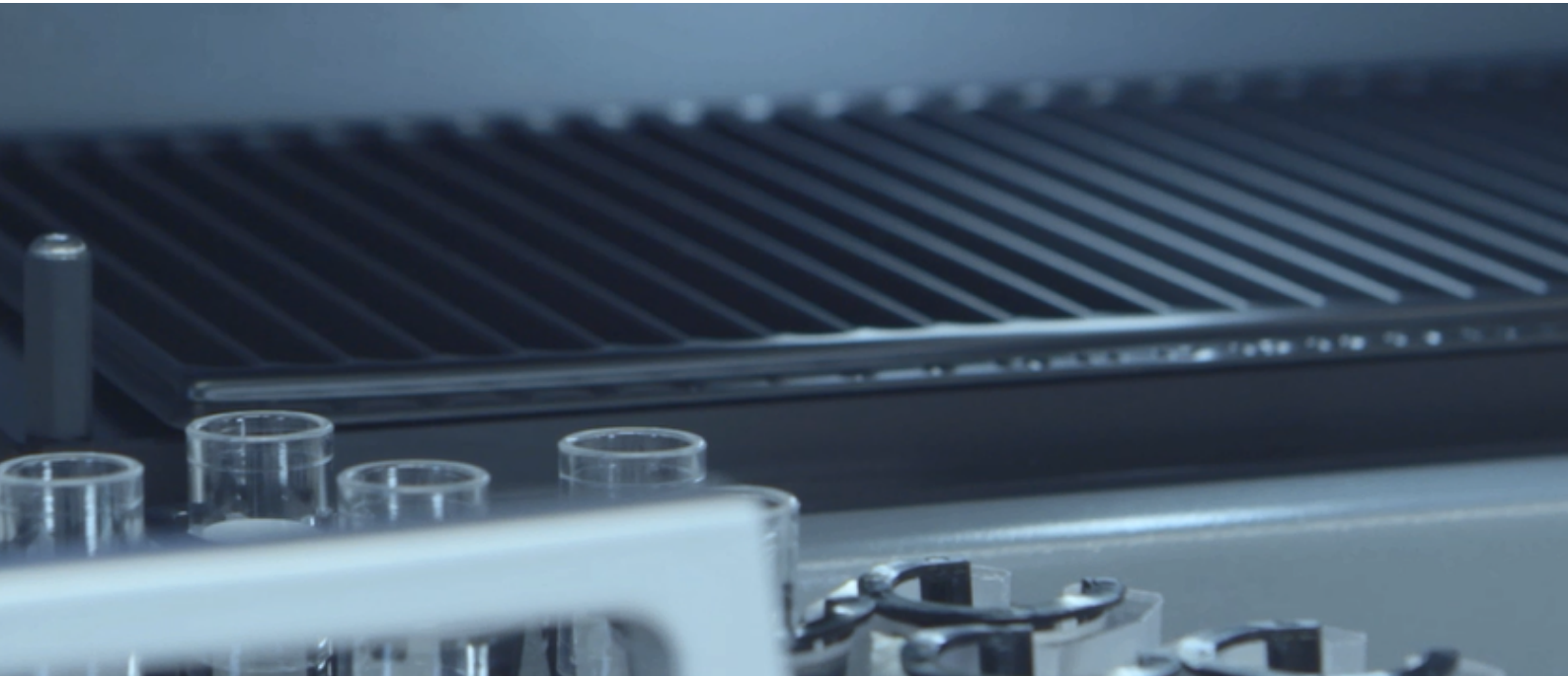


MIKROGEN

DIAGNOSTIK



AUTOMATION

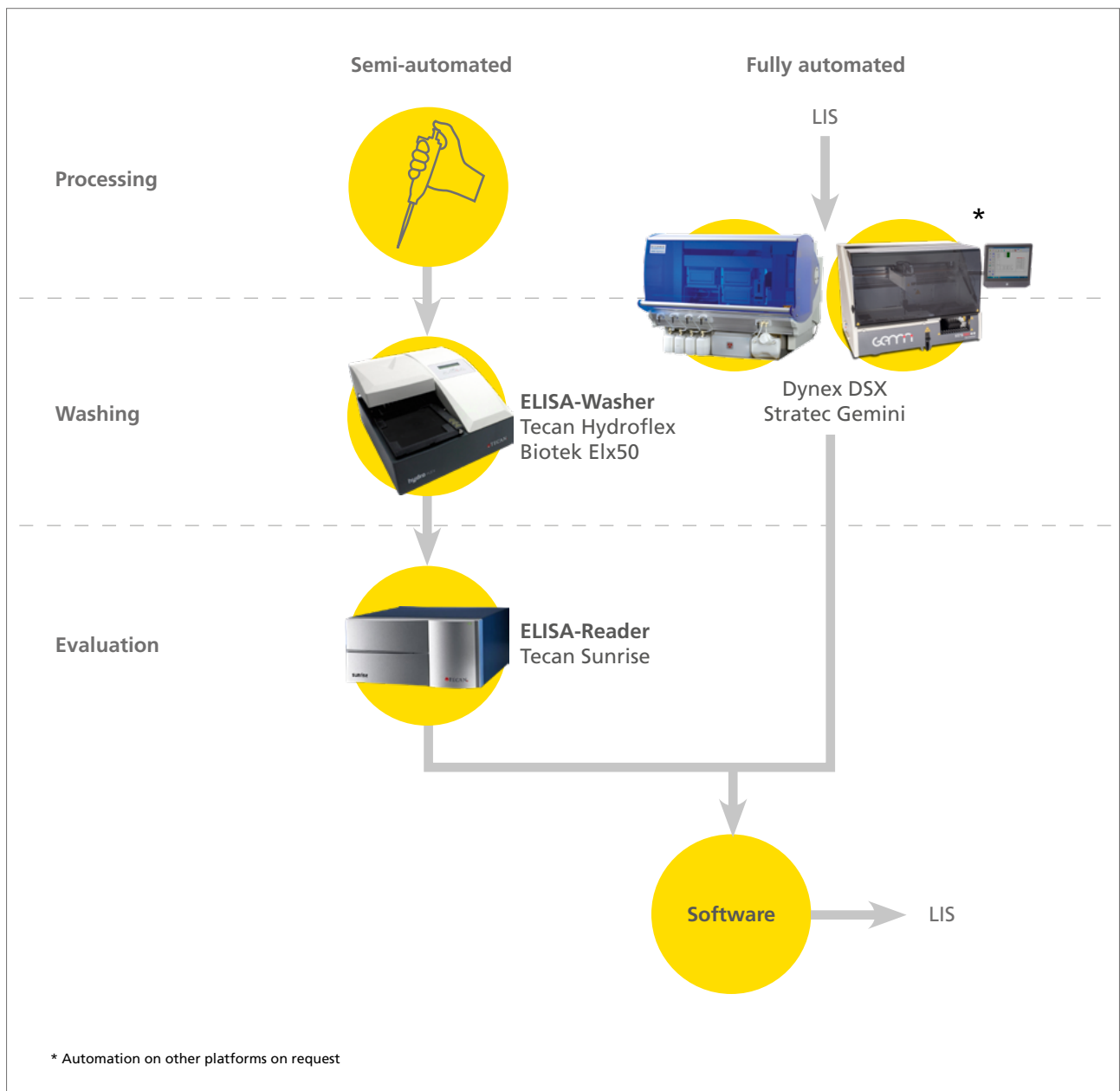
Advanced automation solutions
for fast and safe diagnostics

AUTOMATION OF ELISA

MIKROGEN supplies its customers with the *recomWell* and *NovaLisa*® ELISA test systems for sensitive and reliable identification of pathogen-specific antibodies. This broad portfolio of screening tests covers most of the diagnostic parameters in infectious diseases. Outstanding benefits of these tests are their extraordinary high specificity at a maximum of sensitivity.

Next to manual processing in combination with washing devices and an ELISA reader for evaluation, MIKROGEN offers with the *Dynex DSX* and the *Stratec Gemini* two progressive system solutions in the field of automation and standardization. Processes in the laboratory are hereby made faster, more accurate and safer.

Workflow



ELISA – FULL AUTOMATION DYNEX DSX

Automation with Dynex DSX

The DSX is an open, fully automated analyzer for the complete sample preparation and processing as well as photometric measurement and analysis of microtiter plate tests.

The device control is done through user-friendly Windows software with which the user can program separate assays.

Due to the high flexibility and usability, the DSX supports the daily routine work. The sample preparation can be carried out both directly on the microtiter plates as well as by pre-dilution in the tube or in a deep well plate. The device can process four microtiter plates simultaneously and can thereby be continuously reloaded.



