INSTRUCTION FOR USE

chemagic™
Pathogen NA gDNA Kit H96
Pathogen NA gDNA Kit H96 XL

Product number: **IVD-1049 & IVD-1049-1000**

Reagents for 960 extractions.

UDI-DI: 4260543364182 & 4260543364274

Version: V240503 EN

Manufacturer: Revvity chemagen Technologie GmbH
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CE

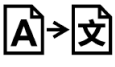
FOR *IN VITRO* DIAGNOSTIC USE.

1. TABLE OF CONTENTS

2. 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.

3. 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

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

4. INTENDED PURPOSE

The chemagic™ Pathogen NA gDNA Kit H96 (IVD-1049) and the chemagic™ Pathogen NA gDNA Kit H96 XL (IVD-1049-1000) are kits for the automated isolation and purification of DNA and RNA from human plasma, blood, saliva and naso- or oropharyngeal swabs for *in vitro* diagnostic purposes.

The products are used on the chemagic™ 360-D instrument and are intended for laboratory personnel trained for the chemagic 360-D instrument in combination with chemagic nucleic acid purification kits. The kits are designed to be used with IVD downstream applications employing enzymatic amplification and detection of DNA/ 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.

5. SUMMARY AND PRINCIPLE

The chemagic Pathogen NA gDNA Kit H96 and chemagic Pathogen NA gDNA Kit H96 XL are based on a magnetic bead technology platform proprietary to Revvity chemagen Technologie GmbH. Cells or other source of DNA/ RNA present in plasma, blood, 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 products are intended to be used with appropriate 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 kits contain reagents sufficient to perform 960 extractions.

The expiry date of the unopened kits 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”).

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, 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 360-D User Manual. This manual will be provided with the chemagic 360-D instrument.

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

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:

- chemagic Pathogen NA gDNA Kit H96: https://chemagen.com/products/chemagen-ivd-products/ce-ivd-chemagic-kits/chemagic-pathogen-na-gdna-kit-h96/
- chemagic Pathogen NA gDNA Kit H96 XL: https://chemagen.com/products/chemagen-ivd-products/ce-ivd-chemagic-kits/chemagic-pathogen-na-gdna-kit-h96-xl/

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 products are 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 Pathogen NA gDNA Kit H96 and chemagic Pathogen NA gDNA Kit H96 XL.

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.

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 chloride and is harmful if swallowed, in contact with skin or if inhaled. Binding Buffer 2, Wash Buffer 3 and Wash Buffer 4 contain sodium perchlorate and ethanol and are flammable liquids and vapors and are harmful if swallowed. Wash Buffer 5 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) available on our webpage.

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 (IVD-1049)

The chemagic Pathogen NA gDNA Kit H96 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 nanoparticular 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  WARNING	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 (pH 6.7-7.2) solution containing guanidinium chloride (30–50 %) and isotridecyl alcohol (1-1.5 %). Lysis Buffer 1 is used to lyse the cells or other DNA/ RNA source present in the sample to release DNA/ RNA in solution.

CAUTION! Lysis Buffer 1 contains guanidinium chloride and isotridecyl alcohol.

Hazard, precautionary and EUH phrases	
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Hazard, precautionary and EUH phrases	
P301+P312	IF SWALLOWED: Call a POISON/ doctor if you feel unwell. P330 Rinse mouth.
P330	Rinse mouth.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313	If skin irritation occurs: Get medical advice/ attention.
P501	Dispose of contents/ container in accordance with local/ regional/ national/ international regulations.

10.3 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 (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.

Hazard, precautionary and EUH phrases	
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  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 5.0-5.6) solution with sodium perchlorate (10–20 %) and ethanol (10–30 %). 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	
H226	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.

10.5 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 Tris-HCl-buffered (pH 5.0–5.6) solution with sodium perchlorate (10–20 %) and ethanol (10–30 %). Used for removing non-DNA/ non-RNA contaminants during washing step.

CAUTION! Wash Buffer 4 contains ethanol and sodium perchlorate.

