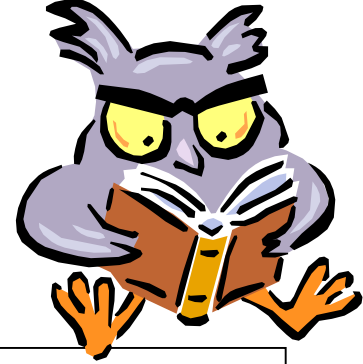


Nordic Reference Interval Project (NORIP)

Traceability of Values Assigned to
NFKK-Reference Sera CAL and X.
Stability and the use of Materials.



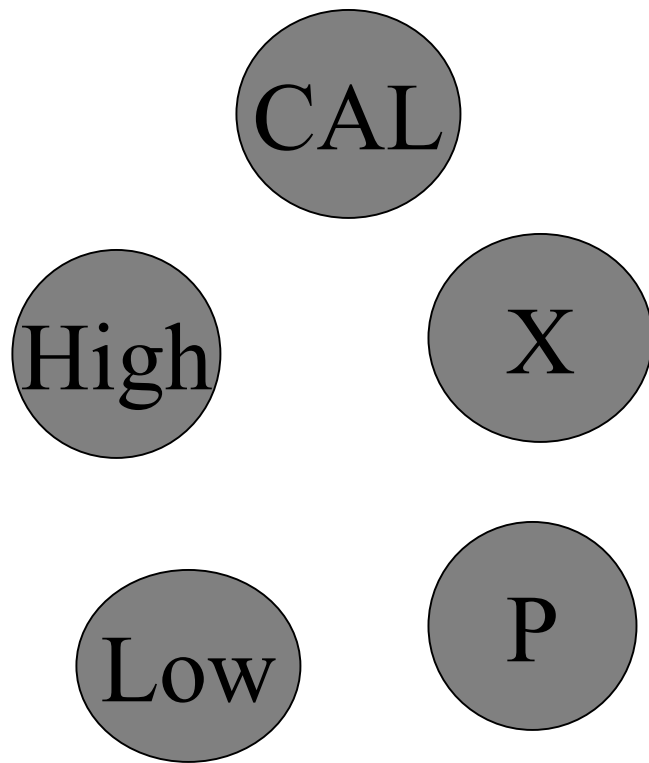
Gitte M. Nielsen, DEKS



Content of Presentation:

- Reference materials used in NORIP
- Description of CAL
- Assignment of Target Values
- Documentation of Stability
- Use of X
- Purchase of NFKK Materials

