Euro Diagnostica
Malmö, Sweden
Euro Diagnostica – in brief

• Founded in 1992
• Family owned by Mr Frederik Paulsen (1)
• Part of Ferring group of companies
  – Ferring Pharmaceuticals (mid-size pharmaceutical company) (2)
  – Nordic Pharma Group (3)
  – PolyPeptide Group (supplier of peptides to pharmaceutical industry) (4)
  – Euro Diagnostica AB
• About 120 employees in Euro Diagnostica worldwide
• Head office in Malmo, Sweden; iLite® R&D in Paris, France
• Traditionally, focus has been on auto-immune clinical diagnostics
• Increased focus on assays and services to pharmaceutical industry

2) http://ferring.com/en/home/
3) http://www.nordicpharmagroup.com/
4) http://www.polypeptide.com/
**Business Units**

**Diagnostic Solutions**
ELISA and RIA kits  
Custom manufacturing, OEM

**Biopharma Solutions**
Cell-based assays and development services

**Laboratory Services**
Diagnostic & bioanalytical services

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Euro Diagnostica branded diagnostic IVD kits:  
We provide a portfolio of ELISA and RIA kits for various autoimmune diseases and treatment monitoring.

Custom manufacturing:  
- Top quality plate coating services.  
- Antigen production  
- Product & production development services.

OEM:  
- Collaboration with several market leaders.

Our cell-based *iLite®* assays:  
- Provide tools for monitoring and development of biological drugs.  
- Are used in customized assays for optimal drug development.

Wieslab offers:  
- Clinical testing within diagnosis, prognosis and monitoring.  
- Bioanalytical services for non clinical and clinical studies (CRO).  
- GLP and ISO 17025 certified environment.
Cell-based assays
Euro Diagnostica merged with Biomonitor in July 2014

• Biomonitor was founded in Copenhagen in 2003. Biomonitor’s unique iLite® cell-based reporter gene technology developed by Dr. Michael Tovey.

• iLite® is a unique reporter gene platform with the ability to measure both drug activity and NABs in biological drugs across a wide range of targets.

• iLite® reporter gene cell lines developed for >10 of the world’s 20 biggest pharmaceutical companies

• iLite® assay ready cells currently used by >50 customers worldwide, mainly US and Europe

• Have been used in a number of FDA and EMA submissions

• TNFα was first cell line to be developed. TNFα cell line used to set Enbrel WHO standard\(^\text{(1)}\)

• TNFα cell line used extensively in clinical monitoring of patients in USA\(^\text{(2,3)}\)

**iLite® Cell-Based Assays**  
**Off-the-shelf Products**

<table>
<thead>
<tr>
<th>Product Name</th>
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<tr>
<td><strong>iLite®</strong> TNF-alpha Assay Ready Cells</td>
<td>BM3044</td>
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**New iLite® Products - Coming Soon!**  

<table>
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iLite® Cell-Based Reporter Gene Assays
Overview and applications
**iLite® Cell-Based Assays**

**Offering & Profile**

Euro Diagnostica offers the *iLite* reporter gene technology, in the form of assay ready frozen cells (off-the-shelf products) and as custom cell line development.

Our *iLite* platform is based on reporter gene technology and used in custom made cell-lines for assessment of drug potency and for detection of neutralizing antibodies (NAbs).

Through its specificity for the drug target and a rapid test format, *iLite* cell-lines are valuable during the whole drug development continuum and facilitate the development of new drugs.
**iLite® Cell-Based Assays**

Applications

Examples of use of available *iLite* cell lines:

- Functional assessment of a drug (e.g. **potency** determination during manufacturing)

- **Screening** for a drug candidate, with a specific functional target

- Comparison between an innovator drug and a **biosimilar**

- Determination of neutralizing antibodies in **immunogenicity** assessment
Potency assessment

The FDA and EMA recommend bioassays for potency assessment during development/manufacture of biologicals:

“Ideally, the potency assay will represent the product's mechanism of action (i.e., relevant therapeutic activity or intended biological effect)” (1)

“Bioassays can include in vivo animal studies, in vitro organ, tissue or cell culture systems, or any combination of these. You may use in vitro or in vivo assays; however, we encourage the responsible limitation of animal use whenever possible” (1)