Software	Revelation Software
Tests per plate	Up to 12 assays
Time management	Time table
Barcode	Optional
Number of plates	4
Plate incubators	4 separate incubator modules
Temperature ranging	+7 to +50°C
Sample capacities	96 samples
Samples tubes	96 (2 racks per 48)
Controls and/or standards	33
Reagents	24
Loading	Continuously (samples, plates, reagents)
Wash buffer containers	4 x 2 liters (level sensor)
Waste container	1 x 8 liters (level sensor)
Pipetting tips capacities	4 racks (per 108 tips / 300 µl), 1 rack (41 tips / 1300 µl)
Min-Max-Volumina	Samples 5 - 250 µl (single shot mode), resp. 25 - 100 µl (multi shot mode), reagent 25 - 1000 µl

ELISA – FULL AUTOMATION STRATEC GEMINI

Automation with Stratec Gemini

- Fully automated microplate processor
- For low throughput applications
- Total walk away system
- Flexible time management with LIS connectivity
- Modularity – open system
- Ease of use, installation and maintenance
- Assay performance with disposable tips
- High process safety with triple pipetting control
- Convenient programming of assay protocols
- Proven reliability
- The system is in compliance with the In-vitro diagnostic directive 98/79/EC



Reader	<p>Photometric range: 0 to 3.0 OD</p> <p>Spectral range: 400 nm to 700 nm (up to 8 filters)</p> <p>Read time: < 15 sec single, < 30 sec dual</p> <p>Precision dual: 1% CV at 1.0 OD</p> <p>Accuracy: ± 0.005 OD or 2.5% (whichever is greater)</p> <p>Linearity: 0 to 2.000 OD ± 1%</p>
Pipettor	<p>Min / max volumes: 10 µl to 300 µl with 300 µl tip; 301 µl to 1000 µl with 1100 µl tip</p> <p>Precision (single dispense): < 3% CV at 20 µl; < 3% CV at 100 µl</p> <p>Precision (multi dispense): < 10% CV at 16 x 20 µl; < 3% CV at 8 x 100 µl</p> <p>Features: Pipetting pressure monitoring, capacitive liquid level detection, tip detection, mixing, multiple dilution steps, archiving</p>
Incubator	<p>Temperature range: Up to 45°C</p> <p>Temperature uniformity: ± 1.5°C (with in-process temperature monitoring)</p> <p>Shaking: 20 Hz</p>

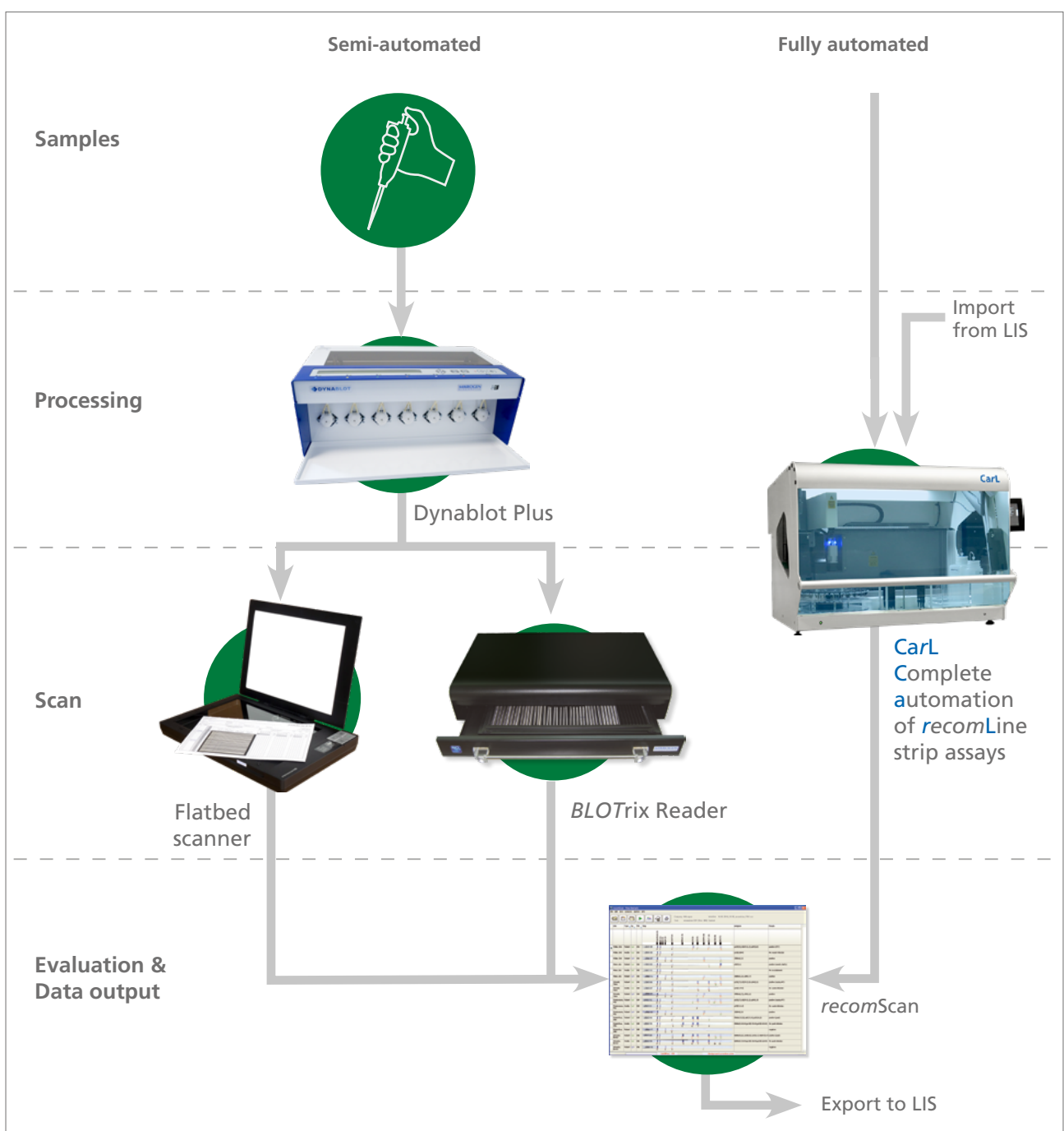
Washer	<p>Precision: 10% CV at 300 µl</p> <p>Residual volume: < 2.5 µl in U-bottom (mean); < 4 µl in flat bottom (mean)</p> <p>Wash buffer capacity: 3 wash buffers</p> <p>Modes: Sweep mode, soak, top and bottom wash, variable pump speed</p>
Sample and reagent capacity	<p>Up to 192 samples</p> <p>Flexible, e.g. 144 samples + 8 reagents + 16 controls</p>
Dimensions	<p>120 cm (W, incl. bottles), 75 cm (H), 67.5 cm (D)</p> <p>Recommended footprint (incl. monitor, PC, waste bag): 158 cm (W) x 110.5 cm (H open) x 67.5 cm (D)</p>

