LABQUALITY

2018-05-28

INSTRUCTIONS

Rivaroxaban 1, 2018

Welcome to this Rivaroxaban round.

Product no. 4391
LQ778818011, LQ778818012/AT

The shipment includes
- specimens according to your order
- instructions

Please check the shipment and if it is incomplete, report immediately to the EQA coordinator.

EQA coordinator
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Please send the results via Labquality's homepage www.labquality.fi not later than

June 20, 2018

Specimens

Specimens **Sample 1** (S001:LQ778818011) and **Sample 2** (S002: LQ778818012) are lyophilised plasmas.

Quality control specimens derived from human blood must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. The specimens have been tested and found to be HBsAg- and HIV-Ab-negative, but no known test method can offer complete assurance that the specimens will not transmit these or other infectious diseases.

Reconstitution, stability and determinations

Store unopened vials in a refrigerator and after reconstitution at room temperature.
Open the vials carefully to prevent escape of dried material. Add the below mentioned amount of distilled water. Let the vials stand for at least 10 minutes at room temperature, swirl the contents until homogenous (avoid foaming) and use as a patient sample.
The clients are asked to analyse the rivaroxaban concentration of the samples.

Reconstitution:

Sample 1 add **1.0 ml** distilled water.
Sample 2 add **1.0 ml** distilled water**.**

Results and method data

Please fill in the enclosed result form and return one copy to Labquality´s office. We recommend return your paper result form as an attachment to info@labquality.fi. Also ordinary mail or fax can be used.

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Barcodes of the specimens

Sample 1	LQ778818011
Sample 2	LQ778818012

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Anticoagulants: Rivaroxaban, May, 1-2018

Specimen S001 | Rivaroxaban, ng/ml

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Berichrom Heparin	-	-	-	-	-	60.4	60.4	-	1
Biophen Heparin	-	-	-	-	-	68.0	68.0	-	1
Chromogenix Coamatic Heparin	64.8	65.8	6.1	9.4	2.7	58.0	73.2	-	5
Innovance Heparin	56.9	56.9	2.7	4.7	1.9	55.0	58.8	-	2
Stago Liquid anti-Xa	65.8	69.5	9.5	14.4	5.5	55.0	72.9	-	3
All	**63.6**	**63.1**	**6.6**	**10.3**	**1.9**	**55.0**	**73.2**	**-**	**12**

Specimen S001 | Rivaroxaban, ng/ml| histogram summaries in LabScala

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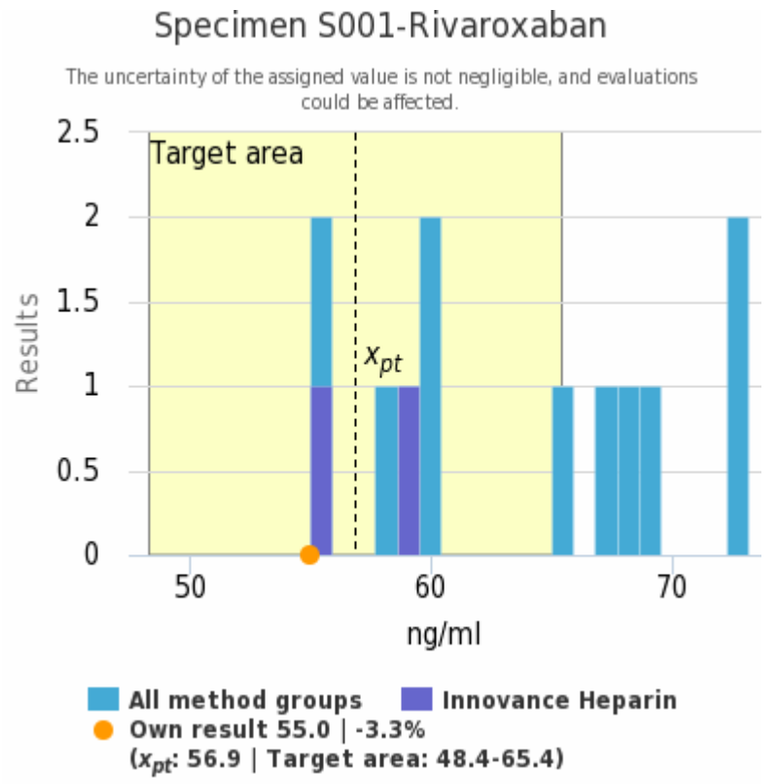
Anticoagulants: Rivaroxaban, May, 1-2018