“For antibodies for which the clinical activity is only dependent on binding/neutralising properties, a potency assay that measures binding to the target (i.e. binding assay) may be deemed acceptable, if appropriately justified. Where effector functions are relevant for clinical activity, a cell-based bioassay or another assay that takes effector functions into account should be performed” (2)

References:
Immunogenicity assessment

Both FDA and EMA recommend bioassays for immunogenicity assessment during development of biologicals:

“Generally FDA considers that bioassays are more reflective (than competitive ligand-binding assays) of the in vivo situation and are recommended” (1)

“FDA recommends that neutralization assays use a cell-based bioassay format depending on the therapeutic protein product’s mechanism of action because, frequently, cell-based bioassays more closely reflect the in vivo situation and therefore provide more relevant information than ligand-binding assays.” (2)

“For most biological products, the most appropriate neutralizing antibody assay is a bioassay which measures the neutralization of the bioactivity” (3)

References:
iLite® Cell-Based Reporter Gene Assays Technology
**iLite® Cell-Based Assays**

Reporter gene technology
Limitations of Conventional Cell Based Assays* ... and the *iLite®* Solution

The *iLite* technology is based on a reporter gene assay format, designed to overcome limitations of conventional cell based assays.

<table>
<thead>
<tr>
<th>Limitation of Conventional Assays</th>
<th><em>iLite™</em> Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject to variation due to changes associated with continuous cultivation of cells in vitro</td>
<td>Available as Assay Ready Frozen cells; <strong>no cell culturing</strong> needed</td>
</tr>
<tr>
<td>Low degree of selectivity</td>
<td><strong>Highly specific</strong>, receptor selective signal</td>
</tr>
<tr>
<td>Subject to non-specific interference including serum matrix effects</td>
<td><strong>Normalization</strong> of cell counts and serum matrix effects by a second reporter gene</td>
</tr>
<tr>
<td>Take several days to complete</td>
<td>Results <strong>within one workday</strong></td>
</tr>
<tr>
<td>Based on complex biological endpoints that are difficult to quantify with precision</td>
<td>Endpoint is light emission easily quantified with a standard luminometer</td>
</tr>
</tbody>
</table>

*Conventional cell-based assays includes proliferation and stimulation assays etc.*
**iLite® Cell-Based Assays Technology**

The special features of the patented *iLite™* technology are:

- **Highly specific** reporter gene cell lines
- **Very sensitive** cell line responses (>10 fold inductions)
- Assay Ready Cells – **ready-to-use** from the freezer, without culturing of cells
- Assays **within a workday** (typically 4-7 hour assays)
- **Normalization** gene, which eliminates unwanted matrix effects
iLite® Cell-Based Assays
Pathway Specific

iLite™ VEGF Assay Ready Cells
Detection of Drug Activity
Exemplified by TNF-alpha Assay Ready Cells

NO DRUG
High Luminescence

HIGH DRUG
No Luminescence

Reporter cell
TNF-α receptor
TNF-α
Drug
Neutralising antibodies

Cell membrane
TNF-α receptor
TNF-α responsive
transducer
Constitutive
transducer
REPORTER CELL
Detection of Drug activity or NAbs in Serum
Exemplified by TNF-alpha Assay Ready Cells

The graphical elements on this page originate from ARUP Laboratories and are used with their permission.
Assay Read-Out
Response curves as exemplified by TNF-α Assay Ready Cells

• Cells treated with:
  – TNF-α
  – TNF-α and TNF-α inhibitor (measure drug activity)
  – TNF-α and TNF-α inhibitor in the presence of NAbs (detection of Nabs)
iLite® Cell-Based Reporter Gene Assays
Performance Data
**iLite® Normalization**

Results are independent of cell number

---

**Without normalization**

![Graph showing RLU vs. TNF without normalization](image1)

**With normalization**

![Graph showing RLU/RU vs. TNF with normalization](image2)

*Adapted from Lallemand et al. (2011) Journal of Immunological Methods*
**iLite® Normalization**
Eliminates Serum Matrix Effects

Adapted from Lallemand et al. (2011) Journal of Immunological Methods
Specificity and Sensitivity

