

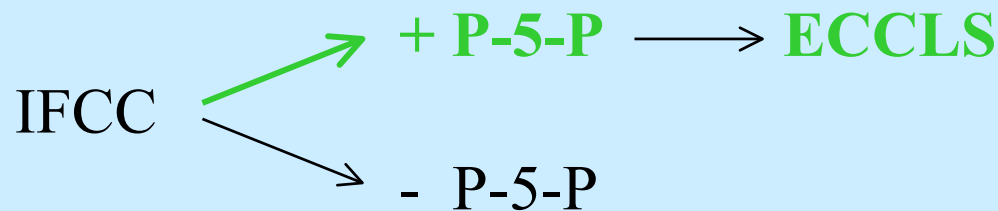
Recommended enzyme methods in the Nordic countries

	<u>1974-79</u>	<u>1991</u>	<u>1.1.2003??</u>
ALT	SCE	ECCLS, 37 C	IFCC, 37 C
AST	SCE	ECCLS, 37 C	IFCC, 37 C
CK	SCE	ECCLS, 37 C	IFCC, 37 C
GT	SCE	ECCLS, 37 C	IFCC, 37 C
ALP	SCE		IFCC, 37 C
LD	SCE		IFCC, 37 C
AMYLASE	Phadebas	Several, 37 C	IFCC, 37 C

Common reference intervals: 1.1.2003?

Enzyme methods in use in the Nordic Countries, 2002

AST / ALT:



Note:

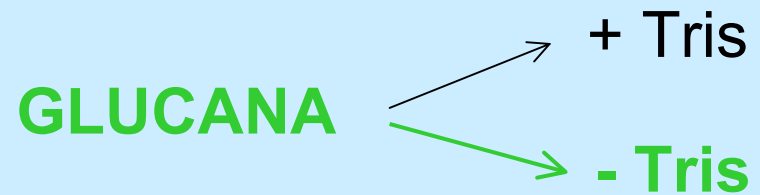
- In the US both versions are used (Olympus, Aeroset, Advia)
- P-5-P is generally supplied as separate tablets
- The tablet is easily forgotten!

Enzyme methods in use in the Nordic Countries, 2002

GT:

”A family of methods”

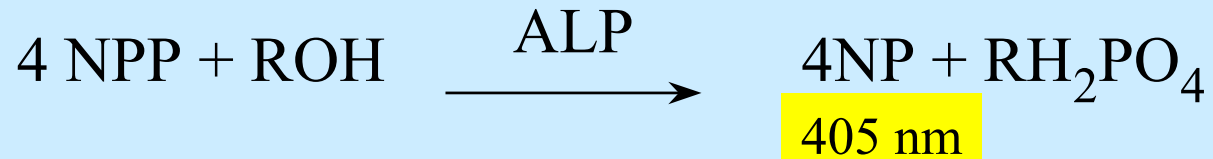
Two alternative substrates: GLUPA



Note:

- All methods may be calibrated to IFCC-level and thereby be traceable to and compatible to the IFCC reference method

Alkaline phosphatase, - ALP



SCE: ROH = DiEthanolAmine buffer, DEA

IFCC: ROH = Amino-MetyloProPanol buffer, AMP,
and water

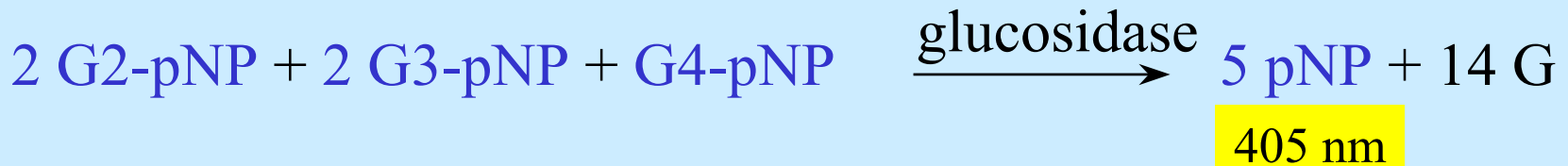
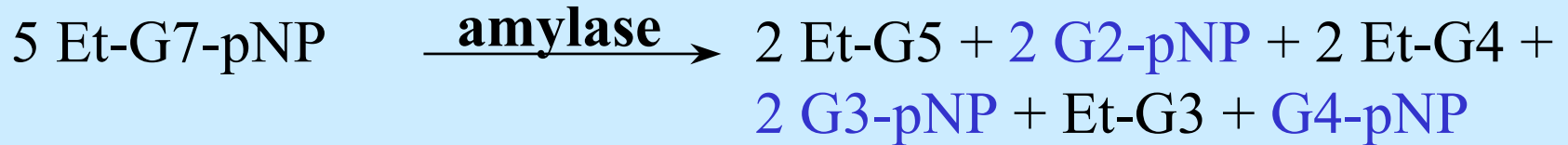
Note:

- Only available IFCC ref. method at 30°!

Lactate Dehydrogenase, - LD



Amylase, - IFCC



Note:

- Different substrates are in use:
other blocked pNP-G7 / pNP-G6 / G4 / blocked pNP-G3 / Starch
giving different activity levels and different balance between
isoenzymes (non compatibility)
- P-amylase is done by this substrate (Et-G7-pNP)

Enzyme methods, Vitros

Enzyme	Method , traceability
ALT } AST }	w / P-5-P Traceable/comparable to the IFCC ref.meth. w/P-5-P at 37°
CK	Traceable/comparable with SCE and the IFCC ref.meth. at 37 °
GT	GluNA Traceable/comparable to the IFCC ref.meth. at 37°
ALP	AMP Traceable/comparable to IFCC ref.meth.(30°) run at 37°
LD	Pyruvate to Lactate (NADH consumption) Traceable/comparable to the the method of Buhl
Amylase	Amylopectin Traceable/comparable to an Et-G7-pNP method at 37°

Selection criteria for computation of reference intervals for the enzymes

Project Description

“The laboratories shall use their routine methods.

However only Vitros and "IFCC 37 °C" methods shall be used for enzymes.....”

Reported method information

According to the Labquality method book 1999-2000:

Reagent name

Instrument name

Method group

Adjustment/conversion factors and intercepts

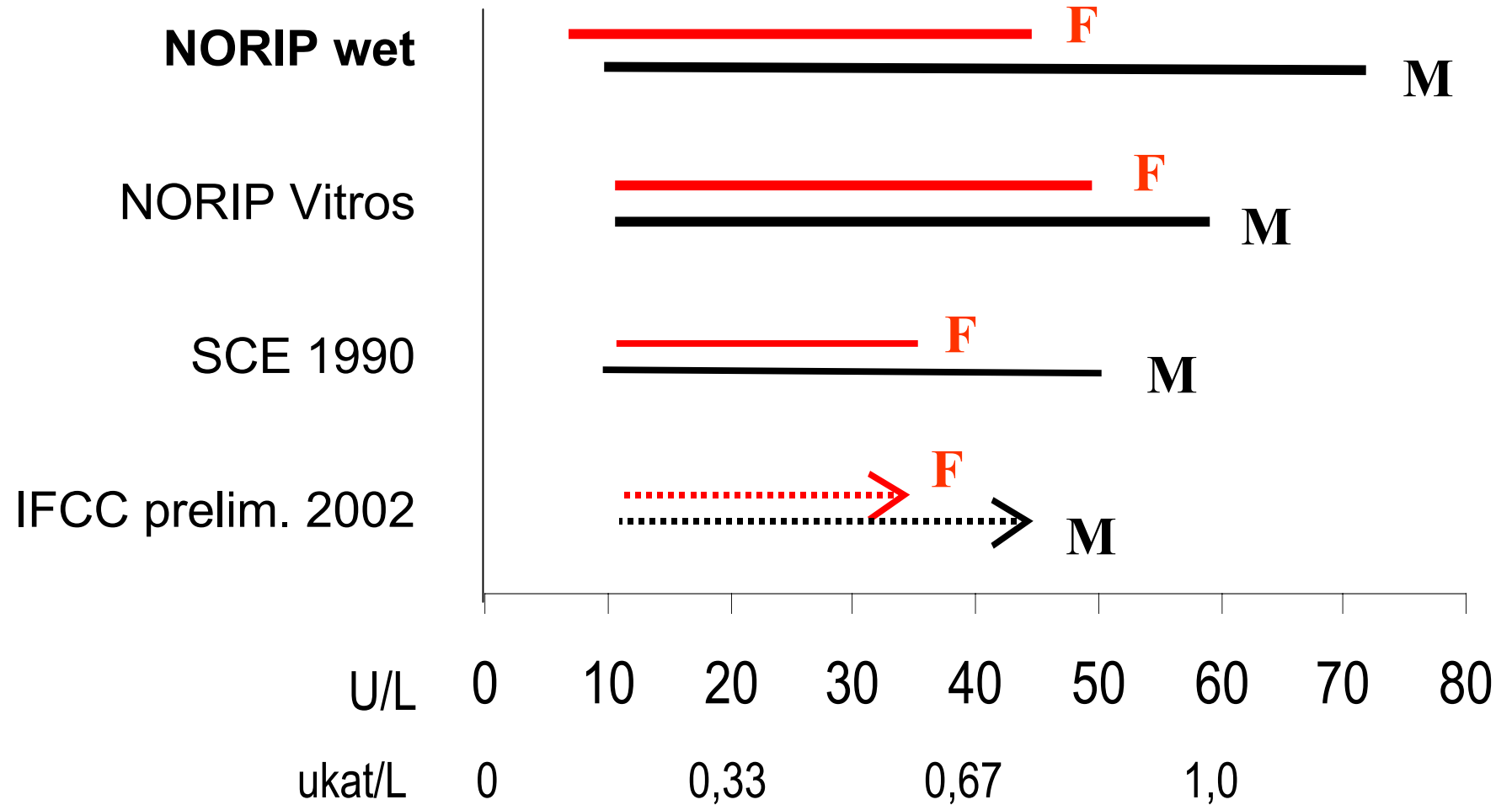
Selection criteria:

- The method used should be traceable to and compatible with the IFCC reference method at 37°:
 - AST, ALT, CK, GT : Stated met.group: **IFCC (ECCLS)**
 - Amylase: Roche/Boehringer EPS (conversion factor 1)
- Results should originate from “complete analysis systems” (same vendor of reagents, calibrator and instrument)
- ALP and LD: reanalysis with IFCC traceable/comparable reagents
- Reported values were recalculated to original values, traceable to the calibrator of the vendor . (All slopes and intercepts were recalculated to 1/ 0)
- Vitros values were calculated separately

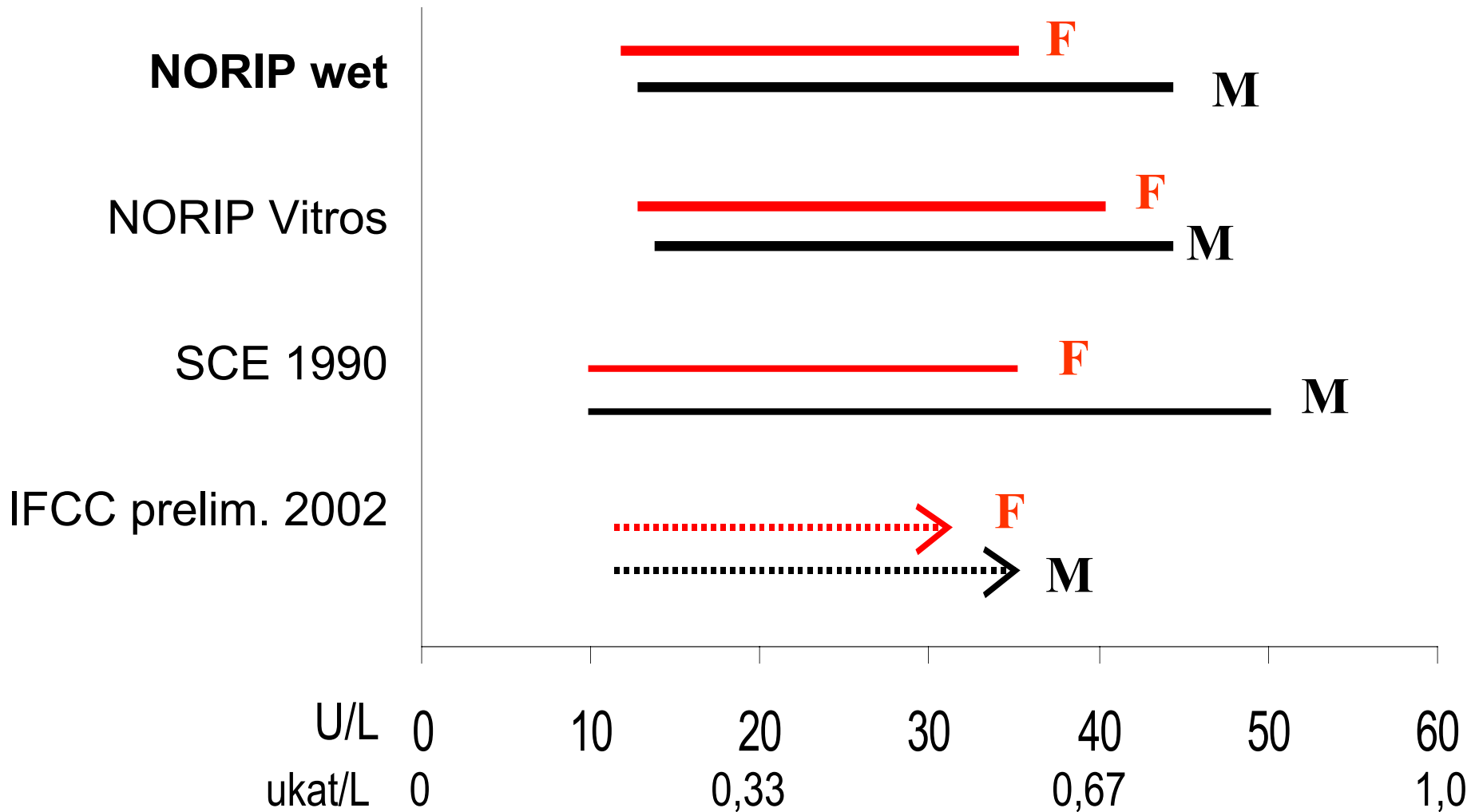
% of the reported results included in the computation of reference values for enzymes

	Total reported		% included	
	wet chem	Vitros	wet chem	Vitros
ALT	2078	674	83	95
AST	1885	565	90	94
CK	1737	528	85	94
GT	1962	594	44	90
Amyl	1345	675	54	90
P-Amyl	1831		60	

