Frederick National Laboratory for Cancer Research Sponsored by the National Cancer Institute SOP Title: Use and Maintenance of the Combination Refrigerator and Freezer Document ID: 26022 Version 2.0 Page 1 of 12 Supersedes 1.0 Effective Date: 07Sep21

Written by:				
Printed Name:	Title:	Signature/Date:		
Ashley McCormack	Research Associate II			

Approved by:					
Printed Name:	Title:	Signature/Date:			
Troy Kemp	Scientific Manager				
QA Approved by:					
Printed Name:	Title:	Signature/Date:			
Hussain Shaffi	QA Specialist IV				

Frederick National Laboratory for Cancer Research sponsored by the National Cancer Institute

Vaccine, Immunity and Cancer Directorate Standard
Operating Procedure

SOP Title: Use and Maintenance of the Combination Refrigerator and Freeze	er
---	----

Document ID: 26022	Version	2.0
Page 2 of 12	Supersedes	1.0

Effective Date: 07Sep21

1. PURPOSE

1.1. The purpose of this procedure is to describe the use and maintenance of the Sanyo Combination Refrigerator with Freezer Unit.

2. SCOPE

2.1. This procedure applies to all combination refrigerator and freezer units.

3. REFERENCES

- 3.1. User Manual for the Sanyo MPR-414F Pharmaceutical Refrigerator with Freezer
- 3.2. 10007: Non-Routine Equipment Maintenance
- 3.3. 10009: General Record Review
- 3.4. HSL_GL_001: Waste Disposal at the Advanced Technology Research Facility

4. RESPONSIBILITIES

- 4.1. The Research Associate, hereafter referred to as Analyst, is responsible for reviewing and following this procedure, and documenting performance of equipment maintenance.
- 4.2. The Scientific Manager or designee is responsible for training personnel in this procedure and reviewing associated documentation.
- 4.3. The Quality Assurance Specialist is responsible for quality oversight and approval of this procedure.
- 4.4. Trained personnel perform equipment maintenance record review per "10009: General Record Review."

5. **DEFINITIONS**

- 5.1. As Needed Maintenance maintenance that is performed outside of routine maintenance but is not performed in response to equipment malfunction.
- 5.2. Non-routine Maintenance maintenance that is performed in response to equipment malfunction or failure.
- 5.3. Routine Maintenance maintenance that is performed at planned intervals to identify and prevent problems before they result in equipment failure.
- 5.4. REES Rees Scientific is a provider of automated temperature monitoring systems

Verify current version prior to use. Use of a superseded or obsolete document is prohibited.

This document contains confidential and proprietary information. Do not copy or distribute without prior, written permission.

Frederick National Laboratory for Cancer Research Sponsored by the National Cancer Institute SOP Title: Use and Maintenance of the Combination Refrigerator and Freezer Document ID: 26022 Page 3 of 12 Supersedes Vaccine, Immunity and Cancer Directorate Standard Operating Procedure Vaccine, Immunity and Cancer Directorate Standard Operating Procedure Vaccine, Immunity and Cancer Directorate Standard Operating Procedure Supersedes 1.0

6. REAGENTS, MATERIALS, AND EQUIPMENT

- 6.1. Combination Refrigerator and Freezer Unit, Sanyo, Model MPR-414F
- 6.2. Incandescent Bulb, T22 E17 (GE, Cat # WB36X10003 or equivalent)
- 6.3. Primary Disinfectant (Cavicide, FNLCR Warehouse, Cat # 79300360)
- 6.4. Secondary Disinfectant (Ster-ahol, VWR, Cat # 14003-358 or equivalent)
- 6.5. Wipe, Low-Lint, Wypalls (FNLCR Warehouse, Cat # 79300335 or equivalent)

