

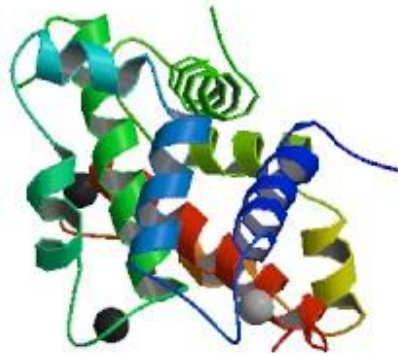
# **External Quality Assessment scheme for Calprotectin - a need for standardisation**

Gunnar Nordin (Marie Lundberg), Equalis

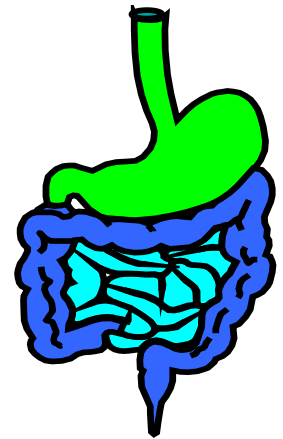
EQALM 2013-10-11

**EQUALIS**

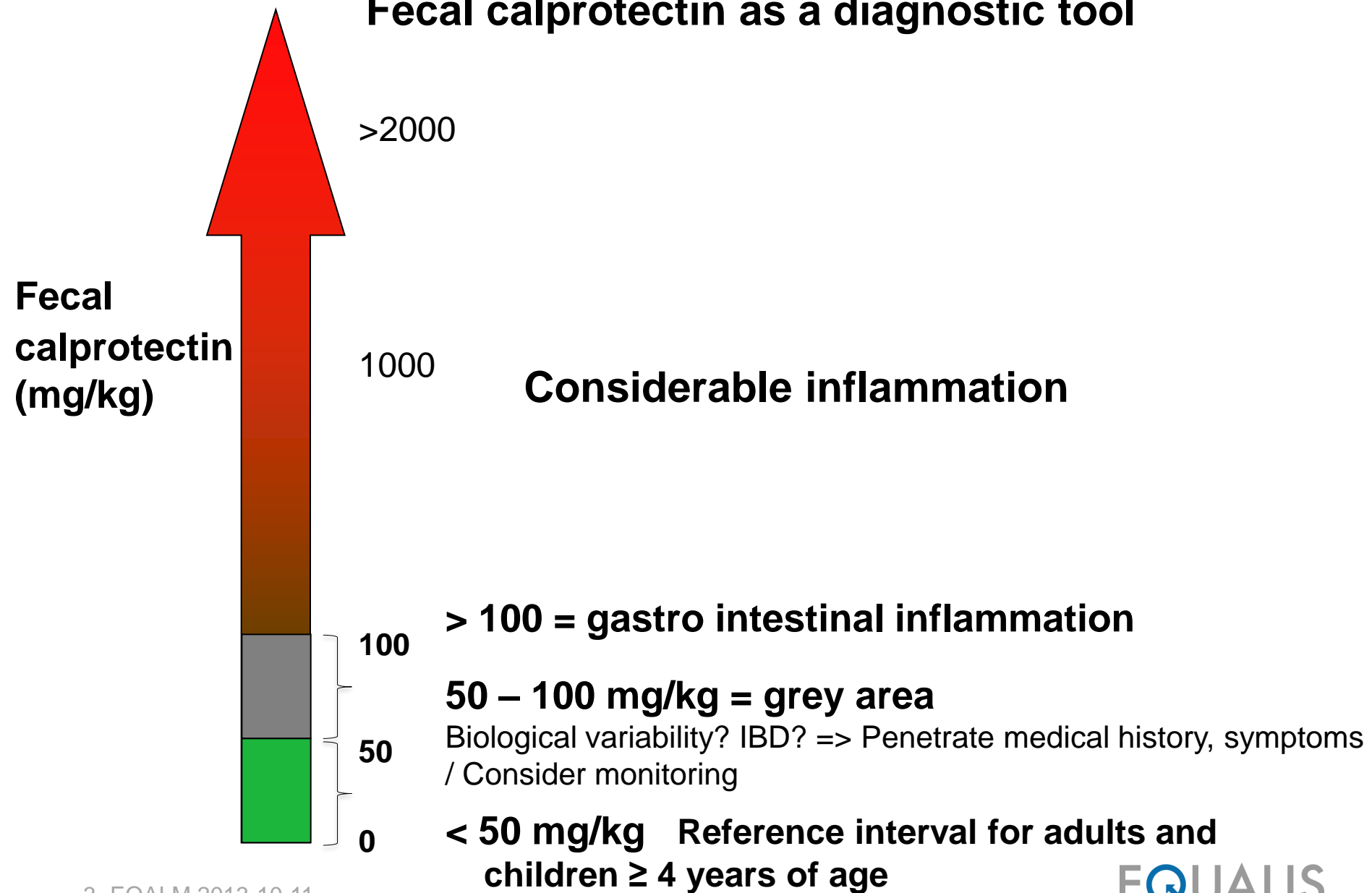
# Calprotectin



- Marker for inflammatory bowel disease (IBD), both for diagnosis and for monitoring patients
- Measurable in various body fluids (blood, cerebrospinal fluid, synovial fluid and faeces) in bacterial, inflammatory and malignant diseases
- Can eliminate the need for invasive colonoscopy



# Fecal calprotectin as a diagnostic tool



# Need for an EQA scheme for Calprotectin

- Simple, cheap, non-invasive and sensitive marker
