INSTRUCTION FOR USE

chemagic™
Viral DNA/RNA 300 Kit H96

Product number: **IVD-1033-S**

Reagents for 960 extractions.

UDI-DI: 426054336415l4

Version: V260206 EN

Manufacturer: Revvity chemagen Technologie GmbH
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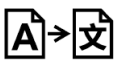
CE

FOR *IN VITRO* DIAGNOSTIC USE.

1. TABLE OF CONTENTS

2. SYMBOLS USED IN THE IFU AND ON LABELS

Symbol	Symbol Title	Symbol	Symbol Title
	CE mark European conformity		Temperature limit
	*In vitro* 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
	GHS02		GHS08
	GHS05		Dangerous goods: Class 3 Flammable liquid
	GHS07		Dangerous goods: Class 8 Corrosive substances

3. EXPLANATION OF THE SIGNAL WORDS IN THIS IFU

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

4. TRADEMARKS

Revvity is a trademark of Revvity Inc. All other trademarks are the property of their respective owners.

chemagic™ is a trademark of Revvity chemagen Technologie GmbH.

5. INTENDED PURPOSE

The chemagic™ Viral DNA/RNA 300 Kit H96 (IVD-1033-S) is a kit for the automated isolation and purification of DNA and RNA from human plasma, saliva and naso- or oropharyngeal swabs for *in vitro* diagnostic purposes.

The product is used on the chemagic™ 360-D instrument and is intended for laboratory personnel trained for the chemagic 360-D instrument in combination with chemagic nucleic acid purification kits. 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).

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

6. SUMMARY AND PRINCIPLE

The chemagic Viral DNA/RNA 300 Kit H96 is based on a magnetic bead technology platform proprietary to Revvity chemagen Technologie GmbH. Cells or other sources of DNA and 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 360-D instrument with a chemagic 96 Rod Head Set or equivalent instrument.

To minimize irregularities in diagnostic results, the product is intended to be used with appropriate controls throughout the process of sample preparation, sample amplification and detection according to the downstream assay used.

7. 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.

8. GENERAL AND STORAGE INFORMATION

The kit contains reagents sufficient to perform 960 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 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.

NOTE: Recap the bottles tightly immediately after use to prevent evaporation.

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 96, provided with the chemagic 360 96 Rod Head Set) is recommended, 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 360-D User Manual. This manual will be provided with the chemagic 360-D instrument.

Kit-related protocol files are available on the Revvity website or will be provided by customer support (see section “REQUIRED PROTOCOL FILES”).

9. ELECTRONIC INSTRUCTIONS FOR USE

Electronic Instructions for Use (eIFU) in different languages are available on the Revvity website.

To download these electronic Instructions for Use please visit:

https://www.revvity.com/de-en/product/chemagic-viral-dna-rna-300-kit-h96-ivd-1033-s.

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.

10. WARNINGS AND PRECAUTION

For *in vitro* diagnostic use.

The product is intended for laboratory personnel trained for the chemagic 360-D instrument in combination with chemagic nucleic acid purification kits.

A thorough understanding of this IFU and the chemagic 360-D User Manual is a prerequisite and necessary for successful use of the chemagic Viral DNA/RNA 300 Kit H96.

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 period stated in the reagent listing of this IFU.

Any deviation from the protocol may affect the results.

The reagents are automatically dispensed in whole rows and therefore the disposable tips in the chemagic Tips 96 Tray should be used also in whole rows on each rod in contact with any reagent solution.

It should also be noted that if partial plates are run, the solutions may not be sufficient for 960 extractions.

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 Engyodontium album serine protease and causes skin irritation and serious eye irritation. It may cause allergy or asthma symptoms or breathing difficulties or respiratory irritation if inhaled. 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) available on the Revvity website.

Follow local regulations for handling ethanolic solutions.

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

11. KIT REAGENTS AND SAFETY INFORMATION

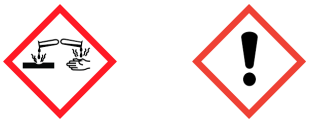
The chemagic Viral DNA/RNA 300 Kit H96 contains the following reagents.

11.1 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 nanoparticular iron oxide encapsulated in a matrix of polyvinyl alcohol.
Magnetic Beads bind the DNA/RNA during the extraction process.

11.2 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 sources present in the sample 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.
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).
P362+P364	Take off contaminated clothing and wash it before reuse.
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.

11.3 BINDING BUFFER 2

Component	Quantity	Shelf life and storage
Binding Buffer 2  DANGER	1 canister (volume: see label)	+2 to +25 °C until expiry date stated on the canister label. 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 (30-50 %) 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.

11.4 WASH BUFFER 3

Component	Quantity	Shelf life and storage
Wash Buffer 3  DANGER	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 Tris-HCl-buffered (pH 4.8-5.6) solution with sodium perchlorate (10-30 %) and ethanol (20-40 %).
Wash Buffer 3 is 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.
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.

11.5 WASH BUFFER 4

Component	Quantity	Shelf life and storage
Wash Buffer 4  DANGER	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 solution contains ethanol (50-70 %).
Wash Buffer 4 is 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.

11.6 WASH BUFFER 5

Component	Quantity	Shelf life and storage
Wash Buffer 5	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.

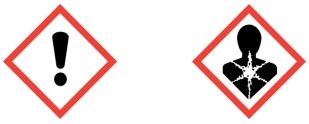
Ready-for-use ultra-filtered water solution.
Wash Buffer 5 is used for removing possible residuals of ethanol.

11.7 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.
Elution Buffer 6 is used for releasing nucleic acids.

11.8 PROTEINASE K

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

Proteinase K is reconstituted by adding 11 mL of purified water.
Proteinase K is added to enhance the efficiency of the lysis step.

CAUTION! Proteinase K contains sodium acetate and is a recombinant serine protease from fungus Engyodontium album.

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 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.

11.9 POLY(A) RNA

Component	Quantity	Shelf life and storage
Poly(A) RNA	10 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.
Poly(A) RNA functions as a DNA/RNA carrier to enhance the efficiency of the extraction process.

11.10 POLY(A) RNA BUFFER

Component	Quantity	Shelf life and storage
Poly(A) RNA Buffer  WARNING	1 bottle (volume: see label)	+2 to +25 °C until expiry date stated on the bottle label.

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+H312	Harmful if swallowed or in contact with skin.
H319	Causes serious eye irritation.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing 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.
P321	Specific treatment (see on this label).
P330	Rinse mouth.
P362+P364	Take off contaminated clothing and wash it before reuse.
P501	Dispose of contents/ container in accordance with local/ regional/ national/ international regulations.
EUH032	Contact with acids liberates very toxic gas.

11.11 FURTHER KIT COMPONENTS

The chemagic Viral DNA/RNA 300 Kit H96 contains the following plastic material.

Component	Quantity	Storage
chemagic Tips 96 Tray	10	+2 to +25 °C
chemagic Deep Well Plate 2 mL	50	+2 to +25 °C
chemagic Low Well Plate	10	+2 to +25 °C

12. REQUIRED PROTOCOL FILES

The following protocol files will be provided by Revvity chemagen Technologie GmbH and are available on the Revvity website (https://www.revvity.com/de-en/software-downloads/chemagic) or will be provided by customer support.