Reference Material used in NORIP



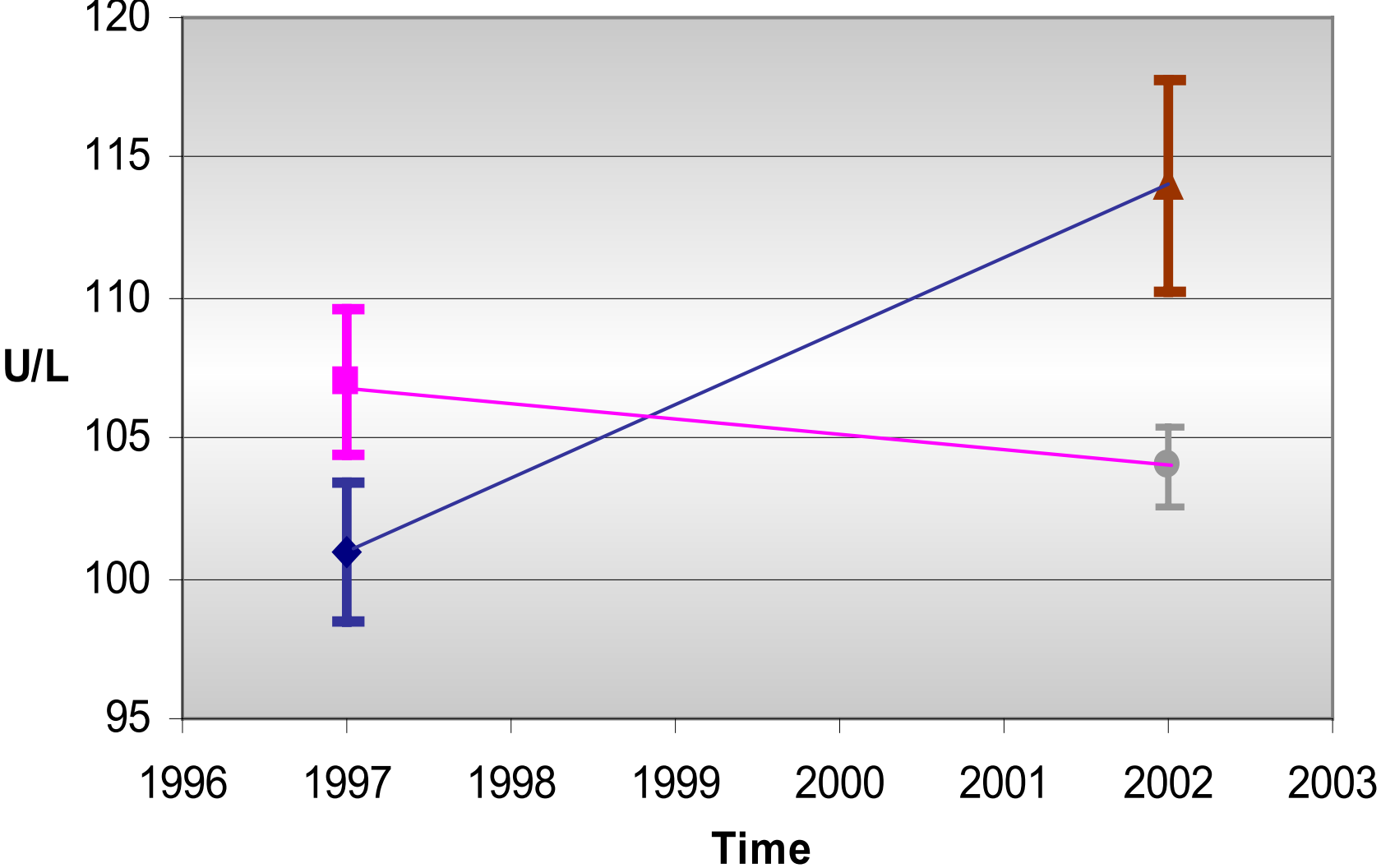
Origin of CAL

- Produced by DEKS in April 1997
- Reference measurement target values for 17 components assigned by Reference Institute of Bioanalysis (RIB) German Society of Clinical Chemistry(DGKC) in 1997
- GUM uncertainty data on 4 components: Cholesterols, Creatinine, Triglycerides & Uric Acid