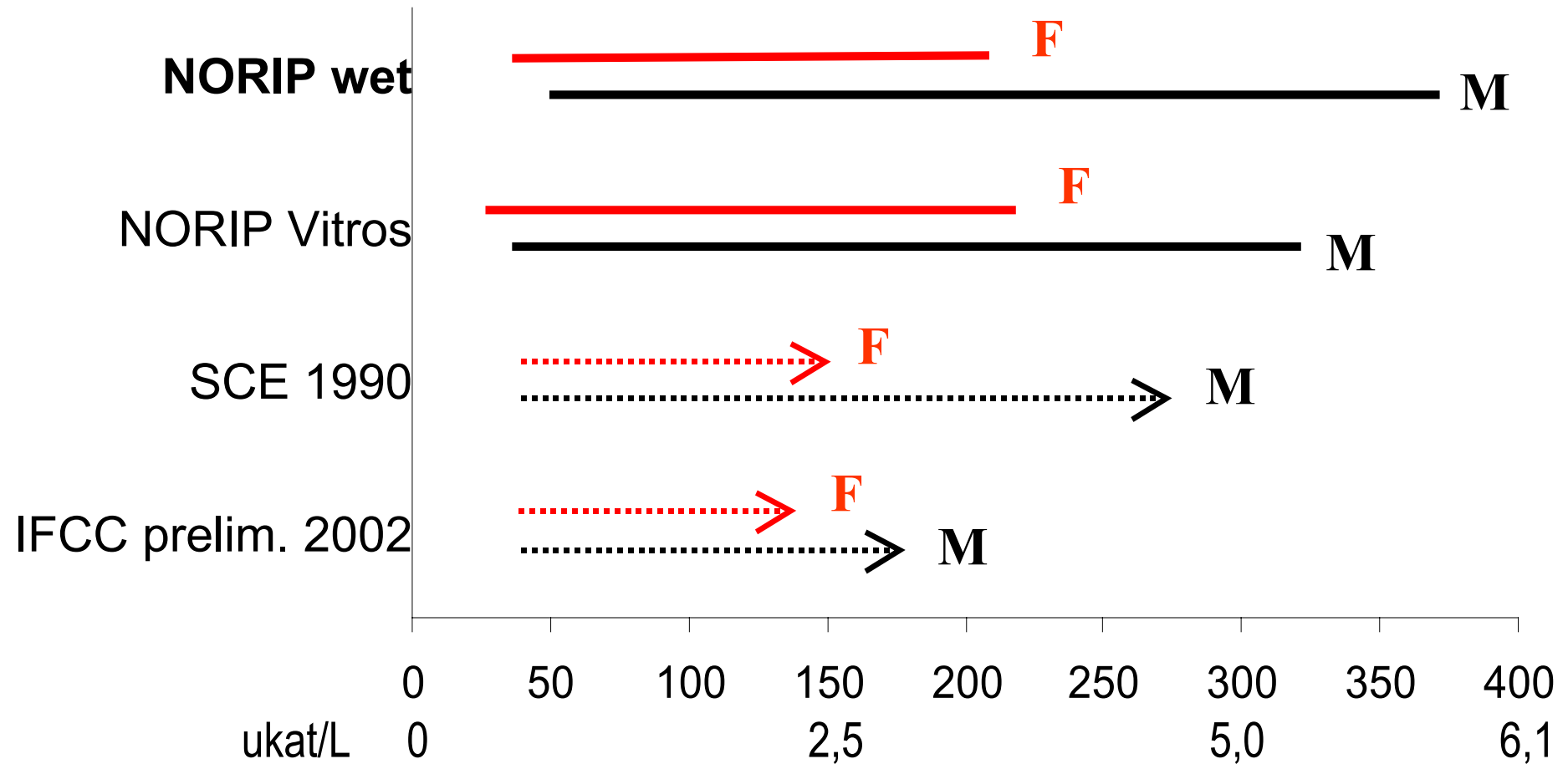
ALT, - suggested reference ranges



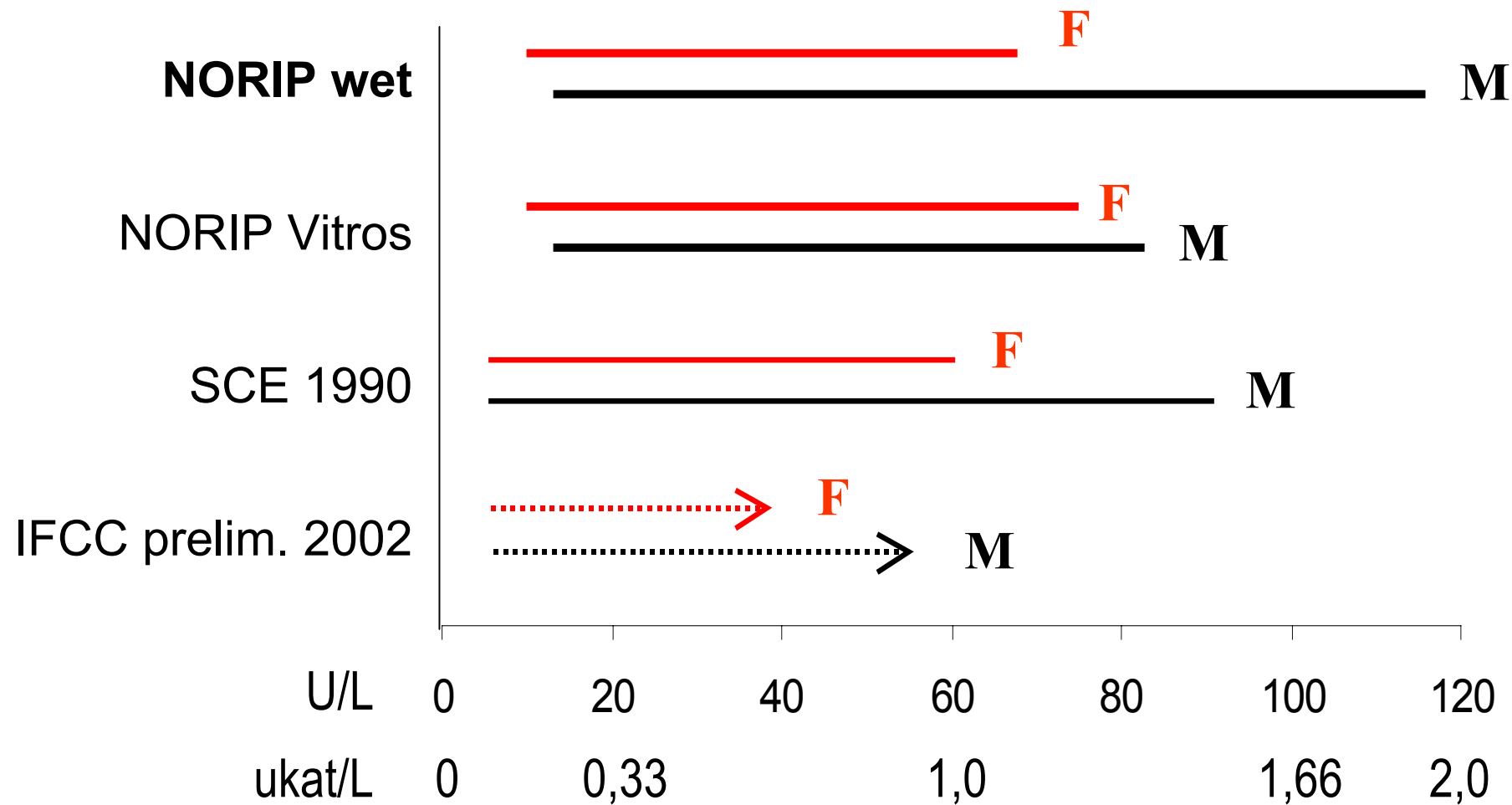
AST, - suggested reference ranges



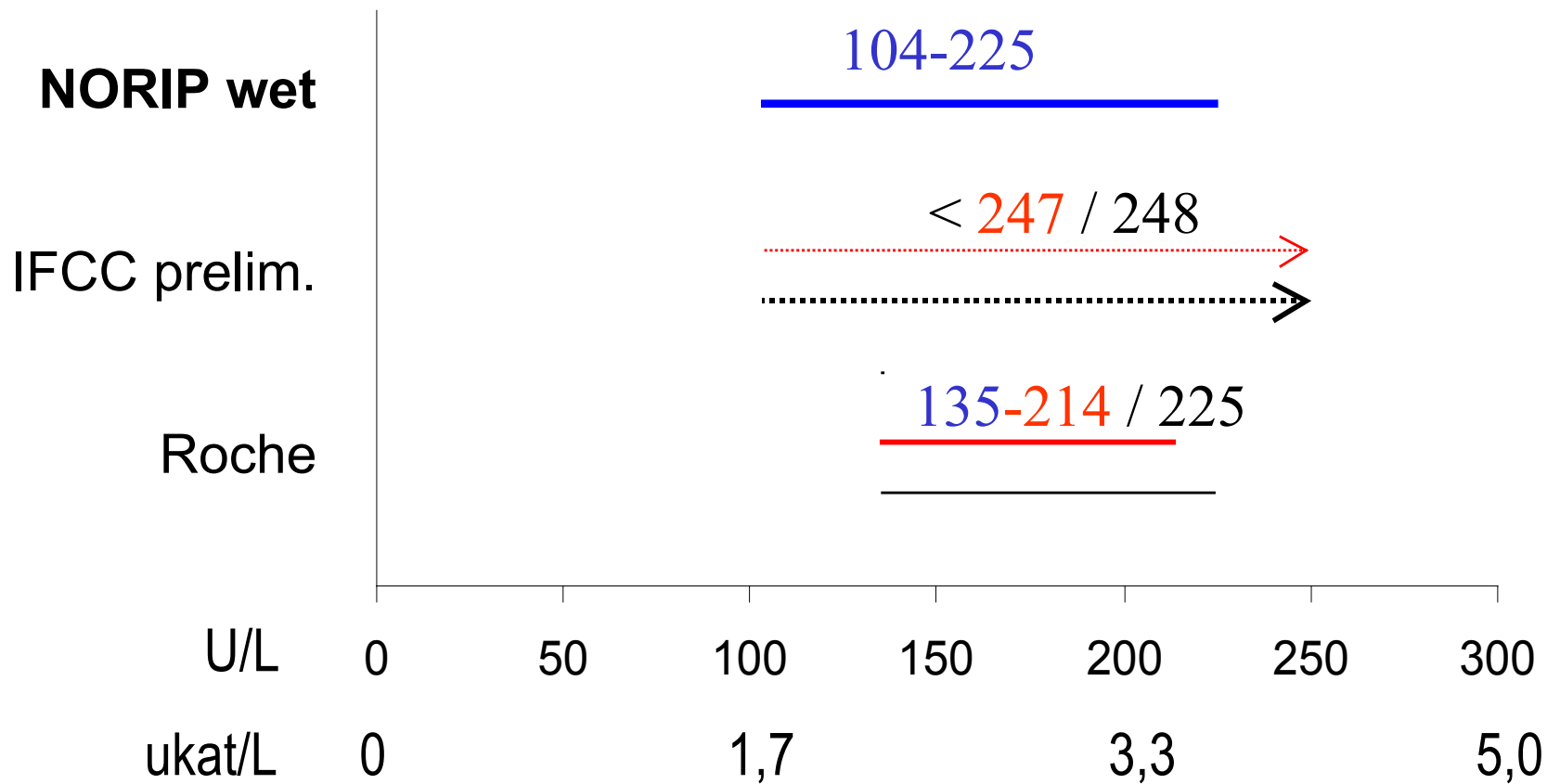
CK, - suggested reference ranges



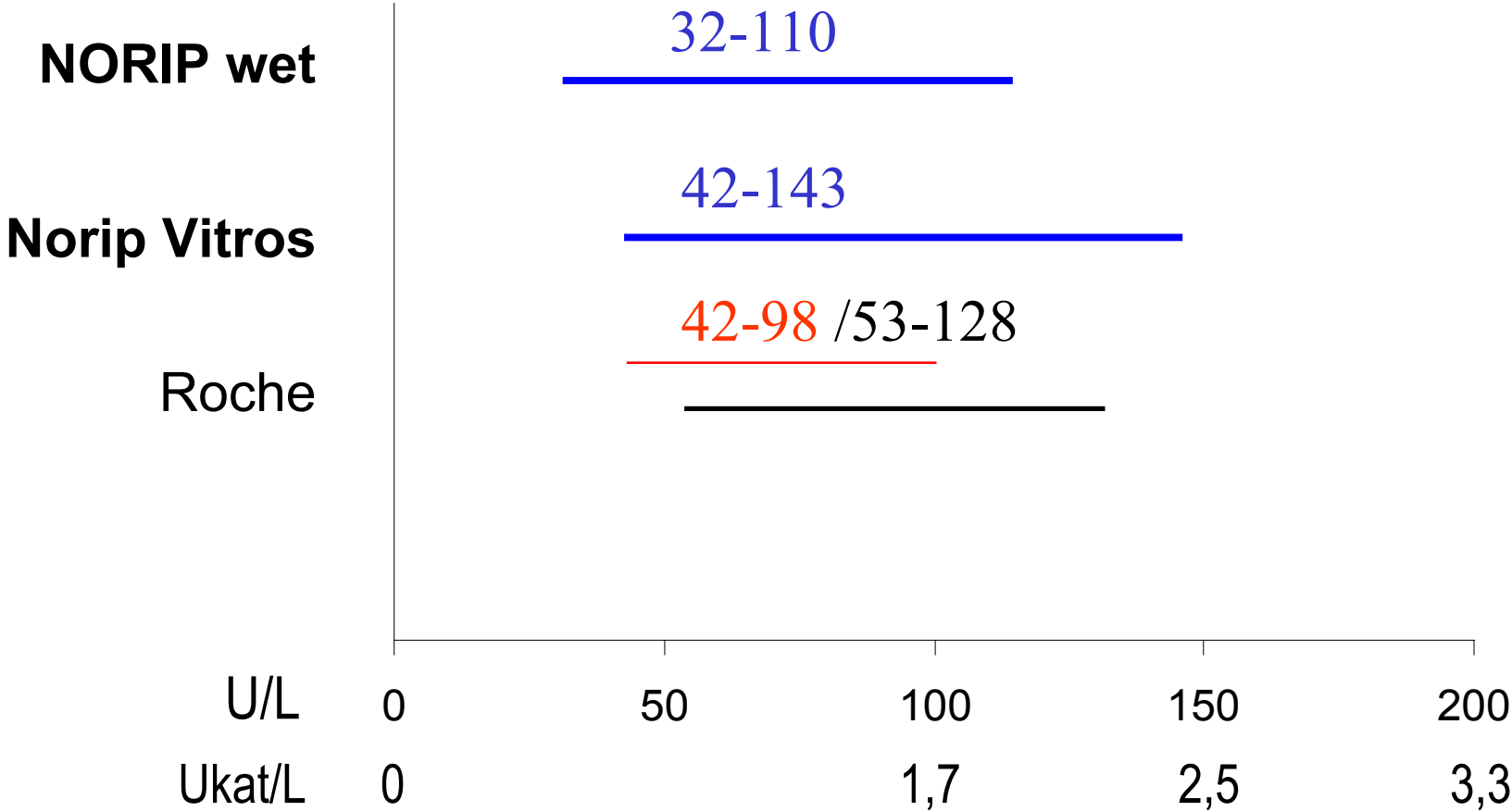
GT, - suggested reference ranges



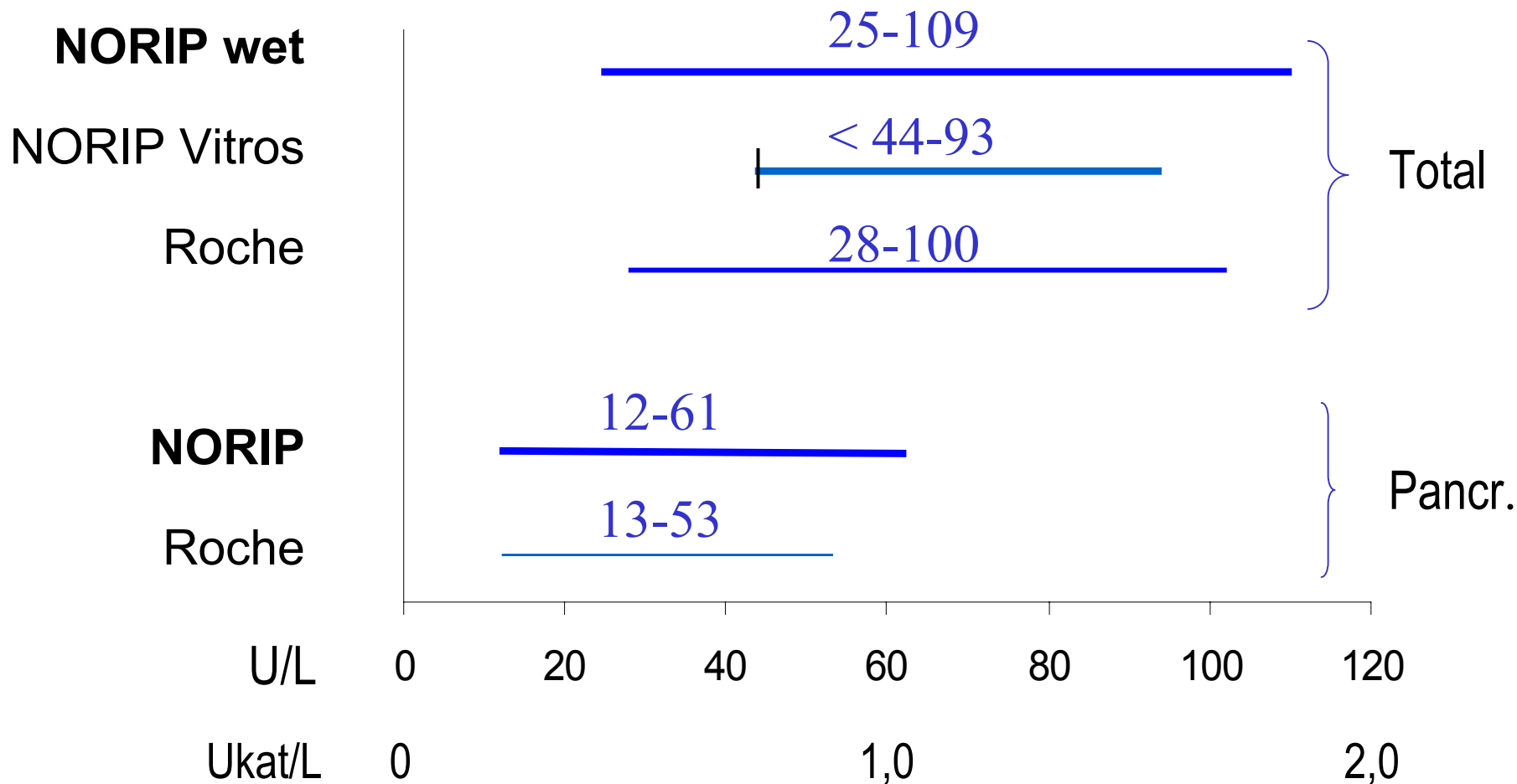