Hazard, precautionary and EUH phrases	
H226	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  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 %). Used for removing last traces of non-DNA/ non-RNA contaminants during washing step.

CAUTION! Wash Buffer 5 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.

10.7 WASH BUFFER 6

Component	Quantity	Shelf life and storage
Wash 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 ultra-filtered water solution. Used for removing possible residuals of ethanol.

10.8 ELUTION BUFFER 7

Component	Quantity	Shelf life and storage
Elution Buffer 7	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.

10.9 PROTEINASE K

Component	Quantity	Shelf life and storage
Proteinase K   DANGER	10 glass vials (lyophilized)	+2 to +25 °C until expiry date stated on the vial label. Once reconstituted, stable for 28 days at +2 to +8 °C.

Proteinase K is reconstituted by adding 1.25 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.

Hazard, precautionary and EUH phrases	
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.

10.10 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. The Poly(A) RNA functions as a DNA/ RNA carrier to enhance the efficiency of the extraction process.

10.11 POLY(A) RNA BUFFER

Component	Quantity	Shelf life and storage
Poly(A) RNA Buffer  WARNING	10 tubes (volume see label)	+2 to +25 °C until expiry date stated on the tube 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	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.

10.12 FURTHER KIT COMPONENTS

The chemagic Pathogen NA gDNA 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	60	+2 to +25 °C

11. KIT REAGENTS AND SAFETY INFORMATION (IVD-1049-1000)

The chemagic Pathogen NA gDNA Kit H96 XL 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  WARNING	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 (pH 6.7-7.2) solution containing guanidinium chloride (30–50 %) and isotridecyl alcohol (1-1.5 %). Lysis Buffer 1 is used to lyse the cells or other DNA/ RNA source present in the sample to release DNA/ RNA in solution.

CAUTION! Lysis Buffer 1 contains guanidinium chloride and isotridecyl alcohol.

Hazard, precautionary and EUH phrases	
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.
P301+P312	IF SWALLOWED: Call a POISON/ doctor if you feel unwell. P330 Rinse mouth.
P330	Rinse mouth.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313	If skin irritation occurs: Get medical advice/ attention.
P501	Dispose of contents/ container in accordance with local/ regional/ national/ international regulations.

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 (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.

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 5.0-5.6) solution with sodium perchlorate (10–20 %) and ethanol (10–30 %). 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	
H226	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.

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 Tris-HCl-buffered (pH 5.0–5.6) solution with sodium perchlorate (10–20 %) and ethanol (10–30 %). Used for removing non-DNA/ non-RNA contaminants during washing step.

CAUTION! Wash Buffer 4 contains ethanol and sodium perchlorate.

Hazard, precautionary and EUH phrases	
H226	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  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 %). Used for removing last traces of non-DNA/ non-RNA contaminants during washing step.

CAUTION! Wash Buffer 5 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.

11.7 WASH BUFFER 6

Component	Quantity	Shelf life and storage
Wash 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 ultra-filtered water solution. Used for removing possible residuals of ethanol.

11.8 ELUTION BUFFER 7

Component	Quantity	Shelf life and storage
Elution Buffer 7	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.

11.9 PROTEINASE K

Component	Quantity	Shelf life and storage
Proteinase K   DANGER	20 glass vials (lyophilized)	+2 to +25 °C until expiry date stated on the vial label. Once reconstituted, stable for 28 days at +2 to +8 °C.

The Proteinase K is reconstituted by adding 1.25 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.

11.10 POLY(A) RNA

Component	Quantity	Shelf life and storage
Poly(A) RNA	20 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.

11.11 POLY(A) RNA BUFFER

Component	Quantity	Shelf life and storage
Poly(A) RNA Buffer  WARNING	20 tubes (volume see label)	+2 to +25 °C until expiry date stated on the tube 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	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.

11.12 FURTHER KIT COMPONENTS

The chemagic Pathogen NA gDNA Kit H96 XL contains the following plastic material.