Protocol file (.che file)	Protocol type/purpose
chemagic Viral300 360 H96 prefilling VD200617.che	Kit-related extraction file for the chemagic 360-D instrument (60 minutes protocol).
chemagic Viral300 360 H96 prefilling 31 min VD201008.che	Kit-related extraction file for the chemagic 360-D instrument (31 minutes protocol).
chemagic Viral300 360 H96 prefilling 18 min VD210204.che	Kit-related extraction file for the chemagic 360-D instrument (18 minutes protocol).
prime manifolds H96 all 360 V150116.che	Filling and priming the chemagic 360-D instrument tubing with reagents.
check manifolds H96 all 360 V150116.che	Checking the functionality of the pumps.
regular cleaning procedure 96 dispenser 360 V150116.che	Regular cleaning of the chemagic 360-D instrument (once per week).
intensive cleaning procedure H96 dispenser 360 V150116.che	Intensive cleaning of the chemagic 360-D instrument (once per month).

13. MATERIAL REQUIRED BUT NOT SUPPLIED WITH THE KIT

The chemagic Viral DNA/RNA 300 Kit H96 requires the following items.

13.1 ITEMS FROM REVVITY CHEMAGEN TECHNOLOGIE GMBH

Item	Product no.
chemagic 360-D instrument	2024-0010
chemagic 96 Rod Head Set	CMG-370

13.2 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 360-D instrument.

13.3 ADDITIONAL OPTIONAL ITEMS FROM REVVITY CHEMAGEN TECHNOLOGIE GMBH

Item	Product no.
chemagic Stand 96 (supplied with the chemagic 96 Rod Head Set)	CMG-301

13.4 OTHER ADDITIONAL OPTIONAL ITEMS

Item	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.

14. SPECIMEN COLLECTION AND HANDLING

The chemagic Viral DNA/RNA 300 Kit H96 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. To this end, 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 11 of the extraction protocol and continue with step 12.

15. DETAILED PROTOCOL DESCRIPTION OF 60 MIN PROTOCOL

15.1 60 MIN PROTOCOL PROCEDURE (VARIOUS SPECIES)

The following procedure describes the preparation and the execution of the extraction protocol using the chemagic 360-D instrument.

The duration of the automated extraction protocol is approximately 60 minutes.

The protocol is suitable for processing up to 96 samples in parallel (see “PROCESSING STEPS” below). For detailed instructions on the use of the chemagic 360-D instrument, please refer to the chemagic 360-D User Manual.

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

Connect the reagent bottles to the chemagic 360-D instrument as follows:

Pump	Buffer	Minimum filling volume
Pump 1	No bottle connected	n.a.
Pump 2	Binding Buffer 2	170 mL
Pump 3	Wash Buffer 3	125 mL
Pump 4	Wash Buffer 4	125 mL
Pump 5	Wash Buffer 5	125 mL
Pump 6	No bottle connected	n.a.

NOTE: Recap the bottles tightly immediately after use or keep the bottles connected tightly to the chemagic 360-D instrument. Binding Buffer 2, Wash Buffer 3 and Wash Buffer 4 contain ethanol. If ethanol evaporates, the optimal yield or detection sensitivity cannot be guaranteed.

15.2 PROCESSING STEPS

1. Check all kit components for integrity. In case of damage, contact your supplier.
2. Before prefilling the plates mark each plate with material in position (samples, Magnetic Beads and buffers).

Note: The reagents are automatically dispensed in whole rows and therefore the tips should be used also in whole rows on each rod in contact with any reagent solution. Please note if partial plates are run, the solutions may not be sufficient for 960 extractions.

3. Reconstitute the Proteinase K and Poly(A) RNA components:

Component	Reconstitution
Proteinase K	Add 11 mL molecular biology grade water to Proteinase K bottle 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.

4. 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 Lysis Buffer 1 should always be visually confirmed before use.
5. Fill and prime the chemagic 360-D tubing with reagents by choosing the protocol "**prime manifolds H96 all 360 V150116.che**". Press [Insert IDs], follow the instructions given in the chemagic QA software and start priming by pressing [OK]. If functions enabling the ID data input are deactivated, start priming directly by pressing [Start].

NOTE: Priming needs to be done when reagent bottles are connected to the chemagic 360-D instrument for the first time or when the instrument's tubing is not already filled with the above-mentioned reagents.

6. If priming is not needed, select the protocol "**check manifolds H96 all 360 V150116.che**" and press [Insert IDs] or - if the enhanced functions are deactivated - [Start]. A small volume of buffer will be dispensed by each pump sequentially starting with the first pump used for this application. If one of the pumps does not show dispensing of buffer through all nozzles, please use the corresponding priming protocol for this pump. Performing several runs a day it is only necessary to check the pumps once at the beginning of the day.

7. Select the protocol "**chemagic Viral300 360 H96 prefilling VD200617.che**" and press [Insert IDs] and follow the instructions given in the chemagic QA software.
8. Ensure chemagic Tips 96 Tray contains enough tips and is aligned with the positions of the samples and place the chemagic Tips 96 Tray in position 1 on the tracking system. The reagents are automatically dispensed in whole rows and therefore the tips should be used also in whole rows on each rod in contact with any reagent solution.
9. Check the volumes in the buffer supply containers and confirm by pressing [OK]. See above "60 MIN PROTOCOL PROCEDURE (VARIOUS SPECIES)" minimum filling volume.

NOTE: Take care that all buffer supply bottles contain enough buffer. Only if the liquid level for all buffers is sufficient 96 isolations can be performed.

10. Select the number of samples for prefilling by using the drop down menu. The scheme for positioning the samples will be shown after selection. Take care to use the given positions. Confirm by pressing [OK].
11. Prefill the selected wells of the sample plate with 300 µL sample. To ensure the homogeneity of the samples, mix the samples gently prior to pipetting in the wells of the sample plate.

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

12. Prefill Elution Buffer 6 (chemagic Deep Well Plate 2 mL) and the thoroughly resuspended Magnetic Beads (chemagic Low Well Plate) in the corresponding plates by pipetting manually according to each corresponding well in use.

Component	Plate position on chemagic 360-D instrument	Volume/well
Magnetic Beads	2	150 µL
Elution Buffer 6	7	50 – 100 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.

13. Add the following reagents to the wells containing sample:
    - 4 µL Poly(A) RNA,
    - 10 µL Proteinase K and then
    - 300 µL Lysis Buffer 1

    It is possible to premix Poly(A) RNA, Proteinase K and Lysis Buffer 1 (choose the appropriate volume of Poly(A) RNA/ Proteinase K/ Lysis Buffer 1 to ensure you have sufficient volume for the number of isolations).

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.

14. Place the chemagic Deep Well Plates 2 mL and the chemagic Low Well Plate on the tracking system according to the instructions given by the chemagic QA software.
15. Place the sample plate in position 3 on the tracking system.
16. Check all plates for accurate orientation and fitting.
17. Close the front door and start the process by pressing [Start].
18. The automated DNA/RNA extraction process is initiated.
19. After the isolation procedure has finished use the [Turn Table] button to unload the tracking system. Each click on [Turn Table] moves the tracking system (table) clockwise by one position.

ATTENTION! Never move the tracking system (table) manually. This might damage the instrument. All movements must be performed with the [Turn Table] function.

