

INSTRUCTION FOR USE

Prepito Viral DNA/RNA 300 Kit

Product number: IVD-2017

Reagents for 180 extractions.

UDI-DI: 4260543364281

Version: V231024 EN

Manufacturer: Revvity chemagen Technologie GmbH
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CE

FOR *IN VITRO* DIAGNOSTIC USE.

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2. EXPLANATION OF THE SIGNAL WORDS IN THIS IFU

Signal word	Description
CAUTION!	Potential hazard that could lead to slight or medium harm.
NOTE:	Errors committed by the operator can cause that the optimal performance of the kit cannot be guaranteed.

3. SYMBOLS USED IN THE IFU AND ON LABELS

Symbol	Symbol Title	Symbol	Symbol Title
	CE mark European conformity		Temperature limit
	<i>In vitro</i> medical device		Contains sufficient for <n> tests
	Consult instructions for use or electronic instructions for use		Quantity
	Manufacturer		Do not re-use
	Batch code		Translation
	Catalogue number		Use-by date
	Do not use if package is damaged and consult instructions for use		This way up

Symbol	Symbol Title	Symbol	Symbol Title
	GHS02		Dangerous goods: Class 3 Flammable liquid
	GHS07		Dangerous goods: Class 8 Corrosive substances
	GHS08	-	-

chemagic™ is a trademark of Revvity chemagen Technologie GmbH.

4. APPLICATION

The Prepito Viral DNA/RNA 300 Kit is to be used for the automated extraction and purification of DNA and RNA from human plasma, saliva and naso- or oropharyngeal swabs using the chemagic™ Prepito instrument or the chemagic™ Prepito-D instrument.

The kit is designed to be used with IVD downstream applications employing enzymatic amplification and detection of DNA and RNA (e.g. PCR, RT-PCR, NGS). The product is intended for trained laboratory personnel and especially trained for the Prepito Viral DNA/RNA 300 Kit and the chemagic Prepito /-D instrument.

For further information please refer to the sections “KIT REAGENTS AND SAFETY INFORMATION“ and “WARNINGS AND PRECAUTION” in this document.

5. SUMMARY AND PRINCIPLE

The Prepito Viral DNA/RNA 300 Kit is based on a magnetic bead technology platform proprietary to Revvity chemagen Technologie GmbH. Cells or other source of DNA/ RNA present in plasma, serum and naso- or oropharyngeal swabs are lysed during the extraction process. The released nucleic acids bind to small magnetizable particles which are then magnetically separated from the sample material. During subsequent steps contaminants are removed and the purified nucleic acids are transferred into an elution buffer. The automated sample processing is performed using the chemagic Prepito or chemagic Prepito-D instrument.

To minimize irregularities in diagnostic results, the product is intended to be used with an internal control as well as positive and negative controls throughout the process of sample preparation, sample amplification and detection according to the downstream assay used.

6. REPORTING OF INCIDENTS

For a user/ third party in the European Union and in countries with an identical regulatory regime (IVDR (EU) 2017/746); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to your national authority and to the manufacturer Revvity chemagen Technologie GmbH, +49 (0) 2401805500 or support.chemagen@revvity.com or it's legal representatives.

The competent authority in Germany is the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). Current contact information can be found on the BfArM website: <https://www.bfarm.de>.

7. GENERAL AND STORAGE INFORMATION

The kit contains reagents sufficient to perform 180 extractions.

The expiry date of the unopened kit is stated on the outer label. Do not use any component beyond the expiry date. Store at +2 to +25 °C.

Once opened, the kit components have a limited stability. The stability after opening is stated for each component separately in the reagent listing below (section “KIT REAGENTS AND SAFETY INFORMATION”).

If Lysis Buffer 1 contains precipitate (formed during transfer or storage), the solution should be heated to 50–60 °C and thoroughly mixed until the solution is clear. The clarity of the Lysis Buffer 1 should always be visually confirmed before use.

The bottles may discolor during storage. The discoloration of the bottles has no effect on the functionality of the assay.

