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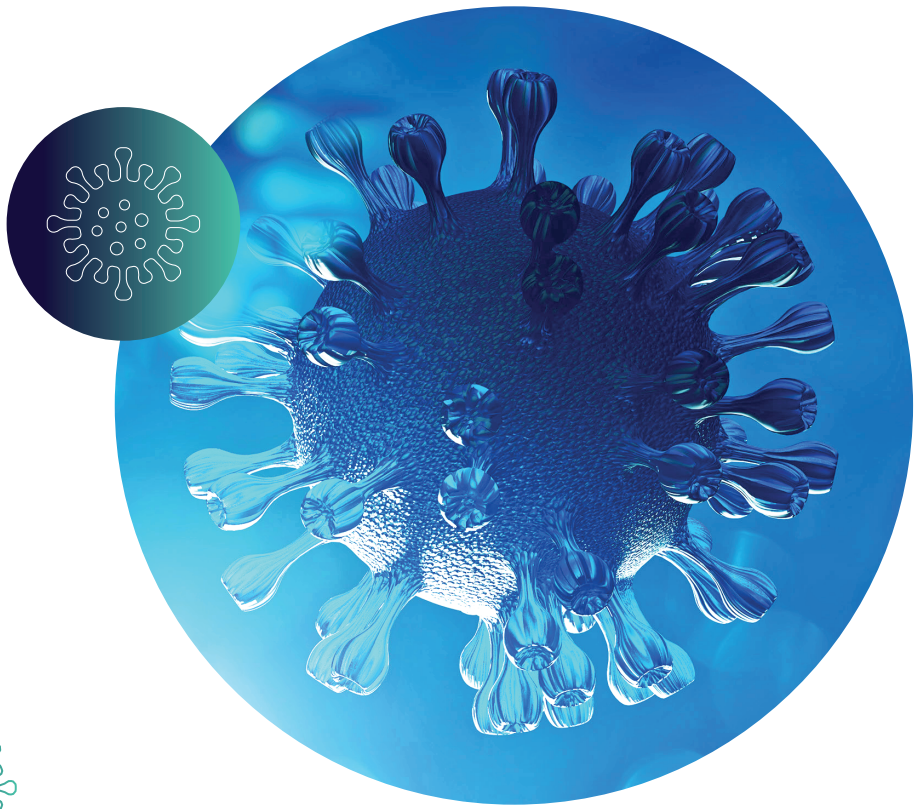

MagRNA-II

Viral RNA Extraction Kit

REF G2M030320

S. No.	Product Name	SKU Code	Pack Size
1.	MagRNA-II Viral RNA Extraction Kit	G2M030320-50T	50T
2.	MagRNA-II Viral RNA Extraction Kit	G2M030320-250T	250T
3.	MagRNA-II Viral RNA Extraction Kit	G2M030320-96T	96T
4.	MagRNA-II Viral RNA Extraction Kit	G2M030320-192T	192T
5.	MagRNA-II Viral RNA Extraction Kit (RX)	G2M030320RX-480T	480T
6.	MagRNA-II Viral RNA Extraction Kit(TK)	G2M030320TK-480T	480T
7.	MagRNA-II Viral RNA Extraction Kit(MG)	G2M030320MG-480T	480T

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Content Table

Intended Use

MagRNA-II Viral RNA Extraction Kit is an *in-vitro* diagnostic test kit, intended for isolation and purification of genomic RNA from cell free body fluids such as plasma, serum, CSF, urine, cell-culture supernatant, nasopharyngeal swab, oropharyngeal swabs.

MagRNA-II Viral RNA Extraction Kit utilizes magnetic bead-based technology can be processed manual or automated on open-ended liquid handling platforms as well as magnetic processors. MagRNA-II RNA Extraction Kit for professional, laboratory trained personnel use only.

Intended User

The assay is intended to be performed by a laboratory professional in clinical laboratory.

Test Principle

This product is based on the purification method of high binding magnetic particles. The sample is lysed and digested under the action of lysis buffer along with Proteinase K & Carrier RNA. After addition of magnetic particles to the lysate, RNA will be adsorbed on the surface of magnetic particles. The adsorbed particles are washed with a washing solution to remove proteins and impurities, followed by washing with ethanol to remove salts, and finally RNA was eluted by Buffer AVE.