NOTE: Opening the chemagic 360-D instrument door while the automated extraction run is ongoing, will terminate the run and the samples in process may be lost.

For information on cleaning the instrument see section “CLEANING AND MAINTENANCE”.

15.3 SHORT DESCRIPTION/ QUICK GUIDE

Automated DNA/RNA extraction run on chemagic 360-D instrument (60 min protocol):

- Select the protocol "**check manifolds H96 all 360 V150116.che**" to flush the tubing prior to starting the automated extraction run.
- Press [Insert IDs], follow the instructions given in the chemagic QA software and start flushing by pressing [OK].
- When using the functions enabling the ID data input, select the protocol "**chemagic Viral300 360 H96 prefilling VD200617.che**" and press [Insert IDs]. Follow the instructions given in the chemagic QA software to fill in the required data.
- Load the plates and the chemagic Tips 96 Tray on the tracking system positions 1-7 as shown in the following overview.
  (Numbers on tracking system refer to the positioning of the plate on the chemagic 360-D instrument.)
- Check all plates for accurate orientation and fitting.
- After all plates are in place, press [OK].
- Close the front door and start the DNA/RNA extraction process immediately by pressing [Start]. Subsequently the sample lysate will be mixed automatically.
- If the functions enabling the ID data input are deactivated, load the plates on the tracking system positions 1-7.
- After all plates are in place, select the protocol "**chemagic Viral300 360 H96 prefilling VD200617.che**", mark the columns in use on the plate map in the dialog and start the extraction run directly by pressing [Start].
- After the isolation procedure has finished use the [Turn Table] button to unload the tracking system. Each click on [Turn Table] moves the tracking system (table) clockwise by one position.

ATTENTION! Never move the tracking system (table) manually. This might damage the instrument. All movements must be performed with the [Turn Table] function.

NOTE: Opening the chemagic 360-D instrument door while the automated extraction run is ongoing, will terminate the run and the samples in process may be lost.

Position	Material in position	Protocol step in detail
1	chemagic Tips 96 Tray	Use disposable tips according to the positions of the samples and place the chemagic Tips 96 Tray. **Note: Tips need to be present in the Tray in full rows.**
2	chemagic Low Well Plate with 150 µL Magnetic Beads	Pipette 150 µL thoroughly resuspended Magnetic Beads in each well in use according to the sample plate and place the plate.
3	Sample plate (chemagic Deep Well Plate 2 mL)	Place the plate with prepared samples (300 µL sample, 4 µL Poly(A) RNA, 10 µL Proteinase K and 300 µL Lysis Buffer 1) on the tracking system. Binding Buffer 2 is dispensed in the plate automatically.
4	chemagic Deep Well Plate 2 mL	Place empty plate on the tracking system. Wash Buffer 3 is dispensed in the plate automatically.
5	chemagic Deep Well Plate 2 mL	Place empty plate on the tracking system. Wash Buffer 4 is dispensed in the plate automatically.
6	chemagic Deep Well Plate 2 mL	Place empty plate on the tracking system. Wash Buffer 5 is dispensed in the plate automatically.
7	chemagic Deep Well Plate 2 mL with 50-100 µL Elution Buffer 6	Pipette 50-100 µL Elution Buffer 6 in each well in use according to the sample positions and place the plate on the tracking system.
8	Empty	Position not in use.

16. PERFORMANCE CHARACTERISTICS

When using this extraction kit with the PerkinElmer SARS-CoV-2 Real-time RT-PCR Assay (2019-nCoV-PCR-AUS; discontinued) the following LoD (limit of detection) data (see below, sections 15.1 to 15.4) was reported (data generated by Suzhou Sym-Bio Lifescience Co., Ltd. No. 115, North Taiping Road, Taicang, Jiangsu Province, China).

When using this extraction kit with the EURORealTime SARS-CoV-2 Real-time RT-PCR Assay (REF MP 2606-0110) the following LoD data (see below, section 16.5) was reported by EUROIMMUN (a Revvity company).

16.1 LOD USING CHEMAGIC 360-D INSTRUMENT FOR EXTRACTION AND APPLIED BIOSYSTEMS™ 7500 PCR SYSTEM

Samples were prepared using pooled clinical oropharyngeal swabs or nasopharyngeal swabs specimen matrix. The pooled matrix was tested using SARS-CoV-2 Real-time RT-PCR Assay and confirmed to be negative. A total of six 2-fold dilutions of known concentrations of inactivated SARS-CoV-2 virus (Isolate 2/231/human/2020/CHN) were prepared in the negative clinical matrix and processed using the chemagic Viral DNA/RNA 300 Kit H96 (CMG-1033) on the chemagic 360-D instrument. Six individual extraction replicates per dilution were tested. The results are summarized in the following tables.

Table 1: Preliminary LoD study using oropharyngeal swabs on chemagic 360-D instrument.

Oropharyngeal Swab							
Dilution fold	N		ORF1ab		Mean Ct		
	Conc. (copies/mL)	Detection Rate	Conc. (copies/mL)	Detection Rate	N	ORF1ab	IC
$2.0 * 10^4$	137.00	6/6	41.85	6/6	36.48	36.82	32.18
$4.0 * 10^4$	68.50	6/6	20.93	6/6	37.04	37.98	32.14
$8.0 * 10^4$	34.25	6/6	10.46	6/6	39.10	38.88	32.21
$1.6 * 10^5$	17.13	5/6	5.23	4/6	38.89	39.77	32.35
$3.2 * 10^5$	8.56	3/6	2.62	2/6	39.35	39.85	32.28
$6.4 * 10^5$	4.28	0/6	1.31	0/6	/	/	32.41
Negative	0	0/6	0	0/6	/	/	32.23

Table 2: Probit predicted 95% detection rate (and confidence interval, CI) using oropharyngeal swabs spiked with SARS-CoV-2 (Isolate 2/231/human/2020/CHN) on chemagic 360-D instrument.

Probit predicted 95% Detection Rate (copies/mL)	
N	ORF1ab
19.08 (95% CI: 14.50 – 37.12)	7.14 (95% CI: 5.34 – 24.00)

Table 3: Preliminary LoD study using nasopharyngeal swabs on chemagic 360-D instrument.

Nasopharyngeal Swab							
Dilution fold	N		ORF1ab		Mean Ct		
	Conc. (copies/mL)	Detection Rate	Conc. (copies/mL)	Detection Rate	N	ORF1ab	IC
$2.0 * 10^4$	137.00	6/6	41.85	6/6	36.65	36.55	32.32
$4.0 * 10^4$	68.50	6/6	20.93	6/6	38.17	36.78	32.38
$8.0 * 10^4$	34.25	6/6	10.46	6/6	38.55	38.24	32.60
$1.6 * 10^5$	17.13	4/6	5.23	6/6	39.40	40.50	32.59
$3.2 * 10^5$	8.56	2/6	2.62	1/6	39.59	40.53	32.86
$6.4 * 10^5$	4.28	2/6	1.31	2/6	39.50	39.70	32.28
Negative	0	0/6	0	0/6	/	/	32.33

Table 4: Probit predicted 95% detection rate (and confidence interval, CI) using nasopharyngeal swabs spiked with SARS- CoV-2 (Isolate 2/231/human/2020/CHN) on chemagic 360-D instrument.

