

Manufacturer Application for Assay Evaluation

L. Joseph Wheat
MiraVista Diagnostics
MiraBella Technologies

IAAM



INVASIVE ASPERGILLOSIS ANIMAL MODELS

ASTEC

ASPERGILLUS TECHNOLOGY CONSORTIUM



Application Process

- Manufacturer contacts AsTeC about interest in evaluation of a device
- Manufacturer and AsTeC implement CDA
 - Address potential conflicts of interest
- Manufacturer completes application
- Manufacturer prepares MTA



Sections of Manufacturer Application

- **Section I: Manufacturer**
- **Section II: Device/Assay Information**
- **Section III: Purpose of Application**
- **Section IV: Device/Assay Conduct**
- **Section V: Device/Assay Performance Characteristics**
- **Section VI: Device/Assay Supplementary Material**

IAAM



INVASIVE ASPERGILLOSIS ANIMAL MODELS

ASTEC

ASPERGILLUS TECHNOLOGY CONSORTIUM

Section II: Device/Assay Information

Name:	
Is this a qualitative or a quantitative assay?	Quantitative Qualitative
Format:	Enzyme Immunoassay or ELISA Real-time PCR
Analyte type to be tested:	Antibody Nucleic Acid
Analyte detected:	<i>Aspergillus</i> Galactomannan <i>Aspergillus</i> RNA
Matrix or specimen type:	Urine Serum