Summary

MagRNA-II Viral RNA Extraction Kit allows rapid, efficient and isolation of of genomic RNA from cell free body fluids such as plasma, serum, CSF, urine, cell-culture supernatant, nasopharyngeal swab, oropharyngeal swabs. Purification requires no phenol/chloroform extraction or alcohol precipitation and involves minimal handling. The kit is based on super paramagnetic particle purification technology with no phenol/chloroform extraction.

Materials Required but Not Provided.

- Water bath or Heating block
- Micropipettes (Adjustable)
- Disposable Barrier (Filter) tips
- 1.5 ml microcentrifuge tubes
- Table top microcentrifuge
- Magnetic Separation Rack
- Molecular biology grade ethanol (96-100%)
- Personal protective equipment (apron, gloves, goggles)
- Disposable Powder-free gloves

Storage, Operating Conditions and Stability

- This product can be stored at room temperature (4°C – 30°C) for the duration of its shelf life, as indicated on the box label. If precipitate forms in any of the reagents of the kit, warm at 55°C to dissolve.
- After reconstitution, 'Proteinase K and Carrier RNA' needs to be stored at -20°C. MagPure Particles MPN shipped at room temperature and stored at 2°C - 8°C.

Instructions Before Use

- Buffer MW1 and Buffer MW2 are supplied as concentrates. Before using for the first time, add the appropriate volume of molecular biology grade ethanol (96-100%) as indicated on the bottle and shake thoroughly.
- After addition of ethanol, Buffer MW1, Buffer MW2 can be stored at room temperature (4°C – 30°C) for the duration of its shelf life, as indicated on the box label.
- Add Proteinase Dissolving Buffer into absolute amount of Proteinase K as mentioned on the label and store it at -20°C.
- Add Buffer AE into absolute amount of Carrier RNA as mentioned on the label and store it at -20°C.
- Spray the sealed package (for Infectious samples) containing the specimen with 75% ethanol in a biosafety Cabinet.

MagRNA-II Viral RNA Extraction Kit Platform-Manual

Product Code-G2M030320 (Pack Size-50T), G2M030320 (Pack Size-250T)

Table 1. Kit Components

Kit Contents	Kit Content Code	Kit Content Quantity	Kit Content Code	Kit Content Quantity
	50 Tests	50 Tests	250 Tests	250 Tests
MagPure Particles MPN	G2MA3-2093-4	1 X 1 ml	G2MA3-2093-3	1 X 5 ml
Proteinase K	G2MA3-3111-1	1 X 22 mg	G2MA3-3111-2	1 X 110 mg
Proteinase Dissolving Buffer	G2MA3-3112-1	1 X 2 ml	G2MA3-3112-2	1 X 7 ml
Buffer MLB	G2MA3-3113-1	1 X 25 ml	G2MA3-2096-4	1 X 115 ml
Buffer MW1	G2MA3-2097-3	1 X 12 ml	G2MA3-3115-1	1 X 60 ml
Buffer MW2	G2MA3-2098-3	1 X 11 ml	G2MA3-3116-1	2 X 27 ml
Buffer AVE	G2MA3-3114-1	1 X 5 ml	G2MA3-3114-2	1 X 15 ml
Carrier RNA	G2MA3-2100-4	1 X 0.15 mg	G2MA3-2100-3	1 X 0.75 mg
Buffer AE	G2MA3-3588-1	1 X 200 µl	G2MA3-3588-2	1 X 1 ml

Manual Protocol

1). In a 1.5 ml microcentrifuge tube, add 20 µl Proteinase K, 20 µl MagPure Particles MPN, 2 µl Carrier RNA and 450 µl Buffer MLB.

2). Transfer 200 µl of the sample to a microcentrifuge tube containing magnetic beads and vortex for 15 sec. Leaveat room temperature for 10 min with several invert mix. Transfer to a magnetic stand, and leave the tubes undisturbed for ~3 min to adsorb the magnetic beads. Carefully discard the supernatant.

3). Add 500 µl Buffer MW1 and vortex for 10 sec. Transfer to a magnetic stand and leave it undisturbed for ~1 min to adsorb magnetic beads. Completely remove and discard the cleared supernatant.

4). Add 500 µl Buffer MW2 and vortex for 10 sec. Transfer to a magnetic stand and leave it undisturbed for 1 to 2 min to adsorb magnetic beads. Completely remove and discard the cleared supernatant.

5). Repeat step 4 again.

6). Discard all the leftover supernantant, and air dry the pellet for ~10 min.

7). Add 30-50 µl Buffer AVE and vortex for the proper mixing. Leave the tubes undisturbed for 5 min, vortex several for efficient mixing.

