

Bản tiêu chuẩn Chủ sở hữu công bố áp dụng

Tài liệu được xác nhận bằng chữ ký số

Hà Nội, ngày 23 tháng 11 năm 2022

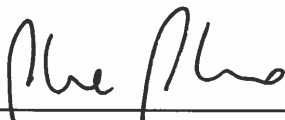
Người đại diện hợp pháp của cơ sở

GIÁM ĐỐC

Uông Tuấn Phương

Release Test SpecificationsProduct Name: **LIAISON Control Insulin****REF: 310361**

Activity	Specification
Checking the correctness of calibration and operating parameters reported in the labels	<p>In order for the checks to be approved at this stage, which ends with the final labeling on the processing sheet, the following requirements must be met:</p> <p>1) For LIAISON Analyzer only. The mean dose determined for the test control falls within the expected label limits (8.8 -13.2 μIU/mL for Control 1 and 88-132 μIU/mL for Control 2).</p> <p>2) For LIAISON Analyzer and LIAISON XL: for each of the 2 platforms the single doses found for Control 1 are included in the range \pm25% of the mean value determined with the test (i.e. the future label range) and the single doses found for the Control 2 are included in the \pm20% range of the mean value determined with the test (i.e. the future label range).</p>
Functional check after packaging in customer mode	All tests performed are valid if the approved Controls are within the expected ranges (label values). If the approved Controls give out-of-range values, repeat the calibration and re-dose Controls and Samples (repeat Run).

Authorised Signatory:

Dr. Andrea Armando

Corporate Director

Regulatory Affairs Operations & China