# Molecular Diagnostics Technical Operations Manual

MB005.8 – *Simplexa*™ *Bordetella pertussis/parapertussis* PCR

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|  | Bordetella PCR Process |  |
| Forms | Procedures and Supporting Documents | Training and Competency |
| **QC Worksheets**   * [MB005.8.F1](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\QC%20forms\Simplexa\Simplexa%20Bordetella\MB005.8.F1%20BOR%20New%20reagent%20QC%20worksheet.docx)   BOR Reagent QC Worksheet   * [MB005.8.F2](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\QC%20forms\Simplexa\Simplexa%20Bordetella\MB005.8.F2%20Bp%20and%20Bpp%20POSC%20New%20Reagent%20QC%20Worksheet.docx)   BOR POSC QC Worksheet   * [MB005.8.F3](../Molecular%20Resources/QC%20forms/Simplexa/Simplexa%20Bordetella/MB005.8.F3%20BOR%20PCTL%20New%20Reagent%20QC%20Worksheet.docx)   BOR PCTL QC  Worksheet  **New lot/shipment Inventory Forms**   * [MB005.8.F4](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\QC%20forms\Simplexa\Simplexa%20Bordetella\MB005.8.F4%20Bp%20primer%20New%20lot%20inventory.docx)   Bp Primer New lot Inventory   * [MB005.8.F5](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\QC%20forms\Simplexa\Simplexa%20Bordetella\MB005.8.F5%20Bpp%20primer%20New%20lot%20inventory.docx)   Bpp Primer New lot inventory   * [MB005.8.F6](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\QC%20forms\Simplexa\Simplexa%20Bordetella\MB005.8.F6%20Bhol%20primer%20New%20lot%20inventory.docx)   Bhol Primer New lot inventory   * [MB005.8.F7](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\QC%20forms\Simplexa\Simplexa%20Bordetella\MB005.8.F7%20BOR%20POSC%20Lot%20Inventory.docx)   BOR POSC New  lot inventory   * [MB005.2.F4](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\QC%20forms\Simplexa\MB005.2.F4%20%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%20TA%20MasterMix%20Lot%20Inventory.docx)   TA MM New lot inventory   * [MB005.2.F7](../Molecular%20Resources/QC%20forms/Simplexa/MB005.2.F7%20TE%20buffer%20Lot%20Inventory.docx)   TE Buffer New lot inventory | Preanalytic Procedures   * [BOR 001](BOR%20001%20Sample%20Handling%20and%20Storage.docx)  **Sample Collection, Handling and Storage**  1. Procedure A: Receiving samples 2. Procedure B: Sample aliquots   Analytic Procedures   * [BOR 002](BOR%20002%20Simplexa%20Bordetella%20pertussis%20and%20parapertussis%20PCR%20overview.docx) ***Simplexa*** **Bordetella PCR Overview and Principle** * [BOR 003](BOR%20003%20Storage%20&%20Stability%20of%20Processed%20Sample%20&%20Reagents.docx) **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: BORDP ASR reagent storage * Table 2: Molecular Grade Water storage * Table 3: TE buffer storage * Table 4: Process Control * [BOR 004](BOR%20004%20Reagent%20and%20Control%20Preparation.docx) **Reagent and Process Control Preparation**  1. Procedure A: Process Control in Matrix Suspension 2. Procedure B: Preparing TE Buffer and NFW 3. Procedure C: MasterMix prep/tables 4. Procedure D: 5% Extran and 70% alcohol    * [BOR 005](BOR%20005%20Simplexa%20Bordetella%20pertussis,%20parapertussis%20Assay.docx) ***Simplexa* *Bordetella* PCR Assay** 5. Procedure A: Testing Preparation 6. Procedure B: Computer set-up 7. Procedure C: Master Mix preparation 8. Procedure D: PCR set-up and amplification 9. Procedure E: Analyzing Completed Runs 10. Procedure F: Exporting Data to LIS 11. Procedure G: Evaluating and interpreting QC results 12. Procedure H: Evaluating and interpreting patient results 13. Procedure I: Repeat testing 14. Procedure J: Computer Shutdown 15. Procedure K: Archiving test specimens 16. Method Performance 17. Proficiency Testing 18. Alternate Method 19. Limitations     * [BOR 006](BOR%20006%20Troubleshooting%20guide.docx) ***Simplexa* Troubleshooting Guide** 20. Procedure A: Assay/Instrument Failure Protocol 21. Procedure B: General Information 22. Procedure C: Exporting a Service Packet to a USB 23. Procedure D: Barcode scanner   Post-Analytic Procedures   * BOR 007 **Reporting and Archiving Results**  1. Appendix BOR 007.A1: Report Examples   Non-Patient Technical Procedures   * + [BOR 008](BOR%20008%20Equipment%20and%20Room%20Decontamination.docx) **Equipment and Room Decontamination**   + [BOR 009](BOR%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 | * + [BORTC 001](file:///G:\LAB\Molecular%20Biology\A.%20Molecular%20Procedure%20Manual\Molecular%20Resources\MB%20Training%20and%20Competency\BORTC%20001%20Simplexa%20Bordetella%20Observed%20Competency.docx)   BOR Observed Competency   * [BORTC 002](../Molecular%20Resources/MB%20Training%20and%20Competency/BORTC%20002%20Simplexa%20Bordetella%20Assay%20Training%20Guide.docx)   BOR Training Guide |