8). Transfer the microcentrifuge tube into a magnetic stand and leave it for 3 min. Transfer the extracted RNA elute to a new 1.5 ml microcentrifuge tube.

MagRNA-II Viral RNA Extraction Kit Platform-Rapi-X16 Automated Nucleic acid extraction system

SKU Code-G2M030320-96T, G2M030320-192T

Table 2. Kit Components

Kit Contents	Kit Content Code		Kit Content Quantity	Kit Content Code		Kit Content Quantity
	96 Tests		96 Tests	192 Tests		192 Tests
MagPure Particles MPN	G2MA3-2956-1	Single Test Cartridge code G2MA3-3118-1	96-Cartridges	G2MA3-2956-2	Prefilled Plates code G2MA3-3119-1	12 Plates (96-well)
Buffer MLB	G2MA3-2957-1			G2MA3-2957-2		
Buffer MW1	G2MA3-2958-1			G2MA3-2958-2		
Buffer MW2	G2MA3-2959-1			G2MA3-2959-2		
Buffer AVE	G2MA3-2960-1			G2MA3-2960-2		
Proteinase K	G2MA3-3111-3		40 mg	G2MA3-3111-4		80 mg
Carrier RNA	G2MA3-3117-1		0.2 mg	G2MA3-3117-2		0.4 mg
Proteinase Dissolving Buffer	G2MA3-2962-1		3 ml	G2MA3-2962-2		5 ml
Buffer AE	G2MA3-3589-1		300 µl	G2MA3-3589-2		600 µl

*96 Prefilled Cartridges, 48 combs with all the buffers and other kit components preloaded.

**12 Prefilled plates, 24 combs with all the buffers and other kit components preloaded.

Automation Protocol (Rapi-X16)

A). For Single Test Cartridge

1). In Single test cartridge the 1st well contains MagPure Particles MPN, 2nd well contains Buffer MLB,the 3rd and 4th wells contain Buffer MW1 and Buffer MW2, respectively, and the 6th well contains Buffer AVE.

2). Add 20 µl of Proteinase K & 2 µl Carrier RNA to the 2nd well of the single test cartridge.

3). If processing only 1 sample, place the cartridge on A and add empty cartridge on G position for balance & select the channel 1-8 in machine window.

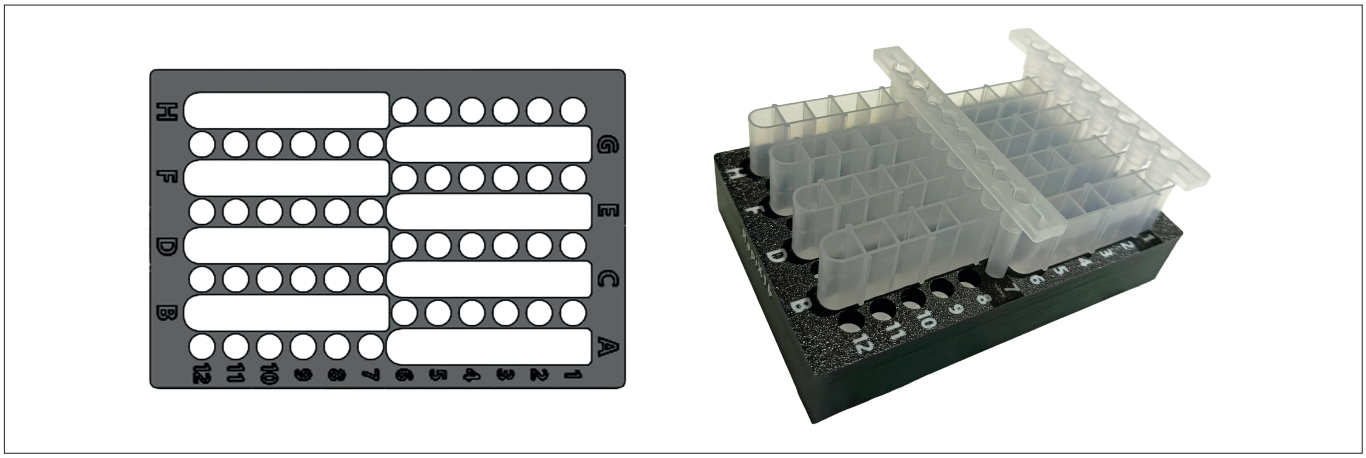
4).For 1 to 4 samples, place cartridges on positions A, C, E, G of the block & select the channel 1-8 in machine window.