Description of CAL

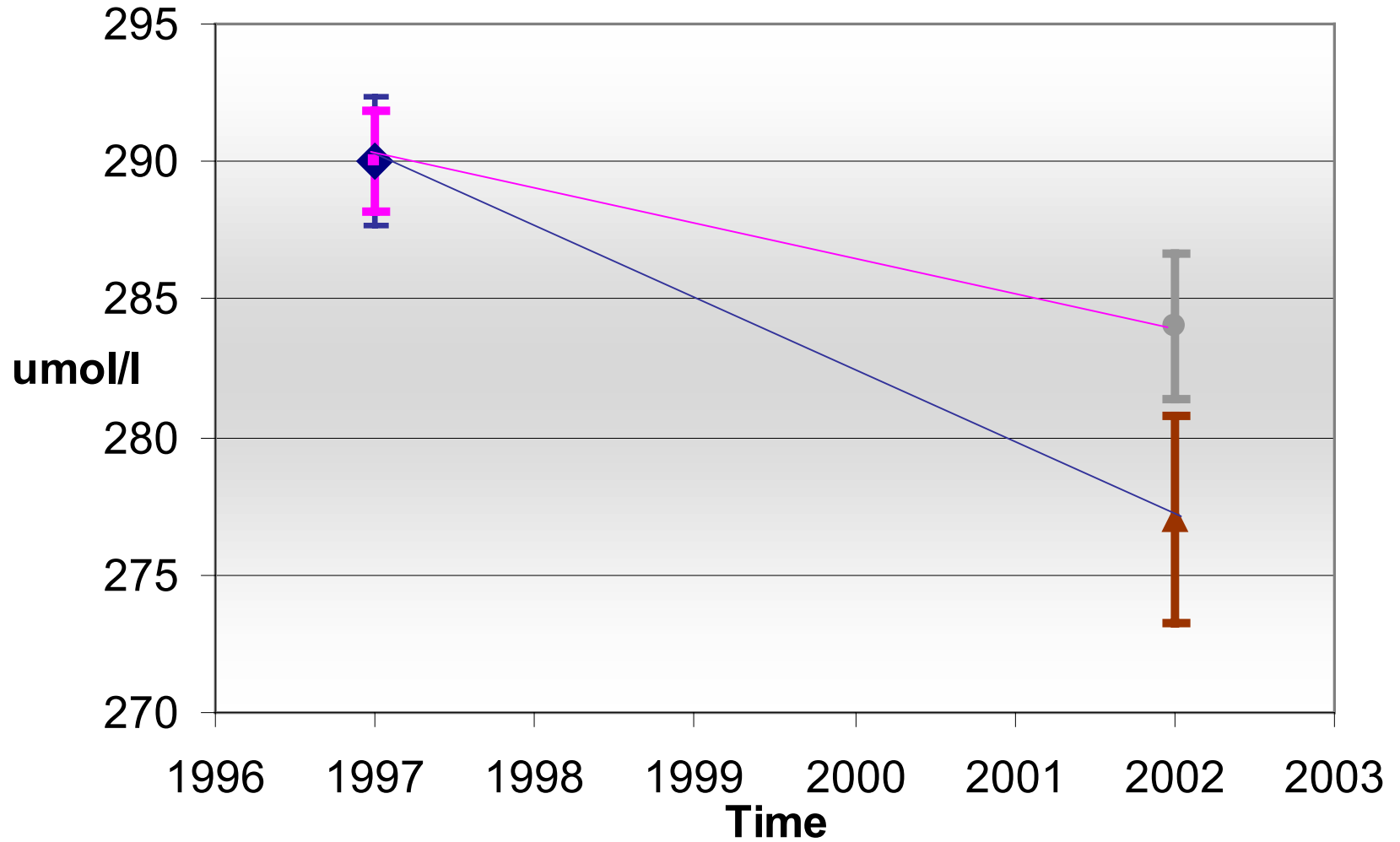
- Stored at $-80\text{ }^{\circ}\text{C}$
- 5 mL vials
- Stability: Send out in the general clinical chemistry survey from Labquality: Short Term Survey in 1997 and 2002

Change in CK concentration depending on time and method



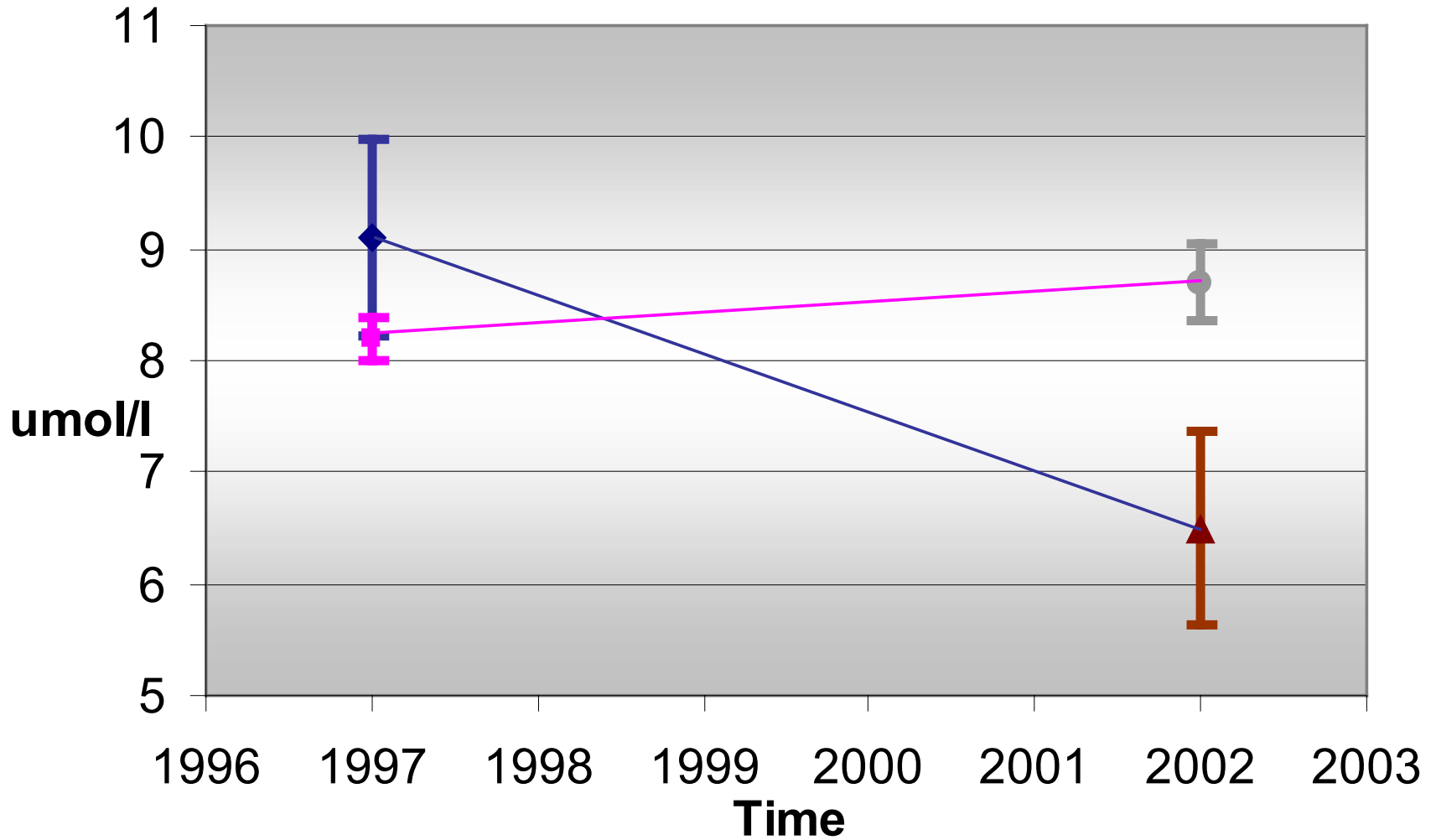
◆ Vitros 250-950 ■ Wet Chemistry ▲ Vitros 250-950 ● IFCC