AUTOMATION OF LINE IMMUNOASSAY

MIKROGEN offers two lines of automation solutions for every diagnostic laboratory: a semi-automated and a fully automated approach. The semi-automated operational procedure includes automated processing of LINE assays with the Dynablot Plus strip processor and scanning of strips with the *BLO*TriX Reader. LINE assays are evaluated in a computer based manner by the

MIKROGEN *recomScan* software for optimal results. The MIKROGEN gold standard is the fully automated *CarL* system, which combines processing, scanning and evaluation in one platform. Choose *CarL* for your diagnostic laboratory to receive the best performance in respect of security, efficiency and minimal hands-on time.

Workflow



Automation with Dynablot Plus

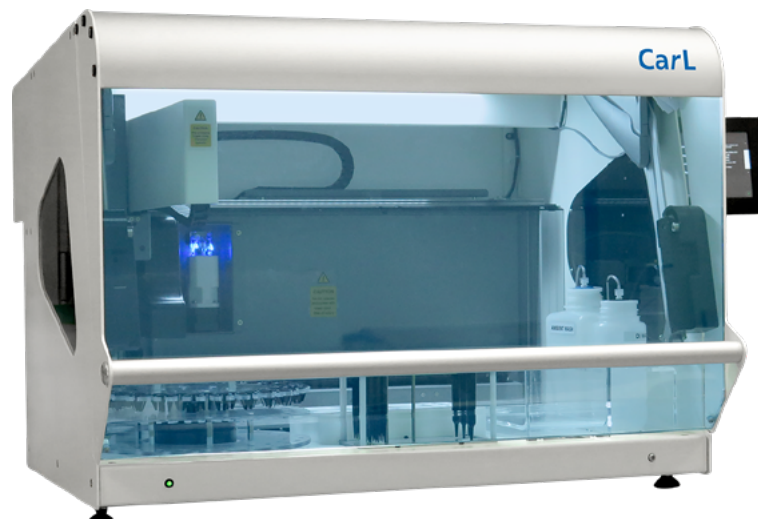
- Ideally suited and validated for the automatic processing of all MIKROGEN strip assays
- Combination of IgG / IgM / IgA and avidity possible in a single run
- **Flexible arrangement of strips:**
 - ▶ Sort by IgG / avidity / IgM / IgA per patient
 - ▶ Sort by Ig class per run
- **High reproducibility:** Variation dispensing accuracy is < 10%
- Minimal space requirement and low noise during operation
- Perfect addition to the automatic evaluation with *recomScan* in combination with *BLOTriX* Reader / Flatbed Scanner
- **Easy and user friendly handling:**
 - ▶ **“Walk-Away” operation:** Instrument operates fully automatic after addition of serum samples
 - ▶ Clear LCD display with current test status and remaining time
 - ▶ Audible indicators (for example, at the end of program)
 - ▶ Easy to load and easy accessibility of reagents
 - ▶ Built-in error detection and display
- **High safety and reliability:** The Dynablot Plus meets the highest standards according to EC-guidelines 98/79/EC for In-vitro diagnostics