Probit predicted 95% Detection Rate (copies/mL)	
N	ORF1ab
26.44 (95% CI: 18.34 – 69.51)	8.32 (95% CI: 5.83 – 20.69)

16.2 VERIFICATION OF LOD USING CHEMAGIC 360-D INSTRUMENT FOR EXTRACTION AND APPLIED BIOSYSTEMS 7500 PCR SYSTEM

For the LoD verification study, pooled negative oropharyngeal swab matrix and pooled negative nasopharyngeal swab matrix was spiked with inactivated SARS-CoV-2 virus at the tentative LoD that was predicted among the two SARS-CoV-2 targets for each matrix (7.14 copies/mL of ORF1ab for oropharyngeal swab matrix and 8.32 copies/mL of ORF1ab for nasopharyngeal swab matrix). Twenty replicates per specimen matrix were prepared and extracted using the chemagic Viral DNA/RNA 300 Kit H96 (CMG-1033) on the chemagic 360-D instrument and tested using the SARS-CoV-2 Real-time RT-PCR Assay. Twenty additional replicates prepared at 1.5x the tentative LoD were also tested. The results are summarized in the following tables.

Table 5: chemagic 360-D instrument LoD verification results for oropharyngeal swab.

Concentration (copies/mL)			Detection Rate		Mean Ct		
LoD	N	ORF1ab	N	ORF1ab	N	ORF1ab	IC
1x	23.38	7.14	95% (19/20)	95% (19/20)	38.44	38.76	33.13
1.5x	35.07	10.71	100% (20/20)	100% (20/20)	38.74	38.11	33.09

Table 6: chemagic 360-D instrument LoD verification results for nasopharyngeal swab.

Concentration (copies/mL)			Detection Rate		Mean Ct		
LoD	N	ORF1ab	N	ORF1ab	N	ORF1ab	IC
1x	27.25	8.32	95% (19/20)	95% (19/20)	38.53	38.44	33.81
1.5x	40.87	12.49	100% (20/20)	100% (20/20)	38.50	37.79	32.72

16.3 LOD VERIFICATION USING CHEMAGIC 360-D INSTRUMENT AND ALTERNATIVE PCR SYSTEMS (EQUIVALENCY OF PCR SYSTEMS)

To expand the use of the SARS-CoV-2 Real-time RT-PCR Assay for use with the Applied Biosystems 7500 Fast/ QuantStudio™ 3/ QuantStudio™ 5 Real-Time PCR Systems and Analytik Jena qTOWER^3/ qTOWER^3 84 Real-Time PCR system, a study was conducted using contrived clinical nasopharyngeal swab specimens. Pooled negative nasopharyngeal swab specimens were spiked with two or three known concentrations of SeraCare RNA reference material containing the entire SARS-CoV-2 viral genome (https://www.seracare.com/AccuPlex-SARSCoV2-Molecular-Controls-Kit--Full-Genome-0505-0159/). Nucleic acids were extracted using the chemagic Viral DNA/RNA 300 Kit H96 (CMG-1033) on the chemagic 360-D instrument and up to 20 individual extraction replicates were tested on each PCR instrument platforms according to the instructions for use. Testing on the original Applied Biosystems 7500 PCR System was included in this study for equivalency comparison. The results are summarized in the following tables. The LoD was confirmed to be 20 copies/mL for ABI7500, ABI 7500 Fast Dx, QuantStudio 3, QuantStudio 5 and qTOWER^3 84, and 10 copies/mL for qTOWER^3. The detection sensitivity of all six instruments is considered equivalent.

Table 7: LoD verification on alternate Applied Biosystems PCR platforms.

Instrument	Concentration (copies/mL)	Target Gene	Mean Ct	Detection Rate for Target Gene	Overall Detection Rate for Algorithm
ABI 7500	6.7	N	40.2	80% (16/20)	90% (18/20)
		ORF	39.4	75% (15/20)	
	20	N	37.8	95% (19/20)	100% (20/20)
		ORF	37.5	95% (19/20)	
ABI 7500 Fast Dx	6.7	N	38.1	45% (9/20)	90% (18/20)
		ORF	39.0	85% (17/20)	
	20	N	37.7	75% (15/20)	100% (20/20)
		ORF	37.5	100% (20/20)	
QS3	12	N	ND	0% (0/3)	67% (2/3)
		ORF	34.1	67% (2/3)	
	20	N	35.7	30% (6/20)	100% (20/20)
		ORF	35.3	95% (19/20)	
	60	N	35.8	45% (9/20)	95% (19/20)
		ORF	33.0	95% (19/20)	
QS5	12	N	ND	0% (0/3)	0% (0/3)
		ORF	ND	0% (0/3)	
	20	N	35.8	25% (5/20)	95% (19/20)
		ORF	37.0	95% (19/20)	
	60	N	36.3	55% (11/20)	100% (20/20)
		ORF	35.1	100% (20/20)	
qTOWER^3	6.7	N	39.3	30% (6/20)	75% (15/20)
		ORF	39.7	65% (13/20)	
	10	N	38.2	65% (13/20)	100% (20/20)
		ORF	37.8	95% (19/20)	
	20	N	38.5	75% (15/20)	100% (20/20)
		ORF	36.9	100% (20/20)	
	40	N	37.9	95% (19/20)	100% (20/20)
		ORF	36.1	100% (20/20)	
qTOWER^3 84	10	N	38.5	35% (7/20)	90% (18/20)
		ORF	38.4	80% (16/20)	
	20	N	39.0	55% (11/20)	95% (19/20)
		ORF	37.3	85% (17/20)	
	40	N	38.0	80% (16/20)	100% (20/20)
		ORF	36.7	100% (20/20)	

16.4 LOD VERIFICATION IN SALIVA MATRIX BACKGROUND

The LoD (20 copies/mL) determined on QuantStudio 5 in the nasopharyngeal swab matrix background (described in section above) was further verified in saliva matrix background using the same instrument. Briefly, SARS-CoV-2 reference control material was spiked into negative saliva matrix to prepare positive samples at 20 copies/mL. In total 20 extraction replicates of this positive sample were extracted on chemagic 360-D instrument and amplified on QuantStudio 5. The results are summarized in the following table and LoD 20 copies/mL was verified by a 20/20 detection rate in the saliva matrix background.

Table 8: chemagic 360-D instrument LoD verification results for saliva.

Concentration (copies/mL)	Detection Rate		Mean Ct		
-	N	ORF1ab	N	ORF1ab	IC
20	100% (20/20)	100% (20/20)	35.53	35.14	30.70

16.5 LOD – ANALYTICAL SENSITIVITY ON VARIOUS PCR

LoD studies determine the lowest detectable concentration of SARS-CoV-2 at which approximately 95% of all (true positive) replicates test positive.

First, a tentative LoD was determined by testing 5-7 serial dilutions prepared by spiking recombinant virus containing SARS-CoV-2 RNA (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, when using the EURORealTime SARS-CoV-2 Real-time RT-PCR Assay, was determined to be 150 copies/mL.

The tentative LoD was confirmed by testing 21 replicates of negative oropharyngeal swab matrix spiked independently with the AccuPlex reference material and extracted with the CMG-1033 chemagic Viral DNA/RNA 300 Kit H96 on the chemagic 360-D instrument. Replicates were tested on the Roche LightCycler 480 II. The final LoD for all extraction methods was determined to be 150 copies/mL. The LoD of 150 copies/mL was then verified for the Applied Biosystems 7500 Fast Real-Time PCR, Bio-Rad CFX 96 Touch, and the Analytik Jena qTOWER³ cyclers using the same procedure described above. The LoD was confirmed by testing 21 extraction replicates.