LD, - suggested reference ranges



ALP, - suggested reference ranges

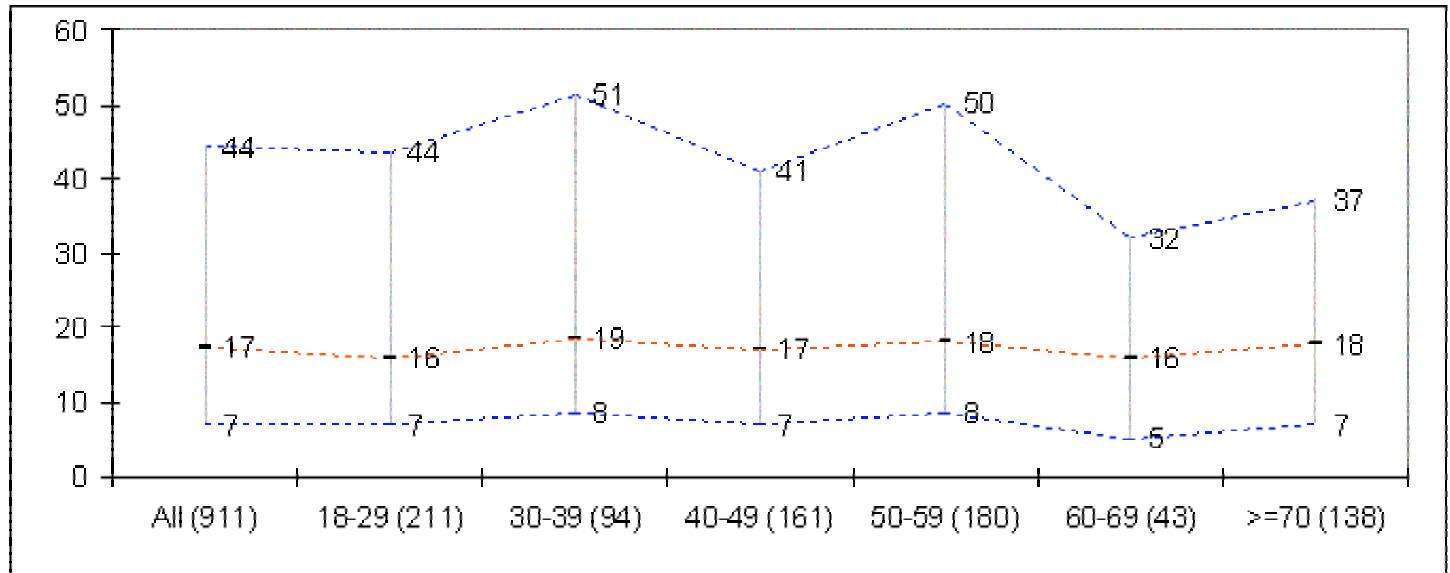


Amylase P-amylase - suggested reference ranges

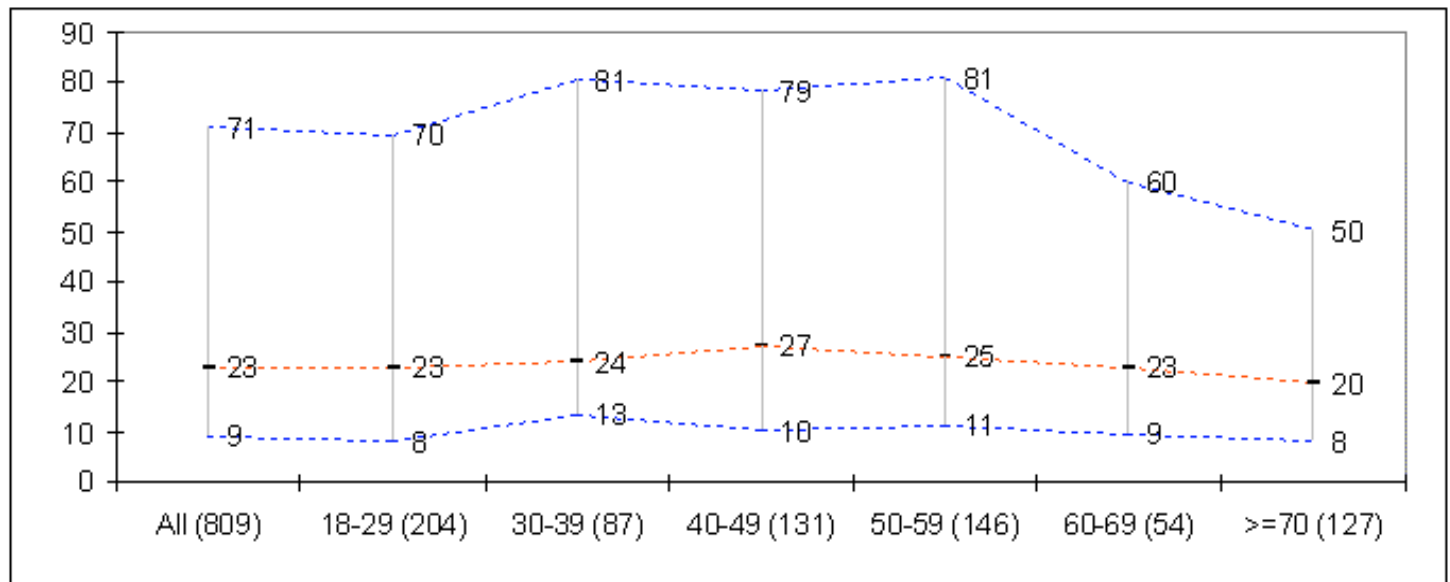


ALT, - age distribution

Female

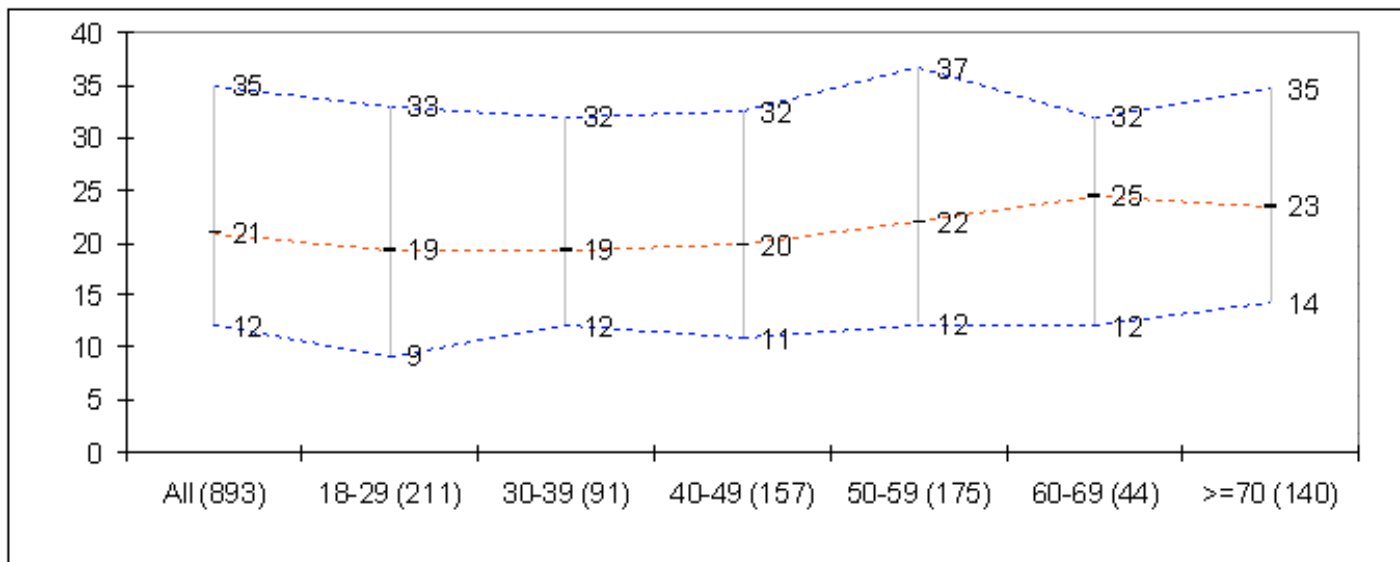


Male

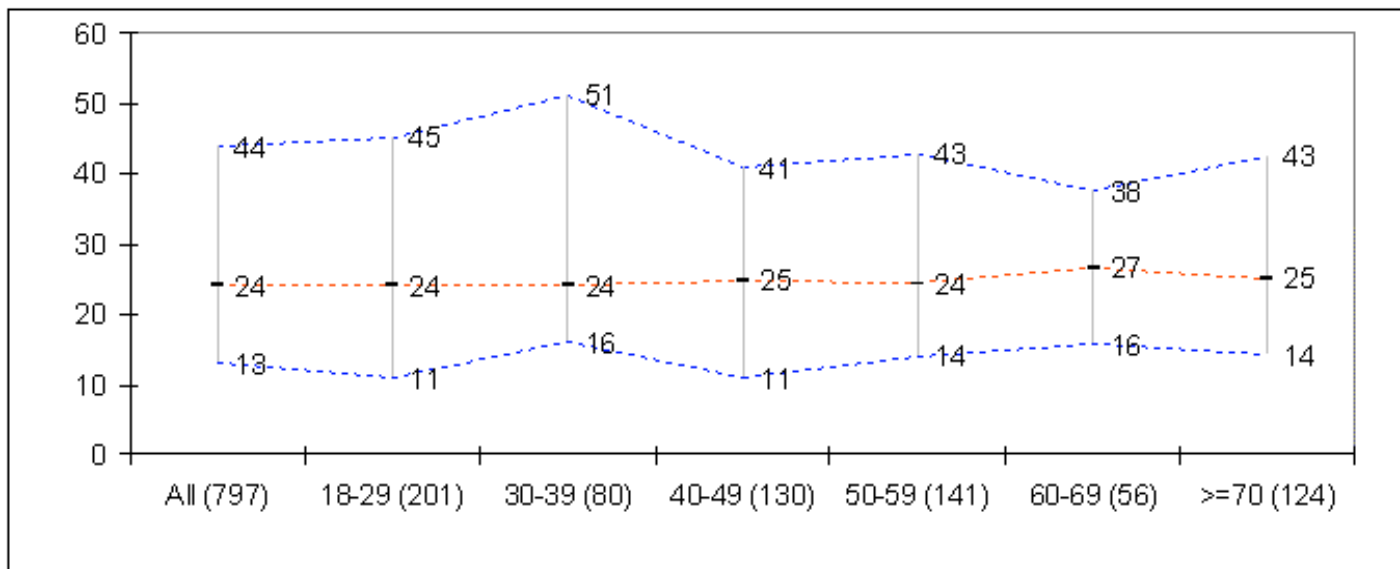


AST, - age distribution