Component	Quantity	Storage
chemagic Tips 96 Tray	10	+2 to +25 °C
chemagic Deep Well Plate 2 mL	70	+2 to +25 °C

12. REQUIRED PROTOCOLS FILES

The following protocol files will be provided by Revvity chemagen Technologie GmbH and are available on the webpage or will be provided by customer support.

Protocol	Protocol type/ purpose
chemagic Body Fluid 200 360 H96 prefilling VD220531.che	Kit-related extraction file (.che file) for the chemagic 360-D instrument (for 200 µL sample material)
chemagic Body Fluid 500 360 H96 prefilling VD220531.che	Kit-related extraction file (.che file) for the chemagic 360-D instrument (for 500 µL sample material)
chemagic Body Fluid 1k 360 H96 prefilling VD220831.che	Kit-related extraction file (.che file) for the chemagic 360-D instrument (for 1000 µL sample material)
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 Pathogen NA gDNA Kit H96 and the chemagic Pathogen NA gDNA Kit H96 XL require 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 7, 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

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

13.4 OTHER ADDITIONAL OPTIONAL ITEMS

Product	Purpose
Isotonic saline solution, sterile	Liquefying of swab material before use and filling up sample volume

14. SPECIMEN COLLECTION AND HANDLING

The chemagic Pathogen NA gDNA Kit H96 and chemagic Pathogen NA gDNA Kit H96 XL are usable with fresh and frozen human plasma and blood, 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 Diagonstics Inc.) as direct aliquots of 200, 500 or 1000 µL per isolation.

Human whole blood (up to 800 µL or 800 µL topped with 200 µL isotonic saline solution) that is fresh, frozen or stored typically for a maximum of 10 days at +2 to +8 °C should be used. For long-term storage, freezing at –20 °C or –80 °C in aliquots is recommended. The recommended blood stabilizers are EDTA or citrate. The use of heparin-stabilized blood samples can cause inhibition in downstream applications and is therefore not recommended. The white blood cell count in the whole blood sample decreases during storage. Prolonged storage of the samples may cause a poor yield of the DNA after extraction.

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 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 250 µL of isotonic saline solution and incubate for 5 min at 15-25 °C before use. 200 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, the specimen for pathogen testing should be inactivated before use.

We recommend incubating the samples at 68 °C for 15 minutes (± 2 minutes) for inactivation. The pathogen inactivation was not validated within IVD-1049/-1000. Transfer the inactivated lysate to the sample deep well plate in step 10 of the extraction protocol and continue with step 11.

15. DETAILED PROTOCOL DESCRIPTION FOR 200 µL SAMPLE MATERIAL

15.1 PROTOCOL PROCEDURE FOR 200 µL SAMPLE MATERIAL (VARIOUS SPECIES)

The following procedure describes the preparation and the execution of the extraction protocol using the chemagic 360-D instrument to be used with the chemagic Pathogen NA gDNA Kit H96.

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
Pump 1	Lysis Buffer 1
Pump 2	Binding Buffer 2
Pump 3	Wash Buffer 3
Pump 4	Wash Buffer 4
Pump 5	Wash Buffer 5
Pump 6	Wash Buffer 6

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, Wash Buffer 4 and Wash Buffer 5 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).
3. Reconstitute the Proteinase K and Poly(A) RNA components:

Component	Reconstitution
Proteinase K	Add 1.25 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.

4. 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.

5. 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.
6. Select the protocol "**chemagic Body Fluid 200 360 H96 prefilling VD220531.che**" and press [Insert IDs] and follow the instructions given in the chemagic QA software.
7. 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.

8. Check the volumes in the buffer supply containers and confirm by pressing [OK].

NOTE: Take care that all buffer supply bottles contain enough buffer. Only if the liquid level for all buffers is above 125 mL 96 isolations can be performed.

9. Select the number of samples for prefilling by using the drop down menu. The scheme for positioning the samples will be shown after selecting. Take care to use the given positions. Confirm by pressing [OK].
10. Prefill the selected wells of the sample plate with 200 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 has to be liquefied before use.

11. Prefill Elution Buffer 7 and the thoroughly resuspended Magnetic Beads by pipetting manually according to each corresponding well in use.

