

**One Hemostasis System.
Five Methodologies.
Infinite
Possibilities.**

Atellica COAG 360 System



Atellica Portfolio of Laboratory Products

Engineered by Siemens Healthineers to deliver control and simplicity so you can drive better outcomes.

Tighter control of your lab, simplified workflow, and more time to focus on driving better business and clinical outcomes—that’s the promise of our Atellica™ portfolio of laboratory products.

Control.
Simplicity.
Better Outcomes.

Specialty Hemostasis Labs Seek Control, Simplicity, and Better Outcomes.

When engineering its new breed of Atellica diagnostic solutions, Siemens Healthineers asked laboratory directors and managers like you to identify their top challenges. You told us that limited test menus and slow turnaround times hamper your ability to drive better outcomes for clinicians and patients. Manual processes add labor costs and, coupled with high supply costs, impact lab management. Meanwhile, increasingly stringent quality assurance documentation requirements complicate accreditation and compliance.

All of these factors hinder labs’ competitiveness in the marketplace. Labs, therefore, are under continuous pressure to:

- Maximize service quality
- Improve cost efficiency
- Meet regulatory requirements
- Stay ahead of competitors

Siemens Healthineers engineered the Atellica™ COAG 360 System* to address the obstacles of specialty hemostasis labs. The result is a next-generation coagulation analyzer that introduces a transformative array of capabilities to streamline and unify hemostasis testing.

The greater the range of tests in your lab’s daily routine—and the faster you deliver accurate results—the better and more cost-efficiently you can support the clinicians and patients who rely on you. The Atellica COAG 360 System enables simplicity, control, and better outcomes as never before.

*Not available for sale in the U.S. Product availability varies by country.



“Now prothrombin F 1+2 can be used as needed as an acute activation marker—routinely, with timely results and high reliability, on a random-access analyzer.”

Dr. Munif Haddad,
Clinical Pathologist,
Labor Lademannbogen,
Hamburg

Lab Goals	Obstacles	Solution: Atellica COAG 360 System
Improve result quality	• Preanalytical variables impact result integrity • Ensuring sample quality is cumbersome and imprecise	• Advanced preanalytical screening for sample integrity (PSI™ checks) • Automated processes minimize errors resulting from visual inspection
Decrease turnaround time	• Increased demand for STAT sample processing • Sample rejections/repeat tests • Manual processes	• INNOVANCE® LOCI assays enable rapid turnaround time • First-run test accuracy • Vast system capacity, true continuous reagent and consumable loading enable uninterrupted sample measurement
Reduce costs	• High skilled-labor costs • Reagent management	• Five methodologies consolidated on one platform • Intelligent reagent and consumable management reduces manual interaction, extends walkaway time
Broaden test menu	• High costs preclude low-volume specialty testing in-house	• Superior onboard reagent stability reduces waste, lowers reagent management costs, maximizes tests per vial • Broad range of assays including easy-to-use INNOVANCE assays consolidate specialty and routine testing
Simplify regulatory compliance	• Growing quality assurance documentation requirements	• In-depth audit and archive capabilities, detailed traceability of results, 21 CFR Part 11 compliance • Full user-/role-based access management strengthens security



Atellica COAG 360 System:
A Game-Changer in Specialty Hemostasis Testing.

A world leader in hemostasis testing for more than 30 years, Siemens Healthineers once again has redefined what’s possible in specialty hemostasis testing. The Atellica COAG 360 System is a fully automated high-volume coagulation analyzer that simplifies lab operations by unifying five methodologies on one platform, streamlining workflow, and delivering infinite possibilities by being the first to integrate LOCI® technology in specialty hemostasis testing. The system is engineered by Siemens Healthineers to deliver:

Control: Reduces manual interaction, extends walkaway time, and offers uninterrupted

sample measurement through intelligent reagent and consumable management as well as continuous access to storage areas.

Simplicity: Integrates high-sensitivity immunoassay using LOCI technology and platelet aggregation testing,† enabling labs to provide faster test results for all samples.