- Increasing number of laboratories that analyze calprotectin
- Increasing number of manufacturers of calprotectin kit.
- Calprotectin is stable in stool samples at least 3 days at room temperature (H. Tøn et al. Clinica Chimica (2000))
  - Sample can be sent by regular mail
- Can the test material consist of extracted feces?



## Calprotectin (291)

Product code:	291
Advisory board:	<a href="#">Protein analysis</a>
Accreditation:	No

### [Scheme details](#)

Calprotectin is used in screening for inflammatory bowel disease (IBD) and for monitoring of IBD patients. The test material is faeces and extracted faeces.

Frequency: 4/year

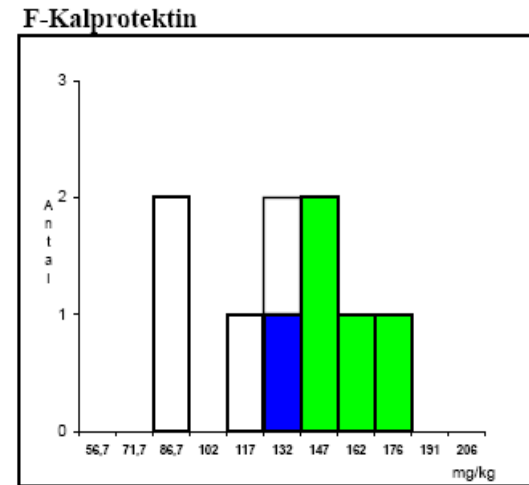
### [Examinations](#)