Component	Plate position on chemagic 360-D instrument	Volume/ well
Magnetic Beads	3	30 µL
Elution Buffer 7	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.

12. Add the following reagents to the wells containing sample.
    - 4 µL Poly(A) RNA and
    - 10 µL Proteinase K.
13. Place the chemagic Deep Well Plates 2 mL on the tracking system according to the instructions given by the chemagic QA software.
14. Place the sample plate in position 2 on the tracking system.
15. Check all plates for accurate orientation and fitting.
16. Close the front door and start the process by pressing [Start].
17. The automated DNA/ RNA extraction process is initiated.

18. 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 (200 µL 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 Body Fluid 200 360 H96 prefilling VD220531.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 follows.
  (Numbers on tracking system refer to the positioning of the plate on the chemagic 360-D instrument.)

Position on tracking system	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 tray in full rows.**
2	Sample plate (chemagic Deep Well Plate 2 mL)	Place the plate with prepared samples (200 µL sample, 4 µL Poly(A) RNA and 10 µL Proteinase K) Lysis Buffer 1 and Binding Buffer 2 are dispensed in the plate automatically.
3	chemagic Deep Well Plate 2 mL with 30 µL Magnetic Beads	Pipette 30 µL thoroughly resuspended Magnetic Beads in each well in use according to the sample plate and place the plate. Wash Buffer 3 is dispensed in the plate automatically.
4	chemagic Deep Well Plate 2 mL	Place empty plate. Wash Buffer 4 is dispensed in the plate automatically.
5	chemagic Deep Well Plate 2 mL	Place empty plate. Wash Buffer 5 is dispensed in the plate automatically.
6	chemagic Deep Well Plate 2 mL	Place empty plate. Wash Buffer 6 is dispensed in the plate automatically.
7	chemagic Deep Well Plate 2 mL with 50–100 µL Elution Buffer 7	Pipette (50-100 µL) Elution Buffer 7 in each well in use according to the sample positions and place the plate.

- 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 Body Fluid 200 360 H96 prefilling VD220531.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.

16. DETAILED PROTOCOL DESCRIPTION FOR 500 µL SAMPLE MATERIAL

16.1 PROTOCOL PROCEDURE FOR 500 µL SAMPLE MATERIAL (VARIOUS SPECIES)

The following procedure describes the preparation and the execution of the extraction protocol using the chemagic 360-D instrument with the chemagic Pathogen NA gDNA Kit H96 XL.

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
Pump 1	Lysis Buffer 1
Pump 2	Binding Buffer 2
Pump 3	Wash Buffer 3
Pump 4	Wash Buffer 4
Pump 5	Wash Buffer 5
Pump 6	Wash Buffer 6

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, Wash Buffer 4 and Wash Buffer 5 contain ethanol. If ethanol evaporates, the optimal yield or detection sensitivity cannot be guaranteed.

16.2 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).
3. Reconstitute the Proteinase K and Poly(A) RNA components:

Component	Reconstitution
Proteinase K	Add 1.25 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.

4. 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.

5. 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.
6. Select the protocol "**chemagic Body Fluid 500 360 H96 prefilling VD220531.che**" and press [Insert IDs] and follow the instructions given in the chemagic QA software.
7. 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.

8. Check the volumes in the buffer supply containers and confirm by pressing [OK].

NOTE: Take care that all buffer supply bottles contain enough buffer. Only if the liquid level for all buffers is above 125 mL 96 isolations can be performed.

9. Select the number of samples for prefilling by using the drop down menu. The scheme for positioning the samples will be shown after selecting. Take care to use the given positions. Confirm by pressing [OK].
10. Prefill the selected wells of the sample plate with 500 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 has to be liquefied before use.

11. Prefill Elution Buffer 7 and the thoroughly resuspended Magnetic Beads by pipetting manually according to each corresponding well in use.

Component	Plate position on chemagic 360-D instrument	Volume/ well
Magnetic Beads	3	50 µL
Elution Buffer 7	7	100–300 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.

