

Clinical Laboratory Diagnostics for Invasive Aspergillosis (AsTeC)
Full Manufacturer Application for Assay Evaluation

Section I: Manufacturer Information	
Manufacturer:	
Contact name:	
Manufacturer's address:	

Section II: Device/Assay Information	
Name:	
Is this a qualitative or a quantitative assay?	<input type="checkbox"/> Quantitative <input type="checkbox"/> Qualitative <input type="checkbox"/> Semi-quantitative
Format:	<input type="checkbox"/> Enzyme Immunoassay or ELISA <input type="checkbox"/> Sandwich Enzyme Immunoassay or Sandwich ELISA <input type="checkbox"/> Lateral flow device <input type="checkbox"/> Conventional PCR <input type="checkbox"/> Real-time PCR <input type="checkbox"/> TMA/NASBA <input type="checkbox"/> Mass Spectrometry <input type="checkbox"/> Microarray <input type="checkbox"/> Other
If Other, specify:	
Analyte type to be tested by AsTeC:	<input type="checkbox"/> Antibody <input type="checkbox"/> Nucleic Acid <input type="checkbox"/> Antigen <input type="checkbox"/> Protein <input type="checkbox"/> Metabolite <input type="checkbox"/> Other
If Other, specify:	
Analyte detected:	<input type="checkbox"/> <i>Aspergillus</i> Galactomannan <input type="checkbox"/> Glucan <input type="checkbox"/> <i>Aspergillus</i> RNA <input type="checkbox"/> <i>Aspergillus</i> DNA <input type="checkbox"/> Host DNA <input type="checkbox"/> Host RNA <input type="checkbox"/> Antibody reactive to <i>Aspergillus</i> antigens <input type="checkbox"/> Protein <input type="checkbox"/> Metabolite <input type="checkbox"/> Other
If Other, specify:	
Describe specific target:	
Matrix or specimen type(s) to be tested by AsTeC:	<input type="checkbox"/> Urine <input type="checkbox"/> CSF <input type="checkbox"/> Serum <input type="checkbox"/> BAL Fluid <input type="checkbox"/> Plasma <input type="checkbox"/> Not specified <input type="checkbox"/> Whole Blood <input type="checkbox"/> Other
If Other, specify:	

Clinical Laboratory Diagnostics for Invasive Aspergillosis (AsTeC)
Full Manufacturer Application for Assay Evaluation

If multiple matrix/specimen types are applicable, please submit additional forms providing the performance characteristics for all specimen types.

Can this assay accommodate frozen specimens? No Yes

If no, contact AsTeC prior to submission of this application.

Read-out:	<input type="checkbox"/> GM Index <input type="checkbox"/> mg/mL <input type="checkbox"/> µg/mL <input type="checkbox"/> ng/mL <input type="checkbox"/> pg/mL <input type="checkbox"/> IU/mL	<input type="checkbox"/> Titer <input type="checkbox"/> Optical Density <input type="checkbox"/> Ct Value <input type="checkbox"/> Copies/mL <input type="checkbox"/> Other
-----------	---	---

If Other, specify:

Cost per specimen:	\$ _____ . _____	<input type="checkbox"/> Not Specified <input type="checkbox"/> Not Applicable
--------------------	------------------	---

Cost per kit:	\$ _____ . _____	<input type="checkbox"/> Not Specified <input type="checkbox"/> Not Applicable
---------------	------------------	---

Number of specimens tested per kit:	<input type="checkbox"/> Not Specified <input type="checkbox"/> Not Applicable
-------------------------------------	---

Other cost details:

Intended Population: BMT, Cancer, SOT, ICU, Neutropenic, Other immunosuppressed, other (specify).

Section III: Purpose of Application to AsTeC

Has this device/assay ever received FDA approval/clearance for any indication? No Yes

If yes, describe the indication, including the matrix and population for which the test is approved

--

Has the FDA provided any guidance for evaluation of this device? No Yes

If Yes, submit a summary of FDA communication (see Section VI).

