



CONFIDENTIAL

MultiGEN High
through put Test
Module for Clinical
Diagnosis

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Automated high through put system to process large number of clinical samples with highest accuracy with cost effectiveness. The system operates on number of proprietary technologies including that of MultiGEN Diagnostic Inc

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High Throughput Module (HTM)

for

DNA Diagnostics

A patented and automated platform in DNA Diagnostics that allows:

- Processing of a large number of clinical samples
- Highest accuracy using sequencing -- the 'Gold Standard' method of DNA identification
- Superior clinical utility
- Cost-effectiveness
- Substantial profitability

EXTRACTION
BULLET
NORDIAG

THERMOCYCLER
APPLIED
BIOSYSTEM

PCR CLEAN UP
BIOMEK 3000
BECKMAN- COULTER

HIGH THROUGHPUT MODULE

GENETIC ANALYZER
3100
APPLIED BIOSYSTEM

**CYCLE SEQUENCING
&
DYE CLEAN UP**
APOLLO 100
INTEGENX





Applications:

- **Infectious Disease Panels**
- **Genetic Susceptibility**
- **Pre-natal diagnostics using Maternal Blood**
- **Companion Diagnostics**
 - **Cancer chemotherapy**
 - **Anti-Viral therapy and prognosis**

MultiGEN: Getting it Right – Pricing it Right – Making it useful!

What is a MultiGEN High Throughput Module (HTM)?

All DNA based diagnostics have the following 3 steps:

1. DNA extraction
2. Target amplification
3. Target identification

An HTM is a set of five off-the-shelf instruments that function together to perform the above steps.

HTM incorporates a proprietary technology, MultiGEN, that allows the identification step to use the 'Gold Standard' method of Sanger sequencing technology to detect multiple targets (e.g. pathogens) simultaneously.

MultiGEN based tests are done in panels to cover all prelevant targets (pathogens, mutations) that are associated with the clinical syndrome.

What are the advantages of an HTM ?

- Superior accuracy (DNA sequencing)
- Verifiable results (electropherogram with nucleotide sequences)
- Cost-effectiveness (multiplexed -- simultaneous processing)
- High throughput (96 well format)
- Only 20% hands on time (2 hr out of total 8-10 hr)
- Same day reporting
- Easy consolidated result reporting



TEST PANELS (current* and planned)

Infectious Diseases

- **Antenatal*** STDs (Chlamydia, Gonorrhea, Group B Strep, Candida, Trichomonas, HSV 1 & 2.)
- **Vaginosis*** (G.vaginalis, C.albicans, M.hominis, U.urealyticum, B.fragilis)
- **Blood viral** (HIV1, HIV2, HepC, HepB)
- **Respiratory viral**
- **Diarrhoeal** (E. coli 0157:H7, L. monocotogenes, S. typhimurium. C. jejuni, Rotavirus)

Genetic Predisposition

- **Thrombophilia*** (Factor V, Factor II, Mthfr 0C677t and A1298C)
- **Warfarin Sensitivity*** Cyp2C9 (Alleles *2, *3,*4,*5,*6) and VKRCO1
- **Cystic fibrosis** (135 mutations)

Companion Diagnostics

- **Cancer therapy – predictors of resistance/sensitivity**
 - **Lung cancer** EGFR (Exon 18,19,20), K ras (codons 12, 13 & 61), EML4-ALK
 - **Co-rectal Cancer** K ras (codons 12,13 & 61), & BRAF
- **HIV resistance**
- **Hepatitis C genotyping**



COMMISSIONING an HTM

MultiGEN shall commission all the instrumentation, which requires three separate areas/rooms:

Area 1 DNA preparation -- Nordiag -- 7 ft bench space

Area 2 DNA amplification -- Thermocycling -- 2 ft bench space

Area 3 DNA clean-up and sequencing

- Biomek 3000 -- 6 ft bench space
- Apollo 100 -- 3 ft bench space
- Genetic analyzer -- 5 ft bench space



TRAINING AND VALIDATION

MultiGEN will do the following:

- Commission the various instruments with SOPs
- Set operational conditions for selected assays
- Train two technicians in the use of all the equipment
- Assist in the clinical validation of the selected assays
- Train in trouble shooting



TECHNICAL HELP and HOT LINE

An HTM agreement incorporates the following:

- Onsite instruction manual and SOPs
- 24 hour trouble shooting Hot Line
- On-site visits as agreed
- Back up help from respective manufacturers
- Temporary sample processing in San Diego if needed