12. Add the following reagents to the wells containing sample.
    - 4 µL Poly(A) RNA and
    - 10 µL Proteinase K.
13. Place the chemagic Deep Well Plates 2 mL on the tracking system according to the instructions given by the chemagic QA software.
14. Place the sample plate in position 2 on the tracking system.
15. Check all plates for accurate orientation and fitting.
16. Close the front door and start the process by pressing [Start].
17. The automated DNA/ RNA extraction process is initiated.

18. 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”.

16.3 SHORT DESCRIPTION/ QUICK GUIDE

Automated DNA/ RNA extraction run on chemagic 360-D instrument (500 µL 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 Body Fluid 500 360 H96 prefilling VD220531.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 follows.
  (Numbers on tracking system refer to the positioning of the plate on the chemagic 360-D instrument.)

Position on tracking system	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 Tray in full rows.**
2	Sample plate (chemagic Deep Well Plate 2 mL)	Place the plate with prepared samples (500 µL sample, 4 µL Poly(A) RNA and 10 µL Proteinase K) Lysis Buffer 1 and Binding Buffer 2 are dispensed in the plate automatically.
3	chemagic Deep Well Plate 2 mL with 50 µL Magnetic Beads	Pipette 50 µL thoroughly resuspended Magnetic Beads in each well in use according to the sample plate and place the plate. Wash Buffer 3 is dispensed in the plate automatically.
4	chemagic Deep Well Plate 2 mL	Place empty plate. Wash Buffer 4 is dispensed in the plate automatically.
5	chemagic Deep Well Plate 2 mL	Place empty plate. Wash Buffer 5 is dispensed in the plate automatically.
6	chemagic Deep Well Plate 2 mL	Place empty plate. Wash Buffer 6 is dispensed in the plate automatically.
7	chemagic Deep Well Plate 2 mL with 100–300 µL Elution Buffer 7	Pipette (100-300 µL) Elution Buffer 7 in each well in use according to the sample positions and place the plate.

- 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 Body Fluid 500 360 H96 prefilling VD220531.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.

17. DETAILED PROTOCOL DESCRIPTION FOR 1000 µL SAMPLE MATERIAL

17.1 PROTOCOL PROCEDURE FOR 1000 µL SAMPLE MATERIAL (VARIOUS SPECIES)

The following procedure describes the preparation and the execution of the extraction protocol using the chemagic 360-D instrument with the chemagic Pathogen NA gDNA Kit H96 XL.

The duration of the automated extraction protocol is approximately 85 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
Pump 1	Lysis Buffer 1
Pump 2	Binding Buffer 2
Pump 3	Wash Buffer 3
Pump 4	Wash Buffer 4
Pump 5	Wash Buffer 5
Pump 6	Wash Buffer 6

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, Wash Buffer 4 and Wash Buffer 5 contain ethanol. If ethanol evaporates, the optimal yield or detection sensitivity cannot be guaranteed.

17.2 PROCESSING STEPS

19. Check all kit components for integrity. In case of damage, contact your supplier.
20. Before prefilling the plates mark each plate with material in position (samples, Magnetic Beads and buffers).
21. Reconstitute the Proteinase K and Poly(A) RNA components:

Component	Reconstitution
Proteinase K	Add 1.25 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.

22. 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.

23. 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.
24. Select the protocol "**chemagic Body Fluid 1k 360 H96 prefilling VD220831.che**" and press [Insert IDs] and follow the instructions given in the chemagic QA software.
25. 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.

26. Check the volumes in the buffer supply containers and confirm by pressing [OK].

NOTE: Take care that all buffer supply bottles contain enough buffer. Only if the liquid level for all buffers is above 125 mL 96 isolations can be performed.

27. Select the number of samples for prefilling by using the drop down menu. The scheme for positioning the samples will be shown after selecting. Take care to use the given positions. Confirm by pressing [OK].
28. Prefill the selected wells of the sample plate in positions 2 and 3 with 500 µL sample each (when using blood only 400 µL each). 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 has to be liquefied before use.