In some cases, traces of Magnetic Beads may be left in the eluate. Though such particles will usually not interfere with PCR or most downstream applications, an additional separation step either using centrifugation or a magnetic separator (chemagic Stand 2x12) is recommended, in order to separate any traces of particles.

Extracted DNA/ RNA should be used immediately after extraction in the desired *in vitro* diagnostic test.

In this IFU we refer to the chemagic Prepito User Manual. This manual will be provided with the chemagic Prepito/-D instrument.

The Kit-related protocol file will be provided by Revvity chemagen Technologie GmbH (see section “REQUIRED PROTOCOLS FILE”).

8. ELECTRONIC INSTRUCTIONS FOR USE

Electronic Instructions for Use (eIFU) in different languages are available on our webpage.

To download these electronic Instructions for Use please visit:

<https://chemagen.com/products/chemagen-ivd-products/ce-ivd-chemagic-kits/>.

The eIFU are provided in at least English (EN), French (FR), Spanish (ES) and Italian (IT) and upon request also in other required languages.

In case of any questions regarding download or the electronic Instructions for Use please contact us: support.chemagen@revvity.com, info.chemagen@revvity.com or +49 (0) 2401805500.

9. WARNINGS AND PRECAUTION

For *in vitro* diagnostic use.

The product is intended for professional users trained for the chemagic Prepito/-D instrument.

A thorough understanding of this IFU and the chemagic Prepito/-D User Manual is a prerequisite and necessary for successful use of the Prepito Viral DNA/RNA 300 Kit.

The reagents supplied with this kit are intended for use as an integral unit. Do not mix identical reagents from kits with different lot numbers.

Do not use kit reagents after the expiry date printed on the kit label. Once opened, the reagents can be used for the time period stated in the reagent listing of this IFU.

Any deviation from the protocol may affect the results.

Check all kit components for integrity. In case of damage, contact your supplier.

Handle all specimens as potentially infectious. Potentially infectious samples shall be inactivated. Please refer to the U.S. Department of Health and Human Services publication "Biosafety in Microbiological and Biomedical Laboratories" or any other local or national regulation.

Lysis Buffer 1 contains guanidinium thiocyanate and is harmful if swallowed, in contact with skin or if inhaled. Binding Buffer 2 and Wash Buffer 3 contain sodium perchlorate and ethanol and are flammable liquids and vapors and are harmful if swallowed. Wash Buffer 4 contains ethanol and is a flammable liquid and vapor. Proteinase K contains Tritirachium album serine Proteinase and causes skin irritation and serious eye irritation, may cause allergy or asthma symptoms or breathing difficulties if inhaled and

respiratory irritation. Poly(A) RNA Buffer contains guanidinium thiocyanate and is harmful if swallowed or if inhaled. See specific precautions for all components in the section "KIT REAGENTS AND SAFETY INFORMATION".

To avoid injuries when working with the kit components, always wear safety glasses, disposable gloves, and protective clothing. For detailed information, please refer to the corresponding safety data sheets (SDS).

Follow local regulations for handling of ethanolic solutions.

Disposal of all waste should be in accordance with local regulations.

10. KIT REAGENTS AND SAFETY INFORMATION


The Prepito Viral DNA/RNA 300 Kit contains the following reagents.

10.1 MAGNETIC BEADS

Component	Quantity	Shelf life and storage
Magnetic Beads	1 bottle (volume see label)	+2 to +25 °C until expiry date stated on the bottle label. Once opened, stable for 60 days at +2 to +25 °C.

Suspension of particles containing nanoparticulate iron oxide encapsulated in a matrix of polyvinyl alcohol. Magnetic Beads bind the DNA/ RNA during the extraction process.

10.2 LYSIS BUFFER 1

Component	Quantity	Shelf life and storage
Lysis Buffer 1  DANGER	1 bottle (volume see label)	+2 to +25 °C until expiry date stated on the bottle label. Store in the dark. Once opened, stable for 60 days at +2 to +25 °C.

Ready-for-use aqueous buffer solution containing guanidine thiocyanate (50–70 %). Lysis Buffer 1 is used to lyse the cells or other DNA/ RNA source present in the sample in order to get the DNA/ RNA in solution.