7. HEALTH AND SAFETY CONSIDERATIONS

- 7.1. Proper safety precautions should be taken while working in a laboratory setting. This includes, but is not limited to, proper protective equipment such as lab coats, safety glasses, closed-toe shoes, and non-latex gloves.
- 7.2. Refer to the respective Safety Data Sheet (SDS) when working with any chemicals.
- 7.3. Refer to "HSL_GL_001: Waste Disposal at the Advanced Technology Research Facility," "EHS-WM-1: Disposal and Minimization of Chemical Waste," and "EHS-WM-2: Biological Waste Handling and Disposal" for waste disposal processes.
- 7.4. Ensure power cord is free of dust and plugged into a grounded power supply with the appropriate rating.
- 7.5. Always disconnect the power supply before performing any repair or maintenance involving direct contact with the electrical system.
- 7.6. If Unit is unplugged or power to unit is interrupted, do not restart unit for at least 5 minutes as this protects the compressor.
- 7.7. Ensure intake and exhaust vents are not blocked to allow for proper circulation of cooled air. Do not over stock Combo Unit. Do not store stock on the floor of the chamber. Do not allow stock to rest against the walls of the refrigerator compartment. See Attachment 2, numbers: 13, 15, 17.

8. PROCEDURE PRINCIPLES

- 8.1. When stocking Combo Unit, do so in small batches to minimize disruption of temperature.
 - 8.1.1. Monitor temperature frequently to avoid causing the temperatures to go too far outside of range.

Frederick National Laboratory for Cancer Research Sponsored by the National Cancer Institute SOP Title: Use and Maintenance of the Combination Refrigerator and Freezer Document ID: 26022 Page 4 of 12 Supersedes Vaccine, Immunity and Cancer Directorate Standard Operating Procedure Vaccine, Immunity and Cancer Directorate Standard Operating Procedure Version 2.0 Supersedes 1.0 Effective Date: 07Sep21

8.1.2. Allow Combo Unit to reach operating temperature before loading it with any product. To stabilize temperature profile, a 24-hour waiting period is recommended by user manual.

9. START-UP

- 9.1. Plug in power cord. Press BUZZER if buzzer sounds to turn off alarm.
- 9.2. Insert key in the switch and turn power on.
- 9.3. Rotate power switch to ALARM ON position when the temperature drops below the warm alarm set-point for both the refrigerator compartment and freezer compartment. (See Settings, Section 11.)
- 9.4. Set refrigerator set-point to 4°C and the freezer set point to -20°C. See Attachment 1: Temperature Setting for instructions on how to set Combo Unit's temperature. (See Settings, Section 11.)
- 9.5. Do not leave doors open for extended periods of time.

10. MAINTENANCE

- 10.1. As Needed Maintenance
 - 10.1.1. Spills
 - 10.1.1.1. If a reagent spill occurs, wipe up liquid and clean with an appropriate cleaner, such as a mild detergent, then wipe with a water-dampened cloth. If condensation forms, wipe it off with a dry low-lint wipe.
 - 10.1.1.2. If a biological spill occurs, clean with Cavicide or appropriate primary disinfectant. If condensation forms, wipe it off with a dry low-lint wipe.
 - 10.1.2. Replacement of Lamp
 - 10.1.2.1. If a light bulb needs to be replaced, see "Attachment 3: Replacement of Lamp" for instructions.
 - 10.1.2.2. Document maintenance performed on 26022-01.
 - 10.1.3. Document As Needed Maintenance in its respective section on form 26022-01.

Frederick National Laboratory for Cancer Research sponsored by the National Cancer Institute

