

### **INNOVANCE** Heparin assay

# Ready-to-use liquid heparin testing

Fewer steps to precise results

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# An assay that delivers accurate, efficient, and secure heparin testing without compromise

The INNOVANCE® Heparin assay is an accurate, efficient, and secure test for the quantitative determination of unfractionated heparin (UFH) and low-molecular-weight heparin (LMWH) activity in citrated human plasma. You can take fewer steps to generate precise results with an automated chromogenic assay that features easy-to-use liquid reagents and a single calibration curve for both UFH and LMWH.

With the INNOVANCE Heparin assay, labs can realize significant operational and economic benefits from a precise and reliable assay that minimizes operator interaction and makes heparin testing more routine.

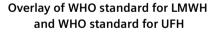
#### Truly ready-to-use

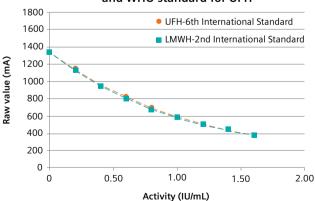
Lyophilized reagents require reconstitution, and some liquid reagents may need to stand for up to 30 minutes prior to testing. By employing liquid reagents, the INNOVANCE Heparin assay does not require manual preparation or standing time before use.

With a simplified handling process, it's easy to integrate this assay into your lab's normal workflow, making heparin testing available 24/7.

#### Simple, secure interpretation of results

Heparin assays may require the use of individual calibrators and calibration curves when testing for UF or LMW heparin. The INNOVANCE Heparin assay features a universal calibrator set that employs a single calibration curve for both types of heparin, streamlining result





Measured with the INNOVANCE Heparin assay on the BCS XP System.

interpretation and eliminating the risk of evaluation on the wrong curve. Because a single curve is used, lab technicians do not have to spend valuable time verifying the type of heparin with which each patient is being treated. The universal calibrator set is traceable to the World Health Organization (WHO) standards for LMWH and UFH, helping to ensure that laboratory personnel can confidently and accurately interpret heparin results.

#### Highly precise, reliable results

The INNOVANCE Heparin assay possesses features that help deliver the same high-quality results that labs have come to expect from the INNOVANCE hemostasis testing line:

- Dedicated two-level controls traceable to the WHO standards for UF and LMW heparin
- Broad and consistent assay range of 0.10 to 1.50 IU/mL for both heparin types
- Single calibration curve that includes five levels for improved accuracy and precision
- Robust assay design that reduces susceptibility to interferences
- High lot-to-lot consistency that helps ensure accurate patient results each time

#### **Precision study**

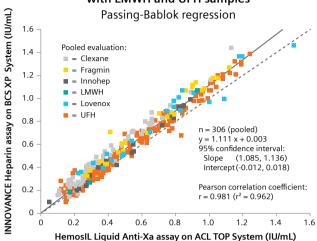
Sample	Mean (IU/mL)	Repeatability (SD/CV)	Within-device precision (SD/CV)
UFH Plasma Pool 1	0.16	SD = 0.010	SD = 0.012
LMWH Plasma Pool 1	0.17	SD = 0.009	SD = 0.013
UF Control 1	0.30	SD = 0.008	SD = 0.010
LMW Control 1	0.46	SD = 0.023	SD = 0.026
UF Control 2	0.63	CV = 1.30	CV = 1.64
LMWH Plasma Pool 2	0.66	CV = 1.50	CV = 1.95
LMW Control 2	1.01	CV = 1.13	CV = 1.63
LMWH Plasma Pool 3	1.07	CV = 1.14	CV = 1.59
LMWH Plasma Pool 4	1.31	CV = 1.03	CV = 1.21
UFH Plasma Pool 2	1.40	CV = 0.72	CV = 1.05

Precision study with the INNOVANCE Heparin assay on the BCS XP System (n = 80).

SD: standard deviation in IU/mL CV: coefficient of variation in %

# Expand precision medicine through improved diagnostic accuracy in heparin testing.

## INNOVANCE Heparin method comparison study with LMWH and UFH samples



#### Efficient use of materials and resources

The liquid reagents and universal calibrator set comprising the INNOVANCE Heparin assay help reduce handling, material, and ordering complexity, improving both the clinical and economic performance of your lab. Once opened, reagents remain stable for 8 weeks at 2–8°C, helping to reduce both waste and cost. The assay runs on multiple platforms, including the BCS® XP and Atellica® COAG 360 Systems from Siemens Healthineers, as well as the Sysmex® CS\* and Sysmex CA-660 Systems; exhibits excellent correlation between analyzers; and requires only 10 µL of sample volume per test.

Each assay kit contains an approximate total of 180 tests packaged in five vials that yield approximately 36 determinations each. Labs can reliably obtain a comparable number of tests per kit, regardless of which Siemens Healthineers or Sysmex system the assay is run on, simplifying ordering and reagent inventory management.

### Instrument comparison: BCS XP System vs. Sysmex CS-2100*i* System

Passing Bablok Regression	n	r	Slope	Intercept
LMWH and UFH	176	0.994	1.00	-0.05
UFH	91	0.998	1.00	-0.04
LMWH	85	0.990	1.00	-0.05

The INNOVANCE Heparin assay offers excellent correlation between Siemens Healthineers and Sysmex systems.

#### About heparin

Heparin is an anticoagulant used to prevent and treat blood clots in at-risk patients. Heparin exists in two forms—unfractionated heparin (UFH) and low-molecular-weight heparin (LMWH)—both of which considerably accelerate the inactivation of coagulation factor Xa by antithrombin. The anticoagulant activity of UFH is somewhat unpredictable. Conversely, LMWH anticoagulant activity is more consistent and predictable, so LMWH is gradually replacing UFH in clinical use, although both are still widely employed.

#### Heparin determination

Administration of excessive amounts of either form of heparin can induce bleeding in patients, so heparin therapy must be carefully managed by clinicians. Typically, UFH is assessed with the use of either an APTT or an anti-Xa test; LMWH can be evaluated with an anti-Xa assay only. The use of an anti-Xa assay with UFH continues to gain in popularity, as clinical data supports several advantages over APTT testing:<sup>1–5</sup>

- A smoother dose-response curve
- More-stable heparin levels during therapy
- Fewer blood samples required
- Fewer dosage adjustments



# The INNOVANCE line of products: Evolution in motion

The new INNOVANCE Heparin assay is part of an expanding menu of hemostasis products that deliver the performance your lab needs to overcome the most difficult testing challenges. Whether for improved workflow or enhanced clinical outcomes, you can trust in Siemens Healthineers to offer the most advanced diagnostic solutions.

Contact your Siemens Healthineers representative today to generate precise results in fewer steps with the accurate, efficient, and secure INNOVANCE Heparin assay.

<sup>\*</sup>Including Sysmex CS-2000i, CS-2100i, CS-2500, and CS-5100 Systems.

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.

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