Xpert® Bladder Cancer Detection

A non-invasive urine test that delivers accurate and actionable results

In Vitro Diagnostic Medical Device

Not available in all countries. Not available in the United States.
Most patients with blood in their urine do not have cancer. We recently demonstrated that using molecular diagnostic urine tests can greatly help us identify those patients who need the most thorough investigation. Based upon the promising performance of the Xpert® Bladder Cancer Detection we are currently investigating how we might use this assay in our haematuria patients.”

Prof. Dr. Bernd Jürgen Schmitz-Dräger, Schön Hospital Nuremberg Fürth, Urology Practice
The Impact

A test that helps clinicians gain additional information for patients with hematuria.

- Non-invasive test to reduce patients’ anxiety, pain, and embarrassment
- High negative predictive value may help patients avoid unnecessary procedures and discomfort
- Easy to implement and train
- Robust test and workflow that does not require a PCR laboratory

Performance

Delivers high sensitivity and NPV for low and high-grade bladder cancer.

Xpert® Bladder Cancer Detection vs. Cystoscopy/Histology

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<thead>
<tr>
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<th>Cystoscopy/Histology</th>
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<tbody>
<tr>
<td></td>
<td>Positive</td>
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<tr>
<td><strong>Xpert Bladder Cancer Detection</strong></td>
<td></td>
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<tr>
<td>Positive</td>
<td>50</td>
</tr>
<tr>
<td>Negative</td>
<td>16</td>
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<tr>
<td><strong>Total</strong></td>
<td>66</td>
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Sensitivity: 75.8% (95% CI: 64.2-84.5)  
Specificity: 84.6% (95% CI: 81.9-86.9)  
PPV: 28.1% (95% CI: 22.0-35.1)  
NPV: 97.8% (95% CI: 96.4-98.6)  
Accuracy: 83.9% (95% CI: 81.4-86.2)  
Prevalence: 7.4% (95% CI: 5.8-9.3)

Xpert Bladder Cancer Detection was evaluated at sites in the E.U. and North America. Subjects included individuals presenting with symptoms of bladder cancer. For study purposes, symptomatic patients were defined as those presenting with macroscopic (gross) or asymptomatic microhaematuria within 12 weeks of enrolment into the study. Results of Xpert Bladder Cancer Detection were compared to cystoscopy, with histology confirmation of positive and suspicious cystoscopies.
Transfer approx. 4.5 mL of voided urine into the urine transport reagent tube. Invert to mix well.

Place 4 mL of this mixture into the sample chamber of the cartridge.

Insert cartridge and start test.

Workflow
3 Simple Steps

Easy to perform test provides results in approximately 90 minutes.

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References: