Manufacturer Application for Assay Evaluation

L. Joseph Wheat
MiraVista Diagnostics
MiraBella Technologies
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
## Section II: Device/Assay Information

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