<table>
<thead>
<tr>
<th>Name of company</th>
<th>Copan Diagnostics Inc</th>
<th>Copan Diagnostics Inc</th>
<th>Diagnostic Hybrids</th>
<th>Idaho Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact information</td>
<td>Gabriela Powers</td>
<td>Gabriela Powers</td>
<td>Christina Dierkes</td>
<td>Wade Stevenson</td>
</tr>
<tr>
<td></td>
<td>gabriela.powers@</td>
<td>gabriela.powers@</td>
<td><a href="mailto:christina_dierkes@dhiusa.com">christina_dierkes@dhiusa.com</a></td>
<td><a href="mailto:wade_stevenson@idahotech.com">wade_stevenson@idahotech.com</a></td>
</tr>
<tr>
<td></td>
<td>copanusa.net</td>
<td>copanusa.net</td>
<td>(740) 589-3300</td>
<td>(801) 736-6354</td>
</tr>
<tr>
<td></td>
<td>(800) 216-4016</td>
<td>(800) 216-4016</td>
<td><a href="http://www.dhiusa.com">www.dhiusa.com</a></td>
<td><a href="http://www.idahotech.com">www.idahotech.com</a></td>
</tr>
</tbody>
</table>

1) **What is the name of your company’s respiratory virus assay product or product line?**

- **Copan Flocked Swabs**

2) **Which pathogen(s) does this product detect?**

- **It is based on lateral flow, PCR, direct immunofluorescence, and viral cell culture.**

3) **What type of technology is this product based on? (PCR, lateral flow, etc)**

- **It is based on lateral flow, direct immunofluorescence, PCR, and viral cell culture.**

4) **Specimen type:**

- **Nasopharyngeal and nasal swabs**

5) **FDA approval (year or status):**

- **N/A**

6) **Length of test cycle:**

- **N/A**

7) **Sensitivity:**

- **N/A**

8) **Specificity:**

- **N/A**

9) **What differentiates this product from others on the market?**

- **Improves specimen collection and release; reduces ONS rejection; improves assay sensitivity; easy to use and patient friendly; performance comparable to washes and aspirates.**

- **Room-temperature stable for 18 months; Specimens can be shipped at RT or at 4°C and maintain their viability for 48 hours; maintains wide spectrum of viruses, chlamydia, mycoplasma.**

- **The only seven-virus DFA kit to go through the FDA 510(k) clearance process. The rapid culture system reduces time to detection. High reported user satisfaction, no back-orders since launch in 2003.**

- **User-friendliness. Five minutes of hands-on time. In 60 minutes the instrument extracts and purifies nucleic acids, performs a massive multiplex PCR, and reports the results for 21 respiratory targets.**
### Luminex Corp
- **Amy Tucker**
  - **Contact:** atucker@luminexcorp.com
  - **Phone:** (512) 219-8020
  - [www.luminexcorp.com](http://www.luminexcorp.com)
- **The Plus Series**
  - **Influenza A and B**, **RSV**
  - **Legionella**, **Strep A**, **Parainfluenza 1, 2, 3**, **Adenovirus**, **Metapneumovirus**, **Rhinovirus**

### Prodesse
- **Andy Shrago**
  - **Contact:** ashrago@prodesse.com
  - **Phone:** (262) 446-0700
  - [www.prodesse.com](http://www.prodesse.com)
- **ProFlu+** for influenza A and B; **ProFlu-ST** for subtyping; **ProParflu+** for parainfluenza 1, 2, 3; **ProAdeno+** for adenovirus;
- **ProFlu+** for influenza A and B; **ProAdeno+** for adenovirus;

### Quidel Corp
- **Drew Hoffman**
  - **Contact:** dhoffman@quidel.com
  - **Phone:** (858) 752-7932
  - [www.quidel.com](http://www.quidel.com)
- **QuickVue Influenza A+B test**
  - **Influenza A and B**
  - **RSV A and B**
  - **Legionella**

### Inverness Medical
- **Amy Tucker**
  - **Contact:** atucker@inmed.com
  - **Phone:** (877) 546-8633
  - [www.invernessmedical.com](http://www.invernessmedical.com)
- **Legionella and Strep A**, **BinaxNOW® RSV**, **BinaxNOW® influenza A & B**, **BinaxNOW®**
- **BinaxNOW**: Strep A, Strep B, Legionella.