Uric Acid



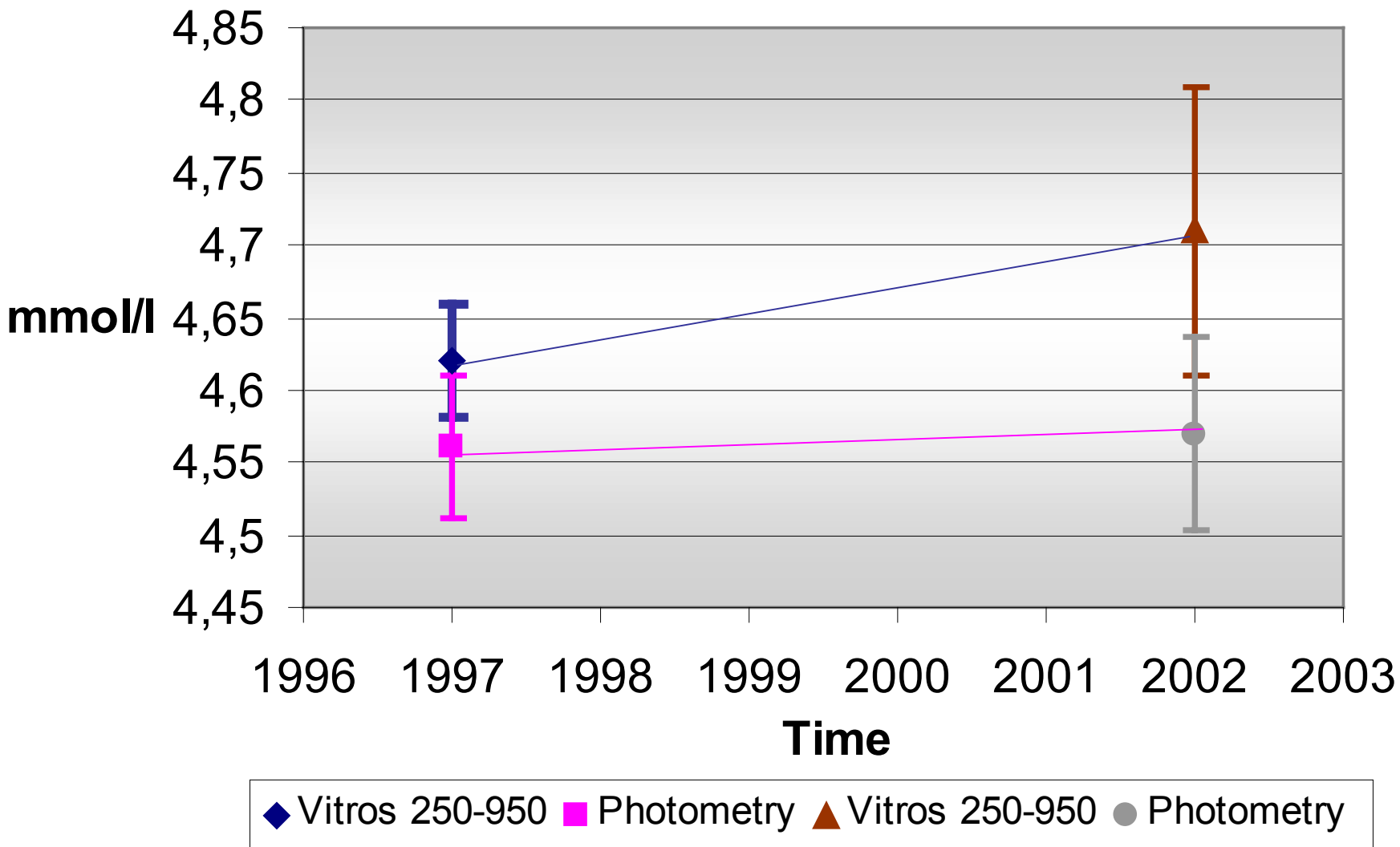
◆ Vitros 250-950 ▲ Vitros 250-950 ■ Wet Chemistry ● Photometry enz