TNF-alpha Reporter Gene Assay: Induction Specificity

Adapted from Lallemand et al. (2011) Journal of Immunological Methods
Batch Reproducibility

Assay-Ready Frozen Insulin-Responsive *iL*ite™ Cells

<table>
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<tr>
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<th>SF1005</th>
<th>SF1005</th>
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<td>182400</td>
<td>183435</td>
<td>179374</td>
<td>199723</td>
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</table>
Structure of TNF blockers

Monoclonal antibodies

- Mix between murine and human IgG sequences

Chimeric proteins

- Antibody binding regions from human/mouse IgG linked to PEG

- Human TNFR2 linked to Fcγ1 from IgG

Remicade® infliximab
Humira® adalimumab
Simponi® golimumab
Cimzia® certolizumab pegol
Enbrel® etanercept

Remicade®, Humira®, Simponi®, Cimzia®, Enbrel®
**iLite® - A Single Assay to Measure Structurally Diverse Drugs**

![Graph showing the effect of different TNFα antagonists on % activity](chart.png)
Ease of Use
Sophisticated but Simple to Perform

• **No cell culturing** - *iLite*® Assay Ready Cells do not require culturing, are used directly from the freezer

• All assays are run in **standard 96 well format**

• **As easy as running an ELISA** but no washing steps

• All assays can be performed within **one workday**
Simple Assay Procedures

- **Pre-incubation**
  - Dilute samples (and mix with target)
  - Incubate (37°C, 5% CO₂) – **30 min**

- **Addition of cells**
  - Thaw, dilute and add cells
  - Incubate (37°C, 5% CO₂) – **3-7h**

- **Develop light reaction**
  - Add substrate
  - Incubate (RT) – **10 min**

- **Read plate**
  - Read plate in a luminometer

*Graph showing relative light units vs. Log anti-VEGF (final conc. ng/ml)*

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iLite cell
iLite® Cell-Based Reporter Gene Assays
Product details
### iLite® Cell-Based Assays

**Off-the-shelf Products**

<table>
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<tbody>
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<tr>
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<td>iLite® Insulin Assay Ready Cells</td>
<td>BM3060</td>
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<td>iLite® VEGF Assay Ready Cells</td>
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<td>iLite® IL-23 Assay Ready Cells</td>
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<td>iLite® IL-12 Assay Ready Cells</td>
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<td>iLite® GM-CSF Assay Ready Cells</td>
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<td>iLite® TLR4 Assay Ready Cells</td>
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<td>iLite® ADCC Effector (V) Assay Ready Cells</td>
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<td>iLite® ADCC CD20 (+) Assay Ready Cells</td>
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<td>iLite® ADCC CD20 (-) Assay Ready Cells</td>
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<tr>
<td>iLite® anti-CD20 ADCC Activity Set</td>
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**New iLite® Products - Coming Soon!**

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### iLite® Cell-Based Assays

#### Off-the-shelf Reagents

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<td>iLite® TNF-alpha (16 ng/mL)</td>
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<td>iLite® Adalimumab NAb positive control</td>
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<td>iLite® Etanercept NAb positive control</td>
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<td>iLite® Diluent A</td>
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<td>iLite® Diluent B</td>
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<td>iLite® IFN beta 1a NAb positive control</td>
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<td>TLR4</td>
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**iLite® TNF-α Assay Ready Cells**

High specificity and sensitivity

![Diagram of TNF-α signaling pathway](image)

**Graph of Specificity**

- TNF alpha
- TGF beta
- EPO
- IFN alpha
- IL1- beta
- IL2
- IFN gamma
- GMCSF
- IFN beta
- LPS
- IL6
**iLite™ TNF-α Assay Ready Cells**

High reproducibility

<table>
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<td>18064</td>
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**iLite® VEGF Assay Ready Cells**

High specificity
Response curves

VEGF activity

Log VEGF (final conc. ng/mL)
Relative light units
0 5000 10000 15000 20000
-1 0 1 2 3

Log anti-VEGF (final conc. ng/ml)
Relative light units
0 5000 10000 15000
-1 0 1 2 3 4 5