Capacity	Up to 44 strips
Memory space	20
Reagent channels	7
Pumps	7 peristaltic and 1 vacuum pump
Rocking shaker	3 speed levels
Dimensions	52,5 x 31 x 25 cm
Weight	14,5 kg
Ports	Serial + USB
Power supply	100 - 240 V
Power consumption	Max. 30 W
Waste container	2 l with liquid level sensor

CarL Complete automation for recomLine strip assays

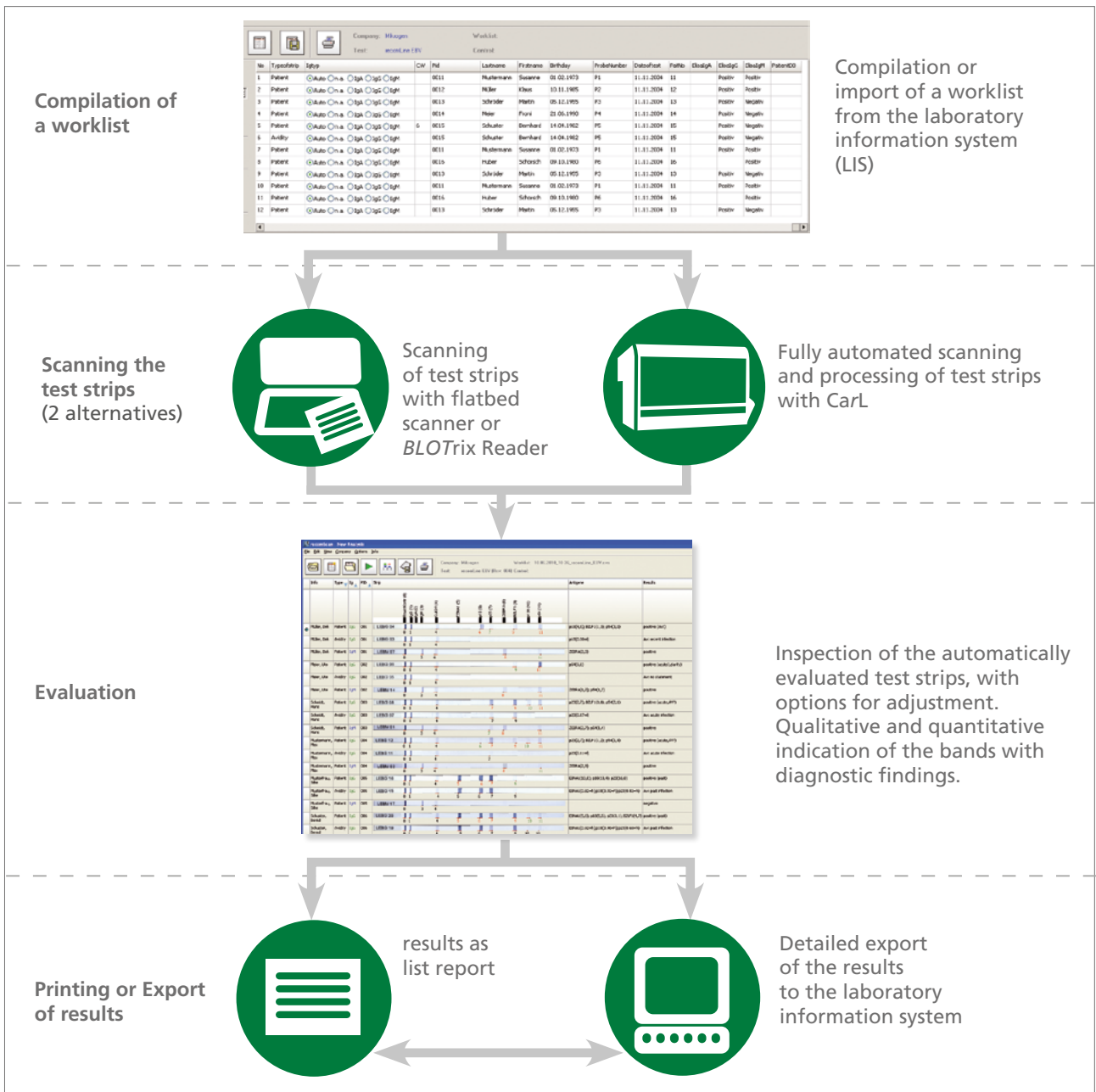
- **Walk-Away:** Full automation from sample to scanning
- **Safe:** Barcode identification and LIS connectivity
- **Convenient:** Integrated drying, 44 strips in one run
- **Flexible:** Combination of all assays with the same sample incubation time
- **Space saving:** Integrated camera for scanning
- **Minimised dead volume:** To save precious reagents
- **No cross-contamination:** Disposable tips for sample pipetting
- **Minimal maintenance:** No daily startup routine and pump calibration required by user
- **Liquid level detection (LLD):** Pressure sensing technology for samples and reagents
- **User-friendly:**
 - ▶ Guided operation via large touch screen
 - ▶ Easy to load and easy accessibility of reagents
 - ▶ Tip Management: Tip picking starts at position according to usage of previous run
- CarL meets the highest standards according to EC-guidelines 98/79/EC for In-vitro diagnostics