F-Calprotectin

# EQA for Calprotectin

Pilot survey February 2010

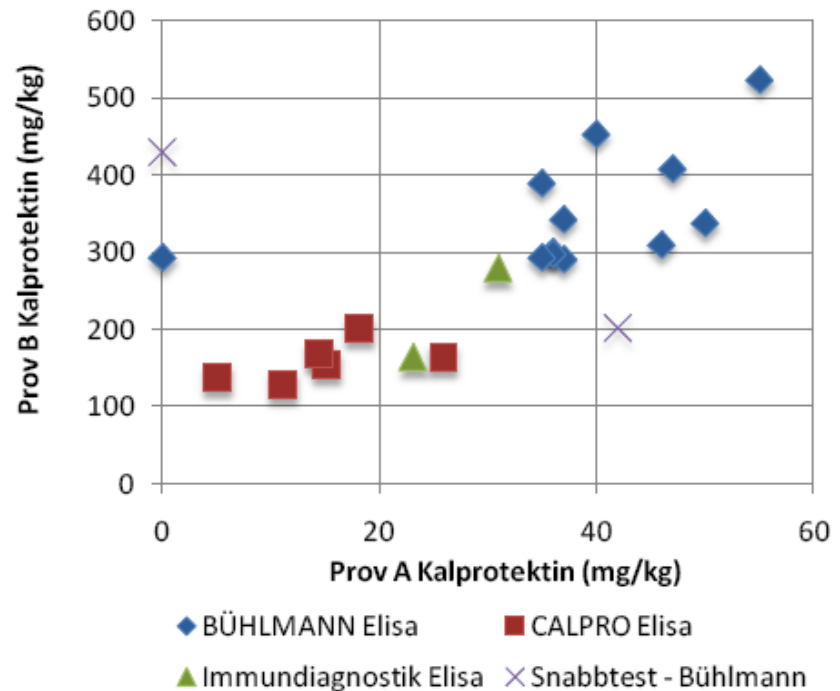
- 10 participants
- Extracted feces in Bühlmanns extraction buffer
- 9 results
- 2 methods
- Bühlmann Elisa: mean value 152 mg/kg  
CV% 14
- Calpro Elisa: mean value 106 mg/kg  
CV%18
- Total CV: 25%



# EQA for Calprotectin

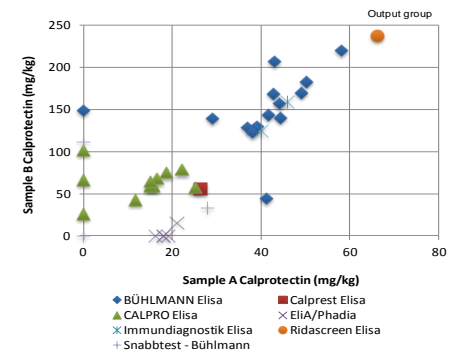
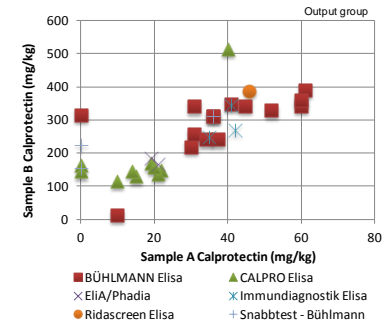
March 2011

- Instructions: Dilute the sample according to the supplier's recommendation and perform ELISA according to your standard procedure for calprotectin.
- 26 participants
- 2 samples of extracted feces in Bühlmanns extraction buffer
- 23 results
- 4 methods;  
3 Elisa  
1 rapid test
- Total CV:  
A – 48%  
B – 44%



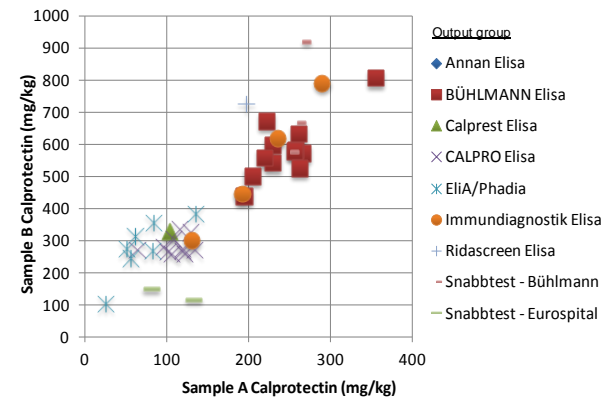
# 2012 Still high CV% → Developments

- To investigate whether instrumentation (in particular automated vs. manual ELISA) may contribute to the wide spread for results in Bühlmanns' group, we have asked what equipment the participants use for the ELISA. Results show that there is no correlation between the observed variation and the instrumentation used for ELISA.
- Users of Phadiaz method and Ridascreen ELISA report different results when the sample is extracted with Bühlmanns extraction buffer. There are several new suppliers and methods for calprotectin on the market. We will send samples extracted in the various producers' buffers.



# 2012 Developments

- Results from Phadia users are much lower than the results from other manufacturers. This may be due to degradation of calprotectin in the extract during transport. Samples will be sent frozen.
- From next year will some of the rounds include sample of non extracted feces.

