# 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:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\QC%20forms\Simplexa\MB005.2.F1%20GAS%20New%20reagent%20QC%20worksheet.docx)   GAS Reagent QC Worksheet   * [MB005.2.F2](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\QC%20forms\Simplexa\MB005.2.F2%20GAS%20POSC%20New%20Reagent%20QC%20Worksheet.docx)   GAS POSC QC Worksheet   * [MB005.2.F8](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\QC%20forms\Simplexa\MB005.2.F8%20GAS%20PCTL%20New%20Reagent%20QC%20Worksheet.docx)   GAS PCTL QC  Worksheet  **New lot/shipment Inventory Forms**   * [MB005.2.F3](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\QC%20forms\Simplexa\MB005.2.F3%20GAS%20Primer%20Lot%20Inventory.docx)   GAS Primer New lot Inventory   * [MB005.2.F4](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\QC%20forms\Simplexa\MB005.2.F4%20GAS%20SEAC%20Lot%20Inventory.docx)   SEAC New lot inventory   * [MB005.2.F5](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\QC%20forms\Simplexa\MB005.2.F5%20GAS%20TA%20MasterMix%20Lot%20Inventory.docx)   TA MM New lot inventory   * [MB005.2.F6](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\QC%20forms\Simplexa\MB005.2.F6%20GAS%20POSC%20Lot%20Inventory.docx)   GAS POSC New lot inventory   * [MB005.2.F7](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\QC%20forms\Simplexa\MB005.2.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&%20Stability%20of%20Processed%20Sample%20&%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,%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:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\MB%20Training%20and%20Competency\GASTC%20001%20Simplexa%20Group%20A%20Strep%20Observed%20Competency.docx)   GAS Observed Competency   * [GASTC 002](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\MB%20Training%20and%20Competency\GASTC%20002%20Simplexa%20Group%20A%20Strep%20Assay%20Training%20Guide.docx)   GAS Training Guide |