29. Prefill Elution Buffer 7 and the thoroughly resuspended Magnetic Beads by pipetting manually according to each corresponding well in use.

Component	Plate position on chemagic 360-D instrument	Volume/ well
Magnetic Beads	4	30 µL
Magnetic Beads	5	30 µL
Elution Buffer 7	8	100–300 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.

30. Add the following reagents to the wells containing sample.
    - 4 µL Poly(A) RNA and
    - 10 µL Proteinase K.
31. Place the chemagic Deep Well Plates 2 mL on the tracking system according to the instructions given by the chemagic QA software.
32. Place the sample plates in position 2 and 3 on the tracking system.
33. Check all plates for accurate orientation and fitting.
34. Close the front door and start the process by pressing [Start].
35. The automated DNA/ RNA extraction process is initiated.
36. 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 (1000 µL 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 Body Fluid 1k 360 H96 prefilling VD220831.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 1-8 as follows.
  (Numbers on tracking system refer to the positioning of the plate on the chemagic 360-D instrument.)

Position on tracking system	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 Tray in full rows.**
2	Sample plate (chemagic Deep Well Plate 2 mL)	Place the plate with prepared samples (400 µL blood or 500 µL of other sample material, 4 µL Poly(A) RNA and 10 µL Proteinase K) Lysis Buffer 1 and Binding Buffer 2 are dispensed in the plate automatically.
3	Sample plate (chemagic Deep Well Plate 2 mL)	Place the plate with prepared samples (400 µL blood or 500 µL of other sample material, 4 µL Poly(A) RNA and 10 µL Proteinase K) Lysis Buffer 1 and Binding Buffer 2 are dispensed in the plate automatically.
4	chemagic Deep Well Plate 2 mL with 30 µL Magnetic Beads	Pipette 30 µL thoroughly resuspended Magnetic Beads in each well in use according to the sample plate and place the plate. Wash Buffer 3 is dispensed in the plate automatically.
5	chemagic Deep Well Plate 2 mL with 30 µL Magnetic Beads	Pipette 30 µL thoroughly resuspended Magnetic Beads in each well in use according to the sample plate and place the plate. Wash Buffer 4 is dispensed in the plate automatically.
6	chemagic Deep Well Plate 2 mL	Place empty plate. Wash Buffer 5 is dispensed in the plate automatically.

Position on tracking system	Material in position	Protocol step in detail
7	chemagic Deep Well Plate 2 mL	Place empty plate. Wash Buffer 6 is dispensed in the plate automatically.
8	chemagic Deep Well Plate 2 mL with 100–300 µL Elution Buffer 7	Pipette (100-300 µL) Elution Buffer 7 in each well in use according to the sample positions and place the plate.

- 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 Body Fluid 1k 360 H96 prefilling VD220831.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.

18. PERFORMANCE CHARACTERISTICS

18.1 DNA YIELDS WITH BLOOD AND SALIVA

The expected DNA yields for the extraction from human blood is depending on the number of white blood cells. The number of the extracted white blood cells is determined by the input volume and the white blood cell count (WBC). For most of the samples the white blood cell count will not be known, but for healthy individuals it is in the range of 4 – 10 mio. white blood cells per mL of blood.

IVD-1049 using the "**chemagic Body Fluid 200 360 H96 prefilling VD220531.che"** protocol extracts in average 5.34 pg DNA per white blood cell. IVD-1049-1000 using the "**chemagic Body Fluid 500 360 H96 prefilling VD220531.che"** protocol extracts in average 6.69 pg DNA per white blood cell and using the "**chemagic Body Fluid 1k 360 H96 prefilling VD220831.che"** protocol in average 4.32 pg DNA are extracted per white blood cell.

Table 1: DNA yields and purity for blood and saliva samples.