5). For 1 to 8 samples, place cartridges on positions A, C, E, G, B, D, F, H of the block & select the channel 1-8 & 9-16 in machine window.

6). Insert combs into positions 1 and 7, ensuring alignment with the 1st well of each cartridge and the block.

7). Close the door and select the program 'MagRNA-II Viral RNA_V1' on the Genes 2Me Rapi-X16 Automated Extraction System, then click 'Start' to begin the run.

8). After completion, collect the eluted nucleic acid (RNA) from the 6th well, ready for downstream applications.



B). For Pre-filled Plates

1). In Pre-filled plate, the 1st well contains MagPure Particles MPN, 2nd well contains Buffer MLB the 3rd and 4th wells contain Buffer MW1 and Buffer MW2, respectively, and the 6th well contains Buffer AVE.

2). Add 20 µl of Proteinase K & 2 µl Carrier RNA to the 2nd well of the Pre-filled plate.

3). In Case of 1-16 samples - Place the combs on position 1 & 7 & place plate properly in machine.

4). Close the door and select the corresponding program 'MagRNA-II Viral RNA_V1' on Genes 2Me Rapi-X16 Automated extraction system & channel 1-8 & 9-16.

5). Click 'Start' to run the current program and wait to finish the operation.

6). After completion, collect the eluted nucleic acid (RNA) from the 6th well, ready for downstream applications.

MagRNA-II Viral RNA Extraction Kit Platform-Rapi-X96 Automated Nucleic acid extraction system & GENFast Automated RNA extraction System

SKU Code-G2M030320RX-480T

Table 3. Kit Components

Kit Contents	Kit Content Code	Kit Content Quantity
	480 Tests	480 Tests
MagPure Particles MPN	G2MA3-2963-1	Pre-mixed in buffer plates
Buffer MLB	G2MA3-2964-1	05 Plates (96-well)
Buffer MW1	G2MA3-2965-1	05 Plates (96-well)
Buffer MW2	G2MA3-2966-1	05 Plates (96-well)
Buffer AVE	G2MA3-2967-1	05 Plates (96-well)
Proteinase K	G2MA3-3111-5	196 mg
Carrier RNA	G2MA3-3117-3	0.98 mg
Proteinase Dissolving Buffer	G2MA3-3120-1	12 ml
Buffer AE	G2MA3-3590-1	2 ml

*20 Prefilled plates, 5 combs with all the buffers and other kit components preloaded.

Automation Protocol (Rapi-X96)

- For Rapi-X96 Automated Nucleic acid extraction system
- Add 20 µl of Proteinase K & 2 µl Carrier RNA into corresponding wells of Buffer MLB plates.
- Add 200 µl of sample into corresponding wells of Buffer MLB plates. Turn on the machine, start the corresponding program.
- Place the pre-filled plates at defined workstations as per table below.
- The operation will be completed after ~25 min.
- After the process is finished, the extracted elute (RNA) will be stored at -80°C.

Table 4.

Workstation	Pre-filled Cartridges
Pos-1	Buffer MLB
Pos-2	Buffer MW1
Pos-3	Buffer MW2
Pos-4	Buffer AVE

Table 5.

Step	Position	Step Name	Time(S)	Volume (µl)	Temperature (°C)
1	3	Get Beads	70	500	OFF
2	1	Binding	490	700	56
3	2	Washing	60	500	OFF
4	3	Washing	70	500	OFF
5	3	Incubate	30	500	OFF
6	4	Elution	330	100	56

For GENFast Automated Nucleic acid extraction system

- Add 20 µl of Proteinase K & 2 µl Carrier RNA into corresponding wells of Buffer MLB plates.
- Add 200 µl of sample into corresponding wells of Buffer MLB plates. Turn-on the machine, start the corresponding program.
- Place the pre-filled cartridges at defined workstations as per table below (Table 5).
- The operation will be completed after ~25 min.
- After the process is finished, the extracted RNA elute shall be preserved at -80°C.

Table 6.

Workstation	Pre-filled Cartridges
Pos-1	Buffer MLB
Pos-2	Buffer MW1
Pos-3	Buffer MW2
Pos-6	Buffer AVE

Table 7. Details of Protocol For GENFast 96.

