RIP Storage and Stability of Samples, Controls and Reagents

PURPOSE

- This procedure provides instructions for storage and stability of sample buffer tubes, controls and reagents.

SAFETY CONSIDERATIONS

- Standard precautions. Refer to MB 2.02 Biohazard Containment
- Use of engineering controls: Refer to MB 3.01 Engineering Controls to Prevent Nucleic Acid Contamination

ABBREVIATIONS

- BSC: BioSafety Cabinet
- BSL: BioSafety level
- MM: master mix
- NEGC: negative control
- POSC: positive control
- RIP: Simplexa RSV & Influenza A/B PC
- RT: room temperature
- UTM: universal viral transport media
- Area/Room 1: Clean room
- Area/Room 2: Processing room
- Area/Room 3: Amplification room

MATERIALS REQUIRED

Equipment	Reagents	Supplies
Room 1: Clean room ▪ -10 to -30° C freezer Room 2: Processing ▪ Refrigerator 2 – 8° C ▪ BSC BSL-2 ▪ -70° C freezer ▪ 100 µl pipette Room 3: Amplification ▪ 3M Integrated Cycler	Simplexa Flu A/B & RSV Direct kit MOL2651 ▪ Reaction Mix (24) 50 µl	Orange barrier wipes
	Simplexa Flu A/B & RSV Control Pack MOL1455 ▪ 10 tubes, 100 µl	Nitrile gloves (powder-free)
	Negative control – UTM	2.0 ml cryovials
		Cryovial storage box
		Pipette tips
		Sterile scissors

PROCEDURE A: Follow the activity below for the proper storage of neat samples

Storage and Stability of Samples and Reagents

Activity	Step	Action	Related Doc
Aliquot NP, nasal washes/aspirates Room 2	1	Number and label a 2.0 mL cryovial for each nasal wash/aspirate and NP specimen to be tested	MB 1.01 Specimen Management MB 9.05 Proc. J for archiving samples

Step	Action
a	Number patients on RIP worksheet in consecutive order
b	Number primary container and associated label with assigned number on worksheet
c	Number cap of a 2.0 mL cryovial according to assigned number on worksheet
d	Properly label cryovial with patient aliquot label matching the number on the cap to the number on the label
e	Vortex sample in original container until well mixed
f	Verify number on primary and secondary containers before transfer
g	Transfer sample to tube with corresponding number on cap

Activity	Step	Action	Related Doc
Sample Storage	2	Store sample aliquots as follows: Step / Temperature / Stability a / Room temperature / 1 hour b / 2 – 8° C / 3 days c / -70° C / 1 year	

PROCEDURE B: Follow the activity below for proper storage of reagents. Refer to Tables 1 – 4.

Information for Reagent Storage

Activity	Step	Action	Related Doc
General Information	1	*Clean gloves are required prior to handling new reagents* RIP reagents are shipped frozen on dry ice ▪ Do not use reagents if thawed upon arrival ▪ Do not use reagents if vials have been damaged ▪ Contact DiaSorin/Focus Customer Service at 1.800.838.4548 for shipping issues	
General Information	2	Store RIP reagents at -10 to -30° C until expiration date located on the vial unless otherwise noted. Refer to Table 1.	MB 5.02 Standards of Practice Waste Management 912.04
	3	Discard reagents that have not been stored properly or have expired according to the Organizational Waste Management policy	
	4	Remove only the required amount of reagents from storage needed for testing.	
	5	Protect from excess heat and light; store in dark	
	6	Reagents are stable through the end of the expiration month as indicated on the packaging	
	7	Thaw MM and POSC at room temperature before use	
	8	Once thawed, MM is good for 30 min ▪ ***Do not refreeze***	
	9	Do not allow contact with reactive vapors from bleach or Extran or dust as these may affect the performance.	
	10	Do not interchange the reagent tube caps	

Table 1: Simplexa RIP Reagents

Reagent	Unopened Reagent		Stability	Opened Reagent		Stability
	Temp (° C)	Location		Temp (° C)	Location	
RIP POSC (Red)	-70	Room 2	expiry date	2 – 8	Room 2	24 h
RIP MM (brown)	-10 to -30	Room 1	expiry date	RT	Room 1	30 min

Table 2: Negative Control – Universal Viral Transport Media

Reagent	Unopened/Opened		Aliquot Storage		In Use Aliquots	
	Temp	Location	Temp (° C)	Location	Temp (° C)	Location
NEGC (UTM)	RT	Micro	2 – 8	Room 2	2 – 30	Room 2

REFERENCES

1. *Simplexa* RSV & Flu A/B Direct PCR Clinical Verification and Validation Study performed at Children's Hospitals and Clinics of MN, 2016
2. Simplexa™ *Flu A/B & RSV* Direct Circular PI.MOL2650.IVD, Rev. F, 18-September-2015, DiaSorin/Focus Diagnostics, Cypress, CA 90630
3. CLSI. Collection, Transport, Preparation and Storage of Specimens for Molecular Methods. 2005; CLSI document MM13-A, Wayne, PA

Historical Record

Version	Written/Revised by:	Effective Date:	Summary of Revisions
1	P. Ackerman	11.20.2016	Initial Version