VEGF inhibitor activity

NAbs towards VEGF inhibitor

Log anti-bevacizumab (final conc. pg/ml)
Relative light units
0 5000 10000 15000
2.0 2.5 3.0 3.5 4.0
Batch reproducibility

Bevacizumab activity

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</table>
New Product Line - *iLite®* ADCC Activity Assays

- **ADCC effector (V)**
- **ADCC target (CD20)**
- **ADCC target (HER2)**
- **ADCC target (EGFR)**
- **ADCC target (mTNF-α)**

**Dec**
- Rituximab (Rituxan) 68

**Jan**
- Trastuzumab (Herceptin) 113

**Feb**
- Cetuximab (Erbitux) 98

**Mar**
- Adalimumab (Humira) 143

**Apr**
Antibody Dependent Cell Cytotoxicity

Integral part of our immune response to pathogens

- Crosslinking of a pathogenic cell with an effector cell through an antibody causes the pathogenic cell to lyse and die.

Diagram:
- Antibody
- Fc receptor
- Target cancer antigen
- NK cell
- Cancer cell
- Perforin and Granzyme released
**iLite® ADCC Product Line**

**General Product Set-Up**

*iLite® ADCC Effector Assay Ready Cells*

*iLite® ADCC Target (+) Assay Ready Cells*

*iLite® ADCC Target (-) Assay Ready Cells*

➢ *iLite® Target ADCC Activity Set*

Effector, Target + and Target -
Unique features!

- Target +
- Target –
- Normalization
- Serum tolerance
**iLite® ADCC CD20 Assay Ready Cells**

**Product information**

CD20 is a surface protein expressed primarily on B-cells. The first antibody-based therapeutic against cancer, Rituximab, targets CD20. In hematological cancers, B-cells become cancerous and divide uncontrollably. The drug’s mechanism of action is in part to induce ADCC targeting the CD20 expressing tumor cells.

**No. of biopharmaceuticals in pipeline: 68**

With *iLite* ADCC CD20 Assay Ready Cells, unique on the market, you can measure:

- The ADCC activity of anti-CD20 drugs in the presence of serum (5h)
# iLite® CD20 ADCC assay performance

## Summary

<table>
<thead>
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<th>Commercially available Effector Cells</th>
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<tr>
<td><strong>Incubation Time</strong></td>
<td>4 hours</td>
<td>6 hours</td>
</tr>
<tr>
<td><strong>EC50</strong></td>
<td>2 ng/ml</td>
<td>120.0 ng/ml</td>
</tr>
<tr>
<td><strong>LLOQ</strong></td>
<td>1 pg/ml</td>
<td>10.0 ng/ml</td>
</tr>
<tr>
<td><strong>Normalization Gene</strong></td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td><strong>Substrate</strong></td>
<td>Dual-Glo or Bio-Glo</td>
<td>Bio-Glo</td>
</tr>
<tr>
<td>Results influenced by loss of effector cells</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>Results influenced by serum matrix effects</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>Results influenced by target cell killing of effector cells</td>
<td>NO</td>
<td>YES</td>
</tr>
</tbody>
</table>
iLite® CD20 ADCC assay vs. commercially available assay
iLite® CD20 ADCC assay vs. commercially available assay
iLite® Cell-Based Reporter Gene Assays
Custom Assay Development
iLite® Custom Assay Development

General Work Plan

- Development projects performed by Dr. Tovey’s team in Paris
- Projects are split into work packages, executed sequentially and/or in parallel
- Bi-weekly or monthly telecons for updates depending on project phase
- Validations can be performed by Euro Diagnostica’s in-house bioanalytical service laboratory
- Project proposal
- Master service agreement
iLite® Custom Assay Development

General Work Plan

Projects typically initiated by a larger pharmaceutical company

Work packages generally include:

- Scientific project design
- Stable transfectant established
- Sub-clone
- Master cell bank
- Working cell bank
- Defined cell replication step
- Stability testing
- Cryo-preservation
- Manufacture of Assay Ready Cells

Project timeline 3-6 months
Thank You!

Euro Diagnostica received the

2013 Frost & Sullivan European
Best Practice Award

for Product Differentiation Excellence in
Autoimmune Disease Diagnostics

AND

2015 Frost & Sullivan European
Best Practice Award

for Customer Value in Theranostic Services