SUBJECT **REVIEW OF CANDIDATE TEST FROM THIRD PARTIES**

PURPOSE To provide guidelines for the review of experimental IA diagnostic tests from third parties for replication and comparison studies based on evaluation of technical, scientific, feasibility and clinical merit.

LEVEL:
Principal Investigator/designee
Third Party Test Review Committee
Co- Principal Investigator
Sub-Contractor Personnel
Assay Testing Laboratory staff
Biological Specimen Repository Staff
NIAID Project Officer

SUPPLIES/EQUIPMENT
Policy and Procedure Manual
Computer
Word Processing Program
Printer

REQUIREMENTS

1. Review Synopsis

   A. The contractor will convene a Review Committee to evaluate the technical, scientific, and clinical merit and feasibility of each proposed experimental test.

      1. The committee will consist of Drs. Wingard, Alexander, Baden, Caliendo, Wheat, and Denning, plus the Project Officer. Additional committee members may be invited at the discretion of the Principal Investigator and/or Project Officer.

   B. The criteria the Committee will use to judge the test will be scientific merit, practicality, and performance characteristics of the assay.

   C. This evaluation will include a comparison of the claims of the third-party with the known characteristics of the predicate device.

2. The evaluation will include a comparison of the claims of the third party with known characteristics of the predicate device.

   A. For molecular assays the following issues will be particularly addressed:

      1. Recovery yield using recommended fungal DNA extraction method.

2. Potential fungal (*Aspergillus*) DNA contamination of samples, reagents and tubes provided by the manufacturer

3. Sensitivity and time requirement of the detection system

4. Exclusion of false negative results in the presence of inhibitors

B. For replication studies, the third party should demonstrate at least sufficient evidence that:

1. The test will detect an *Aspergillus* determinant before consideration by the consortium.

2. The test manufacturer will be expected to provide sufficient information for the consortium to judge feasibility.

3. The contractor will request specimens from the NIAID IAAM animal models contractor or if desirable use banked specimens from existing inventory.

C.. For comparison studies, the test must have been first evaluated by the contractor in a replication study and must have performed satisfactorily in the replication studies before proceeding; as judged by the Review Committee.

1. The experimental test will be compared with the galactomannan assay (at least in initial studies) and the EORTC/MSG diagnostic algorithm.

D.. For evaluation studies of potentially interfering medical conditions, the test must have been tested in replication and comparison studies by the contractor and found to demonstrate improved performance characteristics over the FDA-approved comparator as judged by the Review Committee.

1. The Contractor will suggest the interfering medical conditions to be tested. The list of medical conditions to be tested will be reviewed and possibly added to by the Review Committee.

3. Third Party Review Documentation

A. Time from completed application receipt to review will be no longer than 4 weeks.

B. Formal review reports will be prepared, approved by the Project Officer and forwarded to the Third Party applicant.

C. Applications for review must be complete with all required documentation prior to presentation to the AsTeC Review Committee.

D. Merits and deficiencies of third party applicants will be contained within the final review report.

E. All communications with Third Party applicants will be documented and maintained.

F. Prioritization and approval of candidate tests will be performed according to SOPPM-AT 003.02 (08 07).

ACCEPTABLE ENDPOINTS: N/A

QUALITY CONTROL: N/A

REFERENCES:

ORIGINAL IMPLEMENTATION DATE: _____

APPROVED BY NIH NIAID Project Officer: _____ DATE _____

APPROVED BY PI/designee: _____ DATE _____

APPROVED BY Laboratory Coordinator: _____ DATE _____