HO.p.e. (Hormonal profile evaluation) is a spin-off of the University of Milan, which is developing an innovative kit to differentially evaluate the secretion of the principal isoforms of Growth Hormone (GH) and related molecules.

Our aim is that of providing clinicians and researchers with a new and reliable tool for applications in the field of endocrine diagnostics, hormone abuse (anti-doping) and basic research in biomedicine.
Management

President: Eugenio Müller

Chief Executive Officer: Maria Luisa Nolli

Chief Financial Officer: Federica Nolli

Chief Scientific Officer: Silvano Cella

Chief Operations Officer: Antonello Rigamonti
Partners

Founded in MARCH 2007 HO.p.e is a spin off of the University of Milan

A group of scientists of the Department of Medical Pharmacology of the State University of Milan, always involved in studies on the nervous control of the somatotropic function

areta international is a biotech company dedicated to the contract development and manufacturing of innovative biological drugs and advanced therapy medicinal products.

Clinical institutions will support HO.p.e.’s activity in the selection and collection of human blood samples and in the development of a plasma bank
HO.p.e. is located inside the Insubrias Biopark in Gerenzano where the Research division of areta international has a consolidated experience in the generation of monoclonal antibodies and in the setup and validation of diagnostic kits.
No methods endowed with a sufficient sensitivity and specificity to detect the exogenous administration of human growth hormone (hGH) are currently available.

- hGH abuse is difficult to detect because of its short half-life in blood.

- hGH inappropriately administered is identical to the one endogenously produced, so that the common assay methods cannot discriminate the endogenous from exogenous component.

For antidoping purposes, it is inappropriate to rely on a single determination of hGH plasma levels.
Il Kit

Un kit universale è in grado di:

- dosare contemporaneamente, nello stesso campione ematico, diversi marcatori biologici
- permettere una valutazione completa della funzione somatotropica
- ridurre tempi e costi
Il Kit - caratteristiche

- Originale
- Affidabile
- Semplice
- Economico
Detection of improper use of exogenous hGH, also many days or months from its delivery (anti-doping action).

Evaluation of the hGH at rest or during physical training and/or agonistic performances in elite or amatorial athletes. This information would permit to build-up an individual endocrinological passport that could follow an athlete during his/her agonistic life to constantly monitor health or physical impairments.
Kit use - biomedical

- More appropriate assessment of many forms of GH deficiency in children and adults and monitoring of hGH replacement therapy

- Diagnostic and prognostic assessment of many neoplastic diseases (breast, prostate and ovary tumors) or of serious functional or organic impairments (eating disorders, cachexia, age- or neoplastic-related diseases, etc.)
Areas of applications

- Risk Assessment: Predisposition for developing disease
- Screening/Diagnosis: Early detection
- Prognostic: Predict probable disease course
- Predictive: Predict likely response to a drug
- Monitoring: Monitor efficacy/recurrence

Patient Stratification / Therapy Selection

Therapy adaptation
## Target population

<table>
<thead>
<tr>
<th>country</th>
<th>total population</th>
<th>GH deficiency 1:4000</th>
<th>Turner syndr. 1:5000</th>
<th>Prader Willi 1:25000</th>
<th>Acromegaly 1:8000</th>
</tr>
</thead>
<tbody>
<tr>
<td>US</td>
<td>310,265,000</td>
<td>77.566</td>
<td>62.053</td>
<td>12.411</td>
<td>38.783</td>
</tr>
<tr>
<td>Germany</td>
<td>81,802,257</td>
<td>20.451</td>
<td>16.360</td>
<td>3.272</td>
<td>10.225</td>
</tr>
<tr>
<td>France</td>
<td>65,447,374</td>
<td>16.362</td>
<td>13.089</td>
<td>2.618</td>
<td>8.181</td>
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<tr>
<td>UK</td>
<td>62,008,049</td>
<td>15.502</td>
<td>12.402</td>
<td>2.480</td>
<td>7.751</td>
</tr>
<tr>
<td>Italy</td>
<td>60,402,499</td>
<td>15.101</td>
<td>12.080</td>
<td>2.416</td>
<td>7.550</td>
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<td>Spain</td>
<td>46,072,834</td>
<td>11.518</td>
<td>9.215</td>
<td>1.843</td>
<td>5.759</td>
</tr>
<tr>
<td>Japan</td>
<td>127,390,000</td>
<td>31.848</td>
<td>25.478</td>
<td>5.096</td>
<td>15.924</td>
</tr>
<tr>
<td>Total</td>
<td>188,347</td>
<td>150,678</td>
<td>30,136</td>
<td>94,174</td>
<td></td>
</tr>
</tbody>
</table>
Results

New monoclonal antibodies developed by HOpe:

<table>
<thead>
<tr>
<th>ANTIGEN</th>
<th>AVAILABLE CLONES</th>
</tr>
</thead>
<tbody>
<tr>
<td>GH 20 kDa and 22 kDa</td>
<td>1C6/F9, 11E4/C4, 15G5/E11, 1E9/D6</td>
</tr>
<tr>
<td>GH 22 kDa</td>
<td>11D7/C9, 19A2/H1, 25B4/A5</td>
</tr>
<tr>
<td>IGF-I</td>
<td>3C6/G7, 9G11/A7</td>
</tr>
<tr>
<td>osteocalcin</td>
<td>21F6/H3, 24A11/H7</td>
</tr>
</tbody>
</table>

Lack of cross-reactivity against proteins of the same group (LH, placental lactogen, FSH, TSH and prolactin)

Applications tested: ELISA, Western blot
Combining the available antibodies it is possible to develop a matrix with specific pairs for total GH (20 and 22 kDa) and for 22 kDa GH. These kits can measure directly or indirectly the levels of each substance in plasma or serum.

The kits can therefore provide:

- Measure of 22 kDa GH isoform levels
- Measure of total GH (20 + 22 kDa)
Results

Measure of GH 22 kDa

A sandwich ELISA have been developed for the quantification of 22 kDa GH.

- capture: 25B4/A5 (anti-GH 22kDa)
- detection: 15G5/E11 biotinylated (anti-GH 20/22kDa)

The kit has been validated with biological samples for: Accuracy, Recovery, Repeatability, Intermediate precision, Specificity, Detection limit (LOD), Quantitation limit (LOQ), Linearity, Range
Results

Measure of total GH (20 + 22 kDa)

A competitive ELISA has been developed for the measure of total GH. A single antibody (clone 12E5/E1) have been used as coating, while using biotinylated GH during the detection phase.

Currently under validation
Spin-off dell'Università di Milano

speranze

successi

Licensing-out del kit

Diagnostica

Doping

Raggiungimento degli obiettivi proposti all'inizio del progetto

Spin-off dell'Università di Milano speranze e successi 29 Novembre 2011