### Tests for Influenza A & B, RSV, and Legionella are all 15 minutes to results. The test for Strep A is 5 minutes to results.
- **ProFlu+** cleared January 2008; **ProFlu-ST** to be submitted for EUA September 2009; **Pro hMPV+** cleared November 2008; **ProParflu+** to be submitted for 510(k) in Q2 2010

### Luminex xMAP and xTAG Technologies, PCR
- **All real-time PCR, some products are multiplex real-time PCR**
  - **Lateral-flow immunoassay using highly sensitive monoclonal antibodies specific for influenza antigens.**
  - **Lateral-flow immunoassay using highly sensitive monoclonal antibodies specific for influenza antigens.**

### A nasopharyngeal swab, nasal swab, or nasal wash/aspirate
- **Nasopharyngeal swab**
- **Nasopharyngeal swab**
- **Nasal swab, nasopharyngeal swab, nasal wash, or nasal aspirate samples**
  - **Nasal swab, nasal wash or nasal aspirate samples**

### All BinaxNOW respiratory kits are FDA approved.
- **510(k) clearance in January 2008**
  - **Yes, September 2003**
  - **Yes, September 1999**

### Tests for influenza A & B, RSV, Streptococcus pneumoniae, and Legionella are all 15 minutes to results. The test for Strep A is 5 minutes to results.
- **Approximately 6 hours**
  - **Ranges from 2 to 4 hours**
  - **The test can be completed within 10 minutes of initiation of procedure provided in the package insert.**
  - **The test can be completed within 10 minutes of initiation of procedure provided in the package insert.**

### Ten to 12 viruses and subtypes. Quick, precise, and comprehensive.
- **RT-PCR tests for respiratory viruses. Once cleared, the other assays will be the first and only FDA-cleared real-time PCR tests for respiratory virus.**
  - **Differentiated results for type A and type B from one test; two-color result within 10 minutes from three-step procedure; room-temperature storage and 24-month dating; built-in internal control; and kit includes external controls.**

### Fast, accurate, simultaneous detection of 12 respiratory viruses and subtypes. Quick, precise, and comprehensive.
- **ProFlu+ and Pro hMPV are the only FDA-cleared real-time RT-PCR tests for respiratory viruses.**
- **Two-color result within 10 minutes from three-step procedure; room-temperature storage and 24-month dating; built-in internal control; and kit includes external controls.**
# Respiratory Viruses Survey’09