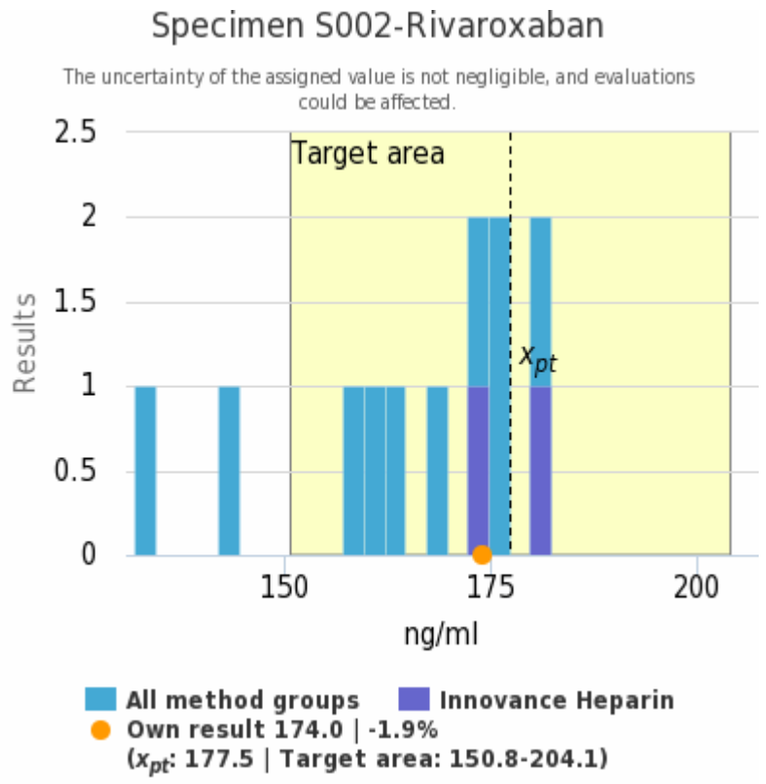
Specimen S002 | Rivaroxaban, ng/ml

Methodics	x_{pt}	Median	sd	CV%	SEM	min	max	Outliers	n
Berichrom Heparin	-	-	-	-	-	173.5	173.5	-	1
Biophen Heparin	-	-	-	-	-	132.0	132.0	-	1
Chromogenix Coamatic Heparin	168.5	167.4	6.6	3.9	3.0	160.3	175.5	-	5
Innovance Heparin	177.5	177.5	4.9	2.7	3.5	174.0	180.9	-	2
Stago Liquid anti-Xa	161.9	159.4	19.3	11.9	11.2	144.0	182.4	-	3
All	**165.7**	**170.5**	**15.1**	**9.1**	**4.4**	**132.0**	**182.4**	**-**	**12**

Specimen S002 | Rivaroxaban, ng/ml| histogram summaries in LabScala

Rivaroxaban |Luize





	x_{pt}	sd	SEM	CV%	n
Innovance Heparin	56.9 ng/ml	2.7	1.9	4.7	2
All methods	63.6 ng/ml	6.6	1.9	10.3	12

	x_{pt}	sd	SEM	CV%	n
Innovance Heparin	177.5 ng/ml	4.9	3.5	2.7	2
All methods	165.7 ng/ml	15.1	4.4	9.1	12

Round	Sample	x_{pt}	Result	diff%	z-score
18/1	Specimen S002	177.5	174.0	-1.9%	-
18/1	Specimen S001	56.9	55.0	-3.3%	-

2018-07-04

FINAL REPORT

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Rivaroxaban 1, 2018

Thank you for participating in this coagulation round among 10 participants from 5 countries.

Product no. 4391
LQ778818011, LQ778818012/AT

Items sent	2018-05-28
Round closed	2018-06-20
Results released	2018-06-27
Report released	2018-07-04

The next *Rivaroxaban* EQA round will be carried out in November 2018.

Specimens
Sample 1 (S001:LQ778818011) and **Sample 2** (S002: LQ778818012) were lyophilised plasmas.

Results
The results have been processed and presented in method groups in accordance with reagent.

Reports
You are now able to see also the method specific histograms in the numerical summary. The histograms are seen in Global report in left hand Rivaroxaban, May, 1-2018. The name of the method is listed on top of the histogram picture.

From the beginning of 2018 we have made some changes in the statistical calculations and reporting. In case the client's result is the only one in the method group, no assigned value will be calculated, no target area shown, and no statistics calculated. In case there are 2-11 results in a method group and the uncertainty of the target value is too large (u(xpt) < 0.1 * maximum allowable error is not true) an automatic text is printed on the report: "The uncertainty of the assigned value is not negligible, and evaluations could be affected." In case there are 2-4 results in a method group, no z-score is calculated, and a text is printed on the report: "Due to the small number of results, the z score is not calculated." In case there are 5-11 results, the z-score is calculated and the report has a text: "Z-score is uncertain due to the small number of observations."

In client specific reports your own result is shown with an orange dot. The target area is presented as a yellow area in the picture.

In the **history** graphs you are able to see your performance graphically with both against the assigned value (x_{pt}) and the z-score area of -2 -- +2.
Z-scores are calculated from the results of the EQA round concerned. Assessment of z-scores is based on the following criteria:

$-2.0 \leq z \leq 2.0$ is regarded as satisfactory;
$-3.0 < z < -2.0$ or $2.0 < z < 3.0$ is regarded as questionable ('warning signal');
$z \leq -3.0$ or $z \geq 3.0$ is regarded as unsatisfactory ('action signal').

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Comments

Altogether 12 results from five methods were received in this Rivaroxaban EQA round. There were two different samples containing direct factor Xa inhibitor rivaroxaban analysed, representing low concentration sample 001 and higher level sample 002. For the sample 001, the average concentration was 63.6 ng/mL with the range of 55.0-73.2 ng/mL. There was only slight variation in the reported results (CV 10.3%). For the sample 002, the mean concentration was higher 165.7 ng/mL with the range of 132.0-182.4 ng/mL. The consistency of the results was good (CV 9.1%).

End of report