Comparison of AssayAssure® Molecular with Standard Culture Media

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|  | Amies Transport Media | Stuarts Transport Media | AssayAssure® Molecular |
| Bacterial Viability at ambient temperature +25°C | 24-48 hours | 24-48 hours | 144 hours\* |
| Stabilized bacterial population – no growth after collection | No | No | Yes |
| Down-regulation of bacterial growth factors | No | No | Yes |
| Protection of DNA and RNA from enzymatic products of lysed cells | No | No | Yes |
| Buffering system | No | No | Yes |
| Cryoprotectant  | No | No | Yes |
| Biological penetrantant | No | No | Yes |
| Stabilization of unculturable bacteria | No | No | Yes |
| PCR/qPCR-ready samples – compatible with all molecular platforms | No | No | Yes |
| Validated for multiplex assays | No | No | Yes |
| Environmental storage constraints | Store at 5º-25º C.Do not freeze or overheat. | Store at 5º-25º C.Do not freeze or overheat. | None |

\* Groups of Gram-negative and Gram-positive bacteria were tested for viability at innocula of 10² and 10³ CFU/ml every 24 hours through 144 hours. No difference in viability (colony counts) or biochemical expression was observed.

Notes:

**Limitations of Amies and Stuarts Transport Media**

1. Specimens taken from transport media will not exhibit the optimal or comparative growth as expected from direct inoculation and cultivation. These media do, however, provide an adequate degree of preservation for those specimens which cannot be forwarded immediately to the laboratory for prompt evaluation.

2. Viability of cells will diminish over time and some degree of multiplication or growth of contaminants can occur during prolonged periods of transit. This is particularly true of fecal specimens that contain substantial numbers of coliform organisms.

3. The condition of the specimen received by the laboratory for culture is a significant variable in recovery and final identification of the suspect pathogen. An unsatisfactory specimen (overgrown by contaminants, containing nonvi- able organisms, or having the number of pathogens greatly diminished) can lead to erroneous or inconclusive results.

4. For transport of specimens that may contain N. gonorrhoeae, the use of a selective medium, such as JEMBECTM or Gono- Pak systems, should also be considered.

<http://www.bd.com/ds/technicalCenter/inserts/Transport_Media.pdf>

**Regulatory Approval**

Devices intended as microbiological specimen collection and transport systems for clinical diagnostics are FDA Class I Medical Devices under [21CFR866.2900](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=866.2900) (product classification code: [LIO](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=2998)) and require 510(k) pre-market approval.

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/detail.cfm?standard__identification_no=25268>