Vaccine, Immunity and Cancer Directorate Standard
Operating Procedure

SOP Title: Use and Maintenance of the Combination Refrigerator and Freezer

Document ID: 26022	Version	2.0
Page 5 of 12	Supersedes	1.0

Effective Date: 07Sep21

10.2. Annual Maintenance

- 10.2.1. Cleaning the Refrigerator
 - 10.2.1.1. Remove all contents of the refrigerator and freezer Unit.
 - 10.2.1.2. Power off Unit and disconnect power cord.
 - 10.2.1.3. Spray the outside of Unit with Cavicide and wipe with a clean low-lint wipe.
 - 10.2.1.4. Spray the internal components of Unit with Cavicide and wipe with a clean low-lint wipe. See "Attachment 2: MPR-414F Diagram" for components.
 - 10.2.1.5. Connect power cord and turn Unit on. Allow unit temperature to stabilize then return contents in batches. See Step 9.1.
 - 10.2.1.6. Document maintenance performed on "26022-01: Combination Refrigerator and Freezer Maintenance Form."
- 10.2.2. Defrosting the Freezer
 - 10.2.2.1. Remove all contents of the refrigerator and freezer Unit.
 - 10.2.2.2. Power off Unit and disconnect power cord.
 - 10.2.2.3. Spray the outside of Unit with Cavicide and wipe with a clean low-lint wipe.
 - 10.2.2.4. Spray the internal components of Unit with Cavicide and wipe with a clean low-lint wipe. See "Attachment 2: MPR-414F Diagram" for components.
 - 10.2.2.5. Connect power cord and turn Unit on. Allow unit temperature to stabilize then return contents in batches. See Step 9.1.
 - 10.2.2.6. Document maintenance performed on 26022-01 form.

10.3. Annual Calibration

10.3.1. Facilities, Maintenance, and Engineering (FME) or a contracted vendor calibrate Unit every year as required, for routine use.

Frederick National Laboratory for Cancer Research Sponsored by the National Cancer Institute SOP Title: Use and Maintenance of the Combination Refrigerator and Freezer Document ID: 26022 Page 6 of 12 Supersedes Vaccine, Immunity and Cancer Directorate Standard Operating Procedure Vaccine, Immunity and Cancer Directorate Standard Operating Procedure Vaccine, Immunity and Cancer Directorate Standard Operating Procedure Supersedes 1.0

- 10.3.2. Units are assessed for recalibration after repair, damage, or if physical, or electronic changes occur that could impact the operation, range, accuracy, or tolerance of the equipment. This is determined by the Scientific Manager or designee.
- 10.3.3. Print calibration report and file.

10.4. Non-Routine Maintenance

In the case that the Combo Unit is not operating correctly, transition processes being performed to another unit (when applicable), post a sign stating the equipment is out of service and initiate non-routine maintenance documentation per "10007: Non-Routine Equipment Maintenance."

Document the nature of any failures or malfunctions, how and when it was discovered, and the personnel involved on "10007-01: Non-Routine Equipment Maintenance Form."

Initiate a service request and complete the non-routine maintenance process following 10007.

11. SETTINGS

- 11.1. Temperature Refrigerator: 2°C to 8°C
- 11.2. Temperature Freezer: -10°C to -30°C
- 11.3. Out of Range Events
 - 11.3.1. Refrigerator
 - 11.3.1.1. If REES system or Refrigerator goes into alarm, acknowledge alarm by emailing the laboratory personnel and log-in to the REES system to inhibit for instrument for no more than 30 minutes. If the instrument maintains a temperature out of range for more than 30 minutes, then transfer biological contents to another unit. Initiate non-routine maintenance per section 10.4.
 - 11.3.2. Freezer
 - 11.3.2.1. If REES system or Freezer goes into alarm, acknowledge alarm by emailing the laboratory personnel and log-in to the REES system to inhibit for instrument for no more than 1 hour. If the instrument maintains a temperature out of range for more than 1 hour, then transfer biological contents to another unit. Initiate non-routine maintenance per section 10.4.

Frederick National Laboratory for Cancer Research sponsored by the National Cancer Institute

Vaccine, Immunity and Cancer Directorate Standard
Operating Procedure

Document ID: 26022	Version	2.0
Page 7 of 12	Supersedes	1.0

Effective Date: 07Sep21

12. ATTACHMENTS

12.1. Attachment 1: Temperature Setting

12.2. Attachment 2: MPR-414F Diagram

12.3. Attachment 3: Replacement of Lamp

12.4. Attachment 4: 26022-01: Combination Refrigerator and Freezer Maintenance Form

13. REVISION HISTORY

Version	Change	Reason
1.0	Create new SOP for the use and maintenance of the combination refrigerator/freezer unit.	New SOP.
2.0	Transferred procedure and form to new template; form now separate.	Consistency between procedures.

