ECAT FOUNDATION

EXTERNAL QUALITY ASSESSMENT PROGRAMME

IN HAEMOSTASIS AND THROMBOSIS

D-DIMER

EXERCISE 2005-2

LABORATORY CODE: 102

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GENERAL INFORMATION

- This was the second time we used a separate closing date for the D-Dimer module. There are still a significant number of participants who did not retrun their results in time. **PLEASE NOTICE THE CLOSING DATE FOR THE D-DIMER MODULE VERY WELL.** If you do not return your results in time next exercise, they will be not included into the evaluation.
- The results of each method used by one or more participants are shown in the part of the report for quantitative methods. However, only methods with at least 10 participants the inter-laboratory variation as well as the Z-score are given.
- For those methods a Z-score could be calculated for both samples, the relationship between both Z-scores is given in a Z-score plot.
- A significant number of laboratories did not report in the units indicated in the kit insert of the method. This is especially the case for users of a method expressing their results in Fibrinogen Equivalent Units. **Please take notice of the correct selection of the unit for your particular method.**
- For the following labcodes, using the Tinaquant method, it was clear that they had reported their results in DD-units in stead of FEU – labcode 389 , 417 and 464. Here we have transformed their result to FEU by multiplying the reported result by 2.
- About 5 participants clearly mixed up their results for the samples 05.22 and 05.23. Before starting data analysis we have corrected for this mistake. **Please notice that you report the correct result for each of the test samples.**

PARTICIPATION

Number of participants : 290

Number of responders : 236

Participation rate : 81.4%

Comments:

There is an increasing number of participants who have returned their results in time. Because for a separate group of German laboratories a wrong closing date was indicated at their report forms we have wait with the evaluation of the results till this date has passed (June 20th).
To further improve the response rate, please notice carefully the closing date for D-Dimer during the next exercises.

PLASMA

Sample	Description	Former used
05.22	Mixture of pooled patient plasma and pooled plasma of apparently healthy volunteers resulting in elevated Dimer levels. (clearly elevated D-Dimer level)	-
05.23	Mixture of pooled patient plasma and pooled plasma of apparently healthy volunteers resulting in elevated Dimer levels. (slightly elevated D-Dimer level)	-

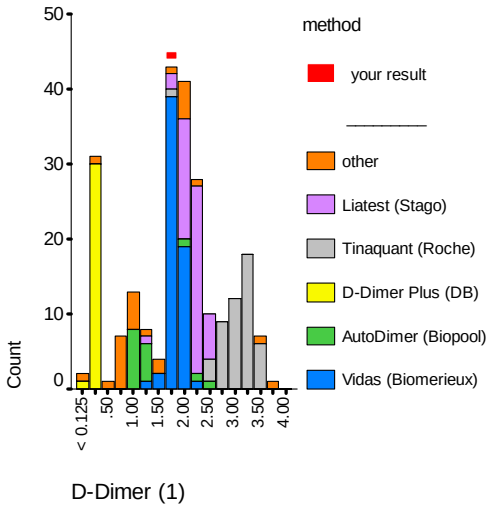
OUTLIERS

Sample	Labcodes
05.22	128 , 351 , 362
05.23	362 , 464

SEMI-QUANTITATIVE METHOD

Semi-Quantitative results (mg/L)	<0.25	0.25-0.50	0.51-1.0	1.01-2.0	2.01-4.0	4.01-8.0	your result
Sample 05.07		**1**					
Sample 05.08	**1**						

QUANTITATIVE METHOD SAMPLE 05.22

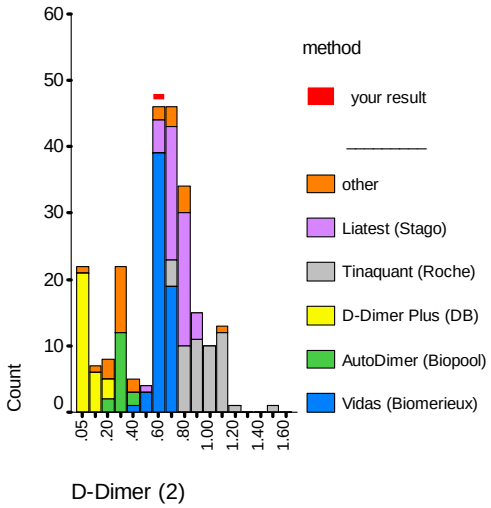


D-Dimer (1)

