

Clinical Laboratory Diagnostics for Invasive Aspergillosis  
Contract No. HHSN266200700023C  
Standard Operating Procedures

<b>SUBJECT</b>	<b>SUBMISSION PROCESS FOR THIRD PARTY TEST REQUESTS</b>
<b>PURPOSE</b>	To provide guidelines for the solicitation and approval of experimental IA diagnostic tests from third parties for replication and comparison studies, and where appropriate, evaluate the effects of potentially interfering medical conditions.
<b>LEVEL:</b>	Principal Investigator/designee Co- Principal Investigator Sub-Contractor Personnel Assay Testing Laboratory staff Biological Specimen Repository Staff NIAID Project Officer
<b>SUPPLIES/EQUIPMENT</b>	Policy and Procedure Manual Computer Word Processing Program Printer

## REQUIREMENTS

1. Methods of Solicitation of Third Party Applications
  - A. AsTeC Website –Contained within the AsTeC website are specific information detailing the purpose and process for the application process by Third Parties.
  - B. Internet Postings – When available and after approval by the Project Officer, public solicitation of third party applications will be posted in web-based society Newsletters.
  - C. Meeting Postings – When available and after approval by the Project Officer, notices of solicitation of third party applications will be posted at meetings related to Aspergillosis.
2. Application overview
  - A. For each candidate test, the contractor will enter into a written legal agreement with the third party that clarifies rights for all data generated;
  - B. The contractor will develop a GLP-compliant SOP for performing the test and performance of various replication, comparison, and evaluation studies of potentially interfering condition.

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- C. The contractor will perform such studies in accordance with FDA requirements after consultation with the FDA to ascertain current requirements.
  - D. Study reports will be generated for each experimental assay tested in accordance with the specifications of the SOW.
3. Application process
- A. A third party (test manufacturer) will complete the consortium's application form that will specify:
    - 1. The test name, details of the assay
    - 2. Type of test and test technology
    - 3. Test target
    - 4. Type of clinical sample to be assayed
    - 5. Type of equipment required, technical and performance limitations
    - 6. The results of prior testing
    - 7. Any other data documenting preliminary performance characteristics of the assay including but not limited to technological characteristics of reagents, instrumentation properties, specification of reagents, indications at what procedural step the testing material is non-infectious, what information is known about specimen collection, transporting, and processing methods and target stability in specimen preparations, specific performance parameters of importance to the operation and successful use of the device, information as to ability to detect genotypic and phenotypic organism variants in matrices, and whether potential interferences have been identified
    - 8. All references
  - B. In accordance with the stipulations of the SOW, only replication tests will be permitted from a third party unless and until replication testing has been conducted by the contractor.
4. Third Party Application Communication and Documentation
- A. Time and date of arrival of all applications will be documented.
  - B. Files for each application will be maintained indefinitely, or unless otherwise directed by the PI, Co-PI, or Project Officer.
  - C. All communications with Third Party applicants will be documented and maintained.

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- E. Review of candidate tests will be performed according to SOPPM-AT 002.02  
(08 07) Review of Candidate Test from Third Parties.

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 \_\_\_\_\_