Sysmex CS-5100 Hemostasis System

Break through the routine with PSI technology

siemens-healthineers.com/hemostasis
Overcome preanalytical errors in hemostasis testing
for faster diagnosis and reliable monitoring

Preanalytical errors may affect testing and patient outcomes

• Underfilling of sample tubes may cause significant sample dilution and provide falsely prolonged clotting times.¹
• Hemolytic specimens are the leading cause of preanalytical variability and have been shown to negatively affect medical care.²
• Icteric specimens cannot be reliably identified by visual inspection alone, requiring photometric detection instead.³
• Lipemic specimens have been shown to affect the activity levels of clotting factors.¹

Diagnostic errors in the lab

Up to 70% Preanalytical Errors³
Up to 15% of errors affect patient care.⁵
Break through routine levels of performance with the Sysmex CS-5100 System with high precision in high-volume hemostasis testing

Fully automated solution features PSI technology and automation connectivity

The Sysmex® CS-5100 Hemostasis System is a random-access, high-volume coagulation analyzer. It offers large and multisite labs advanced features and benefits for a streamlined workflow and reliable test results.

With assay-based preanalytical sample-quality checks using PSI™ technology and simultaneous multiwavelength scanning to identify and manage unsuitable test specimen prior to analysis, the Sysmex CS-5100 System helps high-volume laboratories manage these errors and reduce reruns.

“The high throughput and improved workflow [are] delivered with a high level of precision.”

Woolley A, Kitchen S. Sheffield Teaching Hospitals, UK NHS Foundation Trust

The Sysmex CS-5100 System delivers advanced diagnostic workstation capabilities:

- Speed
- Security
- Capacity
- Consistency
- Connectivity
Boost your lab quality and efficiency

through intelligent sample management and reduced reruns

PSI checks reduce preanalytical concerns

The Sysmex CS-5100 System helps high-volume labs achieve reliable results by identifying and automatically managing potentially problematic test samples prior to analysis, minimizing the need for manual sample inspections and maximizing operator support. The system automates and standardizes sample management for reliable results.

- Automates primary-tube sample-volume checks to identify potential inaccuracies caused by improper sample collection.
  - Sample results from collection tubes with improper sample volume are flagged for review and recording purposes.
- Qualitative detection of hemolysis, icterus, and lipemia (HIL) is provided with a preanalytical scan of the patient sample performed at three wavelengths—405 nm, 575 nm, and 660 nm—allowing assay-based flagging.

Sample result details with reaction curve.
Harness the power of multiwavelength analysis

for a wide variety of test profiles

Simultaneous scanning of clotting reactions

The Sysmex CS-5100 System’s wide optical spectrum provides four different measurement principles, allowing clotting, chromogenic, immunologic, and aggregation/agglutination testing capabilities on a single, high-volume platform.

• Simultaneous multiwavelength scanning of clotting reactions is performed at 340 nm, 405 nm, 575 nm, 660 nm, and 800 nm in all detector channels.
  – Automatic selection of optimal wavelengths reduces effects of interfering substances on absorbance spectra.
  – 20 reaction detectors enable high-throughput capacity for a variety of test profiles.

“Photo-optical clot detection provides multiple advantages over mechanical detection systems.”

Woolley A, Kitchen S.
Sheffield Teaching Hospitals, UK
NHS Foundation Trust

Preanalytical interferences associated with diagnostic errors in hemostasis

<table>
<thead>
<tr>
<th>Falsely Increased Results</th>
<th>Hemolysis</th>
<th>Icterus</th>
<th>Lipemia</th>
<th>Improper Tube Filling</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT, D-dimer, FV, FVII, FX</td>
<td>PT, Fibrinogen</td>
<td>Antithrombin</td>
<td>PT, APTT</td>
<td></td>
</tr>
</tbody>
</table>

| Unaffected Results | APTT | PT, APTT |

| Falsely Decreased Results | APTT, Fibrinogen, Antithrombin, Thrombin Time | Antithrombin | Fibrinogen | D-dimer |

Reliable test results from simultaneous multiwavelength scanning

Spectra of Interfering Substances

The level of hemolysis causing clinically important changes is test-specific; therefore, test-specific thresholds should be used to assess patient samples that have hemolyzed during collection and/or processing.

Simultaneous multiwavelength scanning of clotting reactions help manage interfering substances.
Break through the routine with powerful, high-capacity performance to improve lab productivity

1

High sample-processing throughput with fast TAT facilitates quicker diagnosis and monitoring.

- Processes up to 400 tests per hour for PT/APTT*
- Third-generation cap-piercing technology maintains throughput, regardless of open, capped, or mixed samples.
- Provides full random access with broad test menu, including specialty and agglutination test capabilities.
- Allows priority loading and testing of STAT samples at any time.