Table 9: 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	
CMG-1033 chemagic Viral DNA/RNA 300 Kit H96						
Roche LightCycler 480 II	21	20	37.68	21	30.39	95%
Applied Biosystems 7500 Fast	21	21	36.87	21	29.97	100%
Bio-Rad CFX 96 Touch	21	20	36.42	21	30.38	95%
Analytic Jena qTOWER^3	21	20	37.25	21	28.49	95%

17. DETAILED PROTOCOL DESCRIPTION OF 31 MIN PROTOCOL

17.1 31 MIN PROTOCOL PROCEDURE (ONLY TESTED WITH SARS-COV-2 ISOLATION)

The following procedure describes the preparation and the execution of the extraction protocol using the chemagic 360-D instrument.

The duration of the automated extraction protocol is approximately 31 minutes.

The protocol is suitable for processing up to 96 samples in parallel (see “PROCESSING STEPS” below). For detailed instructions on the use of the chemagic 360-D instrument, please refer to the chemagic 360-D User Manual.

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

Connect the reagent bottles to the chemagic 360-D instrument as follows:

Pump	Buffer	Minimum filling volume
Pump 1	No bottle connected	n.a.
Pump 2	Binding Buffer 2	170 mL
Pump 3	No bottle connected	n.a.
Pump 4	Wash Buffer 4	125 mL
Pump 5	Wash Buffer 5	125 mL
Pump 6	No bottle connected	n.a.

NOTE: Recap the bottles tightly immediately after use or keep the bottles connected tightly to the chemagic 360-D instrument. Binding Buffer 2 and Wash Buffer 4 contain ethanol. If ethanol evaporates, the optimal yield or detection sensitivity cannot be guaranteed.

17.2 PROCESSING STEPS

1. Check all kit components for integrity. In case of damage, contact your supplier.
2. Before prefilling the plates mark each plate with material in position (samples, Magnetic Beads and buffers).

Note: The reagents are automatically dispensed in whole rows and therefore the tips should be used also in whole rows on each rod in contact with any reagent solution. Please note if partial plates are run, the solutions may not be sufficient for 960 extractions.

3. Reconstitute the Proteinase K and Poly(A) RNA components:

Component	Reconstitution
Proteinase K	Add 11 mL molecular biology grade water to Proteinase K bottle 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.

4. 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 Lysis Buffer 1 should always be visually confirmed before use.
5. Fill and prime the chemagic 360-D tubing with reagents by choosing the protocol "**prime manifolds H96 all 360 V150116.che**" Press [Insert IDs], follow the instructions given in the chemagic QA software and start priming by pressing [OK]. If functions enabling the ID data input are deactivated, start priming directly by pressing [Start].

NOTE: Priming needs to be done when reagent bottles are connected to the chemagic 360-D instrument for the first time or when the instrument's tubing is not already filled with the reagents.

6. If priming is not needed, select the protocol "**check manifolds H96 all 360 V150116.che**" and press [Insert IDs] or – if the enhanced functions are deactivated – [Start]. A small volume of buffer will be dispensed by each pump sequentially starting with the first pump used for this application. If one of the pumps does not show dispensing of buffer through all nozzles, please use the corresponding priming protocol for this pump. Performing several runs a day it is only necessary to check the pumps once at the beginning of the day.
7. Select the protocol "**chemagic Viral300 360 H96 prefilling 31 min VD201008.che**" and press [Insert IDs], follow the instructions given in the chemagic QA software.

8. Ensure chemagic Tips 96 Tray contains enough tips and is aligned with the positions of the samples and place the chemagic Tips 96 Tray in position 1 on the tracking system. The reagents are automatically dispensed in whole rows and therefore the tips should be used also in whole rows on each rod in contact with any reagent solution.
9. Check the volumes in the buffer supply containers and confirm by pressing [OK]. See above “31 MIN PROTOCOL PROCEDURE (ONLY TESTED WITH SARS-CoV-2 ISOLATION)” minimum filling volume.

NOTE: Take care that all buffer supply bottles contain enough buffer. Only if the liquid level for all buffers is sufficient 96 isolations can be performed.

10. Select the number of samples for prefilling by using the drop-down menu. The scheme for positioning the samples will be shown after selection. Take care to use the given positions. Confirm by pressing [OK].
11. Prefill the selected wells of the sample plate with 300 µL sample. To ensure the homogeneity of the samples, mix the samples gently prior to pipetting in the wells of the sample plate.

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

12. Prefill the Elution Buffer 6 (chemagic Deep Well Plate 2 mL) and the thoroughly resuspended Magnetic Beads (chemagic Low Well Plate) in the corresponding plates by pipetting manually according to each corresponding well in use.

Component	Plate position on chemagic 360-D instrument	Volume/well
Magnetic Beads	2	150 µL
Elution Buffer 6	7	50 – 100 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.

13. Add the following reagents to the wells containing sample.
    - 4 µL Poly(A) RNA,
    - 10 µL Proteinase K and then
    - 300 µL Lysis Buffer 1.

    It is possible to premix Poly(A) RNA, Proteinase K and Lysis Buffer 1 (choose the appropriate volume of Poly(A) RNA/ Proteinase K/ Lysis Buffer 1 to ensure you have sufficient volume for the number of isolations).

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.

14. Place the chemagic Deep Well Plates 2 mL and the chemagic Low Well Plate on the tracking system according to the instructions given by the chemagic QA software.
15. Place the sample plate in position 3 on the tracking system.
16. Check all plates for accurate orientation and fitting.
17. Close the front door and start the process by pressing [Start].
18. The automated DNA/RNA extraction process is initiated.
19. After the isolation procedure has finished use the [Turn Table] button to unload the tracking system. Each click on [Turn Table] moves the tracking system (table) clockwise by one position.

ATTENTION! Never move the tracking system (table) manually. This might damage the instrument. All movements must be performed with the [Turn Table] function.

NOTE: Opening the chemagic 360-D instrument door while the automated extraction run is ongoing, will terminate the run and the samples in process may be lost.

For information on cleaning the instrument see section “CLEANING AND MAINTENANCE”.

17.3 SHORT DESCRIPTION/ QUICK GUIDE

Automated DNA/RNA extraction run on chemagic 360-D instrument (31 min protocol):

- Select the protocol "**check manifolds H96 all 360 V150116.che**" to flush the tubing prior to starting the automated extraction run.
- Press [Insert IDs], follow the instructions given in the chemagic QA software and start flushing by pressing [OK].
- When using the functions enabling the ID data input, select the protocol "**chemagic Viral300 360 H96 prefilling 31 min VD201008.che**" and press [Insert IDs]. Follow the instructions given in the chemagic QA software to fill in the required data.
- Load the plates and the chemagic Tips 96 Tray on the tracking system positions 1-7 as shown in the following overview.
  (Numbers on tracking system refer to the positioning of the plate on the chemagic 360-D instrument.)
- Check all plates for accurate orientation and fitting.
- After all plates are in place, press [OK].
- Close the front door and start the DNA/RNA extraction process immediately by pressing [Start]. Subsequently the sample lysate will be mixed automatically.
- If the functions enabling the ID data input are deactivated, load the plates on the tracking system positions 1-7.
- After all plates are in place, select the protocol "**chemagic Viral300 360 H96 prefilling 31 min VD201008.che**", mark the columns in use on the plate map in the dialog and start the extraction run directly by pressing [Start].
- After the isolation procedure has finished use the [Turn Table] button to unload the tracking system. Each click on [Turn Table] moves the tracking system (table) clockwise by one position.

