

# **Toxicology Diagnostic Device Update**

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# Toxicology IVD Update

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Recent and novel Toxicology  
IVDs:

Personalized Medicine

# Personalized Medicine

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choose the  
**Right Drug**

in the  
**Right Dose**

for the  
**Right Person**

# Personalized Medicine

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One approach to  
personalized medicine  
is through the use of

**Companion Diagnostics**

# Companion Diagnostic

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## Companion Diagnostic:

A diagnostic test intended to help  
select/guide drug therapy

# Advantages

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## Potential Benefits of Personalized Medicine:

- Provide differential diagnosis of a disorder or identification of a patient subset
- Identify potential responders to a specific drug
- Provide a way to target therapy
- Identify individuals at risk for adverse events
- Be used as an adjunct tool for monitoring responses to drugs
- Advance the field of individualized therapy

# Toxicology IVD Update

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- Pharmacogenetics
- Therapeutic Drug Monitoring
- Breath Tests

# Pharmacogenetics

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The use of a patient's *genetic* information to guide drug selection or dosage

So far focused on  
Drug Metabolizing Enzyme  
Genotyping Assays

# Pharmacogenetics

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## Roche AmpliChip CYP450 Microarray:

- Detects 27 cytochrome P450 2D6 alleles and 3 cytochrome P450 2C19 alleles
- First Microarray cleared for clinical use (Affymetrix)
- FDA review time = 3 days

# Pharmacogenetics

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## Third Wave Invader UGT1A1 Assay:

- Detects 2 promoter variations in UGT1A1
- \*28 allele can result in decreased UDP-glucuronosyltransferase activity which has been shown to lead to a greater risk for neutropenia for drugs such as Irinotecan
- FDA review time = 10 days

# Pharmacogenetics

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Much interest in additional PGx targets:

- Other cytochrome P450 enzymes
- Genes involved in Warfarin metabolism
- Therapy-specific genes in co-development studies

# TDM

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## Therapeutic Drug Monitoring:

- Cyclosporine
- Tacrolimus
- Sirolimus
- Zonisamide
- Interest in developing assays for other drugs

# TDM

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## Therapeutic Drug Monitoring:

- Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA
- General guidance on TDM Assays being developed

# Breath Tests

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Assays that capture exhaled breath to measure a physiological phenomenon

- H. Pylori infection
- Enzyme activity
- GI Absorption
- Other conditions

# Breath Tests

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- Combination Products
- Device = primary mode of Action
- PMA for approval of device and drug together
- Jurisdictional Update: Breath Test Combination Products [<http://www.fda.gov/oc/combination/breathtest.html>]

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