Proposed AsTeC assessment:	<input type="checkbox"/> Pre-approval device/assay development <input type="checkbox"/> Support for Premarket Approval (PMA) application <input type="checkbox"/> Support for 510(k) application <input type="checkbox"/> Other
----------------------------	--

If Other, specify:

Proposed AsTeC evaluation type:	<input type="checkbox"/> Reproducibility (Replication) <input type="checkbox"/> Comparative <input type="checkbox"/> Interfering Medical Condition	<input type="checkbox"/> All <input type="checkbox"/> Other
---------------------------------	--	--

If Other, specify:

If Reproducibility, anticipated source of samples:	<input type="checkbox"/> IAAM <input type="checkbox"/> Other third party animal samples <input type="checkbox"/> Third party human sample repository	<input type="checkbox"/> Spiked matrix <input type="checkbox"/> Other
--	--	--

Clinical Laboratory Diagnostics for Invasive Aspergillosis (AsTeC)
Full Manufacturer Application for Assay Evaluation

Describe source of samples:
Describe source of analyte for spiked matrix:

Section IV: Device/Assay Conduct		
Device/Assay		
Device/Kit storage time (unopened):		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Device/Kit storage time (opened):		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Device/Kit storage temperature (unopened):		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Device/Kit storage temperature (opened):		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Batch size (i.e., maximum number of specimens processed and analyzed with a single device):		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Describe any non-standard staff training requirement:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Estimated time required for specimen processing, including extraction steps:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Estimated time required for specimen testing:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Equipment to be provided by manufacturer:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Computer system requirements (hardware and software):		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified

Clinical Laboratory Diagnostics for Invasive Aspergillosis (AsTeC)
Full Manufacturer Application for Assay Evaluation

Equipment to be provided by AsTeC laboratory:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Linear feet of bench space required:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Other device/assay information:		
		<input type="checkbox"/> Not Applicable
		<input type="checkbox"/> Not Specified

Assay Reagents		
Reagent storage time (unopened):		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Reagent storage time (opened):		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Reagent storage temperature (unopened):		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Reagent storage temperature (opened):		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Calibrators used to quantify analyte:	<input type="checkbox"/> Whole organism <input type="checkbox"/> Purified nucleic acid <input type="checkbox"/> Galactomannan <input type="checkbox"/> Other	<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
If Other, specify:		
Describe specific target:		
Other reagent information:		
		<input type="checkbox"/> Not Applicable
		<input type="checkbox"/> Not Specified

Specimens or Samples		
Preferred collection container:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Minimum specimen volume required for assay:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Specimen storage time:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Specimen storage temperature:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified

Clinical Laboratory Diagnostics for Invasive Aspergillosis (AsTeC)
Full Manufacturer Application for Assay Evaluation

Post-extraction specimen storage time:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Post-extraction specimen storage temperature:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Briefly describe any specimen preparation instructions required before testing:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Other specimen information:		
		<input type="checkbox"/> Not Applicable
		<input type="checkbox"/> Not Specified

Section V: Device/Assay Performance Characteristics		
General Characteristics		
Definition of a positive result:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
50% cut-off point:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Limit of Detection:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Limit of the Blank:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Limit of quantification:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Upper linearity limit:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Lower linearity limit:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Negative internal control specifications:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Positive internal control specifications:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Recommended method to validate repeatability of results:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Repeatability variance (standard deviation):		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Assay acceptability criteria:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified

Clinical Laboratory Diagnostics for Invasive Aspergillosis (AsTeC)
Full Manufacturer Application for Assay Evaluation

Sensitivity and Specificity		
Sensitivity for a single positive:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Sensitivity for a reproducible positive:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Agreement with comparator results for positive specimens:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Specificity for a single negative:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Specificity for a reproducible negative:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Agreement with comparator results for negative specimens:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Positive predictive value		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Negative predictive value		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Precision		
Intra-assay precision:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Inter-assay precision:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Other Performance Characteristics		
Interfering specimen conditions:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Interfering medications:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Interfering medical conditions:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Limitations of the assay:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Analytical specificity:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Analytical sensitivity:		<input type="checkbox"/> Not Applicable <input type="checkbox"/> Not Specified
Other performance characteristics:		
		<input type="checkbox"/> Not Applicable
		<input type="checkbox"/> Not Specified

