# Molecular Diagnostics Technical Operations Manual

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

|  |  |  |
| --- | --- | --- |
|  | Bordetella PCR Process |  |
| Forms | Procedures and Supporting Documents | Training and Competency |
| **QC Worksheets*** [MB005.8.F1](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CQC%20forms%5CSimplexa%5CSimplexa%20Bordetella%5CMB005.8.F1%20BOR%20New%20reagent%20QC%20worksheet.docx)

BOR Reagent QC Worksheet* [MB005.8.F2](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CQC%20forms%5CSimplexa%5CSimplexa%20Bordetella%5CMB005.8.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 QCWorksheet**New lot/shipment Inventory Forms*** [MB005.8.F4](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CQC%20forms%5CSimplexa%5CSimplexa%20Bordetella%5CMB005.8.F4%20Bp%20primer%20New%20lot%20inventory.docx)

Bp Primer New lot Inventory * [MB005.8.F5](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CQC%20forms%5CSimplexa%5CSimplexa%20Bordetella%5CMB005.8.F5%20Bpp%20primer%20New%20lot%20inventory.docx)

Bpp Primer New lot inventory* [MB005.8.F6](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CQC%20forms%5CSimplexa%5CSimplexa%20Bordetella%5CMB005.8.F6%20Bhol%20primer%20New%20lot%20inventory.docx)

Bhol Primer New lot inventory* [MB005.8.F7](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CQC%20forms%5CSimplexa%5CSimplexa%20Bordetella%5CMB005.8.F7%20BOR%20POSC%20Lot%20Inventory.docx)

BOR POSC New lot inventory* [MB005.2.F4](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CQC%20forms%5CSimplexa%5CMB005.2.F4%20%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%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%26%20Stability%20of%20Processed%20Sample%20%26%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%2C%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%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
 | * + [BORTC 001](file:///G%3A%5CLAB%5CMolecular%20Biology%5CA.%20Molecular%20Procedure%20Manual%5CMolecular%20Resources%5CMB%20Training%20and%20Competency%5CBORTC%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 |