Sample Material / Storage Condition	Volume [mL]	WBC [mio. cells/ mL Blood]	Average Yield [µg]	CV [%]	Average Purity [260/280]
Blood 1 / 4°C	0.2	7.2	7.7	13.9	2.1
Saliva	0.2	-	4.6	14.5	2.2
Blood 1 / 4°C	0.5	7.2	24.1	5.6	2.0
Saliva	0.5	-	11.3	5.9	1.8
Blood 2 / 4°C	0.8	7.5	32.4	11.3	1.9

18.2 LOD USING CHEMAGIC 360-D INSTRUMENT FOR EXTRACTION AND QUANTSTUDIO 5 REAL-TIME PCR SYSTEM FROM THERMO FISHER SCIENTIFIC

When using this extraction kit with the EURORealTime SARS-CoV-2 qPCR (EUROIMMUN a Revvity company) the following LoD data was reported. In total, four extraction runs with two kit lots were performed with the extraction protocol "**chemagic Body Fluid 200 360 H96 VD220531.che**". Eight concentrations of AccuPlex™ SARS-CoV-2 Reference Material (AccuPlex SARS-CoV-2 Verification Panel - Full Genome | SeraCare) were spiked into eNAT medium (Copan Italia S.p.A.): 0, 23.45, 46.90, 93.75, 187.5, 375, 750 and 1500 copies per 1 mL eNAT medium. Six replicates were prepared per kit lot and per plate. All eluates per copy number were analyzed with the EURORealTime SARS-CoV-2 qPCR (EUROIMMUN a Revvity company, https://www.fda.gov/media/138761/download) determining the Ct value.

The hit rate for each AccuPlex SARS-CoV-2 Reference Material concentration was calculated by dividing the number of positive replicates by the total number of replicates. The hit rates (y-axis) and corresponding concentrations (x-axis, log 10 concentration) were plotted to determine the probit fit. The copy number corresponding to a hit rate of 0.95 was determined for each kit lot separately and reported as the limit of detection. All four runs were used to determine the limit of detection of each kit lot. For kit lot 1 a limit of detection of 0.743 cp/mL (95 % confidence interval: 0.44 cp/mL to 1.23 cp/mL) was calculated. Kit lot 2 revealed a limit of detection of 0.699 cp/mL (95% confidence interval 0.43 cp/mL to 1.13 cp/mL (Table 2).

Table 2: Number of EURORealTime SARS-CoV-2 qPCR positives samples for the different spiked in copy numbers in eNAT per kit lot.

		Lot 1		Lot 2	
	Concentration [cp/mL]	Number of replicates	Number of positive replicates	Number of replicates	Number of positive replicates
Experiment 1	1500	6	6	6	6
	750	6	5	6	6
	375	6	6	6	6
	187.50	6	5	6	6
	93.75	6	4	6	4
	46.90	6	2	6	2
	23.45	6	1	6	4
	0	6	0	6	0
Experiment 2	1500	6	6	6	6
	750	6	6	6	6
	375	6	6	6	4
	187.50	6	3	6	4
	93.75	6	4	6	4
	46.90	6	2	6	2
	23.45	6	2	6	0
	0	6	0	6	0
Experiment 3	1500	6	6	6	6
	750	6	6	6	6
	375	6	6	6	6
	187.50	6	6	6	5
	93.75	6	3	6	1
	46.90	6	2	6	1
	23.45	6	2	6	1
	0	6	0	6	0
Experiment 4	1500	6	6	6	6
	750	6	6	6	6
	375	6	6	6	6
	187.50	6	4	6	3
	93.75	6	3	6	3
	46.90	6	2	6	1
	23.45	6	2	6	2
	0	6	0	6	0
Overall	1500	24	24	24	24
	750	24	23	24	24
	375	24	24	24	22
	187.50	24	18	24	18
	93.75	24	14	24	12
	46.90	24	8	24	6
	23.45	24	7	24	7
	0	24	0	24	0
LoD		0.743 (0.436 - 1.230)		0.699 (0.431 - 1.134)	

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 will not be used for longer period of time, 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

The following downstream applications were successfully performed and described in literature after isolation of pathogen DNA/ RNA and genomic DNA with the CMG-1049 version.

Table 3: Peer reviewed and published downstream applications.

