Hemostasis Innovation is Here.

ACL AcuStar®
HEMOSTASIS TESTING SYSTEM

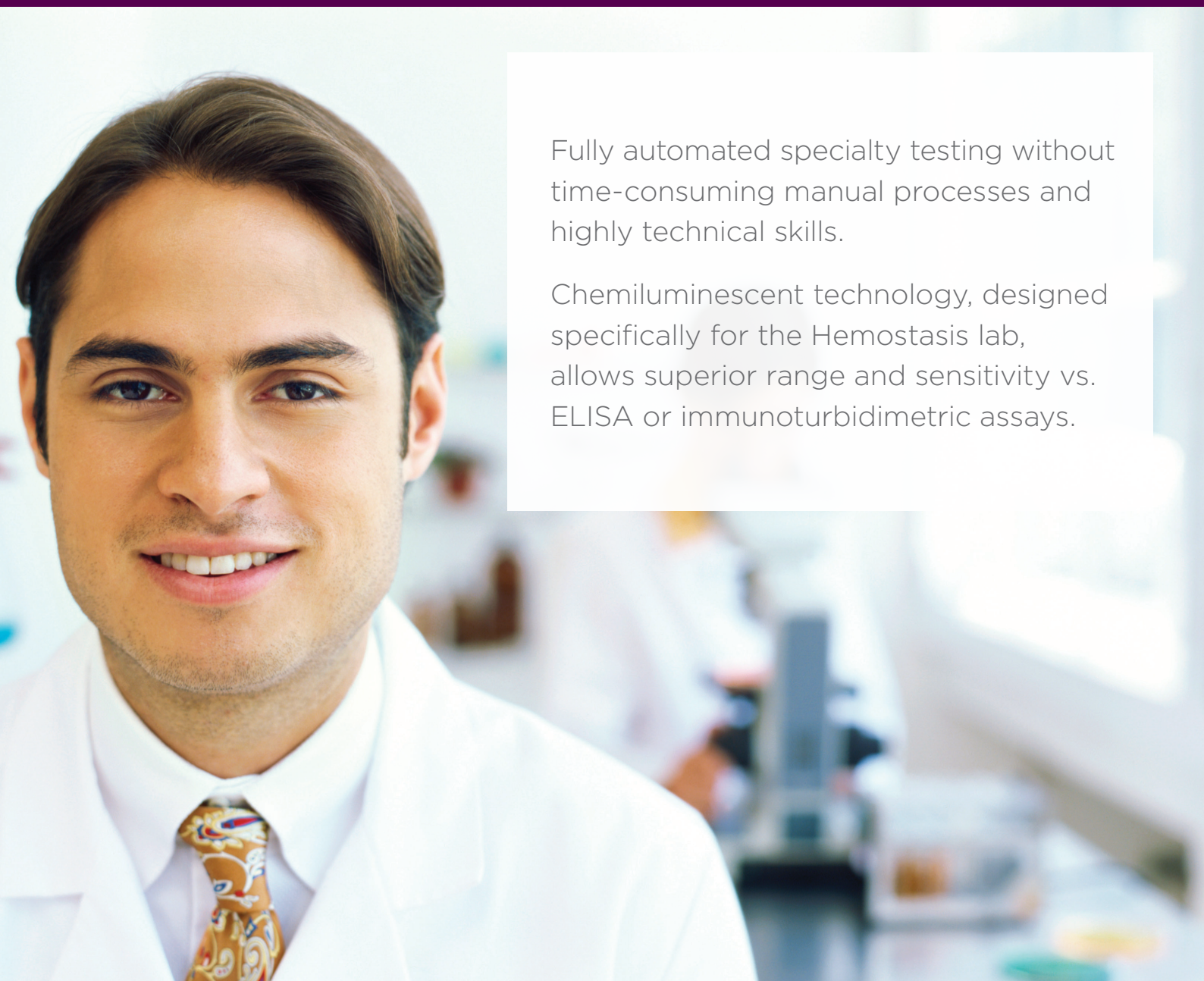
# A breakthrough in specialty testing.

## It's about time. And accuracy.




werfen

# Unprecedented accuracy. Simple to use. Innovative Hemostasis specialty testing.



Fully automated specialty testing without time-consuming manual processes and highly technical skills.

Chemiluminescent technology, designed specifically for the Hemostasis lab, allows superior range and sensitivity vs. ELISA or immunoturbidimetric assays.