CAUTION! Lysis Buffer 1 contains guanidinium thiocyanate.



Hazard, precautionary and EUH phrases

H302+H312	Harmful if swallowed or in contact with skin.
H314	Causes severe skin burns and eye damage.
P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.

Hazard, precautionary and EUH phrases

P103	Read carefully and follow all instructions.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/ doctor.
P321	Specific treatment (see on this label).
P405	Store locked up.
P501	Dispose of contents/ container in accordance with local/ regional/ national/ international regulations.
EUH032	Contact with acids liberates very toxic gas.

10.3 BINDING BUFFER 2

Component	Quantity	Shelf life and storage
Binding Buffer 2   DANGER	1 bottle contained in chemagic 8-pack	+2 to +25 °C until expiry date stated on the 8-Pack. Once opened, stable for 60 days at +2 to +25 °C.


Ready-for-use Tris-HCl-buffered (pH 5.2–6.1) solution with sodium perchlorate (20–40 %) and ethanol (40–60 %). Binding Buffer 2 is used to create the appropriate conditions to get the DNA/ RNA bound to the Magnetic Beads.

CAUTION! Binding Buffer 2 contains ethanol and sodium perchlorate.

Hazard, precautionary and EUH phrases

H225	Highly flammable liquid and vapor.
H302	Harmful if swallowed.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P240	Ground and bond container and receiving equipment.
P241	Use explosion-proof [electrical/ ventilating/ lighting] equipment.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P501	Dispose of contents/ container in accordance with local/ regional/ national/ international regulations.

10.4 WASH BUFFER 3

Component	Quantity	Shelf life and storage
Wash Buffer 3 	1 bottle contained in chemagic 8-pack	+2 to +25 °C until expiry date stated on the 8-Pack. Once opened, stable for 60 days at +2 to +25 °C.
DANGER		

Ready-for-use Tris-HCl-buffered (pH 4.8-5.6) solution with sodium perchlorate (20–30 %) and ethanol (20–40 %). Used for removing non-DNA/ non-RNA contaminants during washing step.

CAUTION! Wash Buffer 3 contains ethanol and sodium perchlorate.


Hazard, precautionary and EUH phrases

H225	Highly flammable liquid and vapor.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P240	Ground and bond container and receiving equipment.

Hazard, precautionary and EUH phrases

P241	Use explosion-proof [electrical/ ventilating/ lighting] equipment.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P501	Dispose of contents/ container in accordance with local/ regional/ national/ international regulations.

10.5 WASH BUFFER 4

Component	Quantity	Shelf life and storage
Wash Buffer 4 	1 bottle contained in chemagic 8-pack	+2 to +25 °C until expiry date stated on the 8-Pack. Once opened, stable for 60 days at +2 to +25 °C.
DANGER		

Ready-for-use solution contains ethanol 50–70 %. Used for removing last traces of non-DNA/ non-RNA contaminants during washing step.

CAUTION! Wash Buffer 4 contains ethanol.**Hazard, precautionary and EUH phrases**

H225	Highly flammable liquid and vapor.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P240	Ground and bond container and receiving equipment.
P241	Use explosion-proof [electrical/ ventilating/ lighting] equipment.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P501	Dispose of contents/ container in accordance with local/ regional/ national/ international regulations.

10.6 WASH BUFFER 5

Component	Quantity	Shelf life and storage
Wash Buffer 5	1 bottle contained in chemagic 8-pack	+2 to +25 °C until expiry date stated on the 8-Pack. Once opened, stable for 60 days at +2 to +25 °C.


Ready-for-use ultra-filtered water solution. Used for removing possible residuals of ethanol.

10.7 ELUTION BUFFER 6

Component	Quantity	Shelf life and storage
Elution Buffer 6	1 bottle (volume see label)	+2 to +25 °C until expiry date stated on the bottle label. Once opened, stable for 60 days at +2 to +25 °C.

Ready-for-use 10 mM Tris-HCl-buffered (pH 7.8–8.4) solution.

10.8 PROTEINASE K

Component	Quantity	Shelf life and storage
Proteinase K 	1 glass vial (lyophilized)	+2 to +25 °C until expiry date stated on the vial label. Once reconstituted, stable for 28 days at +2 to +8 °C.

DANGER

Proteinase K is reconstituted by adding 2.5 mL of purified water. Proteinase K is added to enhance the efficiency of the lysis step.

CAUTION! Proteinase K contains Proteinase, Tritirachium album serine and calcium acetate hydrate.

Hazard, precautionary and EUH phrases


H315	Causes skin irritation.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
P261	Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.
P280	Wear protective gloves/ eye protection/ face protection.
P284	[In case of inadequate ventilation] wear respiratory protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405	Store locked up.
P501	Dispose of contents/ container in accordance with local/ regional/ national/ international regulations.

10.9 POLY(A) RNA

Component	Quantity	Shelf life and storage
Poly(A) RNA	2 tubes (lyophilized)	+2 to +25 °C until expiry date stated on the tube label. Once reconstituted, stable for 30 days at +2 to +8 °C.

Poly(A) RNA is reconstituted by adding 440 µL of Poly(A) RNA Buffer. The Poly(A) RNA functions as a DNA/ RNA carrier to enhance the efficiency of the extraction process.

10.10 POLY(A) RNA BUFFER

Component	Quantity	Shelf life and storage
Poly(A) RNA Buffer 	2 tubes (volume see label)	+2 to +25 °C until expiry date stated on the bottle label.

WARNING

Ready-for-use aqueous buffer solution containing guanidine thiocyanate (20–40 %). Poly(A) RNA Buffer is used for reconstitution of Poly(A) RNA.

CAUTION! Poly(A) RNA Buffer contains guanidinium thiocyanate.

Hazard, precautionary and EUH phrases	
H302	Harmful if swallowed.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P330	Rinse mouth.
P501	Dispose of contents/ container in accordance with local/ regional/ national/ international regulations.
EUH032	Contact with acids liberates very toxic gas.

10.11 FURTHER KIT COMPONENTS

The Prepito Viral DNA/RNA 300 Kit contains the following plastic material.

Component	Quantity	Storage
chemagic Tips S	180	+2 to +25 °C
Prepito Tubes M	360	+2 to +25 °C
Prepito Tubes M Cap Stripes (8 caps/ stripe)	23	+2 to +25 °C
chemagic Deep Well Plate 2 mL	15	+2 to +25 °C

11. REQUIRED PROTOCOLS FILE

The following protocol file will be provided by Revvity chemagen Technologie GmbH and is already preinstalled on the chemagic Prepito/-D, available on the webpage or will be provided by customer support.

Protocol (.che file)	Protocol type/ purpose
031.che (protocol name: Viral DNA/RNA dipping, VD 230515)	Kit-related extraction file for the chemagic Prepito/-D instrument

12. MATERIAL REQUIRED BUT NOT SUPPLIED WITH THE KIT

The Prepito Viral DNA/RNA 300 Kit requires the following items.

12.1 ITEMS FROM REVVITY CHEMAGEN TECHNOLOGIE GMBH

Item	Product no.
chemagic Prepito instrument or	2022-0030
chemagic Prepito-D instrument	2022-0020

12.2 ADDITIONAL REQUIRED ITEMS

Item	Purpose
Pipettes and pipette tips with aerosol barriers	Prefilling of Magnetic Beads, Elution Buffer 6, Proteinase K and Poly(A) RNA
Molecular biology grade water	Reconstitution of the Proteinase K
70% Ethanol	Cleaning of the chemagic Prepito/-D instrument

12.3 ADDITIONAL OPTIONAL ITEMS FROM REVVITY CHEMAGEN TECHNOLOGIE GMBH

Product	Product no.
chemagic Stand 2x12	CMG-300

12.4 OTHER ADDITIONAL OPTIONAL ITEMS

Product	Purpose
Isotonic saline solution, sterile	Liquefying of swab material before use
Sarstedt tube (cat. No. 72.693 or 72.694)	Reaction tube for inactivation of sample material

13. SPECIMEN COLLECTION AND HANDLING

The chemagic Prepito DNA/RNA 300 Kit is usable with fresh and frozen human plasma, stabilized with either EDTA or citrate from common blood collection systems, stabilized saliva (Oragene™ and Spectrum™ collection tubes) and transport media from swabs (e.g. eNAT™ Copan Diagnostics Inc.) as direct aliquots of 300 µL per isolation.

After collection and centrifugation, plasma can be stored at 2–8 °C for up to 6 hours. For long-term storage, freezing at –20 °C or –80 °C in aliquots is recommended. Frozen plasma or serum samples must not be thawed more than once. Repeated freezing–thawing leads to denaturation and precipitation of proteins, resulting in reduced yields of nucleic acids.

Sample material from dried swabs must be transferred into isotonic saline solution. Therefore add 350 µL of isotonic saline solution and incubate for 5 min at 15–25 °C before use. 300 µL of the incubated isotonic saline solution sample should be used per isolation.

NOTE: Do not use phosphate containing buffers for resuspension.

The extraction efficiency of sample material other than the sample types listed above has not been determined.

For safe handling, specimen for viral testing (e.g. SARS-CoV-2 viral RNA extraction) should be inactivated before use. Pipette 4 µL Poly(A) RNA, 10 µL Proteinase K, and 300 µL Lysis Buffer 1 into a 2 mL Sarstedt tube. When more than one sample will be processed for inactivation, a stock solution of this solution can be prepared. Simply multiply the volumes required for one sample by the total number of samples to be processed and include additional volume to the equivalent of 3 extra samples. Invert the tube several times to mix, transfer 314 µL to a 2 mL Sarstedt tube for each sample, and then continue for each sample by adding 300 µL sample to each tube, close the lid, and mix by pulse-vortexing for 10 seconds. Incubate the tube at 68 °C for 15 minutes (± 2 minutes) for inactivation. Transfer the inactivated lysate completely to the sample deep well plate in step 19 of the extraction protocol and continue with step 20.

14. DETAILED PROTOCOL DESCRIPTION

14.1 PROTOCOL PROCEDURE

The following procedure describes the preparation and the execution of the extraction protocol using the chemagic Prepito/-D instrument.

The duration of the automated extraction protocol is approximately 39 minutes.

The protocol is suitable for processing up to 12 samples in parallel (see “PROCESSING STEPS”).

For detailed instructions on the use of the chemagic Prepito/-D instrument, please refer to the chemagic Prepito/-D User Manual.

NOTE: Samples and reagents must be brought to room temperature (+19 to +25 °C) before use.

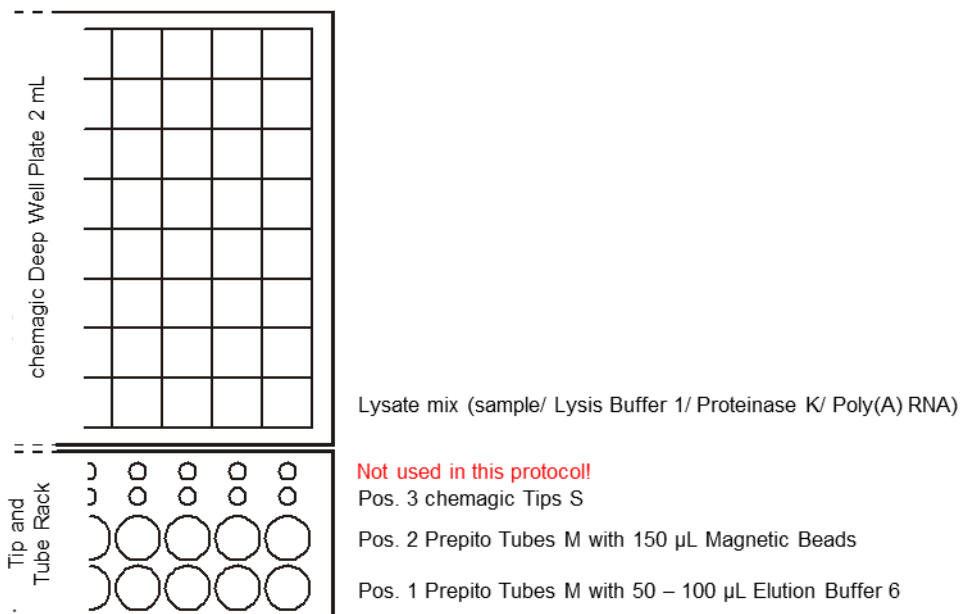
Connect the tubes according to their numbering to the respective counterparts (see below) at the chemagic 8-Pack. Remove the lids from the individual buffer bottles in the chemagic 8-Pack and pierce the septum with the spike placed at the end of each tube. Place the chemagic 8-Pack upside down on the reagent holder and use the manual priming function for a complete filling of the dispensing system.

Connect the tubes as follows:

Pump	Buffer	8-Pack No.
Pump 1	No bottle connected	-
Pump 2	Binding Buffer 2	2
Pump 3	Wash Buffer 3	3
Pump 4	Wash Buffer 4	4
Pump 5	Wash Buffer 5	5
Pump 6	No bottle connected	-

14.2 POSITIONING

See “PROCESSING STEPS” for detailed information.



14.3 PROCESSING STEPS

1. Check all kit components for integrity. In case of damage, contact your supplier.
2. Reconstitute the Proteinase K and Poly(A) RNA components:

Component	Reconstitution
Proteinase K	Add 2.5 mL molecular biology grade water to Proteinase K vial and mix gently until dissolved.
Poly(A) RNA	Add 440 µL of Poly(A) RNA Buffer to the Poly(A) RNA tube and mix thoroughly until dissolved.

3. If Lysis Buffer 1 contains precipitate (formed during transfer or storage), the solution should be heated to 50–60 °C and thoroughly mixed until the solution is clear. Clarity of the Lysis Buffer 1 should always be visually confirmed before use.
4. Switch on the chemagic Prepito/-D and wait until the self-test is finished.
5. Press [Change Protocol].
6. Press [Serum/Plasma] in the “Select Protocol Group” window.

7. Select the Prepito Viral DNA/RNA 300 Kit protocol by pressing [Viral DNA/RNA300] and confirm by pressing [OK].
8. Confirm the protocol selection in the “Select Protocol Group” window by pressing [OK].
9. Enter the 4-digit access code [2364] for authorization and confirm by pressing [enter].
10. Press [Start process].
11. Read the protocol information in the appearing information screen.
12. Confirm by pressing [continue].
13. Select the sample positions and confirm by pressing [continue].
14. Enter the kit barcode with the barcode scanner and confirm by pressing [OK].
15. For the registration of the samples and elution tubes press [Yes] and follow the instructions on the touch screen panel to enter the according barcodes.
16. Prepare the Prepito Tip and Tube Rack with the required material and place one chemagic Tip S in position 3 for each sample according to the sample positions (see section “POSITIONING”).
17. Place two Prepito Tubes M, one in position 1 and one in position 2, and prefill the Elution Buffer 6 and the thoroughly resuspended Magnetic Beads by pipetting manually according to each well in use (see also section “POSITIONING”) as follows:

Component	Position in Tip and Tube Rack	Volume/ tube
Elution Buffer 6	1	50 - 100 µL
Magnetic Beads	2	150 µL

NOTE: The Magnetic Bead suspension should be mixed vigorously before dispensing; otherwise the suspension is not homogenous and the DNA/ RNA yield could be low.

18. Add the following reagents to the into the sample position of the chemagic Deep Well Plate 2 mL defined as sample wells (Pos. "Lysate mix", see section "POSITIONING").
 - 4 μ L Poly(A) RNA and
 - 10 μ L Proteinase K.
19. Add 300 μ L sample material and 300 μ L Lysis Buffer 1 into the well filled with Poly(A) RNA and Proteinase K.

NOTE: Sample material from dried swabs has to be liquefied before use.

NOTE: Proteinase K activity will decrease after incubation longer than 10 minutes in Lysis Buffer 1. Ensure that all samples are mixed with Poly(A) RNA/ Proteinase K/ Lysis Buffer 1 within this time.

