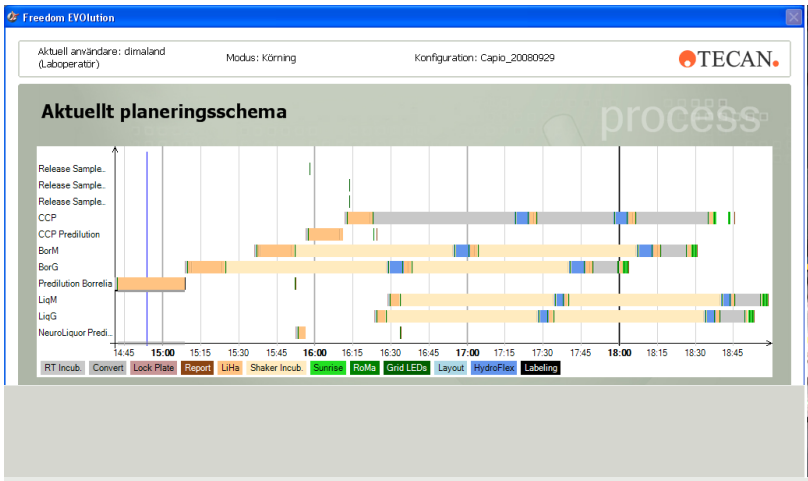

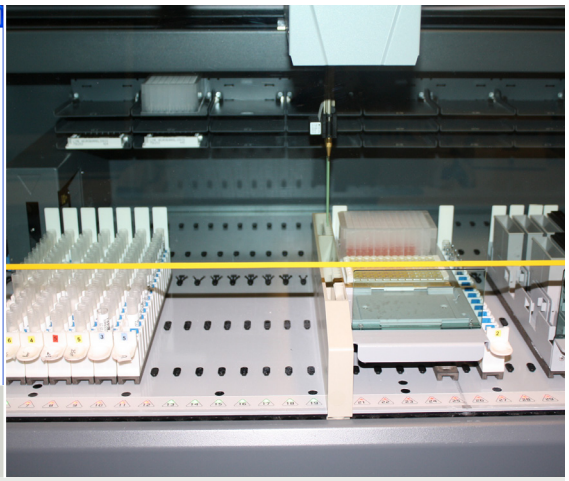

Automation of clinical ELISA screening

Supporting a variety of ELISA testing kits on a single automated platform

Introduction

Controlling the spread of infectious diseases has significant implications in terms of both patient care and cost, requiring rapid and sensitive testing of patient samples to confirm the presence of infection. ELISA testing is used routinely in clinical diagnostics for a variety of applications, providing a highly sensitive and lower cost alternative to radioimmunoassays. Commercialization of ELISA testing is a multi-million dollar industry, with manufacturers offering ELISA testing kits for detection of many infectious agents including *Helicobacter pylori*, *Borrelia burgdorferi* (causing Lyme disease), *Mycoplasma pneumoniae* and *Chlamydophila pneumoniae*. In addition, ELISA testing kits are available for a range of autoimmune disease markers, including myeloperoxidase, proteinase 3, cyclic citrulinated peptide and cardiolipin.

Recent increases in the use of ELISA testing has put significant pressure on hospital and service laboratories to increase their capacity, with many laboratories now using automated systems to meet this demand. However, the varied requirements of each assay kit make it difficult to achieve high throughput automation, preventing optimization of laboratory processes.

Objectives of Unilabs

Unilabs supplies laboratory and radiology services across Europe, to public and private healthcare providers, government agencies and the pharmaceutical industry. The company's laboratory in Skövde specializes in ELISA testing, and offers a clinical diagnostic service for hospitals, clinics and doctors' surgeries across Sweden. The laboratory processes around 600 ELISA samples a week – equating to around 30 to 40 microplates – testing samples from over 300 patients for a range of infectious and autoimmune diseases.

Freedom EVOlyzer® configuration

With increasing emphasis on monitoring and control of infectious diseases in a healthcare setting, Unilabs needs a reliable, high throughput platform capable of handling the varied workload and testing requirements of the laboratory. This requires an automated platform capable of performing a wide range of assays, with varying sample volumes and types.

To allow the laboratory to optimize its workflow based on the 'lean' philosophy and without changing assay kits, Unilabs has selected a Freedom EVOlyzer platform with the following configuration: 150 cm worktable, four-channel liquid handling (LiHa) arm with fixed tips, 37°C incubator with shaking option, ambient temperature incubator, HydroFlex™ microplate washer and Sunrise™ absorbance reader.

The workstation is controlled using Freedom EVOlution™ 2.0 software, and is connected to the company's LIS database, allowing testing requests to be sent directly to the system. Integrated barcode readers on the platform identify individual samples, and import testing instructions directly from the LIS. The required assays are then performed, and the results are automatically exported back to the LIS, without the need for manual intervention.

This set-up has helped the laboratory to improve the efficiency of its workflow, creating a more robust, continuous process.

Walkaway automation of ELISA processing, including overnight runs, offers shorter lead times and enhanced throughput, and allows laboratory staff to perform other tasks (see Fig. 1).

