“MagQu” Virus DNA/RNA extraction kit

REF KT-DRE-001V-MQ1

For *In Vitro* Diagnostic & Professional Use

Product description:

“MagQu” Virus DNA/RNA extraction kit is an in vitro diagnostic device intended to use for the purification of nucleic acid from human cell-free samples by manual method or automated extraction system. However, the kit doesn’t separate DNA from RNA. The RNA or DNA can be obtained by combining the purified material with DNase or RNase, respectively. The purified nucleic acids are suitable for downstream applications such as Real-Time PCR, PCR and other molecular experiments.

Reagents:

Item	**Cat. No.**
“MagQu” Virus DNA/RNA extraction kit ……..1 box (96 tests)	KT-DRE-001V-MQ1

Storage:

Please keep the Proteinase K at -20°C. Except for Proteinase K, please keep the kit at room temperature. The validity is warranted for one year.

Statement of Warnings:

BIOHAZARD

All products or objects that come in contact with human body fluids should be handled, before and after cleaning, as if capable of transmitting infectious diseases. Wear facial protection, gloves, and protective clothing.

1. Except for Proteinase K, do not freeze.
2. Please keep away from events with strong magnetism.
3. For *in vitro* diagnostic use only.
4. For professional use only.
5. Do not use reagents beyond the expiration date printed on the kit.

Contents:

This kit contains reagents for 96 reactions with standard volume input.

Item	Volume (ml)	Storage
Lysis/Binding buffer (Add isopropanol)	40 (40)	Room temperature
Magnetic beads	1 ml X 2	Room temperature
Wash buffer 1 (Add isopropanol)	36 (24)	Room temperature
Wash buffer 2 (Add ethanol)	30 (70)	Room temperature
Elution buffer	10	Room temperature
Proteinase K	1 tube X 2	-20°C (Dissolve each tube in 1ml of PBS before use)

Preparation of buffers for use:

1. Add 40 ml isopropanol to Lysis/Binding Buffer and mix well. Check the box on the bottle and cap.
2. Add 24 ml isopropanol to Wash Buffer 1 and mix well. Check the box on the bottle and cap.
3. Add 70 ml absolute ethanol to Wash Buffer 2 and mix well. Check the box on the bottle and cap.
4. Mix Magnetic beads thoroughly before use.

Required materials not supplied:

Procedure	Item
Manual operation	● Orbital shaker ● Hot plate ● Magnetic pins / rods / stand (MDF-08) ● Nuclease-Free water ● Eppendorf ● Pipetman & Tip
Automated Machine	● Automatic magnetic separation system

Manual nucleic acid purification protocol:

1. Mix Magnetic beads thoroughly before use.
2. Move 20 µl magnetic beads to new eppendorf.
3. Use magnetic pins / rods / stand to capture the Magnetic Beads for 90 secs, then discard the supernatant.
4. Lysis/Binding step: Add 580 µl Lysis/Binding buffer and 20 µl Proteinase K into the eppendorf of magnetic beads.
5. Transfer 300 µl sample into the eppendorf. Mix gently and incubate at 60°C for 10 mins.
6. Use magnetic pins / rods / stand to capture the Magnetic Beads for 90 secs, then discard the supernatant.
7. Wash step1: Add 600 µl wash buffer 1 into the eppendorf. Shake on shaker for 1 min.
8. Use magnetic pins / rods / stand to capture the Magnetic Beads for 90 secs, then discard the supernatant.
9. Wash step2: Add 450 µl wash buffer 2 into the eppendorf. Shake on shaker for 1 min.
10. Use magnetic pins / rods / stand to capture the Magnetic Beads for 90 secs, then discard the supernatant.
11. Wash step 3: Add 450 µl wash buffer 2 into the eppendorf. Shake on shaker for 1 min.
12. Use magnetic pins / rods / stand to capture the Magnetic Beads for 30 secs, then discard the supernatant.
13. Dry out the magnetic beads for 5 mins, and preheat the elution buffer to 56°C.
14. Elution step: Add 100 µl the elution buffer into the eppendorf, mix 5 mins.
15. Use magnetic pins / rods / stand to capture the magnetic beads at least for 90 secs.
16. Transfer the elute from eppendorf to a new eppendorf for final storage (-20 or -80°C).

Automated nucleic acid purification protocol:

1. Before operating, please follow the manual provided by the instrument manufacturer to set the parameters of the instrument.

Instrument settings:

Step	Item	Mix (Minutes)	Collect (Minutes)	Rod	Total volume (µl)	Temperature (°C)	Air Dry (Minutes)
1	Magnetic beads	0	0.5	On	800	NA	0
2	Lysis/Binding buffer	10	0	Off	900	60	0
3	Lysis/Binding buffer	0	1.5	On	900	60	0
4	Wash buffer 1	1	0	Off	600	NA	0
5	Wash buffer 1	0	1.5	On	600	NA	0
6	Wash buffer 2	1	0	Off	450	NA	0
7	Wash buffer 2	0	0.5	On	450	NA	0
8	Wash buffer 2	1	0	Off	450	NA	0
9	Wash buffer 2	0	0.5	On	450	NA	5
10	Elution buffer	5	0	Off	100	56	0
11	Elution buffer	0	1.5	On	100	56	0

2. Enter the default program to warm up the instrument.
3. Mix Magnetic beads thoroughly before use.
4. Move 20 µl magnetic beads and add 780 µl sterile ddH_2O to new eppendorf.
5. Transfer 300 µl sample into the column of Lysis/Binding buffer and Proteinase K.
6. Start the program.
7. After the program is complete, remove the kit from the instrument carefully.
8. Transfer the elute from the column of Elution buffer to a clean eppendorf for final storage (-20 or -80°C).