Female

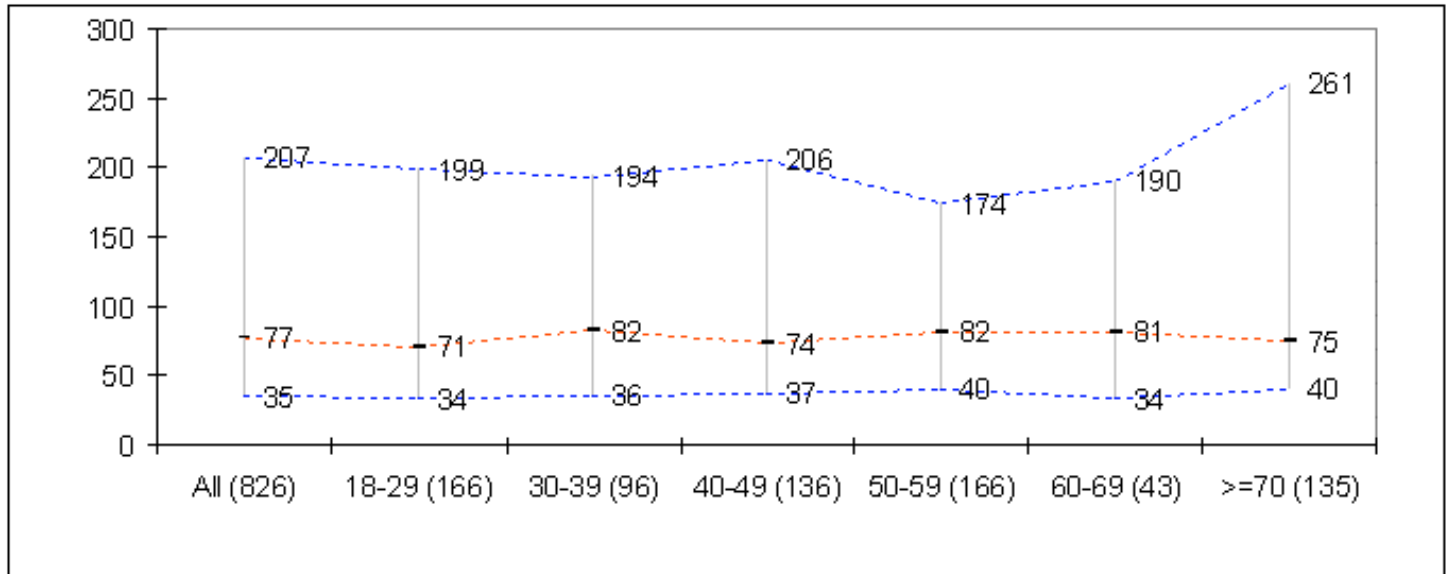


Male

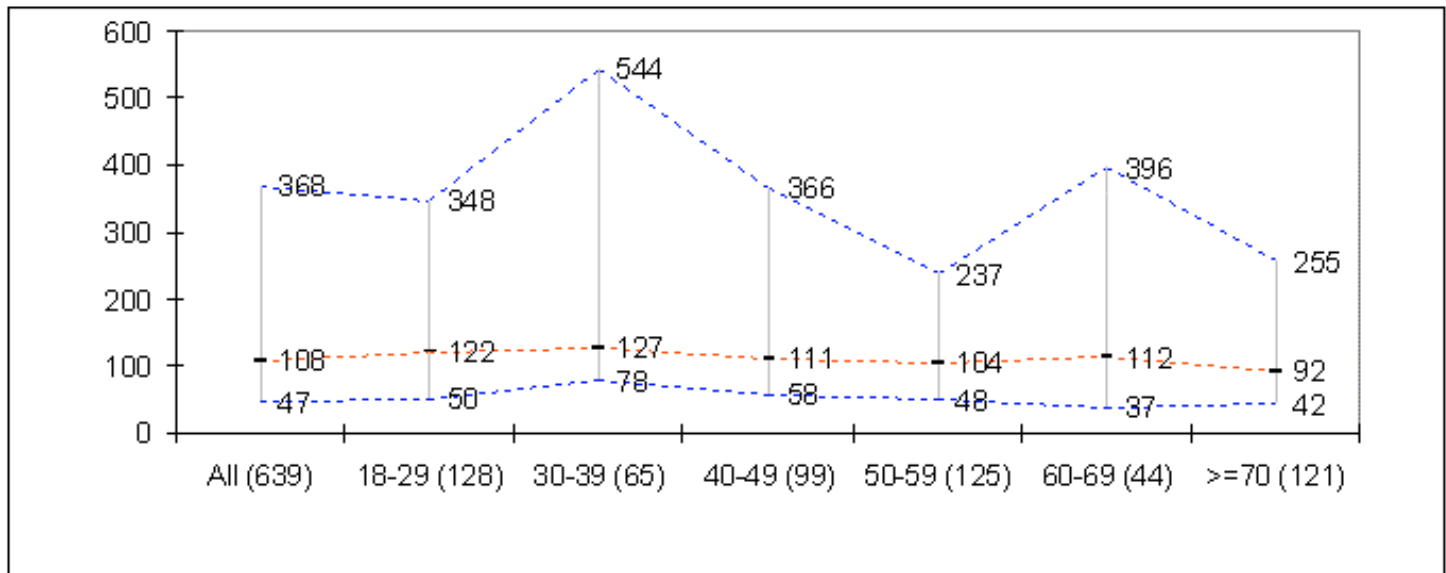


CK, - age distribution

Female

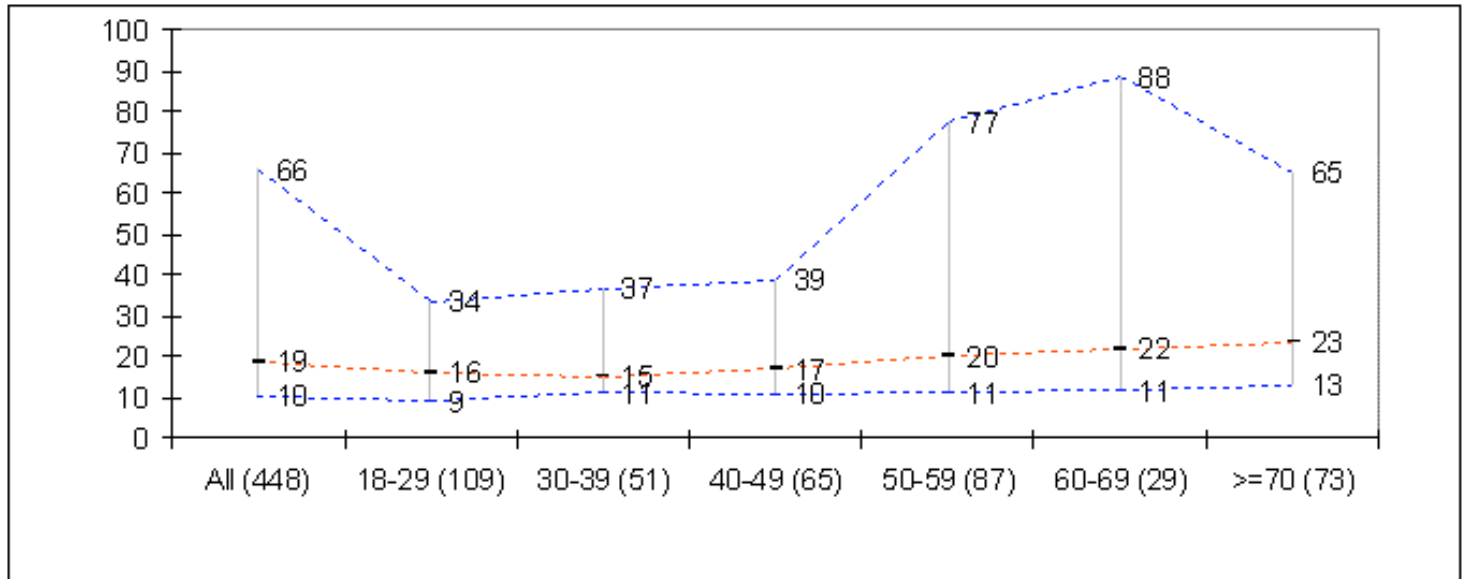


Male

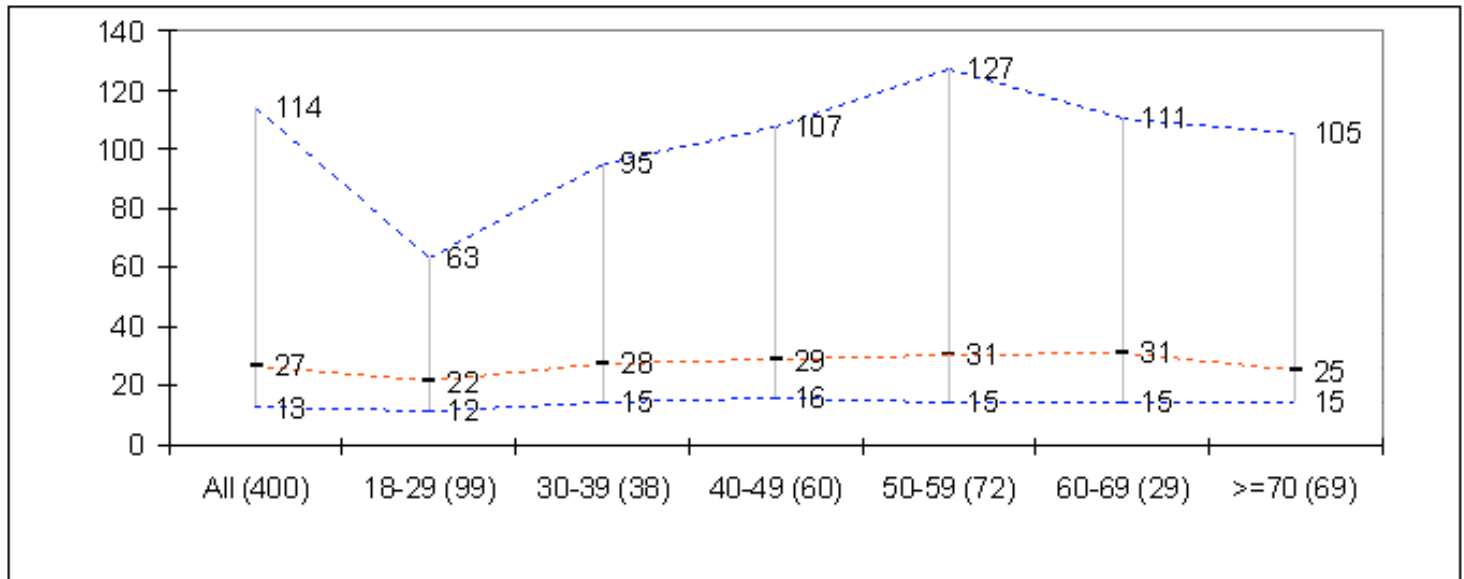


GT, - age distribution

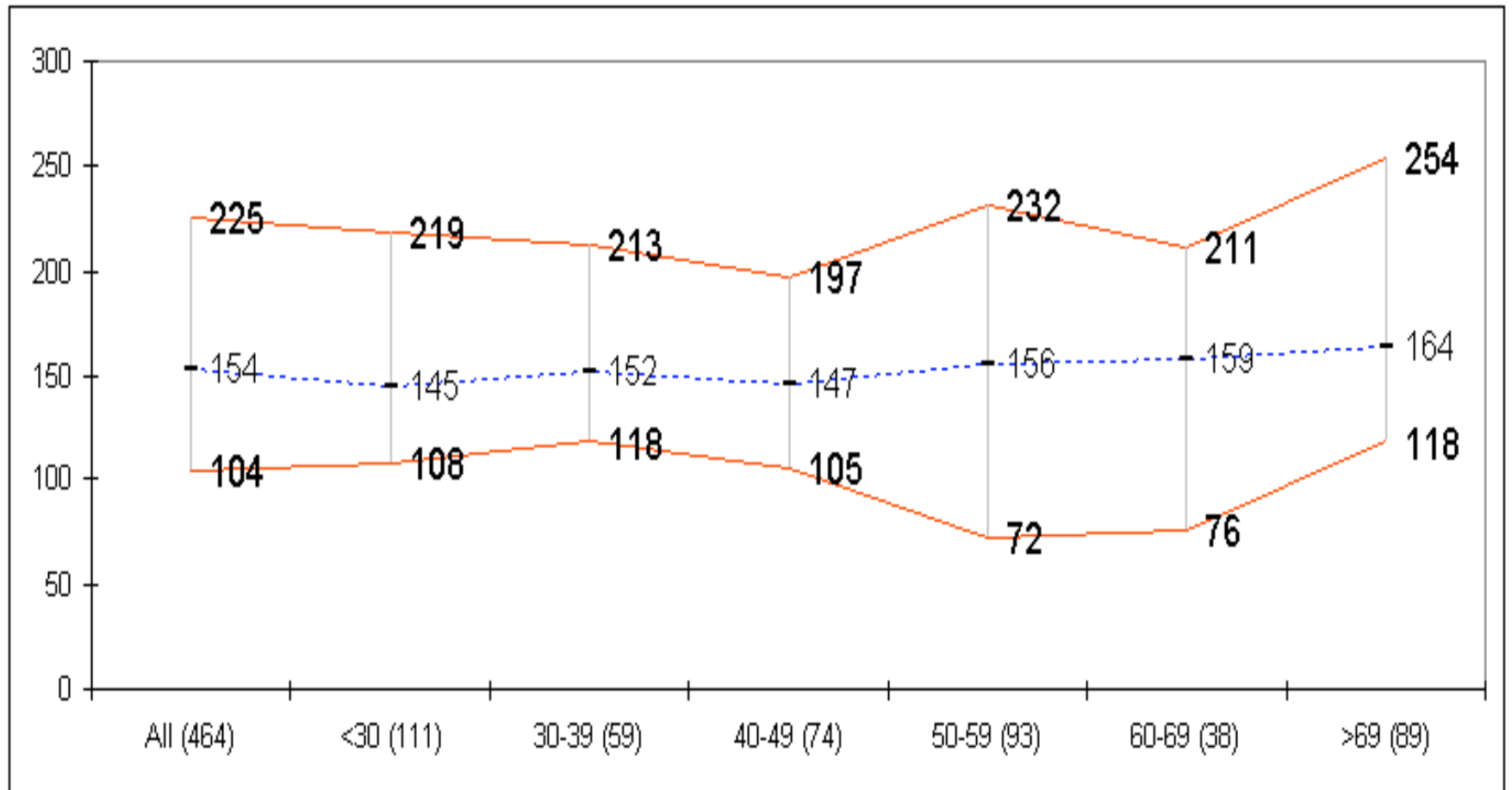
Female



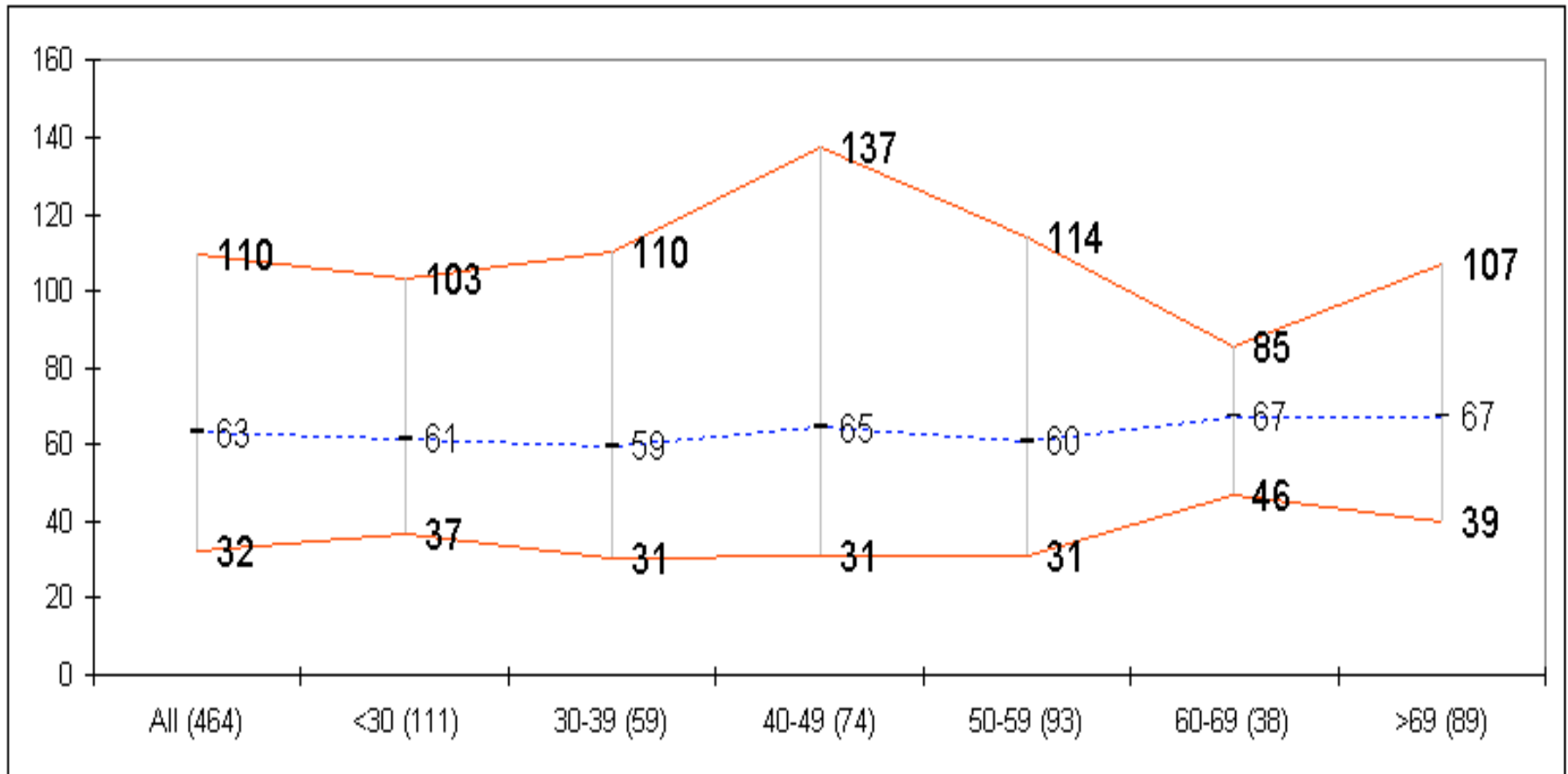
Male



