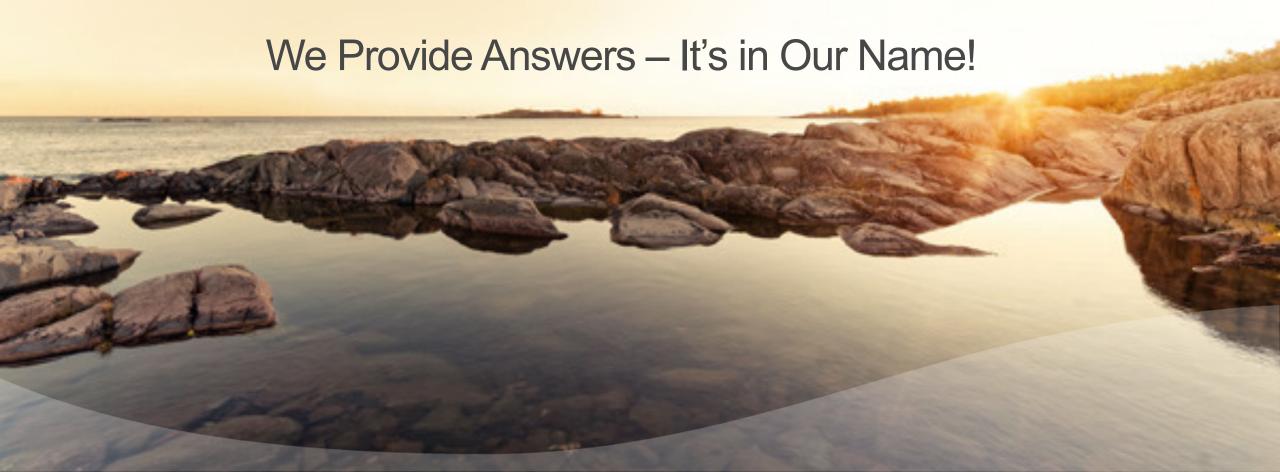


# **VENDOR/ TECHNICAL PRESENTION**

**CASSS BioAssay September 2022** 

Dr. Michael Schwenkert Chief Technology Officer







# **WHO WE ARE**

At Svar Life Science, we combine research and development, manufacturing and regulatory affairs with quality control and quality assurance in a small cross-functional organization.

We offer versatile assay solutions to pharma, biotech and CRO customers, as well as to our partners within diagnostics.



Svar is a Swedish life science company that works to deliver the right answers at the right time in the pursuit of personalized medicine

### THE SVAR LIFE SCIENCE GROUP OF COMPANIES





#### **WIESLAB LABORATORY SERVICES**

### **BIOANALYTICAL SERVICES**

- · Bioanalysis & Biomarkers
- Immunogenicity
- Potency

#### **DIAGNOSTIC SERVICES**

- Autoimmunity
- Neuroimmunology
- Nephrology
- · Drug monitoring

#### **CALPRO AS**

### Total solution for calprotectin in faeces:

- CalproLab<sup>™</sup> ELISA lab test
- EasyExtract extraction device
- CalproSmart <sup>™</sup> HOME home test
   CalproSmart <sup>™</sup> OFFFICE POC test



# WHAT WE DO

Simply put, we provide the answers that our customers need throughout the entire drug development value chain – from early discovery through the clinical.

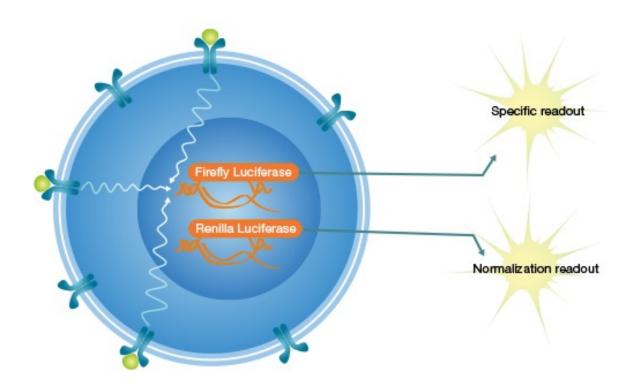
Svar offers a comprehensive product portfolio supporting the development of new drugs and providing tools for patient diagnosis and monitoring within inflammatory diseases.



# **FUNCTIONAL CELL-BASED BIOASSAYS**

If it binds, it shines!





