DNA/RNA Extraction Kit

CATALOGUE NUMBER	KIT SIZE (TESTS)
PCREXT1	64T

Intended Use:
The DNA/RNA Extraction Kit comprises reagents which together are used to isolate and purify DNA or RNA from biological specimens including serum, plasma, urine, swabs (throat and genital), stool samples and sputum. The resulting purified DNA or RNA is suitable for subsequent applications such as real time quantitative PCR.

Test Principle:
In the DNA/RNA Extractor sample is added to the first row of wells which contain lysis reagents and magnetic beads. Bacterial cell walls, cell membranes and viral capsids in biological samples are lysed by the lysing reagents to release DNA and RNA which binds to the magnetic beads. After reagent and sample mixing via mixing sleeves, magnetic rods are lowered into the sleeves in the wells which attract the beads and adsorbed nucleic acids. The rods and surrounding sleeves are lifted into the next row of wells which contain Wash Buffer 1. The rods are lifted out releasing the beads which are mixed in the buffer by the mixing sleeves washing impurities away from the nucleic acid. The process of bead attraction, lifting of rods and sleeves to next rows, bead release and mixing is repeated across rows of the 96 well plate layout until the magnetic beads and nucleic acid have passed through two more wash buffers and finally into a row of wells containing an Elution Buffer. Here the purified nucleic acid is released from the magnetic bead surface into solution. The beads and mixing sleeves are removed by the magnetic rods leaving the final row of wells with the purified nucleic acid sample ready for analysis.

Reagents:
The kit comprises of four 96 well plates prefilled with reagents for 16 tests per plate, the reagents consisting of the following:

REAGENT	SIZE
Lysing Buffer/Magnetic Beads	4 x 16T
Wash Buffer 1	
Wash Buffer 2	
Wash Buffer 3	
Eluting Buffer	

Materials not provided: Magnetic bead DNA/RNA extraction instrument, nuclease-free micropipettes and sterile, nuclease free pipette tips.

Precautions:
For *in vitro* diagnostic use by trained professionals only.
Follow Good Laboratory Practice procedures where samples and kits are handled and treat the kit components and all samples as if potentially infectious. Follow local regulations for correct disposal of samples, unused reagents, used kit components and assay waste.
Wear protective clothing including laboratory coat, disposable gloves and safety glasses when conducting the test. Change gloves often to prevent contamination of samples and reagents. Experimental consumables must be autoclaved.
Do not use any component of the kit after the expiry date. Do not incorporate reagents from different kit batches or reagents from other commercially available kits.
The Lysing Buffer contains a guanidine salt which can form highly reactive products when combined with sodium hypochlorite. Do not add bleach or acidic solutions to reaction tubes or liquid washing waste. Suitable detergent may be added.
Serum and plasma may be used as samples but not whole blood as this tends to result in incomplete washing.
Clean and disinfect the extraction instrument before and after use using 75% ethanol followed by UV light for 15 minutes.
Avoid any of the reagents coming into contact with skin, eyes and mucous membranes. If accidental contact should occur, flush immediately with a copious amount of water.
Do not reuse plastic laboratory consumables.

Storage and Stability:
The kit should be stored in dry conditions at room temperature (15 – 25°C) and protected from exposure to light. The kit is stable up to the expiry date printed on the outer label.

Sample Collection and Preparation:
The DNA/RNA Extraction Kit can be used on respiratory samples, swabs, saliva and nasopharyngeal or oropharyngeal secretion samples stabilised in storage solution, serum, plasma and urine.
Ideally DNA or RNA extraction from the samples should be performed immediately. Alternatively, the samples may be stored up to 24 hours at 2 – 8°C or for longer at -70°C. Avoid repeat freeze-thawing.

Assay Procedure:
Sample Pre-treatment

- For respiratory samples and saliva, vortex the samples to mix then use in the extraction assay.
- For swab samples, cut the tip of the swab into a 1.5 ml nuclease-free centrifuge tube and add 1 ml of Normal Saline (0.9%). Vortex to mix and extract the sample then use in the extraction assay.
- For samples stabilised in storage reagent, vortex the samples to mix then use in the extraction assay.

DNA/RNA Extraction

Before beginning the extraction procedure make sure the plates are intact and without any leaks. Invert the plate several times to evenly suspend the magnetic beads. Flick the plates downwards to collect the reagents at the bottom of the wells or centrifuge in a plate centrifuge (500 rpm for 1 minute). Carefully remove the aluminium foil seal avoiding the splashing of the well contents.

Add 300 µl sample to the 1st and 7th columns of the plate.

Run a typical extraction programme as follows:

No	Column	Name	Waiting (min)	Mixing (sec)	Magnet in (sec)
1	2	Magnetic Beads	0	60	60
2	1	Lysis	0	600	60
3	3	Wash 1	0	60	60
4	4	Wash 2	0	60	60
5	5	Wash 3	0	0	60
6	6	Elution	0	120	90
7	3	Magnetic Beads	0	60	0

Speed	Volume (µl)	Heating State	Temp (°C)
8	550	Closed	-
8	550	Lysis	85
8	600	Elution	85
8	600	Elution	85
8	600	Elution	85
8	60	Elution	85
8	600	Closed	-

- At the end of the programme, transfer the extracted samples located in the 6th and 12 columns into nuclease free tubes.
- The purified DNA/RNA in the eluent can be used immediately for up to 2 hours or store at -20°C or below.

Limitations of the Kit:
The DNA/RNA Extraction Kit is only to be used by laboratory personnel trained in PCR techniques.
The quality of the DNA or RNA is affected by factors including source of sample, sample collection process, collection site and storage conditions.
Occasionally a few magnetic beads may appear in the elution buffer. If so, avoid these when transferring the extracted product to the fresh nuclease free tubes.
If the extraction is being carried out by a manual procedure, clumping of the magnetic beads can occur using certain sample types which can be dispersed by vortexing.
The composition of the elution buffer will affect the absorbance value for a UV/Visible light spectrophotometer. Therefore direct measurement of concentration and purity of extraction product by UV/Visible spectrophotometry is not recommended.
Sample quality has a significant impact on the quality and yield of purified DNA or RNA.
The presence of DNA/RNase in the laboratory environment may cause the degradation of the DNA and RNA during or after the purification process. All equipment, consumables and the workbench should be treated before starting to ensure all surfaces are DNA/RNase free.

Performance:

Precision
Intra-assay precision <3%
Inter-assay precision <3%
The DNA/RNA Extraction Kit can extract up to 96 samples in one run on a magnetic bead DNA/RNA Extraction instrument with good repeatability and reproducibility.

Advantages
Simultaneous extraction of DNA and RNA easily and conveniently with no involvement of organic solvents.

Symbols:

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		Do not reuse
	Keep away from sunlight		

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