RFP-NIH-NIAID-DMID-07-13
Amendment # 3
"Clinical Laboratory Diagnostics for Invasive Aspergillosis"

Amendment Issue Date:	6/6/2006
Proposal Due Date/Time: (UNCHANGED)	7/14/2006 at 3:30 P.M., EST
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Offerors must acknowledge receipt of this Amendment 3 (Questions and Answers, 1st Posting), on each copy of the proposal submitted. Failure to receive your acknowledgment of this Amendment may result in the rejection of your proposal.

The hour and date specified for receipt of proposals HAS NOT been extended.

THE FOLLOWING PAGES PROVIDE ANSWERS CONCERNING INQUIRIES WE RECEIVED FOR THE ABOVE-NUMBERED SOLICITATION:

Question 1 - Can you clarify how to budget for supplies, reagents, salaries, and equipment for performance of the experimental IA tests when we do not know what tests we will be asked to perform and how many of different types of tests we will be asked to do over the course of the seven years?

***Respond to Question** 1* - Please use the uniform cost assumption in preparing your budget.

APPENDIX B is modified to add the following assumption:

Assume one Replication Study, one Comparison Study and one Evaluation of Potentially Interfering Medical Conditions study per quarter. Assume twelve quarters will involve Replication, Comparison, and Evaluation of Potential Interfering Medical Conditions studies using standard diagnostic

technologies (i.e. PCR and antigen based methods). Assume twelve quarters will involve Replication, Comparison and on Evaluation of Potential Interfering Medical Conditions studies using emerging diagnostic technologies (i.e. microarrays, proteomics technologies to detect surrogate biomarkers).

Question 2 - Is it acceptable to budget technician time into a cost estimate for performance of an experimental test to be studied that would not count against the number of FTEs provided in the RFP?

***Respond to Question** 2 -* The FTEs listed in the RFP are just a guide. They are not a requirement. In addition, we hope the uniform cost assumption provided in this response will help with this budgeting issue. In your proposal you need to include both the time and cost for all personnel proposed.

Question 3 - Can you provide some estimate of what work load you anticipate? For example, should we budget for one antigen test for each year and 2 pcr assays per year?

Respond to Question 3 - Please see the uniform cost assumption provided in response to question one.

Question 4 - For each test should we plan for all 3 types of testing (replication, comparison, evaluation) in our budget? For example, we could budget for 2 pcr replication tests, 2 pcr comparison tests, 2 pcr evaluation assays each year.

Respond to Question 4 - Please see the uniform cost assumption provided in response to question one.

Question 5. Please clarify whether performance of the experimental tests in clinical laboratories that are CLIA and CAP certified to perform similar tests (antigen tests and pcr assays) will meet your expectation of GLP. If not, please clarify what different expectations you are looking for.

Respond to Question 5 - The offeror should refer to the Good Laboratory Practices (GLP) guidelines published in Title 21 Code of Federal Regulations.

Question 6. Will we be asked to participate in assay development, such as incorporating a new antibody into an ELISA format, or only to evaluate tests or kits that are close to being available for commercial availability?

***Respond to Question** 6 -* The contract is to evaluate diagnostic tests and does not involve any assay development.