Step	Station	Waiting T (Min)	Mixing T (Min)	Mixing S	Magnet T (Sec)	Magnet S	Volume (µl)
1	3	0	1	3	50	1	500
2	1	0	1	3	0	1	700
3	1	2	0	3	45	3	700
4	2	0	1	4	45	2	500
5	3	0	1	4	45	2	500
6	6	3	1	3	0	1	100
7	6	3	1	3	60	1	100
8	1	0	1	3	0	1	0

Cracking Set (T1)	56.0 °C	Open fan temperature	35 °C	Open time	000 min
Elution Set	56.0 °C	Storage set	000.0 °C		

MagRNA-II Viral RNA Extraction Kit Platform- KingFisher Flex System (Thermo Fisher)

SKU Code-G2M030320TK-480T

Table 8. Kit Components

Kit Contents	Kit Content Code	Kit Content Quantity
	480 Tests	480 Tests
MagPure Particles MPN	G2MA3-2963-1	Pre-mixed in buffer plates
Buffer MLB	G2MA3-2964-1	05 Plates (96-well)
Buffer MW1	G2MA3-2965-1	05 Plates (96-well)
Buffer MW2	G2MA3-2966-1	05 Plates (96-well)
Buffer AVE	G2MA3-2967-1	05 Plates (96-well)
Proteinase K	G2MA3-3111-5	196 mg
Carrier RNA	G2MA3-3117-3	0.98 mg
Proteinase Dissolving Buffer	G2MA3-3120-1	12 ml
Buffer AE	G2MA3-3590-1	2 ml

Automation Protocol KingFisher Flex System (Thermo Fisher)

- Add 20 µl of Proteinase K & 2 µl Carrier RNA into corresponding wells of Buffer MLB plates.
- Add 200 µl of sample into corresponding wells of Buffer MLB plates.
- Turn on the machine, start the corresponding program.
- Place the pre-filled cartridges at defined workstations as per table below.
- The operation will be completed after ~25 min.
- After the process is finished, the extracted RNA will be preserved at -80°C.

Table 9. Details of Work Station For KingFisher Flex System (Thermo Fisher)

Workstation	Pre-filled Cartridges
Pos-1	Buffer MLB
Pos-2	Buffer MW1
Pos-3	Buffer MW2
Pos-6	Buffer AVE

MagRNA-II Viral RNA Extraction Kit Platform- MGISP-960

SKU Code-G2M030320MG-480T

Table 10. Kit Components

Kit Contents	Kit Content Code	Kit Content Quantity
	480 Tests	480 Tests
MagPure Particles MPN	G2MA3-2963-1	Pre-mixed in buffer plates
Buffer MLB	G2MA3-2964-1	05 Plates (96-well)
Buffer MW1	G2MA3-2965-1	05 Plates (96-well)
Buffer MW2	G2MA3-2966-1	05 Plates (96-well)
Buffer AVE	G2MA3-2967-1	05 Plates (96-well)
Proteinase K	G2MA3-3111-5	196 mg
Carrier RNA	G2MA3-3117-3	0.98 mg
Proteinase Dissolving Buffer	G2MA3-3120-1	12 ml
Buffer AE	G2MA3-3590-1	2 ml

Automation Protocol (MGISP-960)

- Add the reagents/sample to the corresponding wells of the deep well plate according to the table below.

Table 11.

Position	Pre-filled Cartridges	Volume/Nos.
Pos1 - Pos4	250 µl automated filter tips	4 Nos.
Pos12	Hard-shell thin-wall 96-well skirted PCR plates, white shell/clear well	1 Nos.
Pos21	Buffer Mixture (360 µl Buffer MLB, 20 µl Proteinase K & 2 µl Carrier RNA, 20 µl MagPure Particles MPN)	402 µl
Pos17	Sample	180 µl
Pos13	Buffer AVE	50 µl
Pos23	Buffer MW1	170 µl
Pos14	Buffer MW2	340 µl

- Double-click the icon of MGISP-960 on the desktop. The mode selection interface is displayed.
- The initialization interface is displayed. Click to initialize. The initialization takes about 2 min.
- Click the Menu button and select Wizard in the Menu.
- In the Wizard interface, click Application. Operation deck layout for the script is displayed and select the (JB-A09-039 MGISP-960 Nucleic Acid Extraction Kit).
- Follow the onscreen instructions to place the consumables, samples, and reagents. Confirm the Placement and close the door.
- Upon completion of the 60 min processing period. After the process is finished, the extracted RNA shall be stored at -80°C.

Troubleshooting Guide

A). Poor yield / low sensitivity

1). Incomplete sample lysis

- Sample mixed with Lysis Buffer and was not thoroughly homogenized. The mixture has to be shaken continuously. Alternatively, prolong the incubation time with Lysis Buffer.

