Performance Characterization of PTS Detect™ Cotinine, a Point-of-Care Device for the Rapid Quantitation of Cotinine from Whole Blood

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Biomarkers of Tobacco Use
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Paper Session 20
Saturday, March 5, 2016
8:54 AM
Tobacco Use Testing

- Wellness Programs
- Employment Decisions
- Insurance
- Cessation Programs
- Current Methods
  - Urine
  - Saliva
  - Breath
  - Self-Reporting
## Biomarkers for Tobacco Use

**Cotinine**

![Cotinine structure](image)

<table>
<thead>
<tr>
<th>Markers</th>
<th>Matrices Analyzed</th>
<th>Half-Life (min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbon monoxide</td>
<td>Breath, plasma</td>
<td>60-180</td>
</tr>
<tr>
<td>Nicotine</td>
<td>Plasma/serum, urine, saliva, others</td>
<td>100-150</td>
</tr>
<tr>
<td>Cotinine</td>
<td>Plasma/serum, urine, saliva, others</td>
<td>770-1130</td>
</tr>
<tr>
<td>Anabasine</td>
<td>Urine</td>
<td>960</td>
</tr>
<tr>
<td>Anatabine</td>
<td>Urine</td>
<td>600</td>
</tr>
<tr>
<td>Myosmine</td>
<td>Toenail, plasma, saliva</td>
<td>Not investigated in humans</td>
</tr>
</tbody>
</table>

### Smokers (Cigarettes/day) vs. Plasma Cotinine (ng/ml)

<table>
<thead>
<tr>
<th>Smokers (Cigarettes/day)</th>
<th>Plasma Cotinine (ng/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-4</td>
<td>84.5</td>
</tr>
<tr>
<td>5-9</td>
<td>167.2</td>
</tr>
<tr>
<td>10-14</td>
<td>236.8</td>
</tr>
<tr>
<td>15-19</td>
<td>255.3</td>
</tr>
<tr>
<td>20-24</td>
<td>310.3</td>
</tr>
<tr>
<td>&gt;25</td>
<td>321.3</td>
</tr>
</tbody>
</table>

### Nicotine Replacement Therapy vs. Plasma Cotinine Concentration (ng/mL)

<table>
<thead>
<tr>
<th>Nicotine Replacement Therapy</th>
<th>Plasma Cotinine Concentration (ng/mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal Spray</td>
<td>5-15</td>
</tr>
<tr>
<td>Gum</td>
<td>6-17</td>
</tr>
<tr>
<td>Inhaler</td>
<td>8</td>
</tr>
<tr>
<td>Lozenge</td>
<td>3.2-10.8</td>
</tr>
<tr>
<td>Patch</td>
<td>11-21</td>
</tr>
</tbody>
</table>

**References**


Competitive Immunoassay Format

Cotinine Strip Before Assay Run

- Cotinine–protein conjugate
- Cotinine antibody particle zone

Cotinine Strip After Assay Run

- Cotinine–protein with bound antibody particles
- Cotinine antibody particle zone

Membranes

- Sprocket Hole
- End Pad
- Nylon
- Nitrocellulose
- Conjugate membrane

Detection Zones

- Test Zone – conjugate stripe
- Ab-Latex conjugate stripe
Competitive Immunoassay Format

Cotinine Strip Before Assay Run

Cotinine–protein conjugate
Cotinine antibody particle zone

Cotinine Strip After Assay Run

Cotinine–protein with bound antibody particles
Cotinine antibody particle zone

Cotinine Dose Response Curve

Reflectance (A.U.)

Cotinine Concentration (ng/mL)
System Design

Monitor

Test Cartridge

Sample Collection System
Test Cartridge Design

- Cartridge Top
- Sample Pad
- Absorbant Pad
- Cartridge Bottom
- Strips
- Zinc Auto Start
- Copper Auto Start

Test Strips
Blood Separation (Top)
Wicking Layer (bottom)
Analytical Performance

Linearity

Total Precision

<table>
<thead>
<tr>
<th>Average Concentration (ng/mL)</th>
<th>SD</th>
<th>CV (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>58.8</td>
<td>2.04</td>
<td>3.47</td>
</tr>
<tr>
<td>129.2</td>
<td>3.26</td>
<td>2.53</td>
</tr>
</tbody>
</table>

Sites

Days

Replicates

- Linear Fit
- Polynomial Fit Degree = 2
- Polynomial Fit Degree = 3
Venous Blood Method Comparison

Capillary vs Venous

<table>
<thead>
<tr>
<th></th>
<th>Venous vs Reference</th>
<th>Venous vs Capillary</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>98</td>
<td>32</td>
</tr>
<tr>
<td>Slope</td>
<td>1.04</td>
<td>1.00</td>
</tr>
<tr>
<td>y-Intercept</td>
<td>7.01</td>
<td>1.99</td>
</tr>
<tr>
<td>“r”</td>
<td>0.90</td>
<td>0.98</td>
</tr>
</tbody>
</table>
Clinical Analysis

Nicotine Use Placement

- **>200 ng/mL** (Heavy Tobacco User): 22
- **41–199 ng/mL** (Light Tobacco User): 19
- **25–40 ng/mL** (Passive Exposure): 4
- **<30 ng/mL** (Non-Tobacco User): 4 (Device provides only a preliminary analytical test result)
- **<25 ng/mL** (Non-Tobacco User): 3

*PTS Detect Cotinine System* | *LC/MS-MS* | *Alere iScreen® OFD*
Summary

• Whole-blood quantitative cotinine test
• Point-of-care
• Equivalent to clinical lab results
• Results in 5 minutes
Acknowledgments

Development Team

- Charles Xie
- Lee Springer
- Pauline Shinkawa
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- Employee of PTS Diagnostics
Questions