tubes.
19. **Repeat steps 14-18 for each sample.**
20. Open the first available well that you intended for a sample.
21. Open the matching Normalization Buffer Tube. Transfer 50 µl of normalized sample to the open well. Do this by using a fresh sterile tip on an automatic pipette. **Pipette 5 times.**
22. Close the well and the tube.
23. **Repeat steps 20-22 for each normalized sample.**

Positive control wells preparation

24. Place one Positive Control Tube in the designated place in the rack.
25. Open the well (SAVD+ 8-well Strip) that you intended for a positive control.
26. Open the matching Normalization Buffer Tube.
27. Open the Positive Control Tube. Transfer 50 µl of Normalization Buffer to the Positive Control Tube. Do this by using a fresh sterile tip on an automatic pipette.
28. Transfer 50 µl of the mixture from the Positive Control Tube to the open well (SAVD+ 8-well Strip). **Pipette 5 times.**
29. Close the well and the tubes.
30. **Repeat steps 24-29 for each positive control.**
31. Change the gloves before moving to the next step.

Preparing the PCR reaction

32. After all SAVD+ 8-well Strips have been prepared, leave the strips at room temperature for about 3 minutes.
33. Take the prepared SAVD+ 8-well Strip in your hand avoiding holding the bottom part filled with liquid. Attach the SAVD+ 8-well Strip to the running vortex while moving the strip over so that each well in turn touches the vibrating element and the liquid is completely mixed. Put the strip back to the rack. Repeat this step for each strip.
34. Transfer the prepared strips to the 8-well mini-centrifuge and centrifuge for a few seconds until all the liquid is on the bottom of the wells and the air bubbles are gone.

Repeat this step for each strip.

35. Place the SAVD+ 8-well Strips into the thermocycler, one by one (in the correct orientation according to the sample settings in the thermocycler software).

36. Set the temperature and time profile on the thermocycler (or use the thermocycler software on the PC), including settings for the fluorescence measurement.

37. Close the thermocycler and run the amplification program.

NOTE: If the preparation time of the SAVD+ test from flooding the first SAVD+ Strip well to insertion into the thermocycler is longer than 30 minutes, store the prepared SAVD+ 8-well Strips at +4°C to +8°C. Maximum refrigerated storage time is 3 hours. Failure to comply with these guidelines will reduce the sensitivity of the SAVD+ test.

Amplification profile

The given profile has been validated on the BIO-RAD CFX96 RT-PCR machine. For other devices, further validation must be carried out. The reading should be set as for the FAM channel (maximum absorption 498 nm and maximum emission 522 nm), HEX channel (maximum absorption 538 nm and maximum emission 554 nm) and Texas Red channel (maximum absorption 586 nm and maximum emission 603 nm) after each cycle.

BioRad CFX96

TEMPERATURE	TIME	RAMP	CYCLES
50°C	3 min	Default	1
95°C	30 s	Default	1
95°C	3 s	Default	35 #
58°C	15 s*	Default	

* Fluorescence reading

User can extend the quantity of cycles as necessary.

Interpretation of the results

Correct test procedure and interpretation of the results are only possible if appropriate control signals are obtained from the reaction.

When analyzing SAVD+ data, please use the following decision matrix below:

Interpretation of the controls:

Channel	NEGATIVE CONTROL	POSITIVE CONTROL	INTERPRETATION
FAM	NO SIGNAL Cq undetermined	Cq < 25	VALID
HEX	NO SIGNAL Cq undetermined	Cq < 25	
TxRed	NO SIGNAL Cq undetermined	Cq < 35	

Interpretation of the tested samples:

Channel	Sample	INTERPRETATION
FAM	Cq undetermined	NEGATIVE
HEX	Cq undetermined	
TxRed	Cq < 35	
FAM	Cq < 35	POSITIVE
HEX	Cq < 35	
TxRed	Cq undetermined or Cq < 35	
FAM	Cq undetermined	UNDIAGNOSTIC (poor swab quality)
HEX	Cq undetermined	
TxRed	Cq undetermined	
FAM	Cq < 35	Inconclusive[1]
HEX	Cq undetermined	
TxRed	Cq undetermined or Cq < 35	
FAM	Cq undetermined	Inconclusive[2]
HEX	Cq < 35	
TxRed	Cq undetermined or Cq < 35	

[1] it is recommended to repeat the test on the same sample

[2] patient's sample should be collected again after 24 h / possible development of infection in the next few days

General information and precautions

1. For *in vitro* Diagnostic Use (IVD).
2. Follow standard infection control precautions. All patients' samples and positive

controls should be considered as potentially infectious and treated appropriately using safe infection control procedures.