Capacity	Up to 44 samples per run
Power	Universal input 100-240 V / 50 - 60 Hz
Sample ID	Integrated barcode reader for sample ID
Carousel for 48 primary tubes	Tube size ranging from 12 mm to 17 mm
Integrated Industrial PC	Integrated PC for connection to LIS and interpretation software
Piston Pump	Volume range 10 µl to 2.5 ml
Peristaltic Pumps	Aspiration and reagent addition
Liquid Level Detection	Pressure sensing technology for samples and reagents
Integrated Camera	Integral camera for image capture of developed strips
Disposable Tips	1 ml and 5 ml disposable tips can be used during the assay
Operator Interface	Integrated touch screen
Footprint	86 cm (W) x 61,5 cm (H) x 69 cm (D). Recommended footprint (incl. touch screen and PC): 182 cm (W) x 99 cm (H open) x 69 cm (D)

Standardised Analysis of strip assays with *recomScan*

- Fast and simple handling
- Reproducible band analysis
- Interpretation of complex band patterns
- Extensive control and expedient correction options
- Histogram view
- Permanent storage of test strip images, easy data retrieval
- Meaningful reports in different detail variants
- Optional: standardised data exchange with laboratory information system
 - ▶ Prevention of reading and transmission errors
 - ▶ Import of worklist
 - ▶ Detailed export of analysis data
- *recomScan* meets the highest standards according to EC-guidelines 98/79/EC for In-vitro diagnostics



