

# UroVysion™ – A New Step Forward For Early Detection of Bladder Cancer.

by John Corso MD ([www.johncorsomd.com](http://www.johncorsomd.com))

Bladder cancer, while not the scary scourge of lung, breast or colon cancer, is still a medium-sized killer, showing up in about 50,000 new people a year and killing about 11,000 of them.

The most we currently do in this country to detect it is to check urine samples once a year for blood that may or may not be visible to the naked eye. The experts with The United States Preventive Services Task Force (USPSTF) don't even recommend that much, since there is not yet evidence that doing so saves lives.

Microscopic levels of blood in the urine are pretty common and usually don't mean cancer of the bladder (or kidney). Small amounts of blood can come from other things like bladder or prostate infection, kidney stones, toxic medications, heavy exercise, menstruation, sexual activity, and the list goes on.

On top of that, urine screening can easily miss cancers that aren't bleeding on the day of our physical. I once gave a clean bill of bladder-health to a patient and colleague based on a normal urine test. Six months later he was urinating blood. He had an aggressive bladder cancer that had gone unrecognized by the standard urine test.

For the past few years I've tried to go a bit farther by offering cytology testing to my patients. This requires submitting that same urine sample to an expert, a pathologist, who can look for both bladder and kidney cancer cells in urine samples. We know we can discover both bladder and kidney cancer a bit earlier this way.

The catch is that while cancer cells in the urine clearly means there is a problem, the absence of cancer cells does not mean we're OK. A single annual cytology test can also miss about half of these tumors. There's been no downside to cytology screening (false-positive results are extremely rare) and the out-of-pocket cost was about 45 bucks.

Enter UroVysion™ – the latest of the high-tech probes now available to screen patients for bladder cancer. This test has been demonstrated to find bladder cancer earlier than any standard screening test. Whether this leads to fewer deaths, while quite likely, is still unproven.

But the beautiful thing is that it looks for four very specific genetic abnormalities which are almost always associated with bladder cancer and so carries a very high level of specificity. This means that, like cytology, it is very unlikely to suggest a cancer problem when there isn't one, making it superior to the common urinalysis testing for blood, which can come from so many other sources.

UROVYSION™  
Bladder Cancer Kit

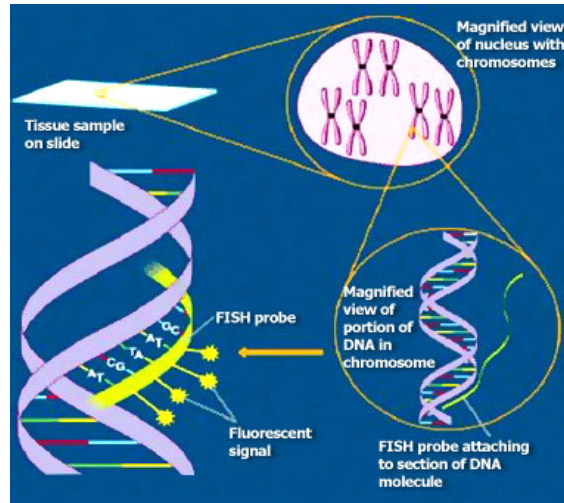


<http://www.urovysion.com>

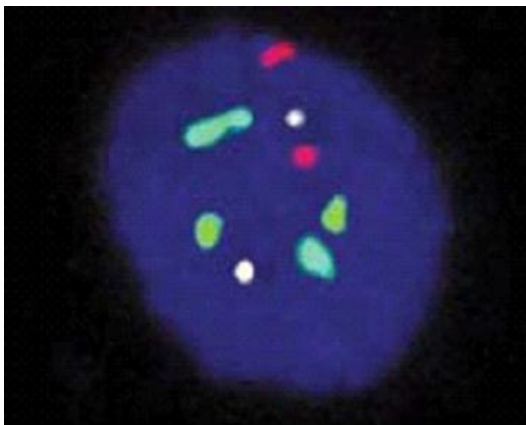
But unlike both cytology and urinalysis, this test is also very sensitive, which means that if a bladder cancer is present, it is very likely to be found. High levels of both sensitivity and specificity are what make a screening test worthwhile, but historically such tests have been rare.

How does it work? Bladder cells that have undergone transition to malignancy will have one or more of the four genetic changes affecting the number of these chromosomes. These abnormal cells are shed in the urine fairly constantly. Cells from the urine sample are affixed to a slide and then exposed to specific DNA probes that will stick selectively to these sites.

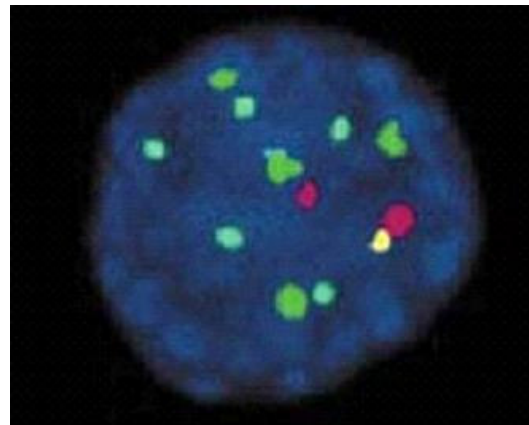
Each of the four molecular probe types is connected to a different colored fluorescent molecule. The result is that a positive discovery of a cancer cell will leave its DNA tagged with a marker that glows one of four colors when exposed to ultraviolet light and the identity of the mutation is determined by the color.



Who should take advantage of UroVysion™? The test has been around since 2002 and was only used to follow actual bladder cancer patients after treatment to see if the cancer was returning to rear its ugly head. More recently the FDA has approved its use as part of the workup for patients with blood in their urine.



**Normal Bladder Cell:** Exactly two of each chromosome. This is the number that should be present for each of out 22 non-sex chromosomes



**Bladder Cancer Cell:** two copies of chromosome 3 (red), four copies of chromosome 7 (green), five copies of chromosome 17 (aqua) and one copy of p16 gene (gold)

However, as we've already seen, if we wait for blood to show up in our annual pee-in-the-cup test it's quite possible to miss bladder cancer for months or years. By restricting the test in this manner we toss out the high sensitivity which makes UroVysion™ so attractive.

So I now plan to offer the test to all patients over forty years of age, especially if they are at high risk for other reasons such as a personal history of smoking. But it doesn't come cheap. There is a lot of expert labor and some expensive DNA-handling reagents that go into this test and the cost is between \$250 and \$800 dollars. (\$250 at my office at this writing)

Add to that the fact that 99% of the time the test will be negative for bladder cancer and it's easy to see why insurance companies will not (and should not) be paying for it on a widespread scale. Like so many cutting-edge screening tests for the less common cancer killers, the cost will need to come down with time before it's reasonable to expect them to do so.

So the choice is yours. If money is no object, then I don't see the downside to requesting this test. If you're just "OK" financially but place a high priority on taking advantage of a really good screening for cancer, even if you are very unlikely to find a problem, then directing your discretionary dollars to UroVysion™ makes as much sense as a few dinners out.

In fact, like many new technologies in the world, those with the means to purchase UroVysion™ will help drive down the cost for everyone else to use it in the future.