Validation of Copan eNAT, a molecular transport medium, for the collection and preservation of urine specimens for the detection of STI infections with the Seegene Anyplex II STI-7 v1.1 Assay.

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Backgrounds

Urine is used for screening sexual transmitted infections with molecular assays. Copan developed the eNAT, a molecular medium that preserves and stabilizes nucleic acids. eNAT medium can be used to collect, transport and store clinical specimens for the detection of infectious pathogens by molecular amplification assays. Seegene recommends the use of dry container for urine collection for the detection of urogenital pathogens with the Anyplex II STI-7 v1.1 assay(STI7).

Results

STI7 Results

<table>
<thead>
<tr>
<th>STI7 Results</th>
<th>3ml Urine dry Containers</th>
<th>1ml eNAT+ 1ml Urine</th>
<th>1ml eNAT+ 2ml Urine</th>
<th>1ml eNAT+ 3ml Urine</th>
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</thead>
<tbody>
<tr>
<td>NEG</td>
<td>43</td>
<td>45</td>
<td>40</td>
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<tr>
<td>POS</td>
<td>37</td>
<td>35</td>
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Objectives

The objective of this study was to validate the eNAT medium for nucleic acid preservation in urines for STDs detection with the STI7 assays.

Materials and Methods

In this study, 102 urines, collected in dry containers from patients attending a Milan STD clinic were tested as per current method and after adding urine to 1ml of eNAT molecular medium.

The first 80 urine samples were used to find the volume of urine to add to 1ml of eNAT medium, that would give the same sensitivity as urine in dry containers.

To individual 1ml eNAT medium tubes were added 1, 2, and 3ml of urine and 3ml of urine were added to a dry container.

While additional 22 samples were tested in duplicate, 3ml of urine in dry containers and 3ml of urine were added to a 1ml tube of eNAT.

All urine samples, in dry containers and in eNAT, were first vortexed and 350ul of each sample were used to extract nucleic acids using the Automated Purification Systems (NIMBUS IVD) and eluted in 100ul of elution buffer.

Purified nucleic acids were tested with the Seegene STI7 assay. (Seegene, distributed by Arrow Diagnostics, Genoa Italy)

Conclusions

Good agreement was found between Copan eNAT 3ml urine and urine in dry containers for the detection of seven sexually transmitted pathogens with the Seegene STI7 assay.

Copan eNAT medium is suitable for the collection, transport and storage of urine specimens for the detection of STI with molecular assays.

Copan eNAT medium, is available in leak proof tube, is easy to transport and store urines, prevents bacterial overgrowth, stabilizes nucleic acids at room temperature and is compatible with the STI7 assay.

Three ml of urine in a 1ml tube of eNAT is the optimal urine combination for testing for the detection of STI.