2

Preanalytical sample-quality checks using PSI technology help reduce preanalytical errors to minimize lab concerns.

- Primary-tube sample-volume check identifies potential inaccuracies caused by improper sample collection.
- User-defined criteria are used to detect and manage hemolysis, icterus, and lipemia (HIL).
- Simultaneous multiwavelength analytical scanning detects and helps to manage unsuitable samples.

3

High-capacity performance streamlines workflow and supports extended walkaway time.

- Provides onboard capacity of up to 3000 tests† with up to 40 reagents.
- Enables more than 11 hours of continuous walkaway time and maximum of approximately 5 hours with cuvette supply.‡
- Innovative cap-piercing technology allows mix of capped and uncapped tubes and cups for dependable throughput.
- Simultaneous processing of primary samples and micro mode for precious pediatric samples help increase productivity.
- Reagent chamber is refrigerated at approximately 10°C for extended onboard reagent stability.

4

Consistency of results optimizes use across multisite labs.

- Results correlate with the Sysmex CS-2500 and CA-600 hemostasis systems.
- Shared reagents, consumables§ controls, and calibrators simplify purchases for multisite labs.
- Similar user software minimizes training requirements for multisite users.
Throughput values were determined by the time to first result; processing capability varies depending on the reagent used. Stated throughput value was determined using Siemens Healthineers study protocol with PT (Thromborel® S Reagent), APTT (Pathromtin™ SL Reagent), INNOVANCE® D-Dimer Reagent, and AT (INNOVANCE AT Reagent) test applications.

§ 3000-test capacity for PT testing; 2880-test capacity for APTT testing; 2880-test capacity for PT/APTT testing; 2840-test capacity for PT/APTT/Fbg testing; 2436-test capacity for PT/APTT/AT3 testing; and 1890-test capacity for PT/APTT/AT3/DD testing.

‡ Based on internal validation data from Sysmex Corporation.

§ Excludes Sysmex CA Systems consumables.

**HYPHEN BioMed application. Not available for sale in the U.S.

†† Instruments require virtual network computing (VNC) or Remote Desktop capability. Not available on all systems.

‡‡ Atellica Process Manager’s functionality on Sysmex CS-5100 System currently excludes real-time reagent status and real-time alerts. Protocol under development. Its future availability cannot be guaranteed.
Transform care delivery through increased workforce productivity

for profit-driven lab management

High sample-processing throughput is optimized with full random access*
• Up to 400 PT tests/hour
• Up to 400 PT/APTT tests/hour
• More than 300 PT/APTT/D-dimer/antithrombin tests/hour

Large reagent, sample, and consumable capacity helps streamline workflow
• Up to 3000 tests onboard,† with up to 100 patient samples per run.
• Reagent chamber refrigerated at approximately 10°C maximizes onboard reagent stability.
• Tilted reagent vial angle provides greater usable reagent volume.
• Intelligent, simultaneous processing of primary and pediatric samples enables increased productivity.
• Ready-to-use cleaning solution simplifies daily maintenance.

Automated mixing studies, integrated platelet aggregation,** and clot waveform analysis (CWA)§§ deliver cost-effective instrument and staff consolidation
• Automated mixing studies help clinicians make decisions regarding factor deficiencies and circulating inhibitor patterns.
• Platelet aggregation testing** simplifies and automates assessment of inherited, acquired, or drug-induced platelet disorders.
• CWA§§ illustrates the optical reaction profile during PT or APTT measurement and provides qualitative and sensitive waveform patterns.
• Powerful, easy-to-use graphical analysis tools simplify operations.

Advanced reagent management helps maintain uninterrupted workflow
• Load up to 40 reagents on the reagent table and five buffers on the buffer rack.
• Two-dimensional bar-code input of TAV for standards, calibrators, controls, and reagents ensures correct transfer of ISI and nominal values.
• QC runs automatically with change of reagent vial and at user-defined time intervals.

Includes advanced cap-piercing technology
• Delivers proven high throughput with both capped and open-vial samples.³
• Enhances operator safety by reducing risk of exposure to biohazardous materials.
• Secure aliquot technology enables multiple tests per sample without the risk of debris from cap-piercing in the measurement system.