ACL AcuStar® HEMOSTASIS TESTING SYSTEM

# Automates and standardizes highly specialized assays and enhances assay performance of routine tests.

Advanced assay technology, complemented with end-to-end automation, provides a quantum leap in simplicity and throughput, while ensuring uncompromised results. Combines testing accuracy and efficiency in ways never before possible.

- Highly sensitive immunoassays significantly improve performance
- Fully automated specialty assays
- Self-contained, reagent cartridges, stable up to 12 weeks onboard
- Assays onboard and available 24 hours/day, 7 days/week
- Assay calibration on lot change only
- Random access—no batching required

## Test menu

Comprehensive HemosIL® line of high-performance chemiluminescent assays.

| | |
|---|---|
| **aCL IgG**<br>**aCL IgM**<br>**aß$_2$GPI IgG**<br>**aß$_2$GPI IgM**<br>**aß$_2$GPI Domain I** | **Fully automated antiphospholipid panel**<br>• Complete diagnostic menu for antiphospholipid syndrome<br>• Differentiates assay Ig isotypes<br>• Reduces test time significantly<br>• Consolidated test panel replaces traditional ELISA assays |
| **D-dimer** | **Fully automated chemiluminescent D-dimer assay**<br>• Aids in the diagnosis of venous thromboembolism<br>• Superior working range, sensitivity, and specificity vs. ELISA and immunoturbidimetric assays<br>• Provides rapid turnaround time and availability 24 hours/day, 7 days/week |
| **HIT-IgG$_{(PF4-H)}$** | **Fully automated heparin-induced thrombocytopenia (HIT) assay**<br>• Helps clarify suspicion of HIT<br>• Eliminates batch testing<br>• Provides rapid turnaround time and availability 24 hours/day, 7 days/week |
| **VWF:Ag***<br>**VWF:RCo***<br>**VWF:CB*** | **From von Willebrand disease (VWD) screening to VWD typing**<br>• Enhances analytical performance for VWD typing<br>• High sensitivity VWF:Ag<br>• True VWF:RCo sensitive to Type II VWD |
| **ADAMTS13 Activity*** | **Only fully automated solution for diagnosis and monitoring of thrombotic thrombocytopenia purpura (TTP)**<br>• The only biologic marker specific for TTP<br>• Ensures timely, informed patient management<br>• Provides rapid turnaround times and availability 24 hours/day, 7 days/week |

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# Innovation through state-of-the-art chemiluminescent technology.

The first instrument to introduce chemiluminescent technology in Hemostasis testing, in combination with innovative assays, to significantly improve testing accuracy, assay range, sensitivity, and specificity, all while saving valuable time.

## Broad sensitivity and working range

- Chemiluminescence offers a wide working range and ability to detect very low and high concentrations of analytes
- Working range of ACL AcuStar chemiluminescent D-Dimer assay is almost 10x other D-dimer assays (54.3–74,000 ng/mL FEU)

## Differentiates among Ig isotypes

- Provides specific isotype, yielding clinically significant results, rather than simply detecting the presence of antibodies
- Assays that cannot differentiate among isotypes may yield false high results due to detection of other non-pathogenic isotypes

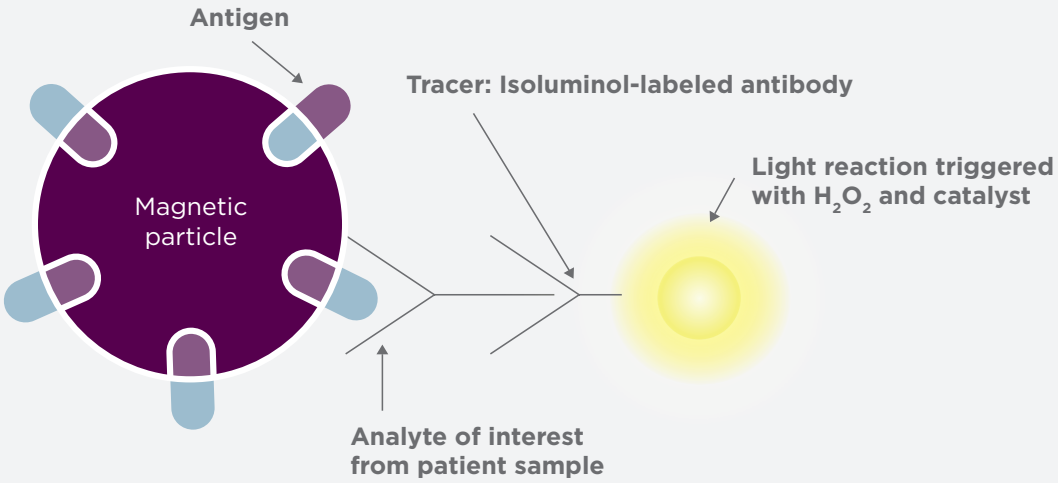
## Virtually no optical interferences

ELISA assays are typically susceptible to contaminants, which can increase absorption at different wavelengths. If this occurs, optical interference can lead to falsely elevated results.