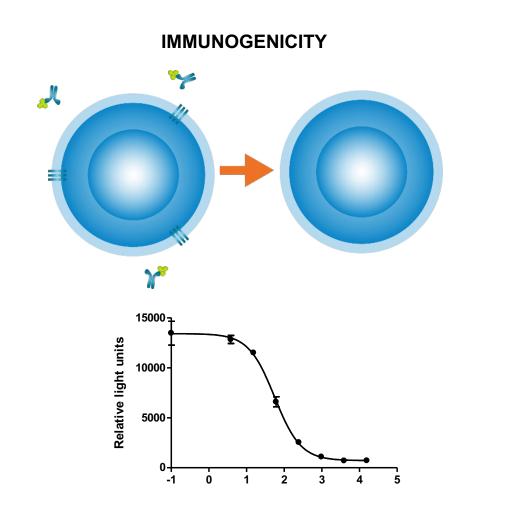
#### *iLITE*<sup>®</sup> CELL-BASED ASSAYS

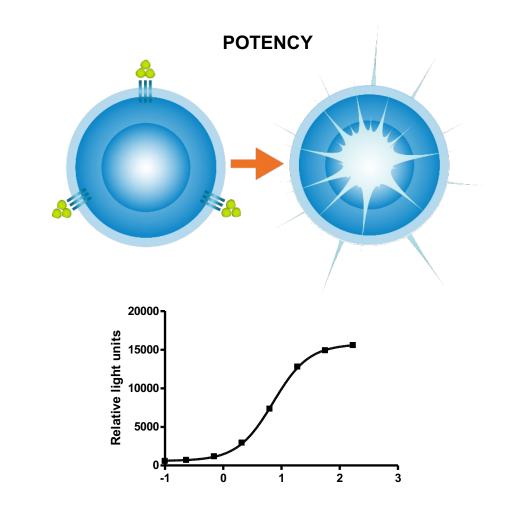
### **FEATURES & BENEFITS**

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

- **Highly specific** reporter gene cell lines
- Very sensitive cell line responses with large assay windows (>10 fold inductions)
- Normalization gene, which eliminates unwanted matrix effects
- Due to format Assay Ready Cells ready-to-use from the freezer, benefits like:
  - No culturing of cells
  - High reproducibility
  - Assays within a workday

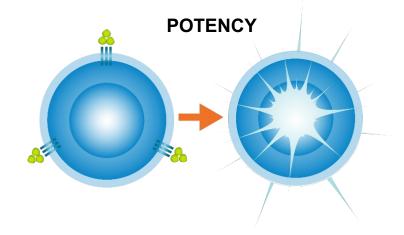
# MAIN APPLICATIONS

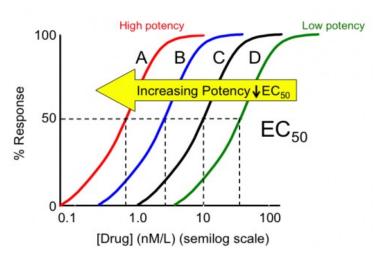




### **POTENCY APPLICATION**

- A potency assay shall represent the product's mechanism of action (i.e., relevant therapeutic activity or intended biological effect)
- Concentration and functionally of the drug can be determine in a dose – response curve, where the amount of light generated is directly correlated o the potency/efficacy and concertation of the drug





### **ASSAY READY FORMAT**

- The Assay Ready format decreases timelines and workload
  - No cell culturing, no pre-seeding
  - Straight forward, easy to use protocol
  - Quick assay turnaround times (3-6h)
- The Assay Ready format gives superior performance





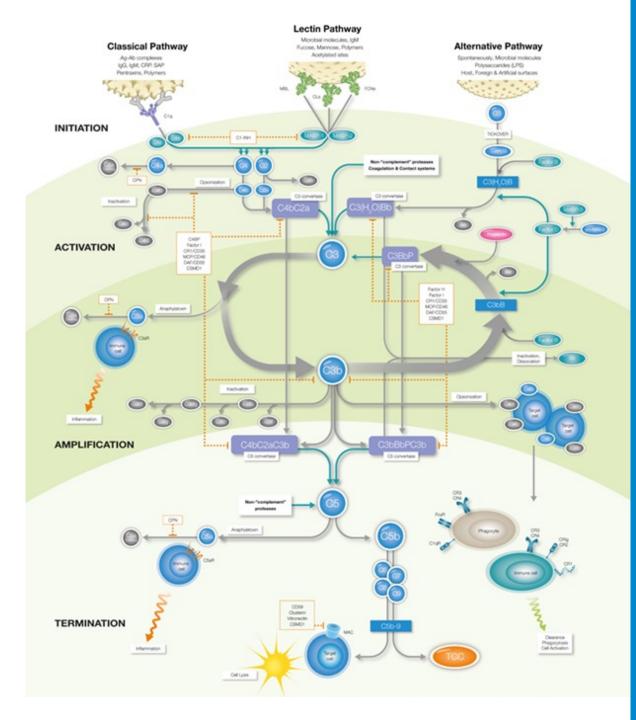




# **FUNCTIONAL COMPLEMENT ASSAYS**

Let us guide you on the Complement Path!