ATTENTION! Never move the tracking system (table) manually. This might damage the instrument. All movements must be performed with the [Turn Table] function.

NOTE: Opening the chemagic 360-D instrument door while the automated extraction run is ongoing, will terminate the run and the samples in process may be lost.

Position	Material in position	Protocol step in detail
1	chemagic Tips 96 Tray	Use disposable tips according to the positions of the samples and place the chemagic Tips 96 Tray. **Note: Tips need to be present in the Tray in full rows.**
2	chemagic Low Well Plate with 150 µL Magnetic Beads	Pipette 150 µL thoroughly resuspended Magnetic Beads in each well in use according to the sample plate and place the plate.
3	Sample plate (chemagic Deep Well Plate 2 mL)	Place the plate with prepared samples (300 µL sample, 4 µL Poly(A) RNA, 10 µL Proteinase K and 300 µL Lysis Buffer 1) on the tracking system. Binding Buffer 2 is dispensed in the plate automatically.
4	Empty	Position not in use.
5	chemagic Deep Well Plate 2 mL	Place empty plate on the tracking system. Wash Buffer 4 is dispensed in the plate automatically.
6	chemagic Deep Well Plate 2 mL	Place empty plate on the tracking system. Wash Buffer 5 is dispensed in the plate automatically.
7	chemagic Deep Well Plate 2 mL with 50-100 µL Elution Buffer 6	Pipette 50-100 µL Elution Buffer 6 in each well in use according to the sample positions and place the plate on the tracking system.
8	Empty	Position not in use.

17.4 NOTES 31 MIN PROTOCOL (ONLY TESTED WITH SARS-COV-2 ISOLATION)

For comparison of the 60 minutes protocol and the 31 minutes protocol extractions were performed using AccuPlex SARS-CoV-2 Reference Material (https://www.seracare.com/AccuPlex-SARSCoV2-Reference-Material-Kit-0505-0126/) spiked into transport medium from eNAT collection devices (Copan Italia S.p.A.) as sample material. The qPCR performance was tested with the EURORealTime SARS-CoV-2 qPCR (EUROIMMUN a Revvity company; kit used according to manufacturer instructions) run on a QuantStudio 5 Real-Time PCR System (96-well, 0.2 mL, desktop, Applied Biosystems, A28574). The 31 minutes protocol for SARS-CoV-2 ("**chemagic Viral300 360 H96 prefilling 31 min VD201008.che**") gives the users the chance to double their daily COVID-testing capacities. This shorter protocol can be used without any modifications or calibrations on the chemagic 360-D instrument. There is just a Ct value shift of 0.5 – 1 Ct compared to the 60 minutes standard protocol. Thus, the sensitivity is hardly reduced although there is a huge runtime and throughput benefit.

18. DETAILED PROTOCOL DESCRIPTION OF 18 MIN PROTOCOL

18.1 18 MIN PROTOCOL PROCEDURE (ONLY TESTED WITH SARS-COV-2 ISOLATION)

The following procedure describes the preparation and the execution of the extraction protocol using the chemagic 360-D instrument.

The duration of the automated extraction protocol is approximately 18 minutes.

The protocol is suitable for processing up to 96 samples in parallel (see “PROCESSING STEPS” below). For detailed instructions on the use of the chemagic 360-D instrument, please refer to the chemagic 360-D User Manual.

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

Connect the reagent bottles to the chemagic 360-D instrument as follows:

Pump	Buffer	Minimum filling volume
Pump 1	No bottle connected	n.a.
Pump 2	Binding Buffer 2	170 mL
Pump 3	No bottle connected	n.a.
Pump 4	Wash Buffer 4	125 mL
Pump 5	Wash Buffer 5	125 mL
Pump 6	No bottle connected	n.a.

NOTE: Recap the bottles tightly immediately after use or keep the bottles connected tightly to the chemagic 360-D instrument. Binding Buffer 2 and Wash Buffer 4 contain ethanol. If ethanol evaporates, the optimal yield or detection sensitivity cannot be guaranteed.

18.2 PROCESSING STEPS

1. Check all kit components for integrity. In case of damage, contact your supplier.
2. Before prefilling the plates mark each plate with material in position (samples, Magnetic Beads and buffers).

Note: The reagents are automatically dispensed in whole rows and therefore the tips should be used also in whole rows on each rod in contact with any reagent solution. Please note if partial plates are run, the solutions may not be sufficient for 960 extractions.

3. Reconstitute the Proteinase K and Poly(A) RNA components:

Component	Reconstitution
Proteinase K	Add 11 mL molecular biology grade water to Proteinase K bottle 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.

4. 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 Lysis Buffer 1 should always be visually confirmed before use.
5. Fill and prime the chemagic 360-D tubing with reagents by choosing the protocol "**prime manifolds H96 all 360 V150116.che**" Press [Insert IDs], follow the instructions given in the chemagic QA software and start priming by pressing [OK]. If functions enabling the ID data input are deactivated, start priming directly by pressing [Start].

NOTE: Priming needs to be done when reagent bottles are connected to the chemagic 360-D instrument for the first time or when the instrument's tubing is not already filled with the reagents.

6. If priming is not needed, select the protocol "**check manifolds H96 all 360 V150116.che**" and press [Insert IDs] or – if the enhanced functions are deactivated – [Start]. A small volume of buffer will be dispensed by each pump sequentially starting with the first pump used for this application. If one of the pumps does not show dispensing of buffer through all nozzles, please use the corresponding priming protocol for this pump. Performing several runs a day it is only necessary to check the pumps once at the beginning of the day.
7. Select the protocol "**chemagic Viral300 360 H96 prefilling 18 min VD210204.che**" and press [Insert IDs], follow the instructions given in the chemagic QA software.

8. Ensure chemagic Tips 96 Tray contains enough tips and is aligned with the positions of the samples and place the chemagic Tips 96 Tray in position 1 on the tracking system. The reagents are automatically dispensed in whole rows and therefore the tips should be used also in whole rows on each rod in contact with any reagent solution.
9. Check the volumes in the buffer supply containers and confirm by pressing [OK]. See above “18 MIN PROTOCOL PROCEDURE (ONLY TESTED WITH SARS-COV-2 ISOLATION)” minimum filling volume.

NOTE: Take care that all buffer supply bottles contain enough buffer. Only if the liquid level for all buffers is sufficient 96 isolations can be performed.

10. Select the number of samples for prefilling by using the drop-down menu. The scheme for positioning the samples will be shown after selection. Take care to use the given positions. Confirm by pressing [OK].
11. Prefill the selected wells of the sample plate with 300 µL sample. To ensure the homogeneity of the samples, mix the samples gently prior to pipetting in the wells of the sample plate.