Chemiluminescent assays on the ACL AcuStar system are minimally impacted by optical interference because contaminants are automatically removed.

## Chemiluminescent technology

**HemosIL AcuStar assay reaction mechanism**




**Tracer binds specifically to the assay target, emitting light when an oxidizer and a catalyst are added.**

Light detector is highly sensitive and detects extremely low levels of light, significantly increasing the linearity (or working range) vs. other technologies.

# Innovative cartridge design offers unmatched simplicity.

Innovative design makes testing simple and efficient—every step of the way.

1. Patented magnetic bead chamber resuspends reagent before pipetting into reaction cuvette for consistent reproducibility.
2. All reagents needed for reaction are contained within chambers of cartridge, eliminating multiple reagent vials used in standard ELISAs.
3. Covered probe access ports, minimizing reagent evaporation.
4. Barcode automatically imports assay type and master calibration curve, facilitating assay set up.



# Unprecedented simplicity.

Makes setup and testing simple. Automates and standardizes testing that, until now, required advanced training and extensive manual processes.

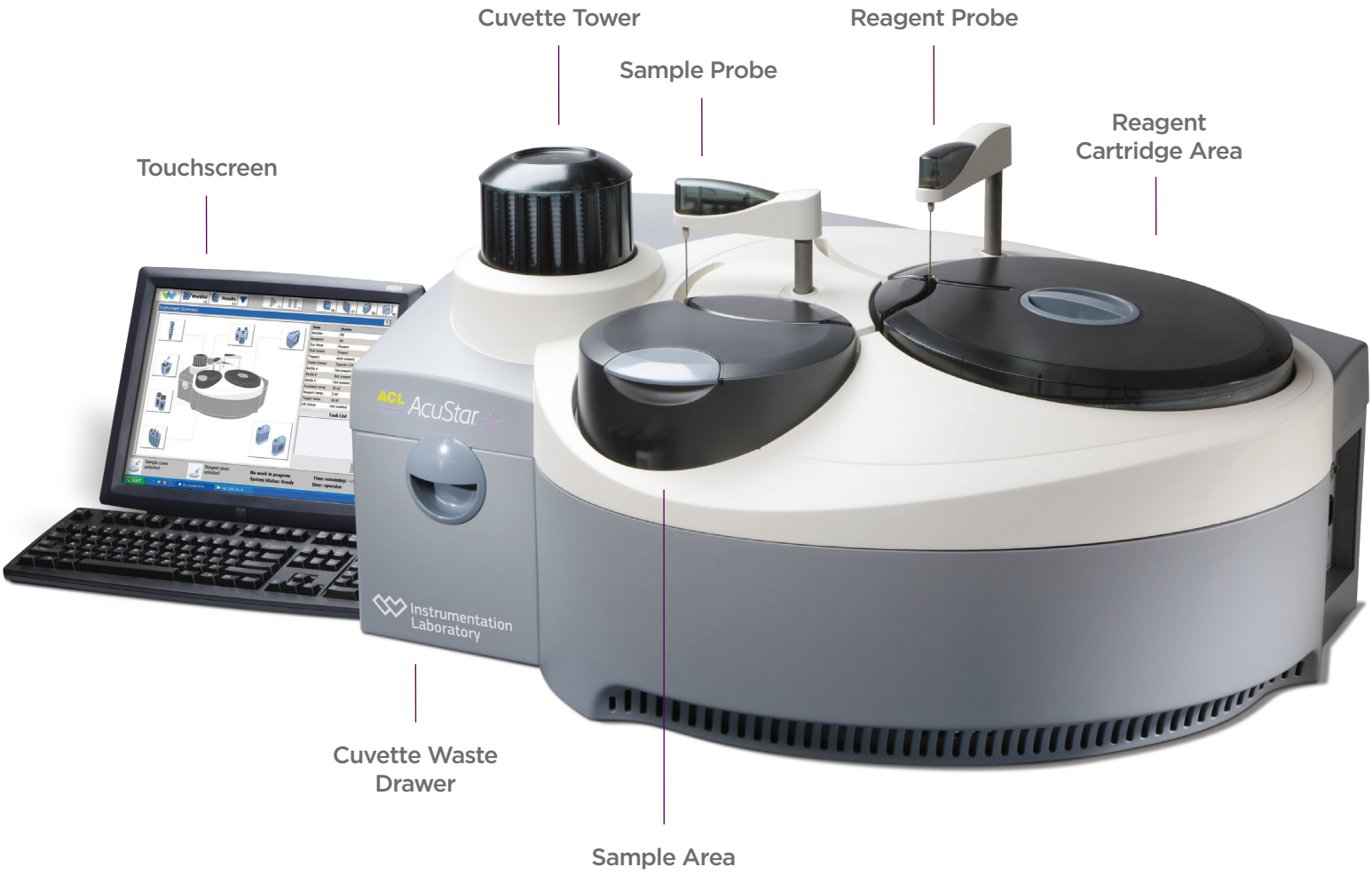
## ‘1-2-3 step’ easy set-up

### For assays

1. **Load assay cartridge**
   Automatically reads cartridge barcode and imports master curve.
2. **Adjust calibration**
   *(for cartridge lot change only)*
   Uses two calibration levels, included in kit, to adjust master curve.
3. **Run quality control**
   Reads control type and assay from barcode on controls vial and runs QC tests.

### For samples

1. **Load barcoded sample**
   Automatically queries LIS for test programming.
2. **Press “Start”**
   Automatically performs analysis and generates results.
3. **Get results fast**
   Automatically calculates results for each assay.



# Uncompromising quality.

Innovative design enhances testing experience for laboratory professionals.

## Complete test panel

- Antiphospholipid panel
- D-dimer
- HIT
- VWD panel*
- TTP*

## Simple to use

- No reagent handling: self-contained, ready-to-use, precalibrated reagent cartridges
- Integrated barcode reader for cartridges and samples
- Cartridges refrigerated at 4°C and stable up to 12 weeks onboard