Analytical Sensitivity:

The analytical sensitivity of “MagQu” Virus DNA/RNA extraction kit is 25 copies for DNA virus and 100 copies for RNA virus.

Results:

Virus DNA was purified from 25-10^5 copy number of Hepatitis B virus (HBV) using the" MagQu" Virus DNA/RNA kit. The copy number of HBV were quantified using COBAS® AmpliPrep/COBAS® TaqMan® HBV Test analysis. Real-time PCR assay was performed according to the manufacturer's instructions with PowerUP™ SYBR Green PCR master mix on a StepOne™ Real-Time PCR instrument (Applied Biosystems). The CP values are showed in Figure 1.

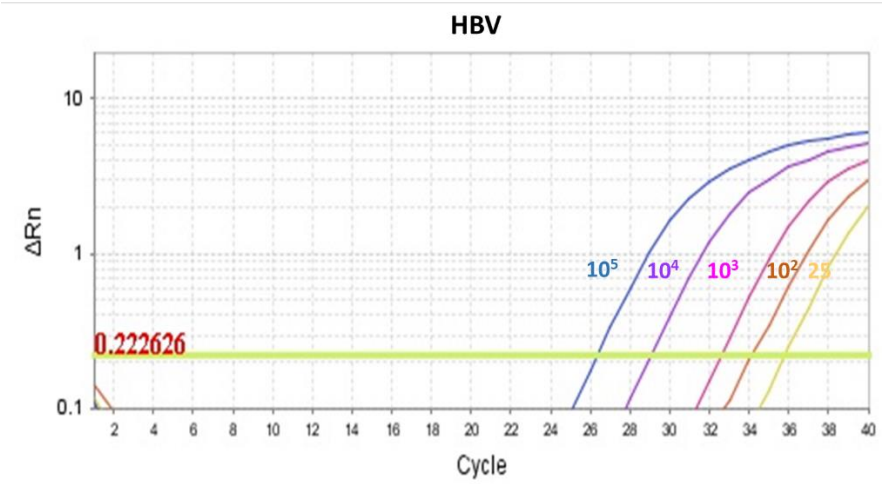


Figure 1. The amplification plot for HBV specific real-time polymerase chain reaction.

Virus RNA was purified from 10^2-10^5 copy number of Hepatitis C virus (HCV) using the" MagQu" Virus DNA/RNA kit. The copy number of HCV were quantified using cobas® HCV Test analysis. Real-time reverse transcription PCR assay was performed according to the manufacturer's instructions with Takara One-Step TB Green® PrimeScript™ RT-PCR System on a StepOne™ Real-Time PCR instrument (Applied Biosystems). The CP values are showed in Figure 2.

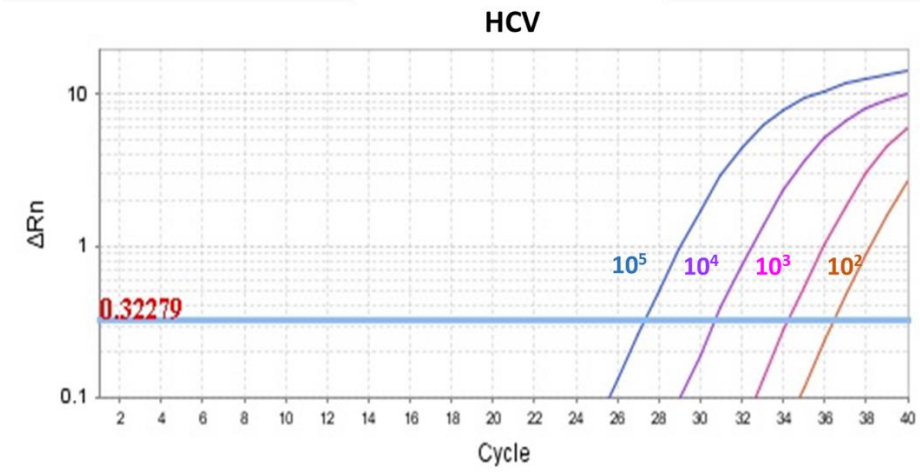
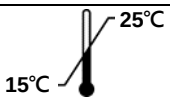


Figure 2. The amplification plot for HCV specific real-time polymerase chain reaction.

Glossary/symbol definition:

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Caution, refer to accompanying documents		Consult instructions for use.
LOT	Batch code		Temperature limitation
REF	Catalogue number,	EC REP	Authorized representative in the EU/EC.
CONT	Content	IVD	In Vitro diagnostic medical device
	Use by Expressed as: CCYY-MM-DD		Manufacturer
	Biological risk		Do not use if package damaged
CE	CE MARK = CONFORM WITH EEC DIRECTIVES		

Manufacturer:

MagQu Co., Ltd.
3F., No.7 and No. 12, Ln. 538, Zhongzhen Rd., Xindian Dist., New Taipei City, Taiwan, R.O.C.
Tel: +886-2-8667-1897 Fax: +886-2-8667-1809
E-mail: info@magqu.com Website : www.magqu.com

Rev. Mar-25-2021