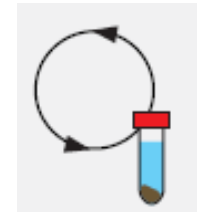
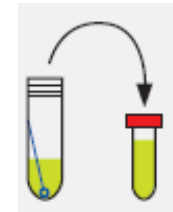
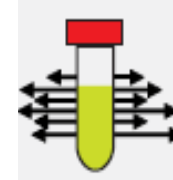
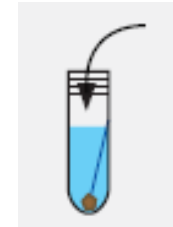
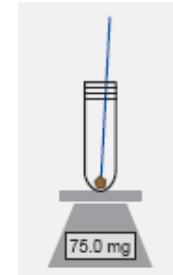




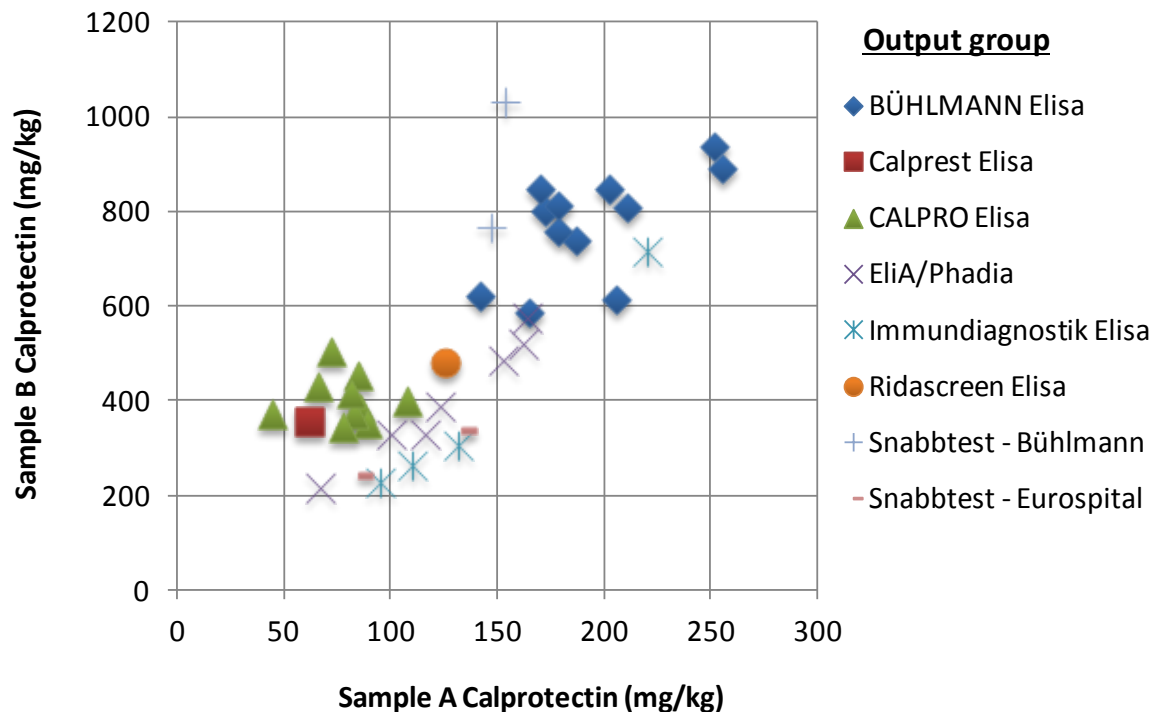
# EQA for Calprotectin

February 2013

- 44 participants – 11 countries
- 2 samples of extracted feces in each company's buffer and 1 sample of extracted feces
- Frozen samples to Phadia users
- 42 results
- 8 methods;  
6 Elisa  
2 rapid test
- Total CV:  
A – 43% (extraction of sample C)  
B – 47%  
C – 38%