20. An information screen indicates the previously selected sample positions. Ensure that the sample positions in the chemagic Deep Well Plate 2 mL correspond to the selected positions.
21. Place the chemagic Deep Well Plate 2 mL on its default position on the tracking system and press [continue].
22. Place the Prepito Tip and Tube Rack on its default position on the tracking system.
23. Check for accurate orientation and fitting of the chemagic Deep Well Plate 2 mL and the Prepito Tip and Tube Rack and lock both by closing the safety latch.
24. Close the front door and start the process by pressing [Start]. The automated DNA/ RNA extraction process is initiated.

14.4 SHORT DESCRIPTION/ QUICK GUIDE

Automated DNA/ RNA extraction run on chemagic Prepito/-D instrument:

- Press [Change Protocol] and select [Serum/Plasma] in the Select Protocol Group window.
- Select the Prepito Viral DNA/RNA 300 Kit protocol by pressing [Viral DNA/RNA].
- Confirm by pressing [OK] and enter the 4-digit access code [2364] for authorization and confirm by pressing [Enter].
- Press [Start Process] and select the sample positions and confirm by pressing [OK].
- Enter the kit barcode with the barcode scanner and confirm by pressing [OK].
- For the registration of the samples and elution tubes press [Yes] and follow the instructions on the touch screen panel to enter the according barcodes.
- Load the Prepito Tip and Tube Rack and the sample plate as follows:

Material (position)	Protocol step in detail
Prepito Tip and Tube Rack position 1	Pipette (50 – 100 µL) Elution Buffer 6 in each Prepito Tube M in use according to the sample plate.
Prepito Tip and Tube Rack position 2	Pipette thoroughly resuspended Magnetic Beads in each Prepito Tube M in use according to the sample plate.
Prepito Tip and Tube Rack position 3	Use chemagic Tips S according to the positions of the samples.
chemagic Deep Well Plate 2 mL (sample plate)	Place the plate with prepared samples (300 µL sample, 4 µL Poly(A) RNA, 10 µL Proteinase K, and 300 µL Lysis Buffer 1) in the instrument.

- Place the chemagic Deep Well Plate 2 mL in the instrument.
- Place the Prepito Tip and Tube Rack in the instrument.
- Check for accurate orientation and fitting of the chemagic Deep Well Plate 2 mL and the Prepito Tip and Tube Rack.
- Lock by closing the safety latch.
- Close the front door and start the DNA/ RNA extraction process immediately by pressing [Start]. Subsequently the sample lysate will be mixed automatically.

15. PERFORMANCE CHARACTERISTICS

When using this extraction kit with the EURORealTime SARS-CoV-2 RT-PCR Assay (Catalog Number: MP 2606-0125, MP 2606-0225, MP 2606-0425, MP 2606-0100, MP 2606-0200 and MP 2606-1000) the following Limit of Detection (LoD) data, see below, was reported (data generated by EUROIMMUN Medizinische Labordiagnostika AG, Seekamp 31, 23560 Lübeck).

15.1 LOD USING CHEMAGIC PREPITO INSTRUMENT FOR EXTRACTION AND ROCHE LIGHTCYCLER 480 II, APPLIED BIOSYSTEMS™ 7500 FAST, BIO-RAD CFX TOUCH AND ANALYTIK JENA QTOWER³ PCR SYSTEMS

A tentative LoD was determined with 5-7 serial dilutions of SARS-CoV-2 recombinant virus (SeraCare, AccuPlex SARS-CoV-2 Reference Material; 5000 copies/mL) into oropharyngeal swab matrix negative for SARS-CoV-2. Each dilution was tested with 3 individual extraction replicates. The tentative LoD was determined at 150 copies/mL (data not shown).

The tentative LoD was validated with 21 replicates of negative oropharyngeal swab matrix spiked with AccuPlex reference material, followed by extraction with the Prepito Viral DNA/RNA 300 Kit. Replicates were then tested on the Roche LightCycler 480 II. The same procedure was repeated for Applied Biosystems 7500 Fast Real-Time PCR, Bio-Rad CFX Touch and the Analytik Jena qTOWER³ cyclers. The LoD was determined to be 150 copies/mL, corresponding data are listed in Table 1.

