RAPID SERODIAGNOSTICS PLATFORM FOR PoC

Invention: Molecular biology assays to accurately and quickly measure immunoglobulins from serum
Indications: Infectious diseases, autoimmune diseases, allergy
Unmet need: Reliable and rapid serodiagnostics in Point-of-Care are lacking
Project status: Proof-of-concept for Puumala Virus, Zika Virus and Coeliac Disease

Novel molecular tools for rapid infectious disease diagnostics are constantly under development to reduce the time between onset of symptoms and diagnosis. Not only is it important to receive appropriate treatment, but also to avoid unnecessary use of antibiotics. The availability of rapid diagnostics is also important when epidemics or pandemics emerge. Although rapid, current point-of-care (POC) tests offer suboptimal sensitivity and specificity. We have applied a novel patented invention to develop immunoassays with sensitivity and specificity rates approaching those of conventional reference tests. Our invention is applicable not only in infectious disease diagnosis, but also in diagnosis of autoimmune diseases and allergies - basically in any disease that can be serodiagnosed. The first applications of our invention are for autoimmune (coeliac disease) and infectious diseases (Zika virus and hantavirus infection).

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Versatile platform to address the needs in diagnosis of various disease classes: infectious diseases, autoimmune diseases and allergy

L-FRET Technology

Zika Virus (IgM) detection performance

<table>
<thead>
<tr>
<th></th>
<th>Zika positive</th>
<th>Zika negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test positive</td>
<td>23</td>
<td>3</td>
</tr>
<tr>
<td>Test negative</td>
<td>0</td>
<td>99</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>100 %</td>
<td>97 %</td>
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Protein L binds all antibody classes (IgG, IgM, IgA, IgE, and IgD), via the light chain

Patents
Patents pending for the protein L FRET assay, and for competitive inhibition FRET assay tailored for IgG detection. PCT/FI2015/050117 and PCT/FI2017/5807

Key Publication
Hepojoki, S. et al., 2015. Rapid homogeneous immunoassay based on time-resolved Förster resonance energy transfer for serodiagnosis of acute hantavirus infection. G. A. Land, ed. Journal of clinical microbiology,

✓ Simple and robust diagnostic assays with competitive cost structure
✓ Turnaround time in less than 10 min
✓ Suitable for point-of-care diagnostics

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