Test menu with broad capabilities, including platelet aggregation testing,** increases lab consolidation

<table>
<thead>
<tr>
<th>Measurement Principle</th>
<th>Assays</th>
<th>Wavelengths (nm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clotting</td>
<td>PT, APTT, Fbg. TT, Intrinsic and Extrinsic Factor Assays, Protein S Activity, Free Protein S Antigen, Protein C Clotting, Lupus Screening and Confirmation, Activated Protein C</td>
<td>340, 405, 575, 660, 800</td>
</tr>
<tr>
<td>Chromogenic</td>
<td>Factor VIII, Factor XIII, Heparin, Antithrombin, α2 Antiplasmin, Protein C, Plasminogen, C1 Inhibitor</td>
<td>340, 405</td>
</tr>
<tr>
<td>Immunologic</td>
<td>D-dimer, vWF Antigen, vWF Activity</td>
<td>575, 800</td>
</tr>
<tr>
<td>Aggregation/Agglutination</td>
<td>Ristocetin Co-Factor, ADP, Epinephrine, Ristocetin, Collagen, Arachidonic Acid</td>
<td>660, 800</td>
</tr>
</tbody>
</table>
Enhance routine performance with powerful connectivity and smart IT solutions
for improved workflow

Flexible connectivity solution for scalable lab automation

The Sysmex CS-5100 System can be part of a customized workflow solution designed to meet the needs of your laboratory’s specific workload requirements. Through the flexible point-in-space design, the Sysmex CS-5100 System can easily connect to Aptio® Automation for true one-touch testing.

Simplify operations and gain greater insights with Atellica Diagnostics IT

Atellica® Diagnostics IT leverages data-driven innovation to simplify workflows. Our scalable, easy-to-use solutions simplify tasks and maximize the effectiveness of your laboratory and staff. Enhance visibility, automate processes, and centralize management across instruments, automation, sites, and networks.

*Throughput values were determined by the time to first result; processing capability varies depending on the reagent used.
Stated throughput value was determined using Siemens Healthineers study protocol with PT (Thromborel S Reagent), APTT (Pathromtin SL Reagent), INNOVANCE D-Dimer Reagent, and AT (INNOVANCE AT Reagent) test applications.
†3000-test capacity for PT testing; 2880-test capacity for APTT testing; 2880-test capacity for PT/APTT testing; 2840-test capacity for PT/APTT/Fbg testing; 2436-test capacity for PT/APTT/AT3 testing; and 1890-test capacity for PT/APTT/AT3/DD testing.
**HYPEN BioMed application. Not available for sale in the U.S.
§§Research use only
Manage complex operations with sophisticated system software for increased walkaway time

The Sysmex CS-5100 System shares powerful, user-friendly Sysmex CS family software—providing a dynamic, customizable user environment

- Software-supported error management and troubleshooting
- Automatic validation of results with bidirectional LIS connectivity

Real-time reagent and consumables monitoring facilitates ease of use and workflow efficiency

- Provides complete, easy-to-understand onboard reagent status information with supporting graphics and data.
- Displays large, intuitive status symbols.
- Identifies and resolves issues with clear status messages.
The Sysmex CS family of systems: true consistency and compatibility for advanced patient care

Facilitates monitoring within and between labs
- Excellent correlation values with the Sysmex CS-2500 System
- Lab-to-lab consistency for confident patient monitoring
- Same reference ranges, assay applications, reagents, consumables, software, and QC
- Compact footprint comparable to the Sysmex CS-2500 System

Excellent correlation of results across the Sysmex CS family of systems

Figure 1. Passing-Bablok regression analysis for method comparison of lupus anticoagulant ratio with LA1/LA2 Reagents: CS-5100 system versus CS-2500 system.

Figure 2. Passing-Bablok regression analysis for method comparison of coagulation factor VIII with Dade® Actin® FS Activated PTT Reagent: CS-5100 system versus CS-2500 system.

Sysmex CS-5100 System
High-volume, fully automated solution featuring PSI technology, automation connectivity, and third-generation cap-piercing technology

Sysmex CS-2500 System
Mid-volume, fully automated solution featuring assay-based HIL checks using PSI technology, automated mixing studies, automated platelet aggregation and clot waveform analysis

Sysmex CA-600 Systems
Compact, fully automated coagulation analyzers offering a variety of configurations for clotting, chromogenic, and immunologic methods

**HYPHEN BioMed application. Not available for sale in the U.S.
§§Research use only.
At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey toward expanding precision medicine, transforming care delivery, and improving patient experience, all made possible by digitalizing healthcare.

An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 120 years of experience and 18,000 patents globally. Through the dedication of more than 50,000 colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

Actin, Aptio, Atellica, Dade, INNOVANCE, Pathromtin, PSI, Thromborel, and all associated marks are trademarks of Siemens Healthcare Diagnostics Inc., or its affiliates. Sysmex is a trademark of Sysmex Corporation. All other trademarks and brands are the property of their respective owners.

Aptio Automation is manufactured by Inpeco SA and is exclusively distributed by Siemens Healthcare Diagnostics Inc.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

This brochure is intended for use outside the U.S. (OUS) only. Display or promotion to U.S. audiences is prohibited.

References: