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 Need

Early and accurate diagnosis of bladder cancer is critical in patients with hematuria. Four out of five people with bladder cancer have blood in their urine. But 80–90% of patients with visible hematuria, and over 95% of patients with non-visible hematuria do NOT have cancer. There are many known causes of hematuria including urinary tract infection, nephrolithiasis (stones), etc. In patients with hematuria, it can be difficult to decide which patients might have cancer and which patients might have a different condition. Primary care physicians are sometimes reluctant to refer patients with visible or significant microscopic hematuria to urology for further investigation. Over 20,000 bladder cancer cases are estimated to be missed annually in the U.S.

The Solution

Xpert Bladder Cancer Detection is a non-invasive biomarker test for patients with hematuria that is used in conjunction with other clinical measures. Five mRNA biomarkers were intensively validated for the detection of bladder cancer. The non-invasive and painless test uses voided urine samples. High NPV and sensitivity increase help to rule out high-grade tumors. The test is performed using a self-contained cartridge and system, and can be performed in any size urology lab. Each cartridge contains three controls for dependable results. Sample stability for up to 7 days in Xpert® Urine Transport Reagent. The test enables flexible testing as required.
The Impact

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

- Non-invasive test to reduce patients’ anxiety, pain, and embarrassment⁷
- High negative predictive value may help patients avoid unnecessary procedures and discomfort⁸
- 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/Histology⁹

<table>
<thead>
<tr>
<th></th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
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<tbody>
<tr>
<td>Xpert Bladder Cancer Detection</td>
<td>50</td>
<td>128</td>
<td>178</td>
</tr>
<tr>
<td></td>
<td>16</td>
<td>701</td>
<td>717</td>
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<tr>
<td>Total</td>
<td>66</td>
<td>829</td>
<td>895</td>
</tr>
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</table>

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.

1. Patient with haematuria  
2. Appointment with physician  
3. Further tests, e.g. ultrasound, cystoscopy etc.  
4. Treatment e.g. TURB &/or BCG/ similar  
5. Monitor for recurrence, in conjunction with other tests, according to local guidelines
Workflow

3 Simple Steps

Easy to perform test provides results in approximately 90 minutes.

1. Transfer approx. 4.5 mL of voided urine into the urine transport reagent tube. Invert to mix well.

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

3. Insert cartridge and start test.

References: