# 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](http://khan.childrensmn.org/Manuals/Lab/SOP/MolBio/Safety/212201.pdf) Biohazard Containment
* Use of engineering controls: Refer to [MB 3.01](http://khan.childrensmn.org/Manuals/Lab/SOP/MolBio/EngCtl/212209.pdf) 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 | * 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 * -70⁰ C freezer | GAS primer pair ( 50 µl) | Orange barrier wipes |
| TA master mix (2 vials, 200 µl ea) | Nitrile gloves (powder-free) |
| NFW (NEGC) | Cryovial storage box |
| TE buffer 1X pH 8.0 (100 ml) | Test tube rack |
| SEAC   * Amplification Control DNA   Amplification Control primer pair | Scissors |
|  | Eppendorf pipette tip, 5 ml |
|  |

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

**Storage and Stability of Processed Specimens**

| **Activity** | **Step** | **Action** | **Related Doc** |
| --- | --- | --- | --- |
| **Specimen Processing**  Room 2 | 1 | Prepare swabs for testing   |  |  | | --- | --- | | Step | Action | | a | Number patients on GASD worksheet in consecutive order | | b | Number primary container and associated label with assigned test number on worksheet | | c | Number cap of a 250 µl TE tube according to assigned number on worksheet | | d | Properly label TE tube with patient aliquot label matching the number on the cap to the number on the label | | e | Verify number on primary container before transfer | | f | Using a barrier wipe, break s swab off in the sample TE buffer tube with corresponding number on cap | | g | Vortex 2 min, vortex setting 9 | | [MB 1.01](http://khan.childrensmn.org/Manuals/Lab/SOP/MolBio/SpecMgt/212197.pdf)  Specimen Management |
| **Sample storage** | 2 | Store sample buffer tubes as follows:   |  |  | | --- | --- | | Temperature | Stability | | Room temp | 4 hr | | 2 – 8° C | 48 h | | -70⁰ 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** |
| --- | --- | --- | --- |
|  |  | ***Always change gloves prior to handling new reagents and cartridges*** |  |
|  | 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 **DiaSorin Customer Service at 1.800.838.4548** for shipping issues | [MB 5.02](http://khan.childrensmn.org/Manuals/Lab/SOP/MolBio/Qual/212231.pdf)  Standards of Practice |
| **General Information** | 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 | |
| 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: Positive and Negative 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

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| 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 | Reformatted for CMS upload |
|  | 3 | J. Laramie | 02.12.18 | Eliminated Positive Control (manufactured) from abbreviations, reagent list, and storage conditions |
|  | 4 | J. Laramie | 02.12.18 | Added Negative Process Control storage conditions |