LD, - age distribution

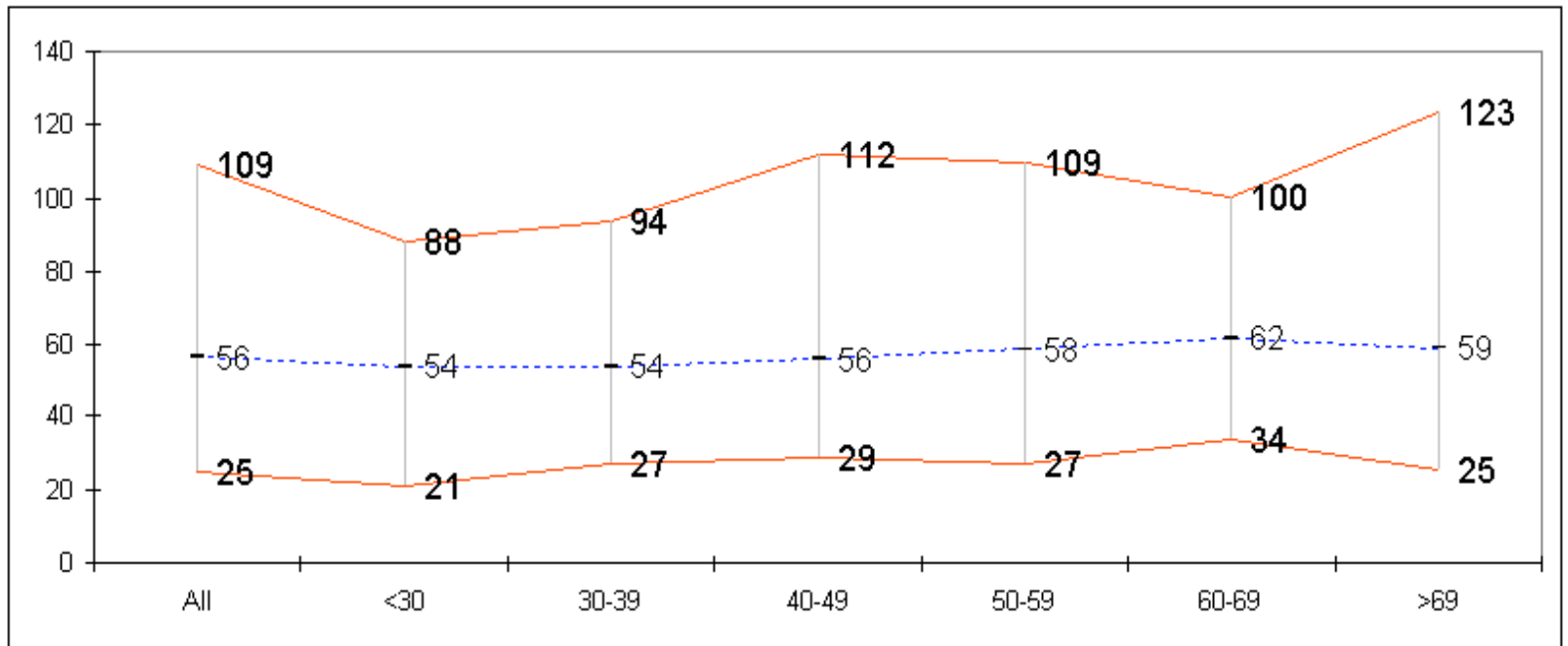


ALP, - age distribution

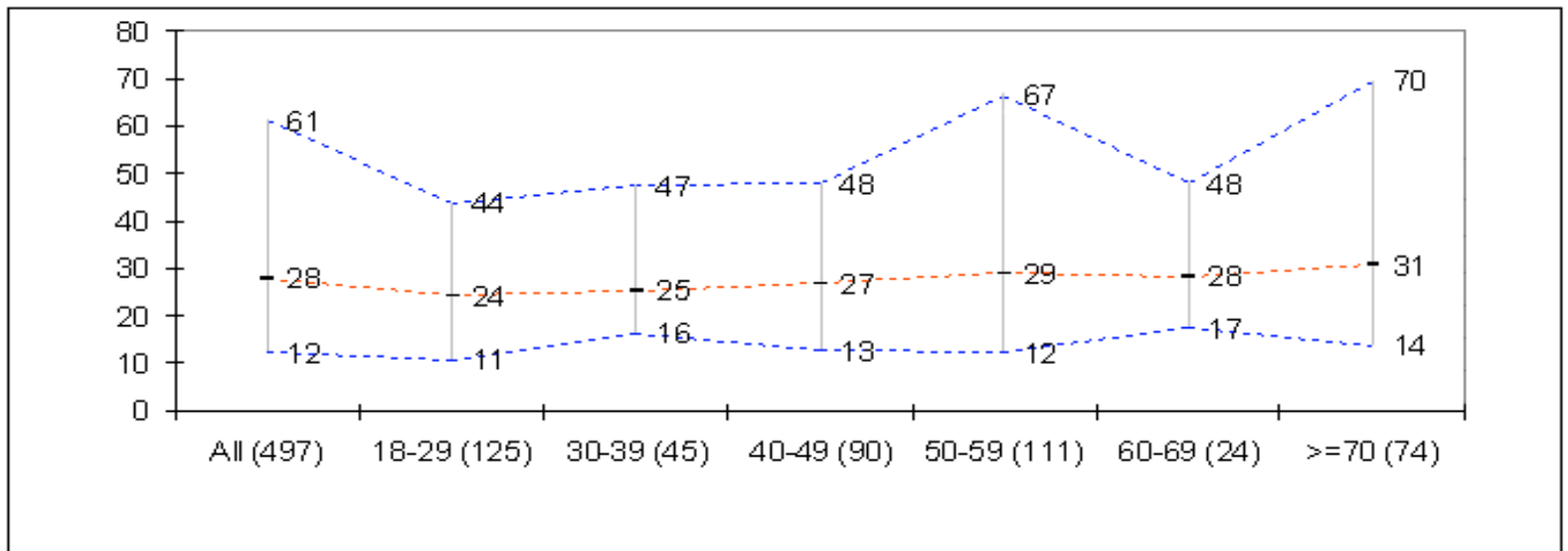


Amyl, - age distribution

Total



Pancr.



Implementation of the NORIP reference limits on enzymes

The method used must be traceable to and compatible with the IFCC reference method at 37°

How to get there?

A. For complete analysis systems:

- Documentation from the vendor:
traceability and compatibility to the IFCC reference method at 37 °, or
- Documentation by the lab(s):
by *interlaboratory comparisons* with documented method
- Or both!

The method used must be traceable to and compatible with the IFCC reference method at 37°

How to get there?

B. For analysis systems where IVD products (reagents, calibrators, instruments) from different vendors are used:

- Documentation by the lab(s):
by *interlaboratory comparisons* with documented method.
- Implementation of adjustment factor and intercept if necessary

Follow up on “trueness”:

- Regular EQA
- EQA, run as Nordic project?
- Interlaboratory comparisons