Ready-to-use Liquid Heparin Testing—Fewer Steps to Precise Results

INNOVANCE Heparin Assay
A novel 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. Now 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, while some liquid reagents may need to stand for up to 30 minutes prior to testing. The INNOVANCE Heparin assay employs liquid reagents that do 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 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.

### Overlay of WHO Standard for LMWH and WHO Standard for UFH

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

**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 either the use of 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.1-5

- A smoother dose-response curve
- More-stable heparin levels during therapy
- Fewer blood samples required
- Fewer dosage adjustments
Highly precise, reliable results
The CE-marked 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

<table>
<thead>
<tr>
<th>Sample</th>
<th>Mean (IU/mL)</th>
<th>Repeatability (SD/CV)</th>
<th>Within-device Precision (SD/CV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>UFH Plasmapool 1</td>
<td>0.16</td>
<td>SD = 0.010</td>
<td>SD = 0.012</td>
</tr>
<tr>
<td>LMWH Plasmapool 1</td>
<td>0.17</td>
<td>SD = 0.009</td>
<td>SD = 0.013</td>
</tr>
<tr>
<td>UF Control 1</td>
<td>0.30</td>
<td>SD = 0.008</td>
<td>SD = 0.010</td>
</tr>
<tr>
<td>LMW Control 1</td>
<td>0.46</td>
<td>SD = 0.023</td>
<td>CV = 1.64</td>
</tr>
<tr>
<td>UF Control 2</td>
<td>0.63</td>
<td>CV = 1.30</td>
<td>CV = 1.64</td>
</tr>
<tr>
<td>LMWH Plasmapool 2</td>
<td>0.66</td>
<td>CV = 1.50</td>
<td>CV = 1.95</td>
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<tr>
<td>LMW Control 2</td>
<td>1.01</td>
<td>CV = 1.13</td>
<td>CV = 1.63</td>
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<tr>
<td>LMWH Plasmapool 3</td>
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<td>CV = 1.14</td>
<td>CV = 1.59</td>
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<tr>
<td>LMWH Plasmapool 4</td>
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<td>CV = 1.03</td>
<td>CV = 1.21</td>
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<tr>
<td>UFH Plasmapool 2</td>
<td>1.40</td>
<td>CV = 0.72</td>
<td>CV = 1.05</td>
</tr>
</tbody>
</table>

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 %

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 Siemens BCS™ XP System and Sysmex® CS-2000i, CS-2100i, and CS-5100 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 or Sysmex system the assay is run on, simplifying ordering and reagent inventory management.

Instrument Comparison: BCS XP System vs. CS-2100i System

<table>
<thead>
<tr>
<th>Passing Bablok Regression</th>
<th>n</th>
<th>r</th>
<th>Slope</th>
<th>Intercept</th>
</tr>
</thead>
<tbody>
<tr>
<td>LMWH and UFH</td>
<td>176</td>
<td>0.994</td>
<td>1.00</td>
<td>-0.05</td>
</tr>
<tr>
<td>UFH</td>
<td>91</td>
<td>0.998</td>
<td>1.00</td>
<td>-0.04</td>
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<tr>
<td>LMWH</td>
<td>85</td>
<td>0.990</td>
<td>1.00</td>
<td>-0.05</td>
</tr>
</tbody>
</table>

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

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 to offer the most advanced diagnostic solutions.

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