3. Do not eat, drink, smoke, use cosmetics or touch contact lenses in areas where reagents are present and human samples are handled.

4. Samples should be processed in accordance with national and local biosafety regulations.

5. If SARS-CoV-2 infection is suspected based on current clinical and epidemiological test criteria, samples should be collected using appropriate infection control measures.

6. The analytical performance characteristics were determined on laboratory RNA samples of SARS-CoV-2 virus and on samples of the upper and lower respiratory tract (as per FDA recommended panel).

Limitations

1. All users, analysts and anyone reporting diagnostic results should be trained to perform this procedure by a competent instructor. They should be able to independently perform and interpret the result before performing the test.

2. SAVD+ is compatible with the GeneMe Sample Collection Kits (CoVi19 TEST Sample Collection Kit and CoVi19 TEST Saliva Collection Kit). The kits vary depending on the sample being analyzed – throat swab, nasopharyngeal swab or saliva sample.

3. Clinical SAVD+ test performance was determined based on SARS-CoV-2 RNA laboratory samples and clinical samples of upper and lower respiratory tract samples (such as nasopharyngeal or oropharyngeal swabs).

4. Negative results do not exclude the possibility of SARS-CoV-2 infection and should not be used as the sole basis for treatment or other clinical decisions. Time to reach the maximum viral load during infection due to SARS-CoV-2 has not been established. It may be necessary to collect multiple samples (types and time points) from the same patient to detect the virus.

5. A false-negative results may occur if the sample is incorrectly collected, transported, or processed. False-negative results can also occur if amplification inhibitors are present in the sample or if there are not enough virus RNA molecules in the sample. Positive and negative predictive values are strongly dependent on disease. False-negative test results are more likely to occur when the morbidity is high. False-positive test results are more likely when the incidence is moderate or low.

6. Do not use any reagents or test components beyond their expiration date.
7. If the virus mutates in the target region, SARS-CoV-2 may not be detected. Inhibitors or other types of interference may give a false-negative results. The effects of commonly prescribed drugs have not been studied.
8. The impact of the epidemiology and clinical spectrum of SARS-CoV-2 infections is not fully known. For example, HCPs and laboratories may not know the optimal types of samples to collect, and when infected, these samples most likely contain viral RNA levels that are easiest to detect.
9. GeneMe did not independently evaluate the stability of the fresh and frozen samples. GeneMe followed the standard practices recommended by the World Health Organization (WHO).
10. GeneMe did not test for interfering substances. GeneMe do not anticipate the intervention of commonly used endogenous substances. No interference testing has been performed with this test but cannot be excluded.
11. GeneMe independently assessed the sensitivity and specificity in- silico and adopted the World Health Organization (WHO) assessment.
12. Patients should not drink, eat or smoke for at least 30 minutes prior to taking the sample.
13. Check the turbidity and viscosity of the swab sample before processing. Turbid and viscous samples can affect the fluorescence and therefore the results. For very turbid samples, we recommend diluting swabs x10, x100 and x1000 before proceeding with the SAVD+ test. However, this action will also lower the Limit of Detection of SAVD+.

Performance characteristics

1. Limit of Detection (LOD)

Dilution series of well-known SARS-CoV-2 RNA concentration were performed and tested with SAVD+. The study showed analytical LOD on purified SARS-CoV-2 RNA of approximately 200 copies of SARS-CoV-2 per millilitre.

2. Cross-reactivity

The SAVD+ test was used to isolate and test organisms (bacteria, viruses) usually living in the respiratory system. Cross-reactivity with any of the pathogens tested was not observed. The pathogens tested are listed in Table 1, and the amplification curves for selected pathogens are shown in Figure 1.

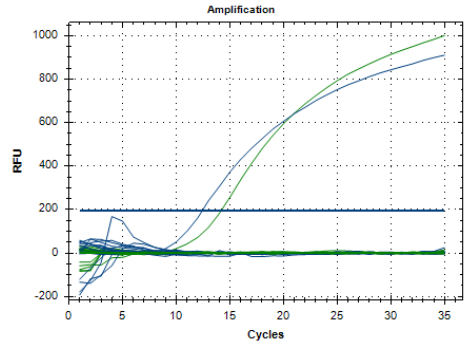

Figure 1. Amplification curves for SARS-CoV-2 (growing curve) and other Coronaviruses (flat lines).