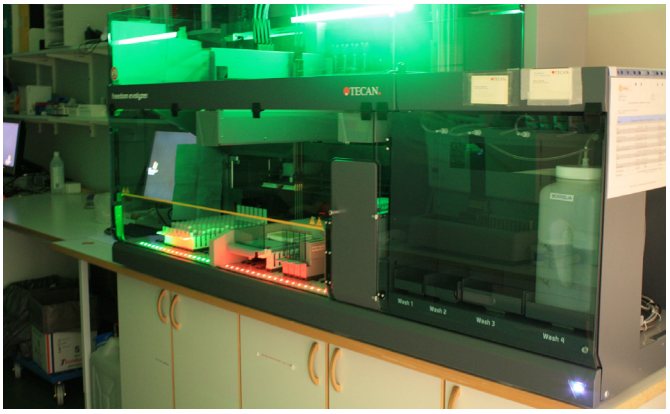

Fig. 1 Overnight run: Freedom EVOlyzer was designed for fully automated and unattended processing. Freedom EVOlution software features, like volume pre-checking, allow the instrument to recognize whether the required amounts of reagents were loaded on the platform. The flashing status lamp and the acoustic alarm let the operator know when intervention is needed.

ELISA technologies supported

The Skövde laboratory currently performs nine different ELISA tests, using kits from six manufacturers:

ELISA kit	Manufacturer	Diagnostic detection purpose
Enzygnost® anti-TBE	Siemens Healthcare Diagnostics	Tick-borne encephalitis
Wieslab® capture PR3 IU	Euro-Diagnostica	Systemic vasculitis
Wieslab capture MPO IU	Euro-Diagnostica	Systemic vasculitis
Immunoscan RA CCPlus®	Euro-Diagnostica	Rheumatoid arthritis
IDEIA™ *Borrelia burgdorferi*	Thermo Fisher Scientific	Lyme disease
C. pneumoniae EIA	Ani Labsystems	Pneumonia
M. pneumoniae EIA	Ani Labsystems	Pneumonia
RELISA® Cardiolipin	Immuno Concepts	Varied
Pyloriset EIA III	Orion Diagnostica	H. pylori infection

Each test is performed according to the manufacturer's recommended protocols to ensure optimal sensitivity and reliability of the assay, with individual testing profiles for each ELISA kit stored in the system's Freedom EVOlution control software. In addition to immunology and infectious disease testing, the laboratory is planning to automate clinical chemistry assays on its Freedom EVOlyzer system.

Summary

The Freedom EVOlyzer platform has the flexibility to deal with the differing processing requirements of ELISA test kits from a wide range of manufacturers, as well as the varied sample types and volumes received by the laboratory for processing (see Fig. 2). The intuitive Freedom EVOlution 2.0 software offers the high level of functionality required for automation of many different assays on a single platform, helping the laboratory to cope with its changing daily workload by interfacing directly with the LIS system, and ensuring optimal scheduling, testing and reporting for all samples.

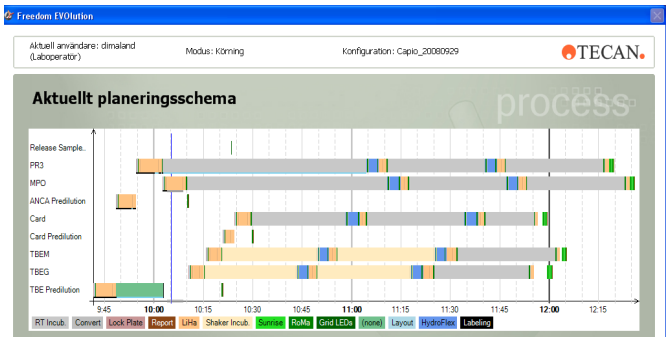

Fig. 2 Example of the processing schedule: ELISAs from different manufacturers are combined within one run. All assays are dynamically planed for optimal usage of the hardware resources.

The Freedom EVOlyzer workstation offers reliable, high throughput processing and ELISA testing without the need for manual involvement, maximizing biosecurity and allowing staff to perform other tasks.

Acknowledgements

We would like to thank Dr Eva Arkblad at Unilabs AB, Skövde, Sweden, for sharing her experience of using the Freedom EVOlyzer workstation in her laboratory's daily work.

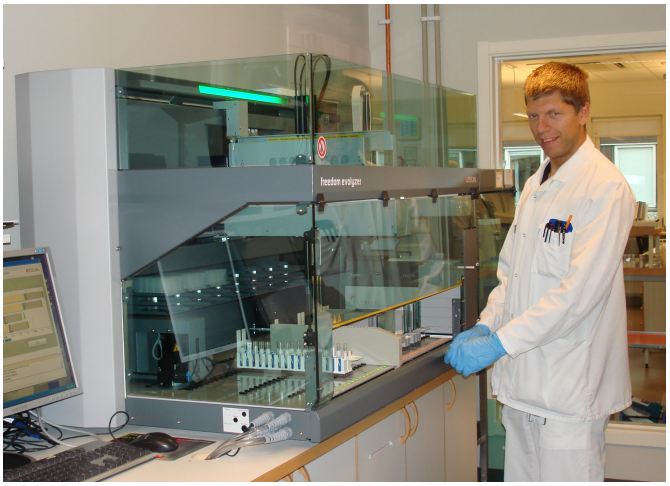

Fig. 3 Jimmy Fransson, biologist, with the Freedom EVOlyzer platform at Unilabs AB

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