2). Insufficient elution buffer volume

- Bead pellet must be covered completely with elution buffer and needs to be fully resuspended. Insufficient performance of elution buffer during elution step.
- Remove all buffers completely from the bead pellet after the binding and wash steps. Remaining buffer reduces the efficiency of the subsequent steps. Aspiration of attracted bead pellet.
- Do not disturb the attracted beads while aspirating the supernatant. This requires special caution when removing the lysate from the beads as the lysate is usually too opaque to allow visual control of the pellet.
- Time for magnetic separation too short or aspiration speed too high.

B). Low Purity/Low Sensitivity Insufficient washing procedure

- Make sure that beads are resuspended completely during the washing procedure. If shaking is not sufficient to resuspend the beads completely mix by repeated pipetting up and down.

C). Poor performance of Nucleic acid in down-stream applications Carry-over of ethanol from wash buffers

- Be sure to remove all of the 80% ethanolic wash solution from the final wash, as residual ethanol interferes with downstream applications. Ethanol evaporation from wash buffers.
- Close the buffer bottles tightly, avoid ethanol evaporation from buffer bottles as well as from buffer filled in reservoirs. Do not reuse buffer reservoirs.

Limitations

- **Sample Variability:** Different body fluids may contain varying amounts of viral RNA, leading to differences in extraction efficiency and yield. Each sample type requires specific preprocessing and the use of appropriate buffers and protocols.
- **Cross-Contamination:** Improper handling or inadequate cleaning of equipment may lead to cross-contamination between samples, compromising the reliability of the extracted viral RNA maintaining a contamination-free environment and following proper cleaning protocols are essential to minimize the risk of cross-contamination.
- **Processing Time:** The extraction process can be time-consuming, particularly when dealing with multiple types of body fluids. This can lead to workflow bottlenecks, especially in high-throughput settings. Efficient workflow management and optimization of extraction protocols are necessary to minimize processing time and increase productivity.
- **Operator Skill:** The efficiency of the extraction process may vary depending on the expertise of the operator. Variability in results between different users can occur if operators lack sufficient training or experience. Standardized protocols and regular training sessions can help ensure consistency in results across different operators.

Safety and Precautions

- **Chemical Handling:** Reagent cartridges/plates contain guanidine hydrochloride/guanidine thiocyanate, which may react with bleach to form highly reactive compounds. In case of spillage, clean with laboratory detergent and water.
- **Biological Samples:** Tissues, body fluids, infectious agents, and blood may carry infectious diseases. Ensure all laboratory personnel are familiar with general safety guidelines for chemical usage, storage, and waste disposal. Refer to relevant Safety Data Sheets (SDS) for specific precautions.
- **Personal Protective Equipment (PPE):** Wear appropriate attire, including lab coats, gloves, goggles, and closed-toe shoes to protect against spills, splashes, and inhalation.
- **Ventilation:** Work in well-ventilated areas or use fume hoods to minimize exposure to harmful vapors or inhalation of chemicals. Handle the chemical waste in designated fume hoods.
- **Storage:** Store the chemicals correctly in designated areas, adhering to guidelines for temperature, compatibility, and segregation.

  Labeling: Ensure all the containers are clearly labeled with the chemical name, concentration, and hazard warnings to prevent accidents or confusion.
- **Handling:** Employ proper techniques, while handling chemicals, pour chemicals carefully and steadily to avoid spills, splashes, and excessive vapor release. Keep chemical containers closed while not in use.
- **Emergency Equipment:** Familiarize yourself with the location and proper use of safety showers, eyewash stations, fire extinguishers, and spill kits for swift response to emergencies.
- **Training:** All individuals must undergo comprehensive training on chemical handling, emergency procedures, and the use of safety equipment as per regulatory and institutional requirements before handling potentially biohazardous materials.

Symbols for Use in the Labeling	
Symbols	**Definition**
	KEEP AWAY FROM SUNLIGHT
	TEMPERATURE LIMIT
	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	UPWARD
	CONSULT INSTRUCTIONS FOR USE
	BATCH CODE
	CATALOGUE NUMBER
	USE BY DATE
	DATE OF MANUFACTURE
	MANUFACTURER
	CONTAINS SUFFICIENT FOR <n> TESTS
	CAUTION
	DO NOT USE IF PACKAGE IS DAMAGED
EC REP	AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/ EUROPEAN UNION
CE	EUROPEAN CONFORMITY

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