Shifting the Paradigm: A Blueprint for value recognition and process improvement in the U.S. drug testing market

Implementing the patented UR Code™ product and effective organizational change.
Marker Test Diagnostics, Inc. is a US based company that manufacturers and sells its patented UR Code™ product to the US Drug Testing and Doping markets. The company bases this executive report on in-depth studies conducted by Marker Test Diagnostics, Universities, and third party laboratories in the United States, Germany, and other European counties that have implemented the UR Code product and non-observed collection testing process. The opinions in this report are the opinions of the author. You may contact the author or send an email to info@markertest.com for more information.

By: Kim Christensen, MA, MT, CLS (NCA)
Chief Executive Officer
Market Test Diagnostics, Inc.
christensen@markertest.com
“There are two key components to implementing a paradigm change in the United States drug testing market;

1. Acceptance of the ingestion of an orally applied marker

and;

2. Moving away from the observed collection process.”

Kim Christensen, CEO

In 2010, drug testing was a two billion dollar a year industry showing significant five year growth projections in every market space where drug testing was being conducted on a day-by-day basis. In 2014, the drug testing market will grow into a four billion dollar a year industry with little chance for growth control. Key driving factors for this growth includes the increased use of prescription pain medication, illegal substance abuse grows, and spiraling organizational costs. The best-demonstrated practice today in drug testing is the “observed” urine collection process, where a gender-appropriate collector observes the donor urinating into a collection cup. This process is usually conducted through a glass window or reflective mirror and cannot guarantee that the donor is actually urinating or that the urine provided is biologically produced by the donor. The observed collection methodology is well-known for margins of error as donors can use commercially available devices; condoms filled with urine from friends, family members, “Pee for Profit” opportunities, or a variety of other cheating methods. The observed collection process cannot eliminate “false negative” urine that is being commercially manufactured as a substitute, or non-donor biological urine placed in the donor’s bladder through a self-catheterization process prior to arriving at the collection site.
The problem is growing! How do we impact and improve this process and change the paradigm that is not working well today?

In the late 1990s, European drug treatment institutions asked laboratories for help with one of the biggest issues in urine drug testing: sample integrity. Even under observation, manipulation was still taking place and posed a risk to the treatment outcome and the patients’ well-being. Ruprecht Keller, MD, PhD, Director of the Central Laboratory for all municipal hospitals in Cologne, Germany, developed the idea to use a “marker” substance that internally “bar codes” urine. The list of requirements for creating such a substance was long: For patient safety it had to be an inactive ingredient cleared for use in humans and without side effects. To function as a marker it could not be found naturally in urine and had to offer the possibility to create a variety of distinguishable markers.

After intense research and testing they found that polyethylene glycols were the perfect substances. Polyethylene glycols are on the FDA’s list of inactive ingredients. They do not have side effects and are completely safe. They are not naturally found in urine and they have different molecular weights that enable the composition of 1,000 different marker types. Within several years the procedure was fully developed and patented in 32 countries around the world. Commercialization of the markers first started in Germany in 2006 and the markers are now used in the treatment, and the highly regulated German Corrections system.

In 2013, Marker Test Diagnostics was incorporated in the State of Delaware to introduce the UR Code product to the numerous drug testing markets and organizations in the United States. The European marker product is called Ruma Marker-System, a liquid based product; the soft get capsule used in the US is trademarked as UR Code™.

After incorporation, Marker Test Diagnostics, Inc. has focused on establishing a U.S.-based manufacturing process, developing several scientific studies to show efficacy of the product in multiple markets, product safety and product reaction studies, physiological blood studies, and athlete participation doping studies. An ivy league university is in the process of conducting these studies and the U.S. Doping Laboratory at UCLA is currently analyzing samples collected from professional athletes using the UR Code product and a non-observed collection process.
Data has been collected and analyzed by Marker Test Diagnostics from participating laboratories in the German markets that have over 700,000 applications over the past five years that show no reactions to the product and have categorized the results of manipulation of one participating laboratory and their reported 12 months of data of 71,000 data points. A time motion study has also been conducted of over 200,000 data points comparing observed collection vs. medication dispensed application and IT data entry processes. (All available data will be presented in this paper).

Why is there a need for change?