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

12. Prefill the Elution Buffer 6 (chemagic Deep Well Plate 2 mL) and the thoroughly resuspended Magnetic Beads (chemagic Low Well Plate) in the corresponding plates by pipetting manually according to each corresponding well in use.

Component	Plate position on chemagic 360-D instrument	Volume/well
Magnetic Beads	2	150 µL
Elution Buffer 6	7	50 – 100 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.

13. Add the following reagents to the wells containing sample.
    - 4 µL Poly(A) RNA,
    - 10 µL Proteinase K and then
    - 300 µL Lysis Buffer 1.

    It is possible to premix Poly(A) RNA, Proteinase K and Lysis Buffer 1 (choose the appropriate volume of Poly(A) RNA/ Proteinase K/ Lysis Buffer 1 to ensure you have sufficient volume for the number of isolations).

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.

14. Place the chemagic Deep Well Plates 2 mL and the chemagic Low Well Plate on the tracking system according to the instructions given by the chemagic QA software.
15. Place the sample plate in position 3 on the tracking system.
16. Check all plates for accurate orientation and fitting.
17. Close the front door and start the process by pressing [Start].
18. The automated DNA/RNA extraction process is initiated.
19. After the isolation procedure has finished use the [Turn Table] button to unload the tracking system. Each click on [Turn Table] moves the tracking system (table) clockwise by one position.

ATTENTION! Never move the tracking system (table) manually. This might damage the instrument. All movements must be performed with the [Turn Table] function.

NOTE: Opening the chemagic 360-D instrument door while the automated extraction run is ongoing, will terminate the run and the samples in process may be lost.

For information on cleaning the instrument see section “CLEANING AND MAINTENANCE”.

18.3 SHORT DESCRIPTION/ QUICK GUIDE

Automated DNA/RNA extraction run on chemagic 360-D instrument (18 min protocol):

- Select the protocol "**check manifolds H96 all 360 V150116.che**" to flush the tubing prior to starting the automated extraction run.
- Press [Insert IDs], follow the instructions given in the chemagic QA software and start flushing by pressing [OK].
- When using the functions enabling the ID data input, select the protocol "**chemagic Viral300 360 H96 prefilling 18 min VD210204.che**" and press [Insert IDs]. Follow the instructions given in the chemagic QA software to fill in the required data.
- Load the plates and the chemagic Tips 96 Tray on the tracking system positions 1-7 as shown in the following overview.
  (Numbers on tracking system refer to the positioning of the plate on the chemagic 360-D instrument.)
- Check all plates for accurate orientation and fitting.
- After all plates are in place, press [OK].
- Close the front door and start the DNA/RNA extraction process immediately by pressing [Start]. Subsequently the sample lysate will be mixed automatically.
- If the functions enabling the ID data input are deactivated, load the plates on the tracking system positions 1-7.
- After all plates are in place, select the protocol "**chemagic Viral300 360 H96 prefilling 18 min VD210204.che**", mark the columns in use on the plate map in the dialog and start the extraction run directly by pressing [Start].
- After the isolation procedure has finished use the [Turn Table] button to unload the tracking system. Each click on [Turn Table] moves the tracking system (table) clockwise by one position.

ATTENTION! Never move the tracking system (table) manually. This might damage the instrument. All movements must be performed with the [Turn Table] function.

NOTE: Opening the chemagic 360-D instrument door while the automated extraction run is ongoing, will terminate the run and the samples in process may be lost.

Position	Material in position	Protocol step in detail
1	chemagic Tips 96 Tray	Use disposable tips according to the positions of the samples and place the chemagic Tips 96 Tray. **Note: Tips need to be present in the Tray in full rows.**
2	chemagic Low Well Plate with 150 µL Magnetic Beads	Pipette 150 µL thoroughly resuspended Magnetic Beads in each well in use according to the sample plate and place the plate.
3	Sample plate (chemagic Deep Well Plate 2 mL)	Place the plate with prepared samples (300 µL sample, 4 µL Poly(A) RNA, 10 µL Proteinase K and 300 µL Lysis Buffer 1) on the tracking system. Binding Buffer 2 is dispensed in the plate automatically.
4	Empty	Position not in use.
5	chemagic Deep Well Plate 2 mL	Place empty plate on the tracking system. Wash Buffer 4 is dispensed in the plate automatically.
6	chemagic Deep Well Plate 2 mL	Place empty plate on the tracking system. Wash Buffer 5 is dispensed in the plate automatically.
7	chemagic Deep Well Plate 2 mL with 50-100 µL Elution Buffer 6	Pipette 50-100 µL Elution Buffer 6 in each well in use according to the sample positions and place the plate on the tracking system.
8	Empty	Position not in use.

18.4 PERFORMANCE NOTES 18 MIN PROTOCOL (ONLY TESTED WITH SARS-COV-2 ISOLATION)

For comparison of the 60 minutes protocol and the 18 minutes protocol extractions were performed using AccuPlex SARS-CoV-2 Reference Material (https://www.seracare.com/AccuPlex-SARSCoV2-Reference-Material-Kit-0505-0126/) spiked into transport medium from eNAT collection devices (Copan Italia S.p.A.) as sample material. The qPCR performance was tested with the EURORealTime SARS-CoV-2 qPCR (EUROIMMUN a Revvity company; kit used according to manufacturer instructions) run on a QuantStudio 5 Real-Time PCR System (96-well, 0.2 mL, desktop, Applied Biosystems, A28574). The 18 minutes protocol for SARS-CoV-2 ("**chemagic Viral300 360 H96 prefilling 18 min VD210204.che**") gives the users the chance to triple their daily COVID-testing capacities. This shorter protocol can be used without any modifications or calibrations on the chemagic 360-D instrument, however the X-offset Bead Collection under Parameter Settings in the chemagic software must be disabled by a service engineer from Revvity. If the X-offset Bead Collection is enabled, the duration of the extraction run is elongated to 21min. There is just a Ct value shift of 0.5 – 1 Ct compared to the 60 minutes standard protocol. Thus, the sensitivity is hardly reduced although there is a huge runtime and throughput benefit.

19. CLEANING AND MAINTENANCE

Cleaning and maintenance of the system is described in detail in the chemagic 360-D User Manual. The system cleaning is performed once per week. Clean the chemagic Dispenser as follows.

- Select the protocol “**regular cleaning procedure 96 dispenser 360 V150116.che**” and press [Insert IDs] or [Start] if the enhanced functions are deactivated. Follow the instructions as given in the software.
- Prior to the next use of the chemagic Dispenser perform the appropriate priming protocol.
- The cleaning of the chemagic Dispenser with 70 % ethanol is recommended once per month. Simply use the “**intensive cleaning procedure H96 dispenser 360 V150116.che**” instead of the regular one for this purpose.
- If the chemagic Dispenser is not used for longer periods, it is mandatory to perform the "regular cleaning procedure" to maintain the performance of the instrument when bringing it back into service.

20. DOWNSTREAM APPLICATIONS

20.1 DOWNSTREAM APPLICATIONS TESTED WITH SARS-COV-2 ISOLATION

The following downstream applications were successfully performed and described in literature after isolation of SARS-CoV-2 samples with the chemagic Viral DNA/RNA 300 Kit H96 (CMG-1033-S).

Table 10: Downstream applications tested with SARS-CoV-2 extraction.