Better outcomes: Integrates LOCI technology for the first time in specialty hemostasis testing and automates determination of prothrombin fragment F 1+2 into labs’ daily routine, with a fast assay turnaround time of less than 15 minutes, four times faster than the current testing protocol.

Delivering Five Methodologies on One Platform.



- Clotting (Optical & Optomechanical†)
- Chromogenic
- Immunologic
- Platelet Aggregation†
- High-sensitivity Immunoassay with LOCI Technology

†Siemens Healthineers applications are under development.

Strengthen Control over Your Lab Operations.

Simplify Workflow. Improve Business and Clinical Outcomes.

“The dedicated, automated module for the detection of HIL interferences improves consistency and reproducibility of results compared to a visual check of samples. This helps us to advance our preanalytical protocol and improve the quality of hemostasis test results.”

Dr. Dörge, Internist for Hematology and Hemostasis, Geesthacht, Germany

Control



1 Streamline workflow through reduced manual interaction, extended walkaway time, and uninterrupted sample measurement.

- Intelligent reagent and consumable management (true continuous loading, unloading, and real-time monitoring).
- Continuous access to all storage areas such as cuvettes, water, waste, reagents and stir bars. Direct plumbing of water and waste.
- Daily/weekly maintenance in less than 2/20 minutes, respectively, recorded at the touch of a button.
- User-defined automated start-up routine.
- Automated reflex, redilution, multidilution analysis, and repeat testing using customizable (lab-specific) rules.

2 Enhance operations through rapid throughput, superior reagent stability, and result traceability.

- Refrigerated chamber and anti-evaporation caps enable similar stability of once-opened and onboard reagents for many applications[‡]—saving you more than 1.5 hours per week.[§] This lowers reagent-management costs, and maximizes tests per vial.
- Rapid throughput for specialty assays and profiles with multiple tests per sample. 24 flexible reaction detector positions and a dedicated LOCI reader enable high-capacity performance for a variety of test profiles. High specialty-testing throughput of 310 results per hour^{**} delivers faster results.
- In-depth audit and archive capabilities allow thorough traceability of results, including >5 years' storage.
- Intuitive system interface leverages user-friendly software structure.

[‡]Please refer to instrument-specific reagent application/reference guide for more information.

[§]Results based on a quantitative study comparing Atellica COAG 360 System and BCS[®] XP System.

^{**}Throughput values were determined by the time to first result using Siemens study protocol with cap piercing and HIL for PT/APTT/AT/DD (Thromborel[®] S, Pothromtin[®] SL, INNOVANCE Antithrombin, INNOVANCE D-Dimer reagents).



3 Unify hemostasis testing as never before possible.

- Combines five methodologies—clotting (optical and optomechanical), chromogenic, immunologic, platelet aggregation, and high-sensitivity immunoassay (LOCI) testing—on one testing platform, speeding test results for all samples.
- Deploys fully automated reaction stirring for optomechanical clotting tests[‡] and aggregation testing[‡], enabling random access for special parameters.
- Eases sample management with cap-piercing technology and the ability to process a large variety of primary and secondary sample tubes.

4 Leverage innovative assays and/or connectivity options to consolidate routine and specialty testing

- Broad, easy-to-use specialty testing menu includes state-of-the-art INNOVANCE and INNOVANCE LOCI assays, consolidating routine and specialty testing onto one system.
- Flexible and multidisciplinary connectivity options allow customizable integration with point-in-space sample transfer design to our automation solutions: Aptio[®] Automation, FlexLab Automation, CentraLink[®] Data Management System.
- Designed to complement the proven Sysmex[®] CS-5100 System.

