Standard Operating Procedure Completing the Laboratory Case Record Form	
Version: 1.1	Date: 08/07/2010

Author: ……..	Approved by: ……
Signature:	Signature:
Date:	Date:

Introduction and Purpose:

The Laboratory Case Record Form (LCRF) is a paper record of all the relevant laboratory data to the trial including how and where they are stored, what analyses are performed on the sample and the results of these analyses. It forms vital part of the clinical study data collection and therefore must follow a set protocol. This standard operating procedure (SOP) describes the procedure for completion of the Laboratory CRF from receipt of the samples into the laboratory.

Who?

This SOP applies to those members of the laboratory research team involved in sample analysis and storage in the laboratory.
These include the following

- Senior Scientist
- Other laboratory workers involved in this study

When?

A new LCRF is opened for every patient from whom samples are received in the laboratory and updated as samples are stored and/or analysed.

Procedure:

1. A new Laboratory Case Record Form (LCRF) is opened by the Senior Scientist (or other designated person) as soon as practically possible after receipt of the samples into the laboratory.

2. The unique Sample ID number present on the patient samples is written on the front page and copied throughout the LCRF

3. The **Sample History (Page 2)** is completed with a record:

Section A

a. The date and time the samples were taken
b. The date and time the samples were received
c. The type and number of aliquots received
d. The date and time of further sample processing

Section B

e. Complete an initial screen to ensure that whole blood samples are within the CE-mark time-frame for SeptiFast (ie commence processing no later than 72h after collection). All whole blood samples and any prepared plasma samples that are outside this time limit cannot be used for SeptiFast, storage or further analyses and should be rejected and disposed of. Should samples be rejected for any other reason, this should be noted here.

Section C

f. Details of the subsequent processing and/or storage of all samples retained following the initial screening process are entered

4. Update the relevant sections of **Sample Storage Log** (Page3) when EDTA Blood, Plasma or Pathogen DNA Extracts are stored. Please note that when storing samples the relevant aliquot number (ie #B1, #P1, #D1) is clearly shown on the tube label. Also note, the date of storage, the volume of each aliquot stored. When aliquots are removed, the date of removal and the intended use of the removed aliquot must be noted.

5. The LSRF will hold a summary of the laboratory analyses performed on the samples from Cach patient. Complete the **Laboratory Results – SeptiFast Sheet (Page 4)** after each SeptiFast run. A copy of the SeptiFast report provided at the end of the assay is appended to the LCRF. Record the lot# and expiry date of the kit used.

6. Report any adverse events which required re-analysis of SeptiFast in the text box – also indicate whether problems have been addressed and by whom.