Through our research, direct contact with collection sites and expertise in the drug testing industry and individual markets, we have identified six key components, outlined below, that support a need for change. Changing to a marker-based process will lead to a decrease in inaccurate testing results, reporting gaps and questionable security of observed sample collections. As a result, sample integrity increases significantly and adequate donor identification and sample accuracy will be improved.

Culture: The prevailing culture within the drug testing industry is that the observed collections method is “as good as it gets.” Unfortunately, studies have shown that clients, agencies, and organizations that implement the UR Code process show an increase in detection of abused drugs by as much as 30 percent. These increases are due to donors’ inability to adulterate or substitute the urine sample. In order to fully integrate a new, more efficient collection and urine marker testing process a paradigm shift will be necessary.

Data: There is a need to better identify the scope of adulteration and sample manipulation in each market space.

Measurement: Each market segment is unique in its management of the urine collection process. Some markets implement the observed process, but some do not. Eliminating this observed process and implementing the UR Code product will standardize the drug testing industry.
**Funding, economics, and regulations:** Reimbursement to end-users (Physicians / Laboratories) may directly correlate to the failure of observed collection process in most physician office and clinics. Reducing organizational costs and increasing revenue can apparently outweigh the need for accurate result reporting.

**Source of Value:** In all market segments the observed collection process is of low value, expensive, and an invasion of privacy.

**Trust and Risk:** Without a better system to capture manipulation and adulteration, and confidence to ensure the organization has “The Right Person, The Right Sample, and the Right Result,” there will be continued risk of errors and therefore extra effort must be expended to ensure a higher quality testing and improved collection process.

These six components illustrate the need for change around the current gold standard process of observed urine collection in terms of current industry culture, specimen accuracy, result accuracy, provider risk, and the economic impact to the overall costs to the drug testing industry.
**What is the significance of change?**

Drug abuse testing will only increase in the coming years. Costs must be controlled and an increase in result accuracy and process efficiency must be implemented. The study below shows a linear increase year-by-year of drug testing. However, given the growth over the past four years, it is clear that a large increase is expected at a minimum of these projections.

*2010 Deloitte Drug Testing Market Analysis*

With much more growth then expected, the problem of manipulation and adulteration would increase as well. Clients who use UR Code have reported that urine manipulation, false urine substitution, and increased detection of abused drugs in donors using the UR Code process have given physicians, corrections administrators, and judges better and more accurate confirmation testing results. This directly impacts their ability to make better treatment decisions by minimizing the risk of prescription medication errors and reactions and providing confidence in results to sanction those participants who attempt to manipulate the sample, process, or results. These improvements also reduce overall operating costs.
The intent proposing and implementing a new and more accurate product and procedure is not to point blame at the laboratories providing testing, or point fingers at independent businesses that provide collection services to the general public. Both are following currently acceptable and standard practices. And, LC/MS/MS technology is the latest state-of-the-art testing but it can only provide answers to what is in any given urine sample. That technology cannot determine whether the urine came from the named donor. The margins of error in the observed collection process are well known and the false negative urines due to a number of available anatomical products, sample substitution by the collectors for profit, catheterization, and other issues will not disappear in the future. A new approach and solution to these issues and concerns must be logically assessed to improve the entire process and quality of care.

One study [1] estimated that organizations can reduce operational costs by as much as $10.00 per sample by eliminating observed collections and gaining better operational efficiencies.

*The UR Code process is simple in its approach:*

All indications show that addicts will do anything to cheat a test by swapping urines with other participants, adulterating the urine with chemicals, and producing false commercially available urine. By using the UR Code product **AND** moving to a non-observed collection process it will be impossible to circumvent the process when a known marker is to be present in the urine.
**Laboratory Statistics**

Below is a sampling of one of the licensed laboratories in Germany that provided 12 months of data collection of samples analyzed from a facility using the marker product.

