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Forensic Technology Testing & Evaluation Report Form

Report Date: April 04, 2008

Project Information

Title: Genebench FX™-100

Evaluation Type: Instrumentation **Manufacturer:** Network Biosystems

Start Date: March 31, 2008 End Date: April 3, 2008

Evaluation Overview

During the demonstration of the Network Biosystems Genebench FXTM-100 microfluidics chip-based system for use in the separation and detection of STR DNA fragments, an evaluation of the portability, ruggedness, ease-of-use, and performance of the instrument was conducted, as well as an assessment of the reproducibility of the data produced by the system.

Evaluation Team

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Product Specifications

Brief Description: A portable CE device using glass microfluidic chips to separate DNA fragments, allowing for mobile genetic analysis.

Product Uses: Mobile applications include forensic applications, port authorities, airports, border security, immigration, mass disasters, and military intelligence.

Detection System Dimensions: 54cm x 74cm x 41cm [21.3" x 29.1" x 16.1"]

Weight: 53 kg (117 lbs)

Evaluation

Standards, Controls, and Samples Used in Evaluation

- Dilution series from 5ng to 0.036ng
- Mixture series to include the following major to minor ratios (10:90, 30:70, 50:50, 70:30, 90:10)
- Several NIST samples (NIST 9947A, NIST1, NIST2)
- Dilution series of 9947A prepared by Network Biosystems
- Allelic ladders

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· Amplification blanks

Synopsis of Experiment(s)

Day One

- 1. Instrument unpacked from shipping crates and set up; chips also prepared
- 2. Run #1 with allelic ladder and samples prepared by Network Biosystems
- 3. Run #2 with allelic ladder and complete dilution series and mixture series
- 4. Data Review

Day Two

- 1. Run #3 with allelic ladders and select samples including some from dilution series, some from mixture series, the NIST samples, and some prepared by Network Biosystems
- 2. Run #3b fast run failed due to chip
- 3. Data Review
- 4. Instrument moved to mobile laboratory
- 5. Instrument set up

Day Three

- 1. Presentation
- 2. Run #4 standard run in mobile laboratory same sample set as Run #3
- 3. Run #5 fast run in mobile laboratory same sample set as Run #3
- 4. Data review

Day Four

- 1. Presentation
- 2. Run #6 Matrix standards
- 3. Data Review
- 4. Instrument packed up in shipping crates

Findings

Strengths

- System set up time is less than 1 hour
- · Power supply requirements are standard
- Rugged design of instrument with shock mounts to help protect the optics
- Rugged design of computer



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- The heating system is enclosed and provides consistent performance generating precise separation from run to run; single base pair resolution close to baseline is achieved
- Baseline resolution
- Dynamic range of 9ng to 0.1ng
- Fast run (17min.) provides similar resolution as standard run (25min.)
- Maintains precision from run to run regardless of instrument location/room conditions due to limited temperature variation during runs (with precision specs = 0.15 bp average), therefore a ladder from previous runs can be used to size data
- Allele calls were concordant with 3130 XL data
- Fast module yields concurrent results (limited data during demonstration) in 17 minutes

Opportunities for Improvement

- It would be beneficial if the currently available glass chips were replaced with easier-to-use, less labor intensive, single-use, plastic disposable chips
- It would be beneficial to miniaturize the entire system, including the computer
- Software applications would benefit from creation of a translation software allowing analysis of data with Applied Biosystems' GeneMapper® ID software and improvement of Genemarker® software applications
- Improvements to matrix/color correction are necessary for multi-component analysis
- Placement of handles on the instrument box would increase ease of transportability

Recommendations

- Generate translation software that allows for integration of data into GeneMapper® ID software
- Modify Genemarker® software to enable stutter filters, improved color correction, minus A filters, and analysis of more samples at a time with less manual data manipulation
- Release instrument "as is", to replace CE for mobile applications
- Make plastic disposable/single use chips available as soon as possible
- Assist in identification of materials and instructions necessary for remote deployment of instrument
- For future technology, strongly recommend working with Applied Biosystems and Promega to allow for optimization of the commercially available kit loci from amplification through separation and detection
- While a fully integrated system will be beneficial for some applications, it may limit some forensic
 applications due to lack of option for sample handling between different steps of the DNA process