5 Reduce errors, minimize repeat testing with reliable test results.

- Advanced preanalytical capabilities using proven PSI technology and simultaneous multiwavelength scanning for accurate and reliable results on the first run.
- Primary-tube sample-volume checks, advanced assay-specific sample quality checks for hemolysis, icterus, and lipemia (HIL) interference.
- Nine predefined, assay-specific HIL interference warning levels used for all Siemens Healthineers applications.
- Simultaneous multiwavelength scanning reduces the effects of interfering substances on the absorbance spectra by automatically selecting optimal wavelengths.

6 Deliver infinite possibilities, focus on value-added services.

- First system to integrate LOCI technology and automate determination of prothrombin fragment F 1+2 into daily routine with a fast assay turnaround time of less than 15 minutes, four times faster than the current testing protocol.
- STAT results in less than 8 minutes allow fast and efficient handling of emergency samples.
- Gain time to shift lab focus from operational tasks to results interpretation, improved clinical outcomes.

[‡]Siemens Healthineers applications are under development.

Simplicity



Better Outcomes



Increase Insight into Hemostatic Disorders. Advance Your Preanalytical Protocol. Simplify Testing.



LOCI technology and INNOVANCE LOCI assays

An innovative homogeneous immunoassay technology developed by Siemens Healthineers, LOCI employs unique oxygen channeling technology and provides high precision with a small sample volume while reducing the risk of interference:

- Increase insight into hemostatic disorders with the new CE-marked INNOVANCE LOCI F 1+2 assay and INNOVANCE LOCI hs D-Dimer assay.^{††}
- Automate the determination of F 1+2 into your daily routine. The INNOVANCE LOCI F 1+2 assay has a rapid turnaround time of less than 15 minutes—four times faster than the current testing protocol.
- Enable single-sample measurement and STAT processing for emergency samples.

Preanalytical interferences associated with diagnostic errors in hemostasis ^{1,2,‡‡}				
	Hemolysis	Icterus	Lipemia	Improper Tube Filling
Falsely Increased Results	PT, D-dimer, FV, FVII, FX	PT, Fibrinogen	Antithrombin	PT, APTT
Unaffected Results		APTT	PT, APTT	
Falsely Decreased Results	APTT, Fibrinogen, Antithrombin, Thrombin Time	Antithrombin	Fibrinogen	D-dimer

Advanced preanalytical sample quality (PSI) checks

Preanalytical errors account for up to 70% of mistakes in laboratory diagnostics.³ Siemens Healthineers pioneered its proven PSI technology to deliver first-run test accuracy. The Atellica COAG 360 System significantly advances preanalytical capabilities:

- Detect underfilled or overfilled samples and accurately identify assay-specific hemolytic, icteric, and lipemic (HIL) interferences using nine predefined levels.
- Reduce the effects of interfering substances by automatically selecting optimal wavelengths using simultaneous multiwavelength scanning at 340, 405, 630, and 850 nm.
- Manage problematic test samples, reduce repeat testing, and drive better outcomes with accurate, reliable results on the first test run.

You spoke, and Siemens Healthineers listened. The Atellica COAG 360 System delivers advantages never before available on a coagulation system.



Automated reaction stirring

For optomechanical clotting[†] and aggregation testing,[†] the Atellica COAG 360 System enables random access for special parameters:

- Combine optical and optomechanical testing in a single instrument for greater efficiencies.
- Leverage a simple, hands-free alternative for certain special samples.
- Reduce your lab's acquisition costs, physical footprint, maintenance, consumable overhead, operator footsteps, and total cost of ownership.

[†]Siemens Healthineers applications are under development.

^{††}Research use only. Not for use in diagnostic procedures.