Sample Material	Downstream Application	Title	Reference
Nasopharyngeal swabs	Whole-genome sequencing	T cell responses to SARS-CoV-2 spike cross-recognize Omicron	Nature (2022-01) https://www.nature.com/articles/s41586-022-04460-3
Residual swab sample	Whole-genome sequencing	Omicron infection enhances Delta antibody immunity in vaccinated persons	Nature (2022-01) https://www.nature.com/articles/s41586-022-04830-x
Nasopharyngeal and oropharyngeal swabs	Sequencing	Emergence and phenotypic characterization of the global SARS-CoV-2 C.1.2 lineage	Nature Communications (2022-04) https://www.nature.com/articles/s41467-022-29579-9
Tissue	Linear Array HPV Genotyping Test	Prevalence of Human Papillomavirus (HPV) Types in Invasive Vulvar Cancers and VIN3 in the United States Before Vaccine Introduction	Journal of lower genital tract disease (2012-10) https://pubmed.ncbi.nlm.nih.gov/22652576/
Nasopharyngeal and oropharyngeal swabs	Whole-genome sequencing	Early transmission of SARS-CoV-2 in South Africa: An epidemiological and phylogenetic report	International Journal of Infectious Diseases (2020-11) https://pubmed.ncbi.nlm.nih.gov/33189939/
FFPE tissue	Linear Array HPV Genotyping Test	Prevalence of human papillomavirus types in invasive cervical cancers from seven US cancer registries prior to vaccine introduction	Journal of lower genital tract disease (2014-04) https://pubmed.ncbi.nlm.nih.gov/24477171/

Sample Material	Downstream Application	Title	Reference
Nasopharyngeal and oropharyngeal swabs	qPCR/ sequencing	Genomic sequence of worldwide strains of SARS-CoV-2: Insights the role of variants in disease epidemiology	International Journal of Advanced Research and Development (2021-01) https://www.researchgate.net/publication/354997878_Genomic_sequence_of_worldwide_strains_of_SARS-CoV-2_Insights_the_role_of_variants_in_disease_epidemiology
Nasopharyngeal and oropharyngeal swabs	qPCR/Illumina sequencing	Whole Genome Sequencing of SARS-CoV-2: Adapting Illumina Protocols for Quick and Accurate Outbreak Investigation during a Pandemic	Genes (2020-08) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7464704/
FFPE cervix/vulva and oropharynx diagnostic tissue samples	Arrays	An Isothermal, Multiplex Amplification Assay for Detection and Genotyping of Human Papillomaviruses in Formalin-Fixed,Paraffin-Embedded Tissues	The Journal of Molecular Diagnostics (2020-03) https://pubmed.ncbi.nlm.nih.gov/31978559/
Whole-blood, synovial fluid (containing bacteria)	qPCR, multiplex tick pannel testing	Evaluation of a Novel High-Definition PCR Multiplex Assay for Simultaneous Detection of Tick-Borne Pathogens in Human Clinical Specimens	Journal of Clinical Microbiology (2020-02) https://pubmed.ncbi.nlm.nih.gov/31852765/
FFPE	HPV Genotyping	Impact of human papillomavirus (HPV) vaccination on HPV 16/18-related prevalence in precancerous cervical lesions	Vaccines (2012-11) https://pubmed.ncbi.nlm.nih.gov/23137842/

Sample Material	Downstream Application	Title	Reference
Exfoliated cervical cells	HPV Genotyping	Type-specific HPV and Pap test results among low-income, underserved women: providing insights into management strategies	American Journal of Obestetrics and Gynecology (2014-10) https://pubmed.ncbi.nlm.nih.gov/24813971/

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 IVD-1049/ IVD-1049-1000 kit is validated for the extraction of DNA and RNA from human plasma, blood, saliva and naso- or oropharyngeal swabs. Other sample materials may be compatible but have not been validated. For such materials, a validation must be performed by the user.

The use of heparin-stabilized blood samples can cause inhibition in downstream applications and is therefore not recommended.

23. 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.

Revvity chemagen Technologie GmbH, its affiliates and its authorized distributors, in such an event, shall not be liable for damages indirect or consequential.

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