Downstream Application	Kits	Reference
RT-qPCR	TaqPath COVID-19 Combo Kit (Applied Biosystems™)	Barrett *et al.* BMC Infectious Diseases (2020) 20:853 https://doi.org/10.1186/s12879-020-05587-2
		Radbel *et al.* Journal of Molecular Diagnostics (2020) Volume 22, Issue 7, 871-875 https://doi.org/10.1016/j.jmoldx.2020.04.209
	SuperScript™ III One-Step RT-PCR System with Platinum™ TaqDNA Polymerase (ThermoFisher)	Streeck *et al. Nat Commun* (2020) **11,** 5829 https://doi.org/10.1038/s41467-020-19509-y
	virella SARS-CoV-2 seqc rRT-PCR kit (Gerbion)	Wandernoth *et al.* Viruses (2020) 12:849 https://doi:10.3390/v12080849
	2019-nCoV CDC EUA Kit (IDT)	Xie *et al.* Processes (2020) *8*(11), 1425 https://doi.org/10.3390/pr8111425
	SARS-CoV-2 real-time RT-PCR assay CE-IVD (Revvity)	Klussmeier *et al.* Biospektrum (2020) **26**, 500-503 https://doi.org/10.1007/s12268-020-1431-1
	NeoPlex COVID-19 kit (Gene Matrix)	Senok *et al.* Infect Drug Resistance (2020) **13**, 3393-3399 https://doi.org/10.2147/IDR.S275152

Downstream Application	Kits	Reference
RT-qPCR	NxTAG® Respiratory Pathogen Panel (Luminex Corporation), Fast Virus 1-Step Master Mix (ThermoFisher)	Kanji *et al.* Journal of the Association of Medical Microbiology and Infectious Disease Canada (2021) **1**, 10-15 https://doi.org/10.3138/jammi-2020-0035
	1) TRUPCR SARS-CoV-2 (Black Bio Biotech) 2) TaqPath RT-PCR COVID-19 Kit (ThermoFisher) 3) Allplex 2019-nCOV Assay (Seegene) 4) Patho detect COVID-19 qualitative PCR kit (My Lab) 5) LabGun COVID-19 RT-PCR Kit 6) Fosun COVID-19 RT-PCR detection kit (Fosun Ltd) 7) Realtime Fluorescent RT-PCR kit (BGI Genomics)	Garg *et al.* Journal of Medical Virology (2021) **93**, 2281-2286 https://doi.org/10.1002/jmv.26691
	Ligh™ix® Sarbeco V E-gene plus EAV control (TIB MolBiol) LightCycler® Multiplex RNA Virus Master (Roche)	Kriegshäuser *et al.* Clinical Chemistry and Laboratory Medicine (CCLM) (2021) **9**, 351-353 https://doi.org/10.1515/cclm-2021-0078
Sequencing	ARTIC V3 protocol	Kanji *et al.* Journal of the Association of Medical Microbiology and Infectious Disease Canada (2021) **1**, 10-15 https://doi.org/10.3138/jammi-2020-0035
		Jonsson *et al.* Nature Communications (2021) **12**, 3633 https://doi.org/10.1038/s41467-021-23883-6
		Tegally *et al.* Nature Medicine (2021) **27**, 440-446 https://doi.org/10.1038/s41591-021-01255-3

Downstream Application	Kits	Reference
Sequencing	**cDNA synthesis:** LunaScript RT Super Mix kit (New England Biolabs), SuperScriptIV (ThermoFisher) **Library prep.:** SureSelectXT Low Input kit CoVHuman6X enrichment capture-based method (Agilent Technologies) ARTIC tiled amplicon multiplex PCR protocol (v3) + NEBNext Ultra II DNA Library Prep Kit (New England Biolabs)	Ellingford *et al.* eLife (2021) **10**, 65453 https://doi.org/10.7554/eLife.65453

20.2 DOWNSTREAM APPLICATION TESTED WITH SARS-COV-2, INFLUENZA A AND B AND RSV ISOLATION

The following downstream application was successfully performed and described in the IFU after isolation of SARS-CoV-2, Infuenza A and B and RSV samples with the chemagic Viral DNA/RNA 300 Kit H96 (IVD-1033-S).

Table 11: Downstream application tested with SARS-CoV-2, Influenza A and B and RSV extraction.

Downstream Application	Kits	Reference
RT-qPCR	res4plex *direct* RT-PCR, FRIZ Biochem	Instruction for Use, res4plex *direct* RT-PCR, FRIZ Biochem https://frizbiochem.de/downloads/

21. 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.

22. LIMITATIONS OF THE PROCEDURE

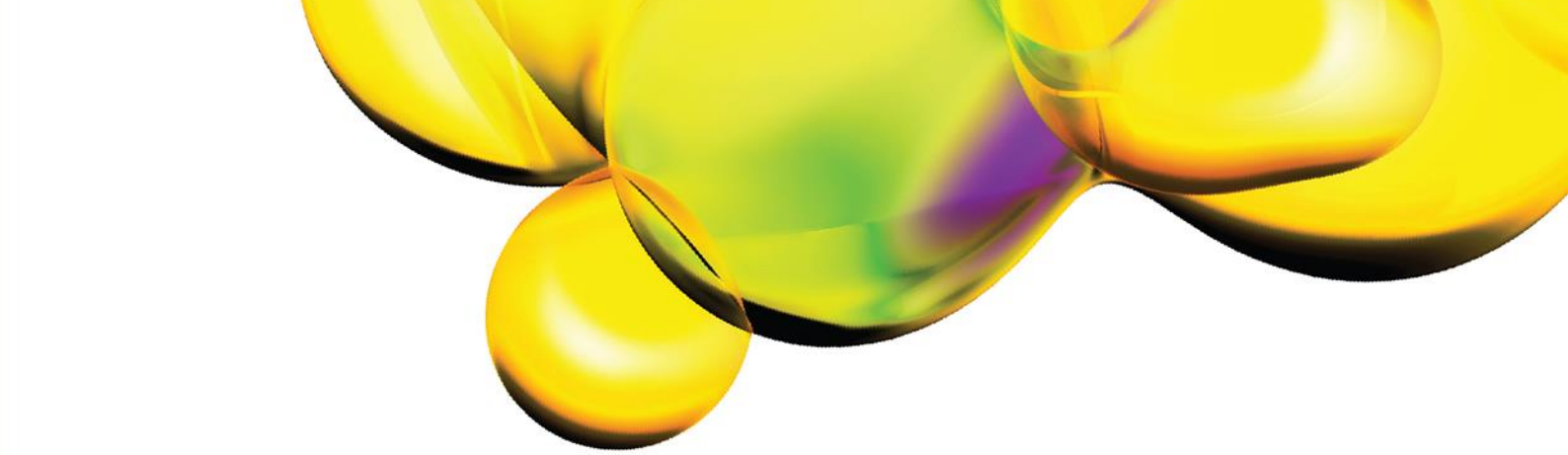
The following collection devices are **not recommended** for use with the chemagic Viral DNA/RNA 300 Kit H96, for further questions please reach out to support.chemagen@revvity.com.

Table 12: 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-1033-S kit is validated for the automated isolation of DNA and RNA from human plasma, saliva and naso- or oropharyngeal swabs on the chemagic™ 360-D instrument. Other sample materials may be compatible but have not been validated.



WARRANTY

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February 2026

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