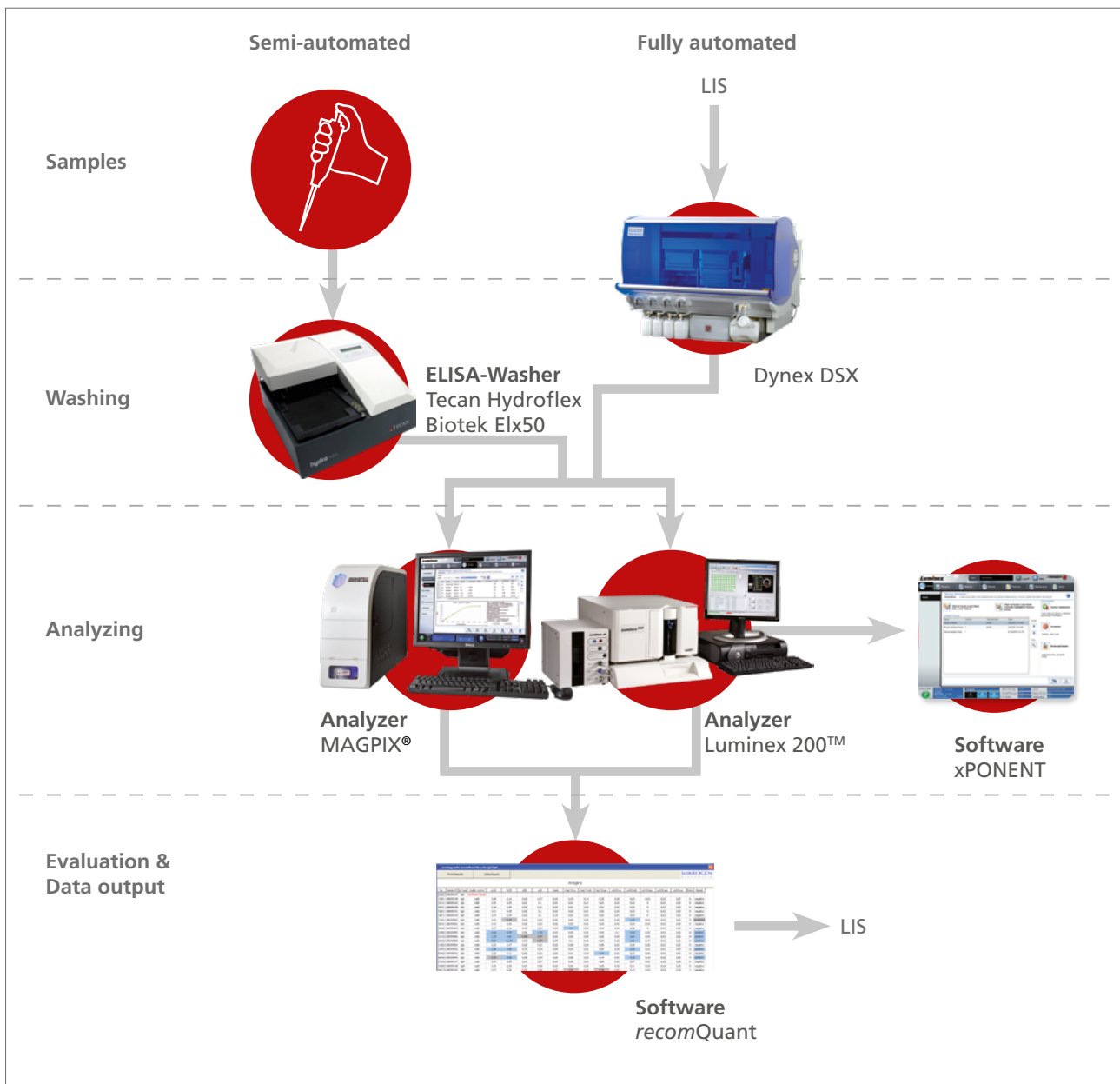
AUTOMATION OF BEAD IMMUNOASSAY

A milestone in immunodiagnostics. Ideally suited for high sample throughput.

The technology is based on microscopic polystyrene beads, so called microspheres. One hundred different bead populations exist. The populations can be distinguished from each other by their specific colour code. Each bead can be coated with a specific antigen or antigen mixture, thus allowing analysis of up to 100 parameters in one single sample simultaneously.

Besides the classical MicroPlex beads a new generation of polystyrol beads with iron core (MagPlex®) has been developed. These can be fixed magnetically to simplify processing. Antigens used are immunodominant and serologically relevant proteins of the pathogen. The detection of antibodies present in a patient sample takes place on the surface of these microspheres. The technology is extremely user friendly and ideal for various applications in medical diagnostics.

Workflow



BEAD – Luminex 200™ AND MAGPIX® SYSTEM

Luminex 200™ System

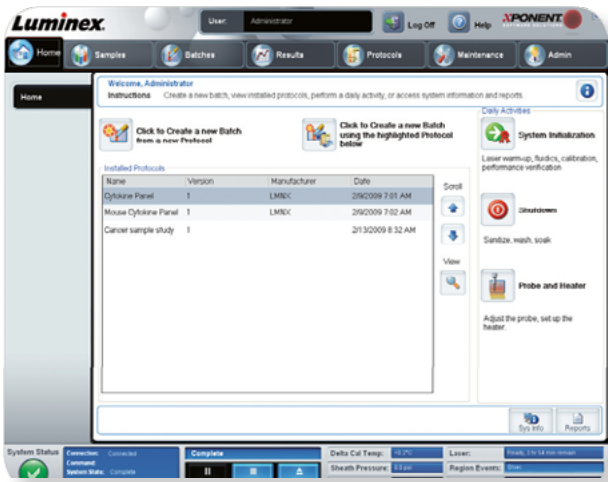
- Flow cytometry with two lasers:
A red laser identifies the colour code of the bead while the quantitative analysis is carried out by a second green laser

MAGPIX® System

- Magnetically fixed beads (MagPlex®)
- CCD camera for detection of beads in the red and green light spectrum
- Short startup and shut-down protocols



	Luminex 200™	MAGPIX®
Optics	Laser/APD/PMT	LED/CCD camera
Hardware	Flow cytometry based	Fluorescence imager
Bead compatibility	MicroPlex, MagPlex®	MagPlex®
Dynamic range	3.5 Log	
Microtiter plate	96 Well	
Footprint (incl. PC)	132 cm (W) x 32 cm (H) x 64 cm (D)	83 cm (W) x 43 cm (H) x 63 cm (D)
Weight	49 kg	17.5 kg
Software	xPONENT	



Luminex® xPONENT Software

The Luminex® xPONENT software is a modular and flexible software package for the control of the MAGPIX® and LX 200 systems.

The software’s graphical user interface follows the typical assay workflow. Navigation wizards and automated routine operations such as startup, shutdown, calibration and performance verification further enhance system usability and result in increased walk-away time. Different access levels enable the user to acquire samples, perform analysis, run system maintenance routines or to administrate the system.

recomQuant Software

The MIKROGEN specific test evaluation is performed by the *recomQuant* software, which can read the raw data from the xPONENT software.

recomQuant offers a high level of security:

