# Molecular Diagnostics Technical Operations Manual

MB005.2 – *Simplexa*™ Group A Strep PCR

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|  | Group A Strep PCR Process |  |
| Forms | Procedures and Supporting Documents | Training and Competency |
| **QC Worksheets*** [MB005.2.F1](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CQC%20forms%5CSimplexa%5CMB005.2.F1%20GAS%20New%20reagent%20QC%20worksheet.docx)

GAS Reagent QC Worksheet* [MB005.2.F2](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CQC%20forms%5CSimplexa%5CMB005.2.F2%20GAS%20POSC%20New%20Reagent%20QC%20Worksheet.docx)

GAS POSC QC Worksheet* [MB005.2.F8](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CQC%20forms%5CSimplexa%5CMB005.2.F8%20GAS%20PCTL%20New%20Reagent%20QC%20Worksheet.docx)

GAS PCTL QCWorksheet**New lot/shipment Inventory Forms*** [MB005.2.F3](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CQC%20forms%5CSimplexa%5CMB005.2.F3%20GAS%20Primer%20Lot%20Inventory.docx)

GAS Primer New lot Inventory * [MB005.2.F4](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CQC%20forms%5CSimplexa%5CMB005.2.F4%20GAS%20SEAC%20Lot%20Inventory.docx)

SEAC New lot inventory * [MB005.2.F5](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CQC%20forms%5CSimplexa%5CMB005.2.F5%20GAS%20TA%20MasterMix%20Lot%20Inventory.docx)

TA MM New lot inventory* [MB005.2.F6](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CQC%20forms%5CSimplexa%5CMB005.2.F6%20GAS%20POSC%20Lot%20Inventory.docx)

GAS POSC New lot inventory* [MB005.2.F7](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CQC%20forms%5CSimplexa%5CMB005.2.F7%20TE%20buffer%20Lot%20Inventory.docx)

TE Buffer New lot inventory | Preanalytic Procedures* [GAS 001](GAS%20001%20Sample%20Handling%20and%20Storage.docx)  **Sample Collection, Handling and Storage**
1. Procedure A: Receiving samples
2. Procedure B: Sample aliquots

Analytic Procedures* [GAS 002](GAS%20002%20Simplexa%20Group%20A%20Strep%20overview.doc) ***Simplexa*** **Group A Strep Overview and Principle**
* [GAS 003](GAS%20003%20Storage%20%26%20Stability%20of%20Processed%20Sample%20%26%20Reagents.doc) **Storage and Stability of Processed Samples, Controls**

 **and Reagents**1. Procedure A: Storage and Stability of Specimens
2. Procedure B: Reagent Storage General Information
* Table 1: GAS ASR reagent storage
* Table 2: Molecular Grade Water storage
* Table 3: TE buffer storage
* Table 4: Process Control
* [GAS 004](GAS%20004%20Reagent%20and%20Control%20Preparation.doc) **GAS Reagent and Process Control Preparation**
1. Procedure A: Process Control in Matrix Suspension
2. Procedure B: Process Control Swabs
3. Procedure C: Preparing TE Buffer and NFW
4. Procedure D: MasterMix prep/tables
5. Procedure E: 5% Extran and 70% alcohol
	* [GAS 005](GAS%20005%20Simplexa%20Group%20A%20Strep%20Assay.docx) ***Simplexa* Group A Strep Assay**
6. Procedure A: Numbering and labeling
7. Procedure B: Computer set-up
8. Procedure C: Master Mix preparation
9. Procedure D: PCR set-up and amplification
10. Procedure E: PCR Analysis and Printing Results
11. Procedure F: Evaluating and Interpreting QC Results
12. Procedure G: Evaluating and interpreting patient results
13. Procedure H: Repeat testing
14. Procedure I: Sample buffer storage
15. Method Performance
16. Proficiency Testing
17. Alternate Method
18. Limitations
	* [GAS 006](GAS%20006%20Troubleshooting%20guide.docx) ***Simplexa* Troubleshooting Guide**
19. Procedure A: General Information
20. Procedure B: Exporting a Service Packet to a USB
21. Procedure C: Barcode scanner

Post-Analytic Procedures* [GAS 007](GAS%20007%20%20Reporting%20and%20Archiving%20Results.docx) **Reporting and Archiving Results**
1. Appendix [GAS 007.A1](GAS%20007.A1%20Group%20A%20Strep%20%20Reporting%20Examples.docx): Report Examples

Non-Patient Technical Procedures* + [GAS 008](GAS%20008%20Equipment%20and%20Room%20Decontamination.docx) **Equipment and Room Decontamination**
	+ [GAS 009](GAS%20009%20New%20lot%2C%20new%20shipment%20QC.docx) **New Lot and/or Shipment Reagent QC**
1. Procedure A: New reagent lot or shipment verification
2. Procedure B: Performance failures
 | * + [GASTC 001](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CMB%20Training%20and%20Competency%5CGASTC%20001%20Simplexa%20Group%20A%20Strep%20Observed%20Competency.docx)

 GAS Observed Competency* [GASTC 002](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CMB%20Training%20and%20Competency%5CGASTC%20002%20Simplexa%20Group%20A%20Strep%20Assay%20Training%20Guide.docx)

GAS Training Guide |