Bilirubin



◆ Vitros 250-950 ▲ Vitros 250-950 ■ Photometry ● Photometry

Glucose



Assignment of Target Values by Means of IMEP17

- IMEP17 has 20 components with GUM uncertainty data:
 - 14 are **certified** to the highest available metrological level (Ca, Cl, Cu, K, Mg, Na, Se, Zn, Glucose, Cholesterol, Creatinine, AMYL, GGT, Li)
 - 6 are **assigned values** (Fe, Urea, Uric Acid, T4, Albumin, IgG)
- Transfer of target values and uncertainty
IMEP17 => CAL and X

Documentation of Long Term Stability at $-80\text{ }^{\circ}\text{C}$

Stability testing:

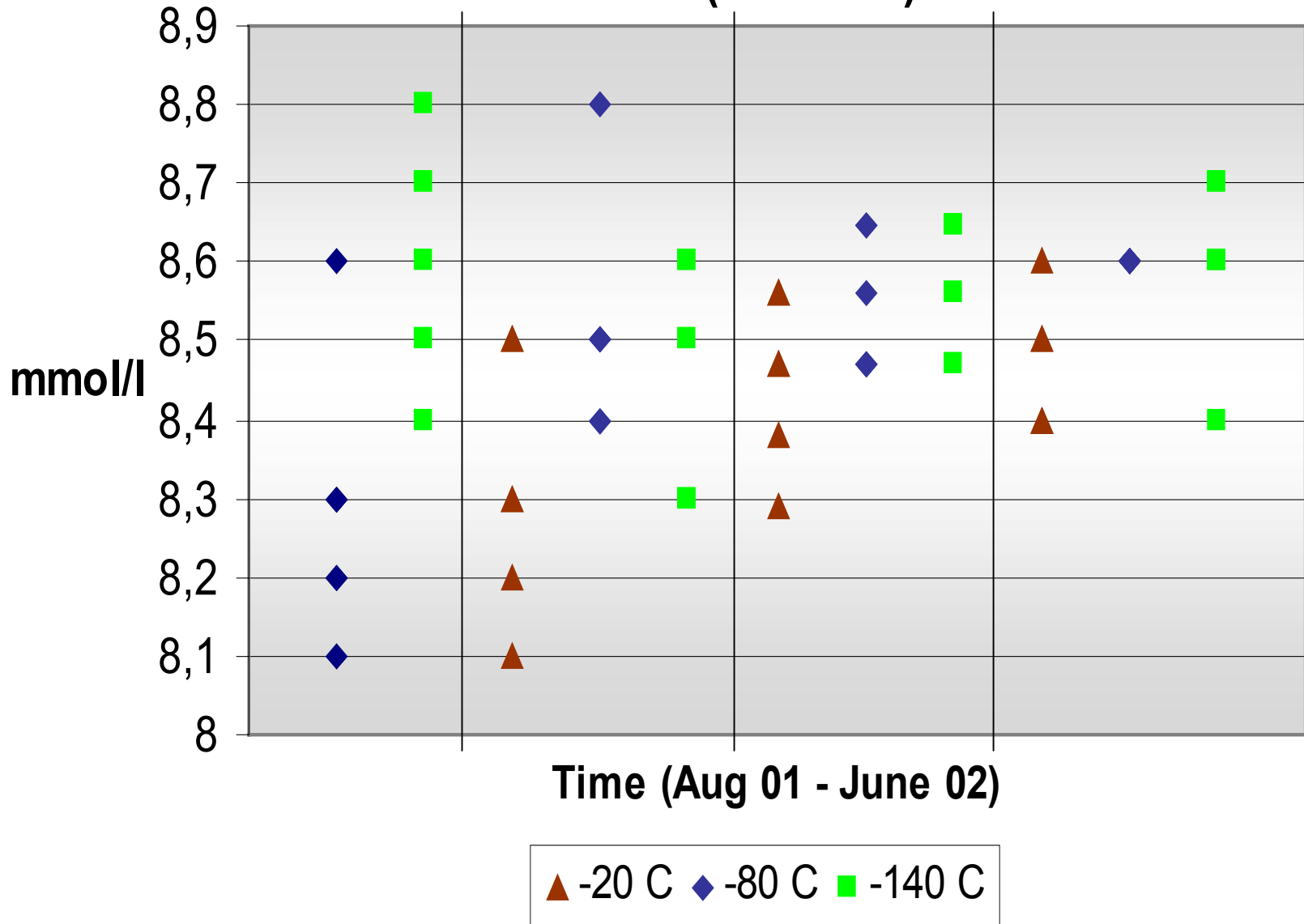
- Consensus values
- Stability results from one laboratory
- Storage at different temperatures:
-150 $^{\circ}\text{C}$, -80 $^{\circ}\text{C}$, -20 $^{\circ}\text{C}$



Documentation of Long Term Stability

- Characteristics of the stability study
 - Measurements on **X** 4 times a year:
 - **6 replicates**: Na, Ca, Total Protein and Albumin
 - **3 replicates**: K, Mg, Fe, P, Carb, Uric Acid, Glucose, LD, Cholesterol, Triglycerid, Bilirubin, Crea, ALAT, ASAT, AMYL, ALP, and CK
- EQA-data will be collected to correct for time dependent bias

Glucose (IMEP 17)

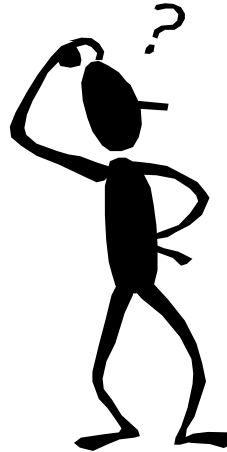


Use of Reference Serum X

- Use/purpose ?

- Control

- Calibrator



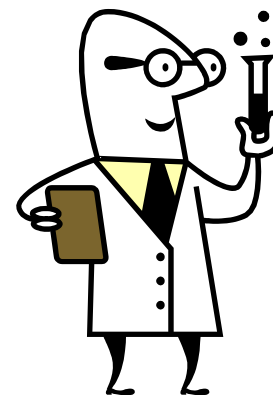
- Contents of **Certificate**:

- Values and their uncertainties of measurement



How to Purchase NFKK Materials

- **”X”**
 - Nordic laboratories can purchase through local EQA organisers
- **Reference individual samples**
 - Apply through NFKK (NOBIDA)



Purchase of NFKK Materials

- Prices are fixed by NFKK (2002 prices)
 - X (3 vials x 5ml): 2000 DKK
 - Additional 1000 DKK: High (2,5ml), Low (2,5ml) and P (2,5ml)
 - Delivery of Reference individual samples (NFKK) and X, High, Low and P: 5000 DKK
 - VAT, post and packing fee are not included

Replacement of X

- What are we going to do when X comes to an end ??



Draft Protocol on Stability Study

- Draft protocol is available on request for comments
- Handout:
 - Summary of protocol
 - Slides from presentation