### **COMPLEMENT SYSTEM**

### **HOW TO MEASURE COMPLEMENT**

- As single components
  - C1q, C3, C4, C5a
  - Factor H, TCC etc.
- As functional assessment
  - Classical pathway
  - Alternative pathway
  - Lectin pathway
- With different techniques
  - Immune complexes (turbidimetry, nephelometry, radial immunodiffusion)
  - Bioassay (hemolytic tests with erythrocytes): CH50, CH100, AH50
  - Immunoassay (ELISA)





WIESLAB BIOANALYTICAL SERVICES

### **ANSWERING TO THE COMPLEXITIES OF BIOASSAYS**

A specialized service laboratory

- with scientific expertise & advanced technologies



## **WHAT WE OFFER**

- Assay feasibility, development and validation
- Immunogenicity Testing
   Detection and confirmation of ADAs and NAbs
- Pharmacokinetics (PK) & Pharmacodynamics (PD)
   Expertise in bioanalysis of large molecules
- Toxicokinetics (TK) testing
   Assessment and characterization of biologic safety of large molecules
- Biomarker testing
   Over 250 immunology markers at your service
- Potency Testing
   Determinate the functional activity of your drug molecule
- Consultancy Services
   Optimize your study's assay strategy and improve submission success



WIESLAB BIOANALYTICAL SERVICE

# **QUALITY SYSTEM & ACCREDITATION**

- OECD GLP
- ISO15189
- GCLP/GCP principles followed
- GMP certification to be expected in 2022
- Electronic QMS

We deliver high quality standards and processes - ensuring that regulatory requirements are met for every project.

### OFFERING THE BEST ANALYTICAL TECHNOLOGIES

### **Ligand-binding assays:**

- MSD (MESO QuickPlex SQ 120)
- Quanterix SIMOA HD-X Analyzer
- Enzyme-linked Immunosorbent Assay (ELISA)
- Standard plate readers (Tecan F50 and F200)
- RIA (3470 Wizard2 Gamma Counter)

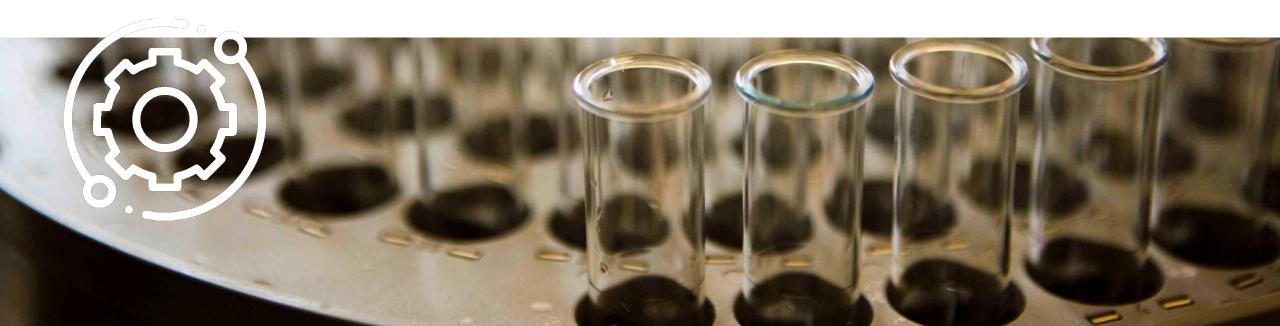
### **Cell-based assays:**

Reporter Gene cell-based assays (*iLite*® or customer provided cell lines)

- Neutralizing antibody assays
- Potency assays

#### Platforms include:

- Absorbance
- Chemiluminescence
- Electrochemiluminescence
- Fluorescence
- Radioimmunochemistry



### SUMMARY

- Svar Life Science
  - Trusted and Proven One Stop Shop for Bioassay needs
- Unique Combination of Products and Services for drug development
- Examples
  - *iLite*® Reporter Cells & Development / Validation of Potency Assay
  - *iLite*® Reporter Cells & Development / Validation of NAb Assay
  - Complement Assays & Screening / Discovery of Complement Drugs