D-Dimer (ng/mL D-Dimer)	n	mean	CV	range	your result	Z-score
MiniQuant (Trinity/Biopool)	1	1.80				
AutoDimer (Trinity/Biopool)	16	1.33	35.3%	0.90 – 2.40		
Auto D-Dimer (Trinity/Sigma)	1	0.80				
D-Dimer Plus (Dade Behring)	31	0.19	19.8%	0.11 – 0.29		
Dimertest Latex (Dade Behring)	1	0.10				
Dimertest Turbiquant (Dade Behring)	1	0.32				
Dimertest (IL)	5	0.80		0.69 – 0.87		
D-Dimer (ILS-LS)	3	0.83		0.55 – 1.08		
D-Dimer (Medirox)	3	1.06		1.03 – 1.13		
Nycocard (Nycomed)	1	1.00				
Dimertest (Ortho)	1	1.95				
Other / Unknown	1	2.08				

D-Dimer (ng/mL FEU)	N	mean	CV	range	your result	Z-score
Vidas (Biomerieux)	62	1.83	7.6%	1.52 – 2.17	**1.79**	**-0.29**
Latex D-Dimer (Biomerieux)	1	0.97				
MDA D-Dimer (Biomerieux)	2	1.47		1.41 – 1.54		
Kokusai D-Dimer test	1	3.50				
Tinaquant (Roche)	49	3.08	9.1%	2.50 – 3.52		
Latex D-Dimer (Roche)	3	2.06		1.96 – 2.17		
Cardiac Reader (Roche)	1	3.80				
Liatest (Stago)	50	2.19	7.8%	1.68 – 2.62		
Asserachrom (Stago)	1	1.94				

QUANTITATIVE METHOD SAMPLE 05.23

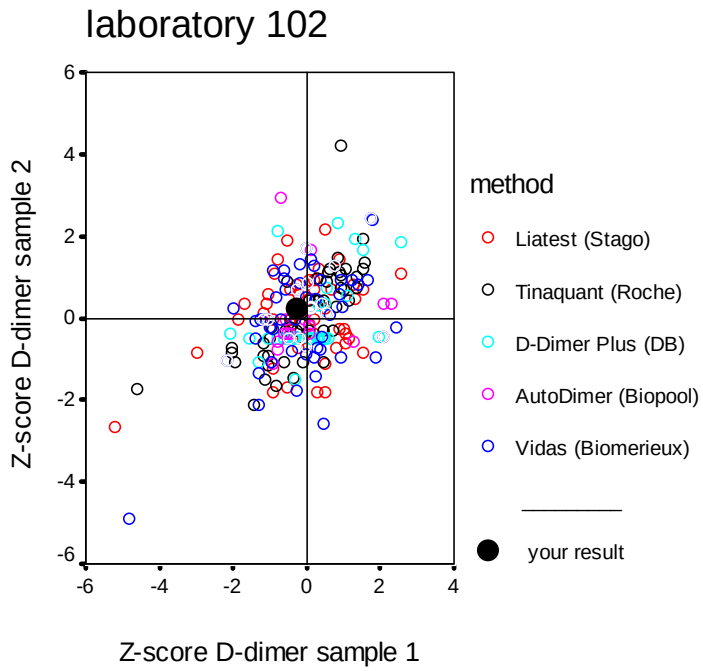


D-Dimer (2)

D-Dimer (ng/mL D-Dimer)	n	mean	CV	range	your result	Z-score
MiniQuant (Trinity/Biopool)	1	0.33				
AutoDimer (Trinity/Biopool)	16	0.28	19.3%	0.22 – 0.44		
Auto D-Dimer (Trinity/Sigma)	1	0.11				
D-Dimer Plus (Dade-Behring)	30	0.07	59.2%	0.01 – 0.17		
Dimertest Latex (Dade Behring)	1	0.05				
Dimertest Turbiquant (Dade Behring)	1	0.26				
Dimertest (IL)	5	0.34		0.20 – 0.43		
D-Dimer (ILS-LS)	3	0.28		0.24 – 0.33		
D-Dimer (Medirox)	3	0.26		0.21 – 0.28		
Nycocard (Nycomed)	1	0.60				
Dimertest (Ortho)	1	0.28				
Other / Unknown	1	0.69				

D-Dimer (ng/mL FEU)	N	mean	CV	Range	your result	Z-score
Vidas (Biomerieux)	62	0.62	6.9%	0.51 – 0.73	**0.63**	**0.23**
Latex D-Dimer (Biomerieux)	1	0.26				
MDA D-Dimer (Biomerieux)	2	0.63		0.59 – 0.67		
Kokusai D-Dimer test	1	1.10				
Tinaquant (Roche)	49	0.94	14.0%	0.66 – 1.20		
Latex D-Dimer (Roche)	3	0.76		0.67 – 0.82		
Cardiac Reader (Roche)	1	0.83				
Liatest (Stago)	50	0.74	11.2%	0.52 – 0.92		
Asserachrom (Stago)	1	0.82				

QUANTITATIVE METHOD



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The Z-score plot shows the relationship between the Z-scores of both samples used in this survey.
In this plot only the Z-scores of methods with at least 10 participants are included.
The relationship of both Z-scores gives you an indication if your deviation from the mean value of your particular method is caused by systematic and/or random errors.