Results are based on 71,000 samples *

17% of the samples show manipulation

- **59341** Marker detected & no signs of manipulation = 83.34%
- **11863** Signs of manipulation = 16.66%

83% Correct Marker Detected

* Labor Dr. Quade, Koeln, Germany

**Methods of Manipulation**

![Bar chart showing different methods of manipulation](chart.png)

- **1714** Marker Missing
- **1363** Marker Concentration low
- **292** Wrong Marker
- **2684** Urine Diluted
- **1185** Added Chemicals
These results show that attempts to manipulate the samples continue; however it is much clearer on how the manipulation is being carried out. One can conclude that the “Marker Missing” result was urine substituted in the bathroom after a marker was ingested. “Marker Concentration Low” resulted from placing negative urine in the bladder or by mixing in the sample with clean urine. For “Wrong Marker,” the urine was swapped with another donor and “Urine Diluted” reflected an attempt to over-hydrate and dilute the urine. And “Added Chemicals” was adulteration of the sample by adding common chemicals to the urine.

This data clearly shows that using a detection urine marker eliminates the possibility of introducing a false negative urine sample regardless of the type. Missing Marker, Marker Concentration Low, and Wrong Marker are methods of manipulation that observed collections would not pick up; they would just be presented as negative urine. Only when a UR Code marker is presented will this data be captured.

**Workflow Efficiency**

Data collected over a period of time in the employment industry clearly shows a significant timesaving by comparing the standard process of data entry to providing a cup to collect a sample vs. a medication dispensing process. The conversion from an observed collection procedure to a marker/non-observed collection process will have a direct impact on organizational efficiencies by eliminating the number of steps needed in the medication dispensing process. Data entry can be minimized, bar codes are attached from the marker bottle and peeled and placed on cup and laboratory requisition, the marker is ingested and the mouth is inspected to ensure the donor swallows the capsule. Individuals who try to bite the capsule to add marker to the sample, will have a blue food dye in their mouth, lips and hands and it will be clear and obvious if they try to circumvent the process.

The following data represents the difference in activities entered into admissions software and the time difference and timesaving that can be realized.
The above collection process information was derived from two years of workplace data, over 50,000 donors and 250,000 tests.
The process above is based on procedures used in the corrections industry to ensure medications are consumed by offender they are prescribed for. **If marker is distributed at the same time as a similar testing activity performance time can be eliminated.**
**Technical Methodology**

Below is the chemical makeup of the polyethylene glycol markers that are used in the formulation of the UR Code product. Polyethylene glycols are often used in manufacturing and can be found in virtually all drug groups, including antitussive tablets that are cleared for use by children. They are also used in sedatives, relaxants, painkillers and other substances as well as an antidote to poisons for external use on the skin. The polyethylene glycols used for the UR Code are absorbed, not metabolized, and quickly cleared through the kidneys.

**UR Code** offers different combinations of polyethylene glycols in the form of a soft gel capsule as a urine identifier. The individual UR Code capsules differ in the number of repetition units and are of different molecular weights and chain lengths. The UR Code soft gel product manufactured in the United States varies from the European liquid marker. The U.S. version uses an FDA-approved food dye in the formulation that will stain the mouth or fingers if the product is tampered with and does not color or affect the urine at the time of collection.

**UR Code™ Technology**

Low molecular-weight polyethylene glycol polymers as an oral liquid (HPLC detection) or soft gel product form (LC/MS/MS detection).

1. \( \text{HO} - \text{CH}_2 - \text{CH}_2 - \text{O} - \text{CH}_2 - \text{CH}_3 - \text{OH} \)
2. \( \text{HO} - \text{CH}_2 - \text{CH}_2 - \text{O} - \text{CH}_2 - \text{CH}_2 - \text{O} - \text{CH}_2 - \text{CH}_3 - \text{OH} \)
3. \( \text{HO} - \text{CH}_2 - \text{CH}_2 - \text{O} - \text{CH}_2 - \text{CH}_2 - \text{O} - \text{CH}_2 - \text{CH}_2 - \text{O} - \text{CH}_2 - \text{CH}_3 - \text{OH} \)
4. \( \text{HO} - \text{CH}_2 - \text{CH}_2 - \text{O} - \text{CH}_2 - \text{CH}_2 - \text{O} - \text{CH}_2 - \text{CH}_2 - \text{O} - \text{CH}_2 - \text{CH}_3 - \text{OH} \)

Low molecular-weight PEG cutoff – set by kidney passive clearance at ~6000 MW.
Markers are ultra-pure mono-dispersed polyethylene glycols and combinations thereof (1024 mixtures possible)

- LC-MS-MS chromatograph of the Marker are distinct and easy to interpret
- Markers are detected within a single LC/MS/MS drug detection run

What would change look like?

