

> TruSentry™

*Powerful multiplex approach for rapid, high-throughput screening
for **infectious and genetic** disease*



PANDEMIC DISEASE SCREENING

CANCER BIOMARKER SCREENING

GENETIC DISEASE AND NEWBORN SCREENING

Akōnni[®]
Biosystems



> *The growing need for rapid screening for infectious disease*

Countries with large populations, frequent foreign visitors, and migrant workers either recognize the potential for a serious health crisis caused by the rapid spread of infectious disease or have already experienced one.

Given the tremendous complexity involved with addressing the issues associated with such a health crisis, what can start as a simple virus or bacteria can quickly change and mutate into a new and unknown entity. As a result, countries have an unprecedented need to rapidly identify a wide range of pathogens and their subtypes in order to protect their populations.

Today's health authorities require a detection system that can screen large patient populations for a variety of bacteria, viruses, and their subtypes while maintaining the flexibility to be updated quickly with targets for new mutations and/or regional-specific content.

Meet the solution—the TruSentry system from Akonni Biosystems.

SIGNIFICANT COST SAVINGS

- > TruSentry gives laboratories the ability to screen for tens of diseases for about the same cost as screening for just one or two

VERSATILE

- > Screen for tuberculosis, HIV, hepatitis, influenza, STDs, cholera, SARS, and other diseases
- > Identify multiple pathogens from a single sample—nasal swab, sputum, or blood
- > Design a new commercial grade assay based on specific analytes of interest

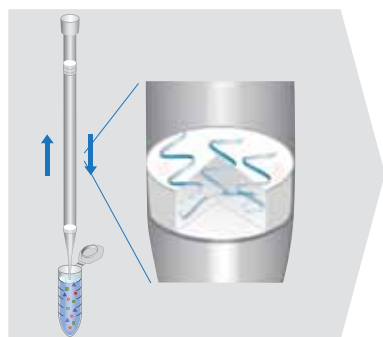
FAST

- > Go from sample preparation to final result in a few hours

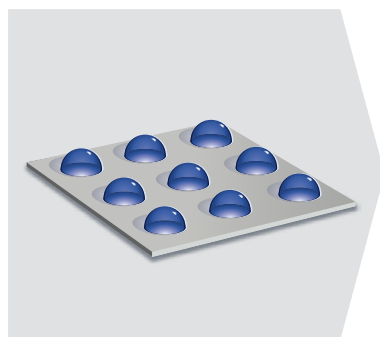
SCALABLE

- > Test tens to thousands of samples per day
- > Rapidly add new tests to the test matrix – test for multiple diseases per sample

*TruSentry
identifies
multiple
pathogens
from a single
sample, at
a highly
affordable
cost per test.*



TRUTIP FOR RAPID EXTRACTION

TRUARRAY FOR
LOW-COST DETECTIONTECAN FREEDOM EVO 200
FOR AUTOMATION

Fast, simple, cost-effective testing

The TruSentry system from Akonni Biosystems is a revolutionary screening system that combines the patented Akonni TruTip™ sample preparation technology with the powerful multiplex detection capabilities of Akonni TruArray®. This innovative approach deployed on the Tecan® Freedom EVO 200 robotic platform enables a laboratory technician to rapidly extract DNA and/or RNA directly from a wide range of samples and test these samples for multiple diseases simultaneously.

With TruSentry, this multiplexing process of testing for multiple diseases with a single test provides rapid disease detection. It's highly reliable, fully automated, and very cost effective. It can test for multiple infectious diseases using a respiratory sample, nasal swab, whole blood, or even in some cases a tiny spot of dried blood.

Once the sample is at the laboratory, it takes TruSentry less than four hours to deliver the result. It's the only system that can rapidly process tens to thousands of samples per day on a microarray.

The ability to scale testing up or down combined with the rapid time to deliver results enables TruSentry to be used for a variety of applications, such as screening foreign visitors, health surveillance monitoring, and even neonatal testing.