Table 1: LoD confirmation in oropharyngeal swab specimens.

Instrument	Valid replicates	SARS-CoV-2		IC		SARS-CoV-2 RNA Detection Rate
		n	Mean Ct	n	Mean Ct	
Roche LightCycler 480 II	21	21	36.18	21	29.30	100 %
Applied Biosystems 7500 Fast	21	21	35.14	21	29.02	100 %
Bio-Rad CFX 96 Touch	21	21	34.94	21	27.85	100 %
Analytik Jena qTOWER ³	21	21	34.66	21	28.38	100 %

16. CLEANING AND MAINTENANCE

Cleaning and maintenance of the system is described in detail in the chemagic Prepito/-D User Manual.

17. DOWNSTREAM APPLICATIONS

The following downstream applications were successfully performed and described in literature after isolation with the Prepito Viral DNA/RNA 300 Kit (CMG-2017).

Table 2: Peer reviewed and published downstream applications (RT-qPCR).

Sample Material	Kit	Title	Reference
Nasopharyngeal swab in viral transport medium	Coronavirus COVID-19 genesig® Real-Time PCR assay (Genesig)	Clinical features of 47 patients infected with COVID-19 admitted to a Regional Reference Center	Olivares et al. Rev. med. Chile (2020), Nov. 148, (11): 1577.1588. https://pubmed.ncbi.nlm.nih.gov/33844763/
Nasopharyngeal swab in viral transport medium	Coronavirus COVID-19 genesig® Real-Time PCR assay (Genesig)	Clinical significance of viral loads in patients infected with SARS-CoV-2 in Fayoum University Hospitals	Hosam-Eldin et al. Egyptian Journal of Medical Microbiology (2022), Oct, 31 (4): 1-4 10.21608/EJMM.2022.262665
Plasma	RealStart HBV PCR Kit 1.0 (Altona)	Seroprevalence of HBV, HCV and HIV-1 and Correlation with Molecular Markers among Multi-Transfused Thalassemia Patients in Western India	Mishra et al. Mediterr J Hematol Infect Dis (2020), Juli, 12 (1):e2020038 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7340250/
Plasma	Real-Star HIV RT-PCR Kit 1.0 (Altona)	Seroprevalence of HBV, HCV and HIV-1 and Correlation with Molecular Markers among Multi-Transfused Thalassemia Patients in Western India	Mishra et al. Mediterr J Hematol Infect Dis (2020), Juli, 12 (1):e2020038 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7340250/
Naso- and oropharyngeal swabs	VIASURE SARS-CoV-2 Real Time PCR Detection kit (CerTest BIOTEC)	Faecal calprotectin in COVID-19 patients with intestinal symptoms	Ellakany et al. Gastroenterology Rev (2022), 17 (4): 332-337 https://doi.org/10.5114/pg.2022.114685

18. FURTHER QUESTIONS

For further application, technical questions, or more information on how the data was generated please contact support.chemagen@revvity.com or +49 (0) 2401805500.

19. LIMITATIONS OF THE PROCEDURE

The following collection devices are **not recommended** for use with the Prepito Viral DNA/RNA 300 Kit, for further questions please reach out to support.chemagen@revvity.com.

Table 3: Collection devices which are not recommended for use.

Description	Brand	Reference No.
Inactivated virus sampling tube (10 mL), containing 3 mL preservation medium (inactivated), 1x oropharyngeal swab with rayon material	Biocomma Limited	YMJ-TE
Virus collection and preservation system inactivated	Jiangsu Kangjian Medical Apparatus Co., Ltd.	KJ502-19C/D

The performance characteristics of these products have not been established.

The IVD-2017 kit is validated for the extraction of DNA and RNA from human plasma, saliva and naso- or oropharyngeal swabs. Other sample materials may be compatible but have not been validated.



20. WARRANTY

Any change or modification of the procedure not recommended by the manufacturer may affect the results, in which event Revvity chemagen Technologie GmbH and its affiliates disclaim all warranties expressed, implied or statutory including the implied warranty of merchantability and fitness for use.

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