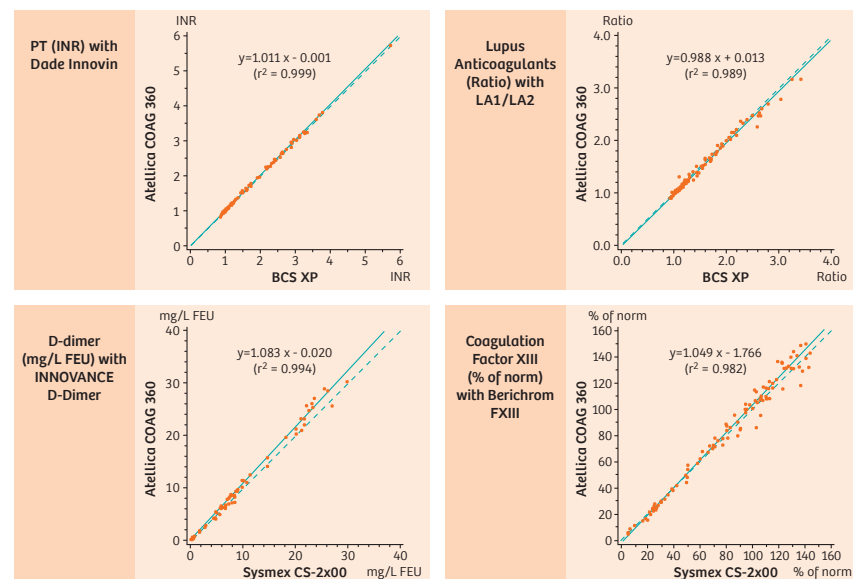
^{‡‡}Effects of preanalytical interferences vary. Please refer to instrument-specific reagent application/reference guide for more information.

Scalable, End-to-End Portfolio of Hemostasis Solutions. Minimize Vendor Complexity. Gain Tighter Control of Your Lab.

The Atellica COAG 360 System is a powerful addition to Siemens Healthineers comprehensive portfolio of hemostasis systems delivering end-to-end capabilities and scalability to meet your lab's current and future needs. Flexible multidisciplinary connectivity options allow customizable integration with Siemens Healthineers automation solutions. For labs running both routine and specialty hemostasis tests, the Atellica COAG 360 System is designed

to complement the proven Sysmex CS-5100 System. For fully automated multidisciplinary testing, each system can connect to Aptio Automation. Siemens Healthineers systems are backed by a broad assay-menu offering, and highly responsive maintenance and educational services. Siemens is the only company that can serve as your single-source provider for complete automation of chemistry, immunoassay, hemostasis, and hematology workflows.

Figures 1–4. Correlation plots for Dade® Innovin®, LA1 screening, LA2 confirmation, INNOVANCE D-Dimer, and Berichrom® Factor XIII Chromogenic assays.



Hemostasis Portfolio		Clotting (Optomechanical)	Clotting (Optical)	Chromogenic	Immunologic	Platelet Aggregation	PSI Checks	Automation Connectivity	High-sensitivity Immunoassay
High Volume ↑ Low Volume	Atellica COAG 360 System*	•†	•	•	•	•†	•	•	•
	Sysmex CS-5100 System		•	•	•	•§§	•	•	
	BCS XP System		•	•	•				
	Sysmex CS-2500 System		•	•	•	•§§	•		
	Sysmex CA-600 Systems		•	•	•				
	BFT™ II System	•							
Point of Care	Xprecia Stride® Coagulation Analyzer								
Platelet Function Testing	INNOVANCE PFA-200 System*								

To learn more about how Siemens Healthineers solutions and services can bring control, simplicity, and better outcomes to your lab environment, please contact your local representative.

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†Siemens Healthineers applications are under development.

§§Applications will be provided by Sysmex and Hyphen BioMedical.

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

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References:

1. Favalaro EJ, Lippi G, Funk (Adcock) D. Pre-analytical variables in coagulation testing associated with diagnostic errors in hemostasis. *Labmedicine*. 2012 Feb;43(2).
2. Lippi G, Plebani M, Favalaro EJ. Interference in coagulation testing: focus on spurious hemolysis, icterus, and lipemia. *Semin Thromb Hemost*. 2013;39:258-266.
3. Lippi G, Banfi G, Buttarello M, et al. Recommendations for detection and management of unsuitable samples in clinical laboratories. *Clin Chem Lab Med*. 2007;45(6):728-736.

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