



ZiXpress® Viral RNA Extraction Kit

[Cat. No. and Packaging Specifications **]**

ZP02205-192 - Pre-filled Reagents for 192 Tests/Box (16 Tests/Plate × 12 Plates)

ZP02205-960 - Non-Pre-filled Reagents for 960 Tests/Box (16 Tests/Plate x 60 Plates)

[Introduction - ZiXpress[®] Magnetic Pillar Technology]

Zinexts Life Science is specialized in developing advanced, efficient and reliable technologies in nucleic acid purification, enabling successful delivery of extraction results from varied sample types. The ZiXpress[®] Nucleic Acid Purification Platform utilizes permanent magnet rods to collect magnetic beads from the solution and release the beads into wells containing reagent for the next step of extraction.

C E IVD

The purification process contains four basic steps: sample lysis, nucleic acid binding, washing and elution. The effectiveness of bead collection and transfer ensures superior washing and elution efficiency.



Lysis/Binding Beads transfer Wash Incubation Elution

Product Name	ZiXpress [®] Viral RNA Extraction Kit
Catalogue Number	ZP02205-192, ZP02205-960
Applicable Instrument Model	All ZiXpress [®] Instrument
Displayed Protocol Name on The Instrument	Viral-RNA
Processing Time	ZiXpress [®] 32 series 15 minutes ZiXpress [®] 64 series 15 minutes ZiXpress [®] 96S series 22 minutes





[Intended Use]

The product purpose is to extract and purify viral nucleic acids from serum, plasma, saliva, sputum samples, clinical swab samples, cell-free body fluids or cerebrospinal fluid (CSF). The elution product has high purity and complete fragments. The nucleic acids purified by using the ZiXpress[®] assortment are suitable for a variety of biological samples, which are essential and broadly used in many molecular biology downstream applications such as, genetic screening, sequencing, food safety, forensic, etc.

[Kit Content]

Catalogue Number: ZP02205-192

Components	Quantity
Reagent 96 Plate (Pre-filled)	(16 x 12) 192
8-Tip Comb	(16 x 12) 192
Mixing Sleeves (96S only)	(8 x 24) 192

Catalogue Number: ZP02205-960

Components	Quantity	
2.2 ml Deepwell 96 plate	(16 x 12 x 5) 960	
(Non Pre-filled)		
8-Tip Comb	(16 x 12 x 5) 960	
Mixing Sleeves (96S only)	(8 x 24 X 5) 960	
Magnetic Beads B	30 ml x 1	
Lysis buffer C	680 ml x 1	
Wash Buffer Z3	680 ml x 1	
Wash Buffer A	900 ml x 1	
Wash Buffer B	900 ml x 1	
RNase-free water	150 ml x 1	
Single Strip* (optional)	(12 x 16 x E) 060	
(Non Pre-filled)	(12 x 10 x 2) 900	
Adapter* (optional)	(2X5)	





[Reagent Plate Content]

Well No.	Components	Volume
1/7	Lysis buffer C	700 µl
2/8	Wash Buffer Z3	700 µl
3/9	Wash Buffer A and Magnetic Beads	930 µl
4/10	Wash Buffer B	900 µl
5/11	Empty	-
6/12	RNase-free water	150 µl

Storage & Stability

Reagent Plate and Accessory Consumables should be stored at room temperature. **Do not** freeze the Reagent Plate. Zinexts Life Science guarantees that all components are stable for 30 months when stored properly.

[Sample Requirements**]**

- **a.** Sample type: Saliva, sputum samples, clinical swab samples, serum, plasma, cell-free body fluids or cerebrospinal fluid (CSF).
- **b.** Sample storage: Fresh or stored at 2-8°C for up to 24 hours. For long-term storage, freezing at -20°C is recommended.
- c. Sample volume: 200 μ l

[Elution Requirements]

- **d.** Elution volume: 150 μl
- e. Store the purified nucleic acid at 4°C (short-term, less than 10 days) or aliquot and store at -70°C (long-term) before performing the downstream analysis.

Operation Protocol

1. Sample Preparation

a. The table below describes the recommendations in virus collection from different kinds of sample type:





