GAS Storage and Stability of Samples, Controls and Reagents

PURPOSE

- This procedure provides instructions for storage and stability of sample buffer tubes 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
- GAS: Group A Strep
- GASD: Group A Strep Detection
- MM: master mix
- NEGC: negative control
- NFW: nuclease free water
- PCTL: process control
- POSC: positive control
- PP: primer – pair
- RT: room temperature
- SEAC: Simplexa extraction and amplification control
- TE buffer: Tris – EDTA buffer
- Area/Room 1: Clean room
- Area/Room 2: Processing room
- Area/Room 3: Amplification room

MATERIALS REQUIRED

Equipment	Reagents	Supplies
Room 1 ▪ Refrigerator 2 – 8° C ▪ -10 to -30° C freezer ▪ Mini-centrifuge ▪ Laminar flow hood ▪ Eppendorf Repeater pipette Room 2 ▪ Refrigerator 2 – 8° C ▪ BSC BSL-2 ▪ -70° C freezer	GAS primer pair (50 µl)	Orange barrier wipes
	TA master mix (2 vials, 200 µl ea)	Nitrile gloves (powder-free)
	GAS positive control (POSC) 100 µl	Cryovial storage box
	NFW (NEGC)	Test tube rack
	TE buffer 1X pH 8.0 (100 ml)	Scissors
	SEAC ▪ Amplification Control DNA ▪ Amplification Control primer pair	Eppendorf pipette tip, 5 ml

PROCEDURE A: Follow the activity below for the proper storage of sample buffers

Storage and Stability of Processed Specimens

<table>
<tr><th>Activity</th><th>Step</th><th>Action</th><th>Related Doc</th></tr>
<tr><td>Specimen Processing
Room 2</td><td>1</td><td>Prepare swabs fpr testing
<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>a</td><td>Number patients on GASD worksheet in consecutive order</td></tr>
<tr><td>b</td><td>Number primary container and associated label with assigned test number on worksheet</td></tr>
<tr><td>c</td><td>Number cap of a 250 µl TE tube according to assigned number on worksheet</td></tr>
<tr><td>d</td><td>Properly label TE tube with patient aliquot label matching the number on the cap to the number on the label</td></tr>
<tr><td>e</td><td>Verify number on primary container before transfer</td></tr>
<tr><td>f</td><td>Using a barrier wipe, break s swab off in the sample TE buffer tube with corresponding number on cap</td></tr>
<tr><td>g</td><td>Vortex 2 min, vortex setting 9</td></tr>
</table></td><td>MB 1.01
Specimen Management</td></tr>
</table>

Activity	Step	Action	Related Doc
Sample storage	2	Store sample buffer tubes as follows: Temperature: Stability Room temp: 4 hr 2 – 8° C: 48 h -70° C: 90 days	

PROCEDURE B: Follow the activity below for proper storage of reagents. Refer to Tables 1 – 3.

Information for Reagent Storage

Activity	Step	Action	Related Doc
General Information		***Always change gloves prior to handling new reagents and cartridges***	MB 5.02 Standards of Practice
	1	GAS PCR 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 **Focus Customer Service at 1.800.838.4548** for shipping issues	
	2	Store reagents at -10 to -30° C until expiration date located on the vial unless otherwise noted. Refer to Table 1.	
	3	Discard reagents that have not been stored properly or have expired according to lab safety policy	
	4	Remove only the required amount of reagents from storage needed for testing. ▪ Clean gloves required	
	5	Protect from excess heat and light; store in dark	
	6	Thaw reagents at room temperature before use	
	7	Once thawed, store reagents at 2 – 8° C up to 30 days ▪ ***Do not refreeze***	
	8	Do not allow contact with reactive vapors from bleach or Extran or dust as these may affect the performance.	
	9	Do not interchange the reagent tube caps	

Table 1: Simplexa GAS Reagents

Reagent	Unopened Reagent		Stability	Opened Reagent		Stability
	Temp (° C)	Location		Temp (° C)	Location	
GAS POSC (red)	-70	Room 2	expiry date	2 – 8	Room 2	30 days
TA MM (green)	-10 to -30	Room 1	expiry date	2 – 8	Room 1	30 days
GAS pp, conc. 15 µM (brown)	-10 to -30	Room 1	expiry date	2 – 8	Room 1	30 days
SEAC (blue)	-10 to -30	Room 1	expiry date	2 – 8	Room 1	30 days

Table 2: Molecular Grade Water (RNase and DNase free)

Reagent	Unopened/Opened		Aliquot Storage		In Use Aliquots	
	Temp	Location	Temp (° C)	Location	Temp (° C)	Location
Nuclease free water (NFW)	RT	Room 1	2 – 8	Room 1	2 – 30	Room 2

Table 3: TE Buffer and Aliquot Storage

Reagent	Unopened/Opened temp		Aliquot Storage		In Use Aliquots, temp (° C)	
	Temp	Location	Temp (° C)	Location	Temp (° C)	Location
TE buffer 1X	RT	Room 1	2 – 8	Room 1	2 – 30	Room 2

Table 4: Process Control Storage

Reagent	Temp (° C)	Location	Stability	Temp (° C)	Location	Stability
GAS Process Control (matrix)	≤ 70	Room 2	1 year	2 – 8	Room 2	7 days
GAS Process Control (swab)	NA	NA	NA	2 – 8	Room 2	7 days

REFERENCES

1. GAS PCR Clinical Verification and Validation Study performed at Children's Hospitals and Clinics of MN August 2014
2. Simplexa™ Group A Strep Molecular Control Circular PI.MOL8033.IVD, Rev. C, 16-April-2013, Focus Diagnostics, Cypress, CA 90630
3. Group A Primer Pair (50 µl) ASR, Circular PI.MOL9033 Rev. C, 21 May 2012, Focus Diagnostics, Cypress, CA 90630
4. Simplexa™ Extracton & Amplification Control Set, Circular PI.MOL9000, Rev. D, CE, 7 Mar 2013, Focus Diagnostics, Cypress, CA 90630

Historical Record

Version	Written/Revised by:	Effective Date:	Summary of Revisions
1	P. Ackerman	9.9.14	Initial Version
2	P. Ackerman	07.26.16	Reformatttted for CMS upload