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<th>5) FDA approval (year or status):</th>
<th>6) Length of test cycle:</th>
<th>7) Sensitivity:</th>
<th>8) Specificity:</th>
<th>9) What differentiates this product from others on the market?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seegene Inc</td>
<td>Hyunsoo Kim, PhD; <a href="mailto:hskim@seegene.com">hskim@seegene.com</a> (301) 762 9066 <a href="http://www.seegene.com">www.seegene.com</a></td>
<td>Seeplex® Flu A ACE Subtyping</td>
<td>influenza A; human influenza A-H1; human influenza A-H3; swine influenza A-H1; avian influenza A-H5</td>
<td>Multiplex Reverse Transcription Polymerase Chain Reaction (mRT-PCR)</td>
<td>Nasopharyngeal aspirates, nasopharyngeal washes, nasal aspirates, and bronchoalveolar lavages</td>
<td>Not yet</td>
<td>Typically 6 hours</td>
<td>PCR amplifications were observed at 10 to 100 copies per reaction. The detection limits of single-targeted RT-PCR and multiplex RT-PCR were the same.</td>
<td>The specificity of the Seeplex® Flu A ACE Subtyping was evaluated by cross-reaction tests with RNA extracted from other subtypes of influenza A viruses. No cross-reactivity with other subtypes of influenza A viruses.</td>
<td>One assay, five results; detection of influenza A; influenza A subtype seasonal H1, H3, H5; and swine influenza A subtype H1. Offer guideline for antiviral drug swine H1, seasonal H3 and H5: Oseltamivir, Zanamivir seasonal H1: Amantadine, Rimantidine.</td>
</tr>
<tr>
<td>Seegene Inc</td>
<td>Hyunsoo Kim, PhD; <a href="mailto:hskim@seegene.com">hskim@seegene.com</a> (301) 762 9066 <a href="http://www.seegene.com">www.seegene.com</a></td>
<td>Seeplex RV5 ACE Screening</td>
<td>adenovirus; influenza A virus; influenza B virus; respiratory syncytial virus; respiratory syncytial virus A; respiratory syncytial virus B; metapneumovirus; parainfluenza virus 1, 2, 3; rhinovirus A/B; coronavirus 229E/ NL63; coronavirus OC43/HKU1, bocavirus</td>
<td>Multiplex Reverse Transcription Polymerase Chain Reaction (mRT-PCR)</td>
<td>Nasopharyngeal aspirates, nasopharyngeal washes, nasal aspirates, and bronchoalveolar lavages</td>
<td>Not yet</td>
<td>Generally 6 hours</td>
<td>PCR amplifications were observed at 10 to 100 copies per reaction. The detection limits of single-targeted PCR and multiplex PCR were the same.</td>
<td>The analytical sensitivity of the multiplex RT-PCR was tested using serial dilutions of plasmid DNA from the ATCC strains. PCR amplifications were observed at 10 to 100 copies per reaction. The detection limits of single-targeted PCR and multiplex PCR were the same.</td>
<td>Rapid identification (flu A, flu B, RSV A/B) and screening (adv A/B/CD/E, PV 1/2/3, Bov, MPV, HRV A/B, CoV 229E/NL63/OC43/HKU1) of most prevalent respiratory viruses.</td>
</tr>
<tr>
<td>Seegene Inc</td>
<td>Hyunsoo Kim, PhD; <a href="mailto:hskim@seegene.com">hskim@seegene.com</a> (301) 762 9066 <a href="http://www.seegene.com">www.seegene.com</a></td>
<td>Seeplex RV12 ACE Detection</td>
<td>adenovirus; influenza A virus; influenza B virus; respiratory syncytial virus A; respiratory syncytial virus B; metapneumovirus; parainfluenza virus 1, 2, 3; rhinovirus A/B; coronavirus 229E/NL63; coronavirus OC43/HKU1</td>
<td>Reverse Transcription Polymerase Chain Reaction (mRT-PCR)</td>
<td>Nasopharyngeal aspirates, nasal washes and aspirates, nasopharyngeal swabs, and throat washings/swabs</td>
<td>Not yet, but approved CE mark (September 2007) and Health Canada (November 2008)</td>
<td>Time required to complete the assay (from viral nucleic acid isolation to data analysis) is 6 hours.</td>
<td>The analytical sensitivity of the multiplex RT-PCR was tested using serial dilutions of plasmid DNA from the ATCC strains. PCR amplifications were observed at 10 to 100 copies per reaction. The detection limits of single-targeted PCR and multiplex PCR were the same.</td>
<td>The multiplex PCR identified each respiratory viral clone was used. The multiplex PCR identified each specific respiratory virus. No cross-reactivity with other respiratory viruses or bacteria was observed.</td>
<td>See package insert</td>
</tr>
<tr>
<td>Trinity Biotech</td>
<td>Ron Cruver; <a href="mailto:ron.cruver@trinityusa.com">ron.cruver@trinityusa.com</a> (800) 325-3424 <a href="http://www.trinitybiotech.com">www.trinitybiotech.com</a></td>
<td>Bartels Viral Respiratory Screening and Identification Kit</td>
<td>adenovirus; influenza A &amp; B; parainfluenza type 1, 2, 3; respiratory syncytial virus</td>
<td>IFA</td>
<td>Nasopharyngeal aspirates, nasal washes and aspirates, nasopharyngeal swabs, and throat washings/swabs</td>
<td>Yes</td>
<td>2 x 30 minutes</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**Contact information**

Seegene Inc

Hyunsoo Kim, PhD; hskim@seegene.com

(301) 762 9066

www.seegene.com

Seeplex® Flu A ACE Subtyping

Seeplex RV5 ACE Screening

Seeplex RV12 ACE Detection

Trinity Biotech

Ron Cruver; ron.cruver@trinityusa.com

(800) 325-3424

www.trinitybiotech.com

Bartels Viral Respiratory Screening and Identification Kit

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**Vendor Data**

- **Directigen** is a trademark of Becton, Dickinson and Co.

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**References**


4. Now ProFlu + is making news of its own…

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**Vendor Information**

- **Seegene Inc**
  - Web: www.seegene.com
  - Phone: (301) 762 9066

- **Trinity Biotech**
  - Web: www.trinitybiotech.com
  - Phone: (800) 325-3424