NO.	SAMPLE	CQ	TIME [MINUTES]
1.	SARS-CoV-2	12.4	13.6
2.	Human Coronavirus NL63	NOT DETECTED	NOT DETECTED
3.	Human Coronavirus 283E	NOT DETECTED	NOT DETECTED
4.	Human Coronavirus OC43	NOT DETECTED	NOT DETECTED
5.	Human Coronavirus 223E	NOT DETECTED	NOT DETECTED
6.	Human Coronavirus 229E	NOT DETECTED	NOT DETECTED
7.	*Streptococcus pyogenes* ATCC 19615	NOT DETECTED	NOT DETECTED
8.	*Haemophilus influenzae* ATCC 33391	NOT DETECTED	NOT DETECTED
9.	*Bordetella parapertussis* ATCC 15311	NOT DETECTED	NOT DETECTED
10.	Klebsiella pneumoniae ATCC 13883	NOT DETECTED	NOT DETECTED
11.	*Staphylococcus aureus* ATCC 12600	NOT DETECTED	NOT DETECTED
12.	*Pseudomonas aeruginosa* ATCC 10145	NOT DETECTED	NOT DETECTED
13.	Respiratory Syncytial virus ATCC VR-1540	NOT DETECTED	NOT DETECTED
14.	Epstein-Barr Virus	NOT DETECTED	NOT DETECTED

15.	Rhinovirus ATCC VR 283	NOT DETECTED	NOT DETECTED
16.	Influenza A H1N1 A/Virginia/ATCC/2009.	NOT DETECTED	NOT DETECTED

Table 1. The list of tested pathogens for potential cross-reactivity.

3. *In-silico* specificity of primers

GeneMe performed oligonucleotide primer alignment for the upper airway panel in accordance with FDA EUA recommendations and all publicly available SARS-CoV-2 sequences (as of January 13, 2021). All matches showed 100% identity with the available SARS-CoV-2 sequences and no significant match with the sequences of other upper respiratory pathogens.

4. Clinical Efficacy

Clinical swabs (100) in transport media routinely collected by GeneMe Service Laboratories from patients were tested using the SAVD+. The test was performed using directly transported reaction medium without the need for an RNA purification step. Real-time RT-PCR (Gensig Primer Design) was used as a reference method to compare the results. This RT-PCR was performed by using purified RNA swab (100 µl swab was taken for the RNA isolation process). In this experiment, the SAVD+ was successfully validated in clinical trials. Validation with clinical samples gave the same results as real-time RT-PCR in 49 of the 50 positive samples and confirmed all negative (50) results obtained with the reference RT-PCR method.

4.1 Diagnostic specificity and sensitivity

The diagnostic specificity and sensitivity were determined based on RT-PCR sample testing as the reference method and SAVD+ as the research method. Based on the above results, the diagnostic specificity of the SAVD+ test was defined as the ability to detect healthy people, i.e., the ratio of the true negative results to the sum of true negative and false positive using the equation:

SPECIFICITY = (TN / TN + FP) × 100

100% diagnostic specificity SAVD+ was determined for this panel (95% CI 92.75% to 100.00%).

The diagnostic sensitivity of a test is defined as the ratio of the true positives to the sum of true positives and false negatives, i.e., the diagnostic test's ability to detect people suffering from the disease, by the equation:

SENSITIVITY [%] = (TP / TP + FN) × 100

98.04% diagnostic sensitivity SAVD+ was determined for this panel (95% CI 89.55% to 99.95%).

Complaints

Every Customer has the right to file a complaint. We will check every problem you report and act where it is necessary. To help us to manage your complaint efficiently we ask you to complete the Complaint form to determine the cause of your complaint.

NOTE: You should make your complaint within 14 working days of the incident. This time limit can sometimes be extended if it is still possible to investigate your complaint.

How to make a complaint?

1. Request F-29 Complaint Form from: complaints@geneme.eu
   It is also available on our website.
2. Complete the F-29 Complaint form and email to: *complaints@geneme.eu* giving as much details as possible. We will not be able to start the complaint procedure without fully completed F-29 Complaint form.

NOTE: If the F-29 form is incomplete, we will need to return it to you to complete. You can email complaints team if you need any assistance.