Rapid screening for the most common and dangerous infectious diseases

TruSentry can provide rapid, high-throughput screening for infectious diseases such as tuberculosis, HIV, hepatitis, SARS, cholera, and influenza, in addition to other similar maladies that are spread by a number of vectors.

While identifying one or two of these diseases separately is straightforward with the rapid tests in regular use by most laboratories, the process of identifying multiple diseases with a single test—at an affordable cost—has been both logistically and financially challenging.

TruSentry meets the challenge by making it possible to test mass populations for numerous diseases, including those with regionally unique mutations, at once—all for much less than performing individual tests.

TruSentry provides users with complete flexibility to add new targets as they become known.

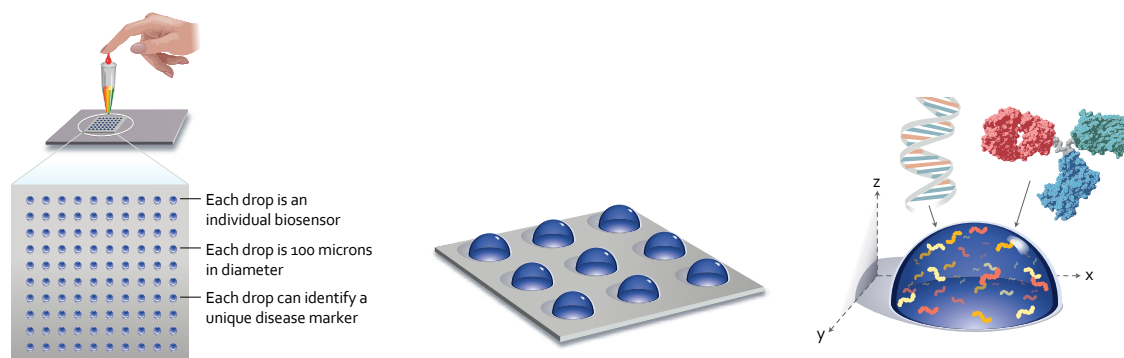


Akonni's effective nanoscale biosensor technology

TruSentry uses Akonni's patented nanoscale biosensor technology printed on a microarray. Capture probes are covalently attached to an ultra-high surface area hydrogel polymer backbone of discrete, tuneable three-dimensional gel-drops rather than a two-dimensional substrate. Consequently, individual gel drops behave as individual nanoscale test tubes, and enable highly multiplexed "panel" testing from a single sample source. This configuration, called a TruArray, results in a highly cost effective and easy-to-use interface for surveillance applications.

Akonni's screening system also includes a patented sample preparation tool called TruTip that shortens sample preparation time from 40 minutes to four minutes for up to 96 samples at a time, saving countless hours of technician time and accelerating time to results.

Save countless hours of technician time and accelerate time to results.



The first rapid screening system based on a microarray

Akonni developed TruSentry over the past 15 years through significant investment from the Department of Energy, Department of Defense, Department of Justice, National Institute of Allergy and Infectious Disease, Centers for Disease Control, Argonne National Laboratory, and other US government entities.

The system uses nanoscale biosensor technology on a microarray, making it the first commercially available screening system for "panel" testing of the most common communicable diseases from a single sample.

The name TruSentry highlights the system's ability to provide truly accurate and trusted results, combined with alert detection and reporting on the world's most prevalent and dangerous infectious diseases.

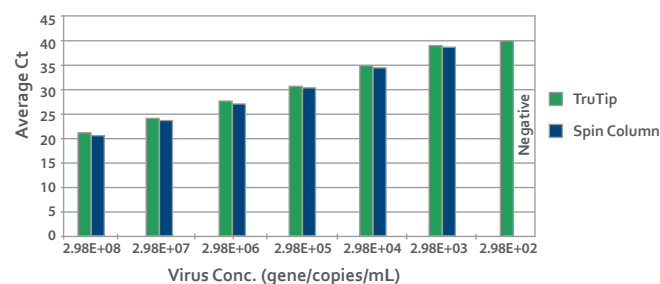
TruTip vs. Spin Column Extraction Times and Results (n=5)

TruTip gDNA Blood Kit vs. "gold standard." Comparing different input volumes of whole blood. Results show higher yield and higher concentrations on same samples for TruTip.