Sample type	Procedure			
For serum, plasma,	1. Transfer 200 μ l sample to Well 1 and Well 7.			
cerebrospinal fluid (CSF)	1. If the sample volume is lower than described, please complete			
or cell-free body fluids.	the volume with appropriate amount of PBS.			
	<u>Swab without preservation solution:</u>			
	1. Collect swab samples in 1 ml PBS.			
	2. Vortex the collection tube and incubate for 30 minutes at			
	room temperature.			
	3. Transfer 200 μ l sample to Well 1 and Well 7.			
For swab samples	Swab in liquid-based preservation solution:			
	1. Collect swab samples in liquid transport media.			
	2. Vortex the collection tube and incubate for 30 minutes at			
	room temperature.			
	3. Transfer 200 μ l sample to Well 1 and Well 7.			
	1. Transfer 200 μ l sample to Well 1 and Well 7.			
	2. If the sample volume is lower than described, please complete			
For saliva sample	the volume with appropriate amount of PBS.			
	* Liquefaction could be done by using fresh DTT stock solution			
	with BL2 Buffer (not supplied in the kit) *.			
	1. Collect viscous samples. (e.g., sputum, BAL or other mucus			
	specimen)			
	2. Add 120 μl sample in 1.5 ml tube, mixing with 120 μl BL2			
	Buffer (not supplied in the kit) *.			
	3. Prepare a fresh DTT stock solution for liquefaction**. (e.g., 5X			
	DTT stock is about 0.75%)			
For sputum samples	4. Add DTT solution in the sample (final concentration: 0.15%).			
	5. Incubate the sample (e.g., with shaking at 850 rpm for 30			
	minutes at 37°C) until it can be pipetted easily.			
	6. Transfer 200 μl to Well 1 and Well 7.			
	*BL2 buffer could be purchased from Zinexts.			
	** Liquefaction could be done by using other solutions, such			
	as NALC (N-Acetyl-L-Cysteine).			

2. Reagents Plate Preparation

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a. Remove the aluminum foil sealing membrane on the reagent plate carefully and avoid liquid splashing.





- **b.** Add 200 μl viral sample to Well 1 and Well 7, which contains the pre-filled lysis buffer. Mix the sample with the lysis buffer 3-5 times by pipetting gently.
- c. Optional: For viral DNA isolation, incubate 200 μl sample with 200 μl BL6 buffer* and 10 μl Proteinase K* (10 mg/ml) at 56°C and shaking at 1000 rpm for 5 minutes. Then transfer the lysate to Well 1 and Well 7 and mix 3 times by pipetting gently.
 - * BL6 buffer and Proteinase K buffer could be purchased from Zinexts.

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- **a.** Load the specified buffer into specified wells of the 96 Plate according to Reagent Plate Content listed above.
- b. Optional (Single Strip method): Put the Single Strip* on the Adapter* and use it as Reagent Plate.

* Single Strip and Adapter could be purchased from Zinexts.

- **c.** Add 200 μl viral sample to Well 1 and Well 7, which contains the pre-filled lysis buffer. Mix the sample with the lysis buffer 3-5 times by pipetting gently.
- d. Optional: For viral DNA isolation, incubate 200 μl sample with 200 μl BL6 buffer* and 10 μl Proteinase K* (10 mg/ml) at 56°C and shaking at 1000 rpm for 5 minutes. Then transfer the lysate to Well 1 and Well 7 and mix 3 times by pipetting gently.

* BL6 buffer and Proteinase K buffer could be purchased from Zinexts.

3. Automated Extraction Setup & Consumables Preparation

Turn on the power switch and wait for the screen to show the Home Page.

3-1. ZiXpress 32 & ZiXpress 64

- **a.** Set up the 8-Tip Combs on the 8-Tip Comb track, and make sure the 8-Tip Combs enter the track completely.
- b. (1) Put the reagent plate on the plate track and release heater locks. (For first generation)

(2) Insert the reagent plate into the plate track and ensure it fit well. (For second generation)

(Note: Please check the direction of "recognition corner" on the Reagent 96 plate, it must be on the left.)

(3) Optional - ZP02205-960 (Single Strip method): Please follow step (2) to insert the Adapter (Reagent Plate) into the plate track and ensure it fit well. (For second generation)





First generation:





Second generation:

- **c.** Close the instrument door.
- **d.** Protocol Selection: Select the appropriate protocol on the instrument or edit a new protocol on the blank space. (Page1 to Page 12)

Step No.	Well	Name	Standby (min)	Mix (min)	Volume (μl)	Mix Speed	Mag (sec)	Тетр (℃)
1	3	Transfer	0	0	900	0	10	0
2	1	Lysis	0	5	900	3	20	80
3	2	WASH 1	0	1	700	3	20	0
4	3	WASH 2	0	1	900	3	20	0
5	4	WASH 3	0	1	900	3	20	0
6	6	ELUTE	2	1	100	3	90	80
7	4	WASTE	0	1	900	2	0	0

Viral-RNA process as below: (Process time: 15 minutes)

- e. Press "▶" to start process.
- f. After the experiment program is finished, transfer the extracted products located at Well 6 and Well 12 into nuclease-free tubes. Store the purified nucleic acid at 4°C (short-term, less than 10 days) or aliquot and store at -70°C (long-term) before performing the downstream analysis.

3-2. ZiXpress 96S

- **a.** Set up the Mixing Sleeves on **Well 2** and **Well 8** of Reagent Plate. Make sure Mixing Sleeves are in the right place.
- **b.** Insert the Reagent Plate into the plate track and ensure it fit well.

(Note: Please confirm the direction of "recognition corner" on the Reagent 96 plate, it must be on the left.)







- **c.** Press " to close the instrument door.
- **d.** Protocol Selection: Follow the information in the below list to create a protocol on the instrument.

Step	Name	Well	Stir	Magnetic	Wait	Speed (rpm)	Volume (μl)	T Control (℃)
1	Transfer	3	00:10	00:45	00:00	1600	900	0
2	Lysis	1	05:00	00:30	00:00	2000	900	120
3	WASH 1	2	02:00	00:20	00:00	2000	700	90
4	WASH 2	3	01:00	00:20	01:00	2000	900	90
5	WASH 3	4	01:00	00:20	00:00	2000	900	120
6	ELUTE	6	05:00	00:35	00:00	2500	120	120
7	WASTE	4	00:10	00:00	00:00	2500	900	0

Viral-RNA process as below: (Process time: 22 minutes)

e. Press " **b**" to start process.

f. After the experiment program is finished, transfer the extracted products located at Well 6 and Well 12 into nuclease-free tubes. Store the purified nucleic acid at 4°C (short-term, less than 10 days) or aliquot and store at -70°C (long-term) before performing the downstream analysis.





[Precautions]

Please read the instructions before using the kit:

- **a.** When working with chemicals or clinical samples, always wear a suitable lab coat, disposable gloves, and protective goggles. All of the experiment supplies, such as pipettes, tubes, tips must be autoclaved. Operator should wear gloves and masks.
- **b.** Before usage, the ZiXpress[®] Nucleic Acid Purification Platform should be disinfected with the internal UV light program. We recommend cleaning the instrument with 75% ethanol and disinfecting it by performing the UV light program in the instrument.
- c. Proteinase K is suggested to be stored at 2-8°C.
- **d.** After the experiment, all samples and reagents must be properly disposed.
- **e.** Magnetic beads may occasionally appear in the elution buffer after extraction. If so, please carefully avoid the magnetic beads while transferring the extracted elution product.

Please report any serious incident occurred in relation to the device to your local representative/ agent or the manufacturer, and to the competent authority of your country/state.

Sample TypeSerum, plasma, saliva, sputum, clinical swab samples, of free body fluids or cerebrospinal fluid (CSF).	
Target Nucleic Acid Total viral nucleic acids (DNA and RNA)	
Sample Volume	200 μl * If the sample is less than 200 μl, please add 1X PBS to fill up to 200 μl.
Controls/Optional Internal Control [#]	Add controls/internal control in the extraction procedure if needed for the downstream analysis.
Elution Volume	150 μl

(Starting Material)





[Expected Purity and Yield]

Using HCV serum from patient as sample to extract viral RNA by ZiXpress[®] Viral RNA Extraction Kit. 200 μ l sample was extracted and eluted in 120 μ l. 15 μ l elution was used for real-time PCR by AmpliSens[®] HCV/HBV/HIV-FRT PCR kit. Two repeat samples can be detected, proving the excellent reproducibility of the isolation procedure.



[Warranty]

Zinexts Life Science is committed to providing our customers with high-quality products and services. Our goal is to ensure that every customer is 100% satisfied with our products and our services. If you have any questions or concerns about our products or services, contact our Technical Support Representatives.

Zinexts Life Science guarantees the performance of all products according to specifications stated on our product literature. The purchasers/users must determine the suitability of the product for their particular use. We reserve the right to change, alter, or modify any product to enhance its performance and design.

This warranty limits Zinexts Life Science Corporation's liability only to the cost of the product. No warranty is granted for products beyond their listed expiration date. No warranty is applicable unless all product components are stored in accordance with instructions.

Technical Support

For technical assistance and further information, please visit our website <u>www.zinexts.com</u>, contact our Technical Support or your local distributor.





(Symbols)

The following symbols are used on labels and in Instructions for Use (IFU), in compliance with EN ISO 15223-1 standard.

Symbol	Explanation
CE	CE mark
IVD	For In Vitro Diagnostic Use
REF	Catalogue number
LOT	Lot/Batch number
Σ	Sufficient for [n] samples
HB	Instructions for Use / Handbook
	Expiry date
15°C	Storage temperature (15°C - 25°C)
	Manufacturer
EC REP	European Authorized Representative
	Caution





[Product List]

Catalog Number	Packaging Specification (Adapted System)
ZP02205-192-BL	Pre-filled Reagents for 192 Tests/Box (2 nd generation ZiXpress 32/64)
ZP02205-192-HT	Pre-filled Reagents for 192 Tests/Box (ZiXpress 96S)
ZP02205-960-BL	Non Pre-filled Reagents for 960 Tests/Box (2 nd generation ZiXpress 32/64)
ZP02205-960-B-BL	Non-Pre-filled Reagents for 960 Tests/Box (Bottles only, without consumables, 2 nd generation ZiXpress 32/64)
ZP02205-960-C-BL	Non-Pre-filled Reagents for 960 Tests/Box [Bottles (No ethanol) only, without consumables, 2 nd generation ZiXpress 32/64]
ZP02205-960-HT	Non-Pre-filled Reagents for 960 Tests/Box (ZiXpress 96S)

[Manufacturer Information]

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Product of Origin:	Taiwan (R.O.C.)

[Revision History]

Version	Date	Description
1.5	22. Aug. 2022	List of IVD symbols added



Version: 1.5 Rev. Date: 22.08.2022



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