

# Validated Methods

## • LC/MS Biomarker Methods

### Biomarker Method Development and Validation Expertise

Amino Acids

Rat Hcpidin

Lipids

Neurotransmitters

Nucleotides

Peptides

Proteins – immunoprecipitation, digestion, immunoaffinity LC/LC/nano LC/MS/MS

## • Immunoassay Biomarker Methods

Biomarker/Analyte on ELISA Platform	Range	Volume Required	Matrix
HER-2/neu	2.5 – 35 ng/mL	20 µL	Human serum
β-NGF (free)	1 – 500 pg/mL	50 µL	Human serum
IGF-1 (total)	0.15 – 6 ng/mL	20 µL	Human serum
IGF-1 (free)	0.15 – 6 ng/mL	20 µL	Human serum
sECAD	0.625 – 20 ng/mL	20 µL	Human serum
sEGFr	12.5 – 300 ng/mL	20 µL	Human serum

## • LC/MS/MS Methods

Analyte/Metabolite	Range	Extraction Volume	Matrix/ Anticoagulant
Acyclovir; Valaciclovir	10 – 1000 ng/mL	50 µL	Human plasma/K <sub>3</sub> EDTA
Amlodipine	0.1 – 10 ng/mL	100 µL	Human plasma/heparinized
D-Amphetamine; L-Amphetamine (chiral)	0.5 – 75 ng/mL	200 µL	Human plasma/sodium EDTA
<i>Available in May 2011</i>			
D-Amphetamine (achiral)	0.5 – 200 ng/mL	100 µL	Human plasma/sodium EDTA
Atorvastatin; <i>o</i> -Hydroxyatorvastatin; <i>p</i> -Hydroxyatorvastatin	0.25 – 25 ng/mL	200 µL	Human plasma/sodium heparin
Bortezomib	0.1 – 25 ng/mL	100 µL	Human plasma/K <sub>3</sub> EDTA and sodium heparin
Capecitabine; 5'-DFCR/ 5'-DFUR/ 5-FU/ FBAL	10 – 5000 ng/mL 50 – 25000 ng/mL 2 – 1000 ng/mL 15 – 7500 ng/mL	200 µL	Human plasma/sodium EDTA
Carbamazepine/ Carbamazepine 10,11-epoxide	20 – 5000 ng/mL 20 – 500 ng/mL	50 µL	Human plasma/sodium EDTA
Clopidogrel/ Clopidogrel Acid/ Clopidogrel Active Metabolite	0.05 – 50 ng/mL 5 – 5000 ng/mL 0.0706 – 70.6 ng/mL	200 µL	Human plasma/K <sub>2</sub> EDTA
Cytarabine	25 – 1000 ng/mL	20 µL	Human plasma/sodium heparin
Daunorubicin; Daunorubicinol	1 – 500 ng/mL	100 µL	Human plasma/K <sub>2</sub> EDTA
Digoxin	0.1 – 20 ng/mL	200 µL	Human serum
Digoxin	5 – 1000 ng/mL	100 µL	Human urine

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• **LC/MS/MS Methods continued**

<b>Compound/Metabolite</b>	<b>Range</b>	<b>Extraction Volume</b>	<b>Matrix/ Anticoagulant</b>
<i>Available in May 2011</i>			
Docetaxel	1 – 2500 ng/mL	200 µL	Human plasma/K <sub>2</sub> EDTA
Donepezil	0.2 – 100 ng/mL	200 µL	Human plasma/sodium heparin
Duloxetine/ Atomoxetine; S,S-Reboxetine	0.2 – 200 ng/mL 0.5 – 500 ng/mL	50 µL	Human plasma/K <sub>3</sub> EDTA
Erlotinib	1 – 3000 ng/mL	50 µL	Human plasma/sodium heparin
5-Fluorouracil (5-FU)	10 – 10000 ng/mL	100 µL	Human plasma/sodium heparin and K <sub>2</sub> EDTA
Fenofibric Acid	20 – 10000 ng/mL	100 µL	Human plasma/sodium EDTA
Gemcitabine	10 – 10000 ng/mL	25 µL	Human plasma/lithium heparin
Glyburide	0.025 – 2 ng/mL	100 µL	Human PFF (non-protein bound)
Glyburide (total)	1 – 250 ng/mL	200 µL	Human plasma/sodium heparin
Imatinib (Gleevec®)/ N-Desmethyl Imatinib	100 – 10000 ng/mL 50 – 5000 ng/mL	50 µL	Human plasma/K <sub>2</sub> EDTA
Lamivudine (as part of Combivir®)	2 – 1000 ng/mL	200 µL	Human plasma/sodium heparin
Lamivudine (as part of Combivir®)	2 – 1000 ng/mL	200 µL	Human urine
Lovastatin; Lovastatin Acid	0.25 – 100 ng/mL	500 µL	Human plasma/sodium heparin
Methotrexate/ 7-Hydroxymethotrexate	1 – 1000 ng/mL 1 – 150 ng/mL	200 µL	Human plasma/lithium heparin
Methotrexate (Low Curve)	50 – 1000 ng/mL	20 µL	Human urine
Methotrexate (High Curve)/ 7-Hydroxymethotrexate	1000 – 50000 ng/mL 50 – 1000 ng/mL	20 µL	Human urine
Methylphenidate; α-Phenyl-α-(2-Piperidyl)Acetic Acid	0.05 – 25 ng/mL	100 µL	Human plasma/acid citrate dextrose
Midazolam; 1'-Hydroxymidazolam	0.1 – 100 ng/mL	100 µL	Human plasma/sodium and lithium heparin
Moxifloxacin	25 – 5000 ng/mL	50 µL	Human plasma/K <sub>2</sub> EDTA
Omeprazole/ 5'-Hydroxyomeprazole; Omeprazole Sulfone	0.5 – 500 ng/mL 0.5 – 250 ng/mL	50 µL	Human plasma/sodium heparin
Paclitaxel; 6-Hydroxypaclitaxel	10 – 5000 ng/mL	200 µL	Human plasma/K <sub>2</sub> EDTA
Ritonavir	10 – 5000 ng/mL	50 µL	Human plasma/K <sub>3</sub> EDTA
Rosiglitazone	5 – 3000 ng/mL	25 µL	Human plasma/K <sub>3</sub> EDTA
Rosuvastatin/ Rosuvastatin Lactone; N-desmethyl Rosuvastatin	0.5 – 100 ng/mL 0.5 – 50 ng/mL	100 µL	Human plasma/K <sub>2</sub> EDTA
Simvastatin; Simvastatin Acid	0.1 – 30 ng/mL	200 µL	Human plasma/K <sub>3</sub> EDTA
Tolterodine; 5-Hydroxymethyl Tolterodine	0.2 – 50 ng/mL	100 µL	Human plasma/sodium heparin
Valproic Acid	1 – 100 µg/mL	100 µL	Human serum
R-Warfarin; S-Warfarin (chiral)	0.1 – 10 ng/mL	200 µL	Human PFF (non-protein bound)
R-Warfarin; S-Warfarin (chiral)	1 – 2500 ng/mL	100 µL	Human plasma (total)/sodium and lithium heparin
Zidovudine (as part of Combivir®)	2 – 1000 ng/mL	200 µL	Human plasma/sodium heparin
Zidovudine (as part of Combivir®)	2 – 1000 ng/mL	200 µL	Human urine
Ziprasidone	0.5 – 150 ng/mL	200 µL	Human plasma/sodium heparin

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