Extraction Time (after 10 minute incubation)	TruTip			Spin Column		
	Tip Type	Avg. Conc. (ng/ μ L)	Avg. Yield (μ g)	Type	Avg. Conc. (ng/ μ L)	Avg. Yield (μ g)
400 μ L/100 μ L	LPT 2 mL	134 \pm 13	13.36	Spin Col.	128 \pm 13	12.83
200 μ L/100 μ L	SPT 2 mL	89.8 \pm 6.0	9.75	Spin Col.	82.4 \pm 4.9	8.24
100 μ L/100 μ L	SPT 2 mL	34.4 \pm 4.9	3.44	Spin Col.	30.5 \pm 5.9	3.05

TruTip Correlation to Spin Column

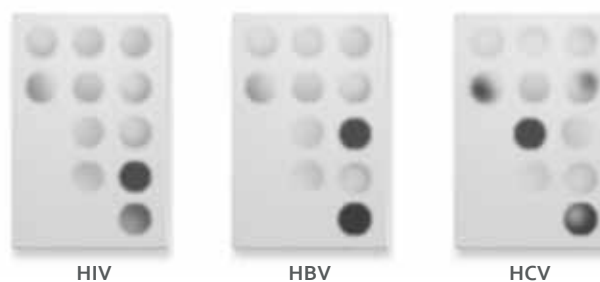
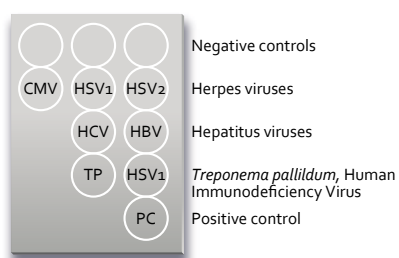
Ct value comparison for dilution study extractions of FluA shows equivalent recovery from TruTip and Spin Column extraction methods.



Flexible, automated, accurate

A TruSentry system can simultaneously process a wide range of sample types for infectious diseases such as tuberculosis, multidrug-resistant tuberculosis, HIV, viral hepatitis B, hepatitis C, syphilis, SARS, and influenza. Sensitivity for viral vectors is delivered at ~100 plaque-forming units (PFU)/milliliter (mL) and bacterial pathogens of ~100 colony-forming units (CFU)/mL.

What's more, the test panel can be upgraded from several infectious diseases to tens of diseases with no significant changes to the lab infrastructure or capital equipment. Future upgrades could easily include emerging infectious diseases such as H1N1, avian flu, SARS, malaria, and others, and can easily be adapted to handle regionally specific mutations.



TruSentry can differentiate among a number of different infectious diseases. For example, these sample images are representative of an array that has detection probes to screen blood for herpes 1, herpes 2, hepatitis C, hepatitis B, HIV, and syphilis.

TruSentry can also screen for genetic diseases

TruSentry enables large numbers of genetic tests to be conducted simultaneously and analyzed quickly, accurately, and cost-effectively. Upon regulatory clearance, the TruSentry system will be a fully automated, hands-free testing platform for multiplexed identification of many different kinds of genetic diseases, such as newborn, autoimmune, and cancer screening, and for various pharmacogenomic applications, such as testing a person's ability to metabolize certain drugs.

These high-volume screening assays make it possible to test people for several different nucleic acid or immuno-markers linked to critical diseases. Each of these conditions can cause severe ailments or even death if left untreated. But, if detected early through testing, effective treatment can be initiated. Multiplexing these tests together from a single sample offers significant improvements in testing efficiency.



However or wherever it's deployed, the TruSentry System completely automates the screening process, from sample preparation to results and analysis. The system can:

- Read 2D barcodes on tube racks
- Automatically de-cap tubes
- Transfer and process nasal swab, sputum, and blood samples
- Use Thermocycler PCR plates
- Transfer sample to the TruArray microarray plates
- Four-color laser scanner scans TruArray microarray plates
- Automatically process and analyze results

Tecan and Akonni are creating today's most advanced and highly automated solutions for clinical researchers.

The high cost of infectious diseases – to \$20 billion and more

Highly communicable infectious diseases such as tuberculosis, HIV, hepatitis, influenza, and SARS are leading causes of human suffering, disability, and death worldwide—there were more than 1.8 million fatalities from TB alone in 2008. This number can easily grow to more than 100 million deaths in years of global pandemic, such as during a major influenza outbreak.

The economic impact of such diseases is tremendous. For example, the estimated cost to Asian countries of the 2003 SARS epidemic was \$20 billion—approximately \$2 million per case. In order to mitigate such large-scale human and economic impact, health authorities are moving quickly to deploy rapid, high-throughput disease surveillance and reporting programs, which are crucial for the identification, management, and containment of disease.



384 ARRAYS



96 ARRAYS



16 ARRAYS



8 ARRAYS



1 ARRAY

Versatility is built in

Each gel-drop acts as a nano-scale biosensor, capable of identifying infectious diseases or drug resistance markers, such as for HIV, HepB, and/or MTB.

With a gel-drop microarray printed at the bottom of each well in single-well, 8-well, 16-well, 96-well, or 384-well plates, dozens of diseases markers can be tested from a single sample, 8 to 384 samples at a time.

Leveraging industry standard robotic systems, TruSentry delivers fully automated sample prep to final result for hundreds to thousands of samples per day.

Deploy it where and how it's needed

The TruSentry system is a custom-built solution that can be deployed in multiple configurations depending on the user's requirements and the throughput required.

For example, it can be used in a single national reference lab processing millions of samples per year as well as part of a larger network of separate satellite facilities that are at—or closer to—the point where samples are collected. It can also be used within centralized visa processing centers, regional surveillance centers, or even at well-equipped field sites near the point of an outbreak. In these situations, the use of a rapid, cost-effective multiplex screening system can greatly help immigration and health care officials identify and slow the spread of potentially dangerous diseases.

*Can process
as few as 8
to more than
10,000 unique
samples
per day.*

This is especially critical in light of increased international mobility in countries that have large numbers of short term and temporary visitors. For example, in Saudi Arabia approximately 10 million people apply for visas to visit the Kingdom each year—7 million workers, and 3 million pilgrims. And across the Middle East and North Africa, with a population approaching 350 million, the number of people applying for visas or temporary travel permits reaches 30 million in some years, and is continuing to grow.





Find out more

Learn more about how TruSentry will revolutionize the way you screen for infectious diseases. Please call us at **301-698-0101**, send an email to info@akonni.com, or visit us online at www.akonni.com.

About Akonni Biosystems

Akonni Biosystems was founded in 2004 and has over 20 patents issued with 13 others pending. Our core technology is based on work developed at Argonne National Laboratory and the Engelhardt Institute of Molecular Biology, and utilizes gel-drop array technologies optimized for medical applications. We have also developed core IP in the area of ultra-rapid nucleic acid extraction. Supported by a series of government grants and contracts from NIH, CDC, DOE, DOD, NIJ, and NSF, we have significantly advanced the original technology by improving the system's capabilities from sample preparation to final result. Commercial products and those in our near-term pipeline include TruTip ultra-rapid sample preparation methodologies for nucleic acid extraction; TruArray multiplex panel assays for detecting multidrug-resistant tuberculosis (MDR-TB), upper respiratory infections, viral encephalitis, and hospital-acquired infections (MRSA); TruDx® test readers; and the TruSentry solutions. > TSS-PC-002 | 1101.1

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