# The Phenomenome Clinical Analyzer Platform *Highlights Page*

## THE PLATFORM

An integrated platform containing a vertical dual-source triple-quadruple mass spectrometer that can deliver over 1000 patient results per day, complete with integrated quality reporting and patient results reporting. PDI risk assessment test kits are designed to work in perfect harmony with the platform.

- Platform is manufactured under ISO13485:2003 with OEM sourced components and is FDA compliant
- Installation and maintenance protocols in place
- Consumables manufactured and supplied by PDI

## CLINICAL CHALLENGES WITH MASS SPECTROMETRY

Mass spectrometry is the gold standard to accurately measure different types of molecules in complex biological samples such as human blood. Despite the unquestionable analytical superiority of mass spectrometry in terms of sensitivity and specificity, mass spectrometry-based analytical methods have remained widely unavailable due to specialized laboratory requirements and the need for highly-trained technicians for operation and maintainence.

PDI simplified the complexity of mass spectrometry by rethinking every aspect of the workflow from sample preparation to reporting of patient results.

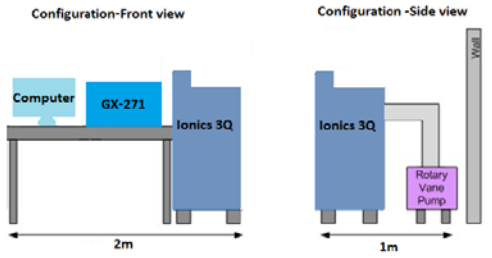
## KEY PLATFORM COMPONENTS

Platform hardware and software

- Sample preparation (customized Gilson® GX-271)
- Sample introduction and fluidics
- Mass spectrometry analysis (Ionics 3Q)
- Data processing (PDI software)

Consumables

- Chemistry and packaging (test kits)




## AUTOMATION AND THROUGHPUT

The customized Gilson® GX-271 Liquid Handler is an automated sample injection and solvent delivery system equipped with test software. The sample loading rack can accommodate nine 96-well microplates which have the capability of loading up to 864 samples at one time. High throughput analysis can achieve a sample loading and injection cycle of less than one minute. When data acquisition is complete, a report is automatically generated for each plate.

## AUTOMATIC REPORTING

The software automatically generates the tune check report and the test report which includes the method check results, QC results, standard curve result, and the patient test results.

- Tune check: verifies the operational performance of the mass spectrometer (mass accuracy and resolution)
- Method check: verifies the operational performance of Test Kit prior to running patient samples
- Calibration curve: multi-point concentration curve for accurate quantitation
- Quality controls: three quality control (QC) samples containing low, medium and high analyte levels are run along with patient samples in each batch to track the run acceptability

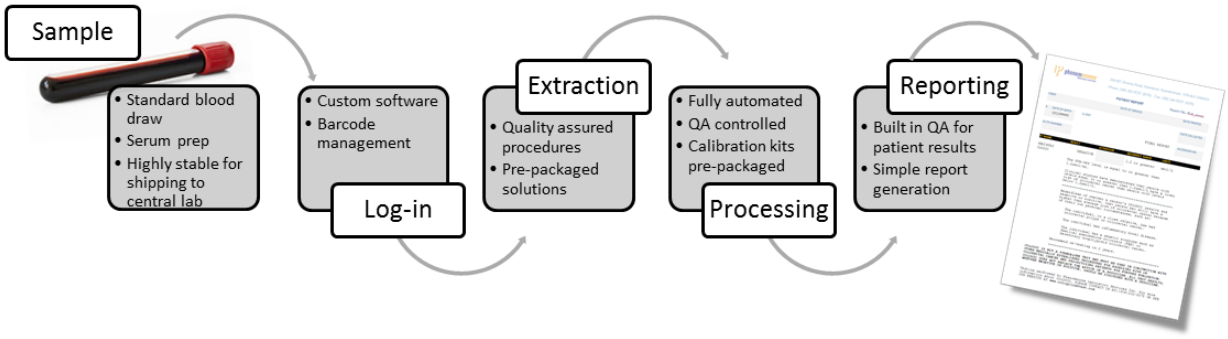
TUNE CHECK REPORT

| | Target Peak Intensity | Observed Peak Intensity(cps) | Observed Deviation | Acceptable Deviation Range | Pass/Fail |
|---|---|---|---|---|---|
| Peak 1 | 20000.0 | 7940000.0 | 7920000.0 | >= 30.0% | Pass |
| Peak 2 | 20000.0 | 3930000.0 | 3910000.0 | >=30.0% | Pass |
| | Target Mass (amu) | Observed Mass(amu) | Observed Deviation(amu) | Acceptable Deviation Range(amu) | Pass/Fail |
| Peak 1 | 356.15 | 356.32 | 0.17 | -0.35 to 0.35 | Pass |
| Peak 2 | 529.46 | 529.62 | 0.16 | -0.35 to 0.35 | Pass |
| | Target Peak Width | Observed Peak Width(amu) | Observed Deviation(amu) | Acceptable Deviation Range (amu) | Pass/Fail |
| Peak 1 | 0.7 | 0.61 | -0.09 | -0.3 to 0.3 | Pass |
| Peak 2 | 0.7 | 0.5 | -0.2 | -0.3 to 0.3 | Pass |

# The Phenomenome Clinical Analyzer Platform

KEY POINTS

## SYSTEM OPERATIONS OVERVIEW




## CUSTOMIZED GILSON® GX-271 LIQUID HANDLER

Optimized flow injection analysis system for mass spectrometry.

- ISO 13485:2003 certified
- Hard-coded methods
- Stable, synchronized flow rates
- 9 x 96 sample capacity
- Dual injectors
- Fixed loop injection volume

## MASS SPECTROMETRY: IONICS 3Q

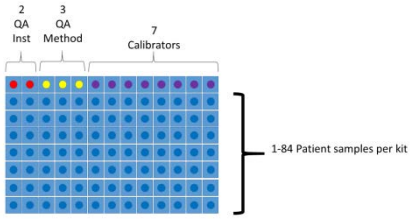
The Ionics 3Q Molecular Analyzer is a triple quadrupole mass spectrometer with high sensitivity, simple operation, and low maintenance.

- ISO 13485:2003 certified
- Dual source
- Hard-coded methods
- High signal sensitivity
- High signal stability
- Low maintenance
- Real-time quality monitoring

## INTEGRATED SOFTWARE

Analyzer software developed at PDI is used for work orders, run set up, and data analysis.

- ISO 13485:2003 certified
- Method-centric workflow design, minimal user inputs and training
- Inventory management
- Automated run list creation and monitoring
- Hard-wired methods
  - oRun list structure
  - oLC methods
  - oMS methods
  - oData processing
- Complete quality control tracking of all systems




Software automatically distributes QA and patient samples between calibrators

## PDI RISK ASSESSMENT TEST KITS

The Phenomenome clinical analyzer platform is intended to run PDI manufactured and certified test kits:

- Cologic® colorectal cancer test
- PanaSee™ pancreatic cancer test
- AlzID™ Alzheimer's disease test
- OvAware® ovarian cancer test (in production)

Cologic® Know your risk. PanaSee™ Know your risk. AlzID™ Take control. OvAware® Know your risk.

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