3. If the form is completed correctly, we will issue the acknowledge letter with complaint number and the resolution date. Please quote the complaint number in the future correspondence with us.
4. While your complaint is being investigated, we may need to ask you for more details.
5. Before or on the resolution date you will receive an official notification about the decision of your complaint.
6. If you disagree with our conclusion, you can inform us in writing, detailing your arguments, within 14 days of the receipt of our decision. We will take your points into consideration and aim to resolve dispute amicably.
7. If we are unable to reach a mutual agreement: We will be dealing with further dispute as per contract agreement.

SAVD+
by GENEME

LIMITED PRODUCT WARRANTY

This warranty applies to products manufactured by GeneMe where such products have been purchased directly from GeneMe or a GeneMe authorised distributor. Any products coming into the possession of a user via another source are without warranty and should not be used under any circumstances.

GeneMe warrants to the purchaser this product is free from defects in workmanship or materials for a period of 6 months from the date of production, under normal use, provided that the product has been kept in appropriate storage conditions and used in accordance with the instruction of use. The sole and exclusive remedy under this limited warranty is replacement of defective products or parts thereof. Replacement products or parts thereof will be furnished solely on an exchange basis and are obtainable only by the purchaser. The purchaser shall return the defective product, or part thereof, properly packaged, postage or shipping costs prepaid to GeneMe. Loss or damage during shipment shall be at the risk of the purchaser. Geneme does not give any express or implied warranties or representation on the accuracy levels of the product.

The warranties set out here apply to defects that appear under the conditions of operations provided for by the agreement and in particular do not apply in any of the following cases: (a) the products have been subject of replacement necessitated by accident, neglected, misused, relocation, unauthorized repair or modification of the product; (b) the products have been altered or repaired by anyone other than GeneMe without GeneMe's prior written consent; (c) the products have been damaged by circumstances beyond the reasonable control of Geneme; (d) the products have been improperly used or maintained by the purchaser; (e) the products have been subject to conditions of use and/or maintenance not in conformity with GeneMe's instructions; (f) the products have been used by non – professional users; (g) the products have been damaged by: abuse, negligence in use, including using the product in a manner incompatible with the instruction of use, improper storage or transportation or handling.

Subject to the limitations resulting from the mandatory provisions of law Geneme shall not be liable to any third party the purchaser, its staff or its customers under contract, tort (including negligence) or statute for loss of revenue, loss of profit, loss of opportunity, loss of goodwill, loss of data or the cost of replacement goods and services, or any indirect, consequential or incidental loss.

Geneme shall not be liable for any failure of this warranty if the GeneMe's obligation performance becomes impossible due to a force majeure. Force Majeure means an event out of any GeneMe's control, which occurs unexpectedly, extraordinarily, which makes it impossible to rationally carry out GeneMe's obligations.

Upon receipt of the product, either directly from GeneMe or GeneMe authorised distributor, the purchaser shall examine it for material and performance defects* and the suitability for the purpose expressly stated in the IFU without undue delay, but not later than 14 calendar days from the date of delivery the product to the purchaser (when the products have been purchased directly from Geneme) or to the authorized distributor (when the products have been purchased from authorized distributor). In the described above situation, the purchaser shall give GeneMe (when purchased directly) or authorised distributor (when purchased from authorized distributor) immediate written notice of any defects, within 14 days from the date of delivery, or upon usage of a maximum of five percent of the delivery whichever is first. After this 14-days period, notification of any defects shall be made within 14 days of the date of identification defects by the purchaser and shall be precisely specify the type and extent of the defect in writing and shall include comprehensive details of any product transportation, product LOT number, run files from any PCR machine used, and a full and detailed description of storage conditions and any variations of those conditions. Any such notices of defects must be received by GeneMe (when purchased directly) or by GeneMe authorised distributor (when purchased from authorized distributor) within the warranty period.

THE ABOVE LIMITED WARRANTY IS THE SOLE WARRANTY PROVIDED BY GENEME. NO OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, ARE PROVIDED WHATSOEVER. NO GENEME AGENT OR EMPLOYEE MAY MODIFY, EXTEND OR ADD TO THE ABOVE LIMITED WARRANTY. NOTHING IN THIS WARRANTY SHALL OPERATE TO EXCLUDE OR LIMIT A GENEME'S LIABILITY FOR FRAUD OR FRAUDULENT MISREPRESENTATION.

This Agreement contains the entire agreement between Geneme and the purchaser relating to the product's warranty. This warranty shall be interpreted in accordance with polish law.

*A performance defect is a substantive deviation from the performance range as detailed in the IFU.

6 months from production date

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