- Easy rack-loading system accommodates up to 30 samples
- Windows interface and touchscreen, flat LCD monitor with intuitive prompts

## Fast and efficient

- Unprecedented efficiency for key specialty assays
- Up to 20 reagent cartridges onboard
- Up to 20 different assays onboard and available 24 hours/day, 7 days/week
- Up to 60 tests/hour
- Time to first results: ~30 minutes
- STAT or batch sample processing

## Highly accurate

- Automated chemiluminescent technology boosts accuracy and sensitivity
- Each assay lot is factory precalibrated to assure accuracy and standardization
- High sensitivity (secondary antibody linked to isoluminol as tracer)
- Broad working range with one-stage or two-stage immunoassays
- Virtually no optical interference
- Differentiation among Ig isotypes

## Reliability

- Automatic reflex testing
- Automatic results validation
- Westgard Rules
- Levey-Jennings charts

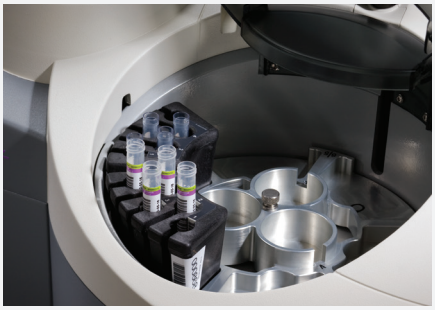
**Reagent cartridge area**



**Reagent cartridges**



**Sample area**



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# Technical specifications

| | |
|---|---|
| **Detection technology** | Chemiluminescence |
| **Continuous sample loading** | YES |
| **Continuous reagent loading** | YES |
| **Continuous operation** | YES |
| **Samples transport system** | Sample racks |
| **Samples onboard** | 30 (5/sample rack) |
| **Reagents transport system** | Cartridges |
| **Reagents onboard** | 20 (refrigerated) |
| **Reagents barcode reader** | YES (integrated) |
| **Barcoded reagents** | YES (barcode includes lot, exp. date and size) |
| **Cuvettes onboard** | 280 |
| **Tests per sample** | 20 |
| **Throughput** | ~30 min. to first result, 60 samples/hr. |
| **Rerun testing** | YES (configurable) |

| | |
|---|---|
| **Results autovalidation** | YES |
| **Security system** | YES (configurable) |
| **Events log system** | YES |
| **Bi-directional interface** | YES |
| **Host query function** | YES |
| **PC** | External (dedicated) |
| **Operating system** | Windows 7 |
| **Monitor** | 17" color LCD touchscreen (external) |
| **Keyboard/mouse** | YES (external) |
| **Printer** | YES (external) |
| **User interface** | Windows 7-based |
| **Unit dimension h x d x w (cm)** | 54 x 62 x 87 |
| **Analyzer weight (kg)** | 77.25 |


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