Frederick National Laboratory for Cancer Research sponsored by the National Cancer Institute	Vaccine, Immunity and Cancer Directorate Standard Operating Procedure		
SOP Title: Use and Maintenance of the Combination Refrigerator and Freezer			
Document ID: 26022 Version 2.0			
Page 8 of 12 Supersedes 1.0			
Effective Date: 07Sep21			

Attachment 1: Temperature Setting

	Attachinent 1. Temperature Setting				
	Operation	Key operated	Indication after operation		
1	Connect to the power source and turn on the power switch.		The current refrigerator or freezer temperature is displayed.		
2	Select refrigerator (REF.)by pressing display select key.	REF. FREEZ.	The refrigerator indicator lights and the current refrigerator temperature is displayed.		
3	Press SET key.	SET	The current set temperature is displayed and the second digit of the temperature display flashes.	005	
4	Set to 004 by using digit shift key	*	Pressing the key leads the flash of the first digit.	005	
†	and numerical value shift key.	★	Pressing the key shifts up the figure of the current digit.		
5	Press SET key.	SET	The value is stored in memory and the current refrigerator temperature is displayed.		
6	Select freezer (FREEZ.) by pressing display select key.	REF. FREEZ.	The freezer indicator lights and the current freezer temperature is displayed.		
7	Press SET key.	SET	The current set temperature is displayed and the second digit of the temperature display flashes.	-)20	
8	Set to -25 by using digit shift key	*	Pressing the key leads the flash of the first digit.	<u>-12)Ö</u>	
0	and numerical value shift key.	★	Pressing the key shifts up the figure of the current digit.	-25	
9	Press SET key.	SET	The value is stored in memory and the current refrigerator temperature is displayed.	_	

Frederick National Laboratory for Cancer Research

sponsored by the National Cancer Institute

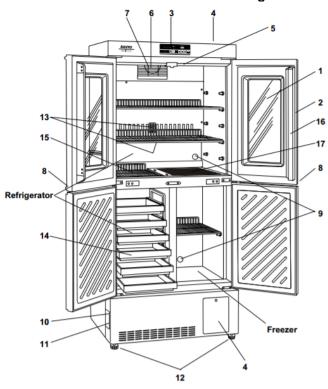
Vaccine, Immunity and Cancer Directorate Standard
Operating Procedure

SOP Title: Use and Maintenance of the Combination Refrigerator and Freezer

Document ID: 26022	Version	2.0
Page 9 of 12	Supersedes	1.0

Effective Date: 07Sep21

Attachment 2: MPR-414F Diagram



MPR-414F with drawers (optional component)

- 1. **Glass window**: Water can sometimes condense on the glass in areas of high humidity. Wipe off the condensation with a dry soft cloth.
- 2. Magnetic door gasket: This prevents the cool air from escaping. Always keep clean.
- 3. **Control panel**: The operation status is displayed on this panel. And the temperature setting is available through this panel.
- 4. **Mounting space for temperature recorder**: Space for an automatic temperature recorder available separately.
- 5. **Lamp**: This lamp lights up when the refrigerator door is open to illuminate the chamber.
- 6. **Air intake vent**: Ensure this vent is never blocked. Failure to do so will result in unstable temperature distribution in the refrigerator.
- 7. **Circulating fan**: This is for cooling the refrigerator uniformly. Fan is installed inside the enclosure. Do not insert anything into the enclosure. The air exhaust vent is located at the upper of the fan.
- 8. **Lock**: Turn key clockwise through 180 degree to lock the door. The right-side lock is for the right upper and lower doors and left side lock is for the left upper and lower doors.
- 9. Access port (rear): This port allows cables to be passed into the cabinet.
- 10. **Power switch (also functions as a circuit breaker)**: The power switch also used as a circuit breaker. Normally put a cover on the switch. The round button under the power switch is a leakage

Frederick National Laboratory for Cancer Research sponsored by the National Cancer Institute	Vaccine, Immunity and Cancer Directorate Standard Operating Procedure			
SOP Title: Use and Maintenance of the Combination Refrigerator and Freezer				
Document ID: 26022 Version 2.0				
Page 10 of 12 Supersedes 1.0				
Effective Date: 07Sep21				

test button. The operation check of the circuit breaker can be performed by pressing this button. But note the power supply to the unit is disconnected when this button is pressed.