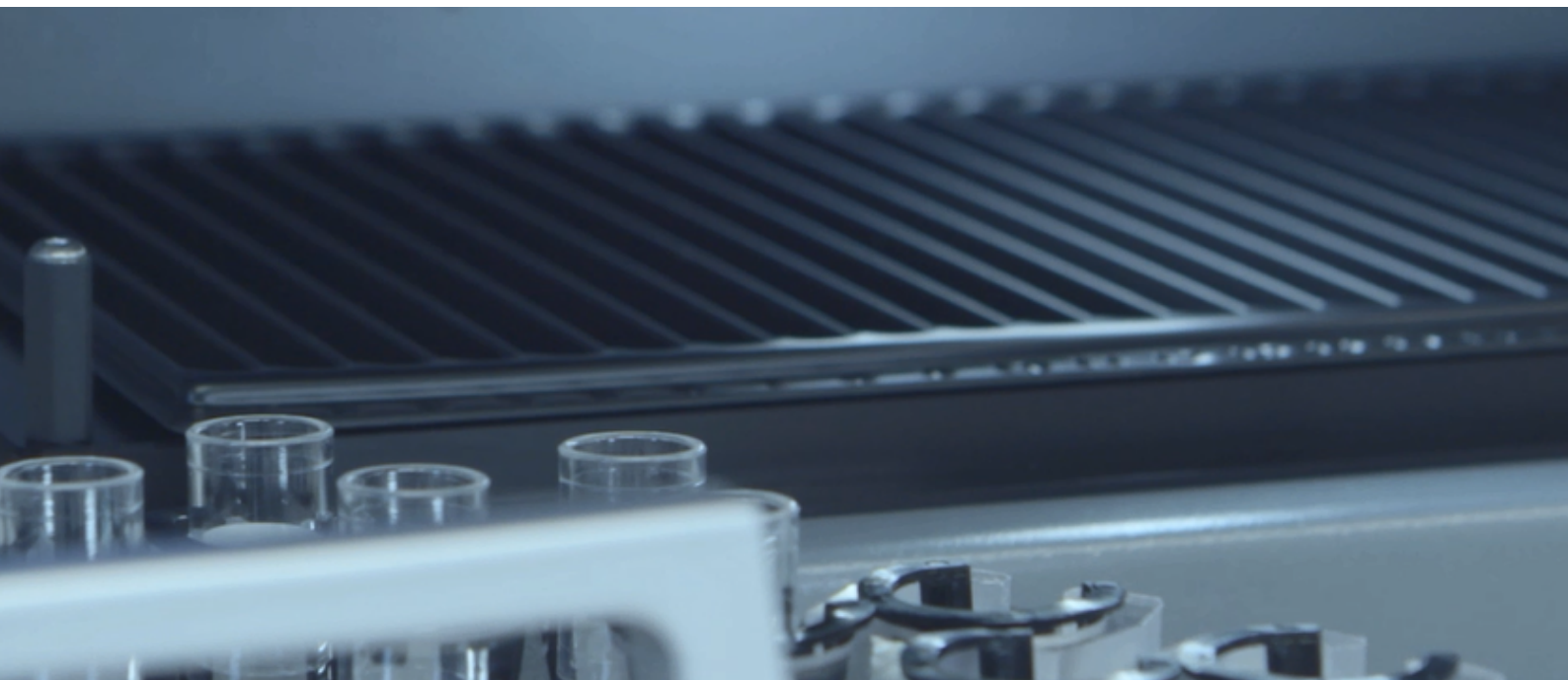
Lot data can be imported via download or by scanning a 2D-barcode. In addition, lot data are connected to the shelf life of the kits. Integrated controls in every well are automatically evaluated to ensure presence of sample and conjugate.

The integrated negative control detects unspecific background reactions.

User advantages *recomQuant*

- Simple and intuitive data import and export
- Clear result presentation
- Connectivity to LIS systems included

Print Results		Data Export		Antigens															Positiv	Result									
Sample ID	Is Type	Quality control	p100	WtC	p10	p100	OpqC	OpqC.1	OpqC.2	OpqC.3	OpqC.4	p100.1	p100.2	p100.3	p100.4	p100.5	p100.6	p100.7	p100.8	p100.9	p100.10	p100.11	p100.12	p100.13	p100.14	p100.15	Positiv	Result	
1	KC1	IgG	valide	0,01	0,07	0	0,09	0,01	0,02	0,01	0,01	0	0	0	0	0,02	0	0	0,02	0	0	0	0	0	0	0	0	0	negative
2	KC1	IgG	valide	0,01	0,07	0	0,09	0,01	0,02	0,01	0,01	0	0	0	0,02	0	0	0,02	0	0	0	0	0	0	0	0	0	0	negative
3	022014401	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
4	048654001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
5	048654001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
6	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
7	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
8	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
9	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
10	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
11	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
12	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
13	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
14	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
15	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
16	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
17	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
18	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
19	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
20	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive
21	050291001	IgG	valide	0,04	0,06	0,01	0,11	0,01	0,02	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	0,01	positive



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