Change will look different depending on the market and cost benefit ratio determined by the participants in those markets. A product like UR Code will not have the same high value benefit in each market, rather a varying degree of benefit due to the influences that are unique to business, such as:

1. Pain Management Market/Addiction markets: UR Code will increase the effectiveness of a pain management programs since patients will produce legitimate urine samples for compliance monitoring without the need for observed collections.

2. Criminal justice markets: UR Code will eliminate the opportunity for sample substitutions and the need for observed collections. This will improve prisoner and staff safety by ensuring they have the right results from the right sample for the right inmate.

3. The insurance industry will show significant savings in claims by eliminating false negative urines and denying claims when positives are detected earlier.
4. Workplace/employment market: Workplace testing will be improved by utilizing UR Code to eliminate false negative drug tests due to sample manipulation or substitutions.

5. Athletic organizations will have a huge benefit by increasing the integrity of athletes’ samples while eliminating the possibility of manipulation or substitution.

One area that no one can put a dollar value on is eliminating the embarrassing, dehumanizing, degrading and invasive process of having someone observe the urination process. Even individuals in drug treatment, or a competitive sports environment where samples are required often, never get used to the observation process. And it is much worse for the occasional donor who must submit to a random sampling or pre-employment testing. Eliminating this process will improve confidence in the system and ensure better quality results while upholding donor morale and self-respect.

**How do we measure and evaluate the success of change?**

Measuring and evaluating the change can be accomplished in different ways. Key performances indicators (KPI’s) should be identified that serve each of the key components in each market space. Several data categories will be established:

**Laboratory Statistics:**
- Correct marker detected
- Wrong marker detected
- Missing marker in urine
- Excessive mono-dispersed polyethylene glycol in sample
- Adulteration methods
- Urine dilution
- Chemicals added to sample (bleach, chromium, etc.)
Industry measurements:
- Number of new clients per market per year converting to UR Code product
- Sales revenue tracking and reporting
- Client positivity rate monitoring
- Customer satisfaction surveys by laboratory client, overall and individual market customer segments and company initiated satisfaction surveys.
- Measurement of reported reactions (if any).
- Comparative blood studies to baseline reports (targeted accounts, donors)
- Measure client intake and workflow efficiencies

What costs are associated with change?
Change always involves some cost. However, once a timeline has been established to adopt the UR Code product and eliminate observed collections, several considerations must be made:

Establish a conversion timeline that includes the following:
- a. Train laboratories’ sales and marketing staff on the product and process – this will be a mutual process between company and client.
- b. Determine end-user main contacts and establish an on-site training conversion program - client assumes its own customer training process.
- c. Establish a “Go-Live” date and begin informing clients that a change will occur from the observed collection process to an orally-applied marker procedure. This may take 30 to 60 days to complete, depending on the end user site. Simple printed handout cards can keep the change process in the forefront of the clients mind.
- d. Establish a procedure protocol that explain the steps:
  1. Office personnel dispenses the capsule to the donor with a small amount of water or juice
  2. Personnel examines the mouth for adulteration of the capsule (blue dye)
  3. Documentation of the acceptance
  4. The patient takes a seat, sees the health care provider etc. for the remainder of the 30 minutes, then provides a donor-collected sample – no change or added costs.
- e. There will also be a negotiated cost of the marker materials, which will be offset by operational savings or value in sample integrity and accurate results.
Summary

There are two key components to implementing a paradigm change in the drug testing market;

1. **Acceptance of the ingestion of an orally applied marker**

   And;

2. **Moving away from the observed collection process.**

The data that has been presented clearly shows that an orally applied marker can improve the drug testing market over the current standard practice of observed collection. There is significant value in detecting as much as a 30 percent increase in abused drugs that are currently being missed by using a non-marker product, the elimination of the false negative urine, and removing the extreme negative connotation surrounding the process of observed collections.

Additional studies and white papers have shown, and will continue to show, that there is no evidence that the marker causes any type of adverse physical reactions, physiological, enzymatic, or metabolic changes in the human body. The UR Code product has FDA concurrence, is patented, and will be available in the US market in Q4 of 2014.

Citations:

(1) Quest Diagnostics