- 11. Remote alarm terminal: This is used to alarm the abnormality to the remote location.
- 12. Leveling feet: Use these bolts to adjust the height and level the unit for installation.
- 13. **Cool air exhaust vent**: Ensure this vent is never blocked. Note the items exposed to the direct air flow can be frozen.
- 14. **Drawer**: Drawers are available as an optional component (MPR-41R).
- 15. **Shelf (at the opening between upper and lower chamber)**: Ensure this surface is never blocked by the stored items so that the cool air can be circulated into the lower chamber.
- 16. **Movable center pillar**: The pillar contact the door gasket firmly when the door is closed and functions as a block between the chamber and outer air. When the door is opened, the pillar angle is changed by 90 degree. Take care not to change the pillar angle.
- 17. **Protective sheet**: The stored material may be frozen if it is put on the chamber bottom directly. Always put the sheet in the refrigerator compartment (upper and lower left chamber).

Frederick National Laboratory for Cancer Research Sponsored by the National Cancer Institute SOP Title: Use and Maintenance of the Combination Refrigerator and Freezer Document ID: 26022 Page 11 of 12 Supersedes Vaccine, Immunity and Cancer Directorate Standard Operating Procedure Supersedes 1.0

Attachment 3: Replacement of Lamp

Replacement of lamp

Follow the procedure below at the time of replacement of the lamp. The lamp is located at the upper front side of refrigerator chamber.

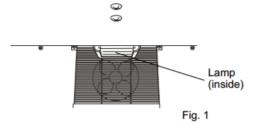
- 1. Disconnect the power supply plug.
- **2.** To remove the lamp cover, hold the both sides of the cover with flexure and push it backward.
- 3. Remove the bulb from the socket by turning it to counterclockwise

Caution: Take care not to injure the fingers as the bulb can be hot!

< Bulb for replacement >

Incandescent lamp (T22E17) 125V, 10W (for AC 110/115V) (T22E17) 250V, 15W (for AC 220/230/240V)

4. Mount a new bulb and replace the lamp cover.



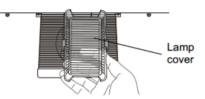
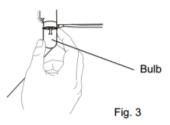


Fig. 2



Frederick National Laboratory for Cancer Research sponsored by the National Cancer Institute	Vaccine, Immunity and Cancer Directorate Standard Operating Procedure				
SOP Title: Use and Maintenance of the Combination Refrig	erator and Freezer				
Document ID: 26022	Version	2.0			
Page 12 of 12	Supersedes	1.0			
Effective Date: 07Sep21					

Attachment 4: 26022-01: Combination Refrigerator and Freezer Maintenance Form

Frederick National Laboratory for Cancer Research sponsored by the National Cancer institute			Vaccine, Immunity and Cancer Directorate Standard Operating Procedure Form			
Form Title: Combin	ation Refrigerator an	nd Freezer Ma	intenance Form			
Document ID: 26022-01			Version	Version:		
Associated SOP: 26022			Effective Date:		7Sep21	
Supersedes:	1.0		Page 1 of 1			
Maintenance Year:	ir: Er		Equipment ID:	quipment ID: HSL_		
Annual Maintenance): ::	<u>'</u>				
Cavicide Lot Nur	mber:					
Cavicide Expiration	n Date:					
Performed by/d	ate:					
Reviewed by/d	ate:					
As Needed Mainten Date		: DVA Activity Performed		Recorded by/date	Reviewed by/da	
N/A						
N/A						
			orcoded or obcole	ete document is probib	pited.	
Verify cur	rent version prior to us	se. Use of a su	reiseded of obsole	ste document is promit		