# February 2013

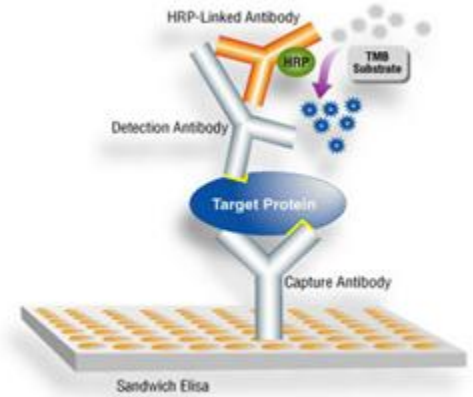


Supplier	Sample A (variation in results – mg/kg)	Sample B (variation in results – mg/kg)	Sample C (variation in results – mg/kg)
BÜHLMANN ELISA	142 - 256	586 - 939	75- 242
CALPRO ELISA	45 - 108	352 - 506	39 - 142
IMMUNDIAGNOSTIK ELISA	95 - 221	227 - 716	126 - 203
EliA/Phadia	67 - 164	218 - 576	96 - 148

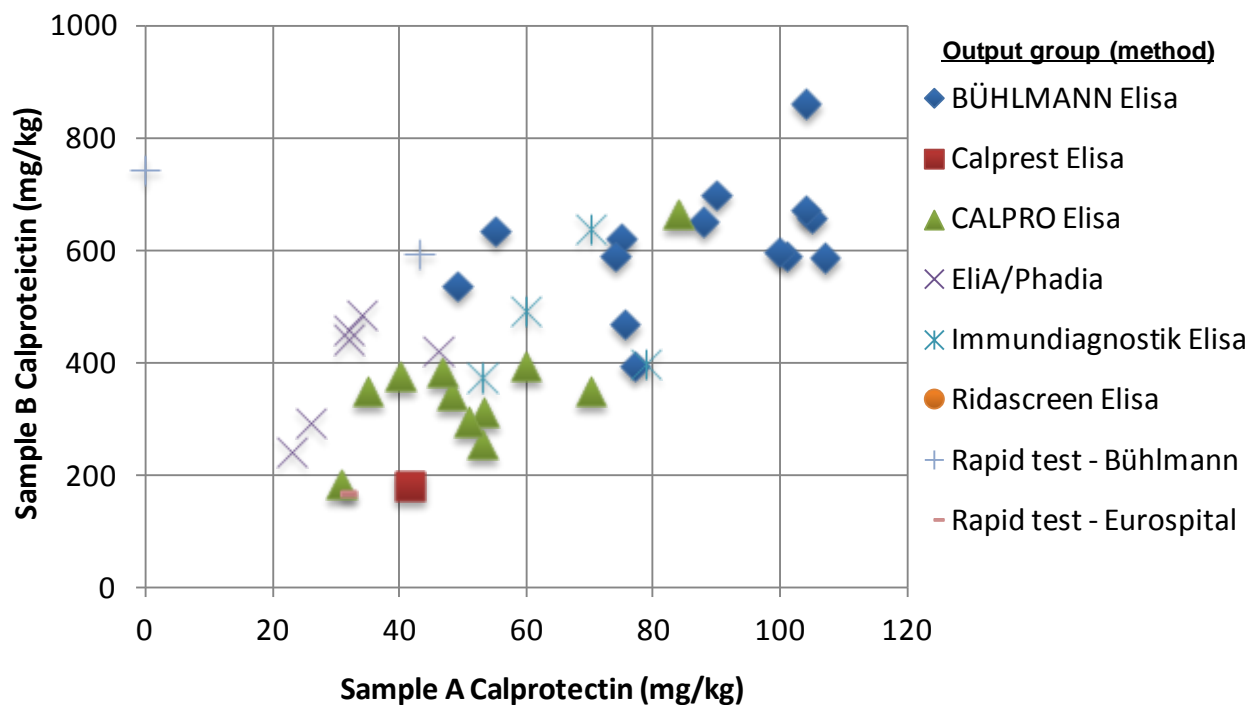
# EQA for Calprotectin

May 2013

- Instructions: Analyze the sample according to your standard procedure for calprotectin.
- 48 participants – 11 countries, 5 manufacturers
- 2 samples of non extracted feces
- 44 results
- 8 methods;  
6 Elisa  
2 rapid test
- Total CV:  
A – 47%  
B – 40%



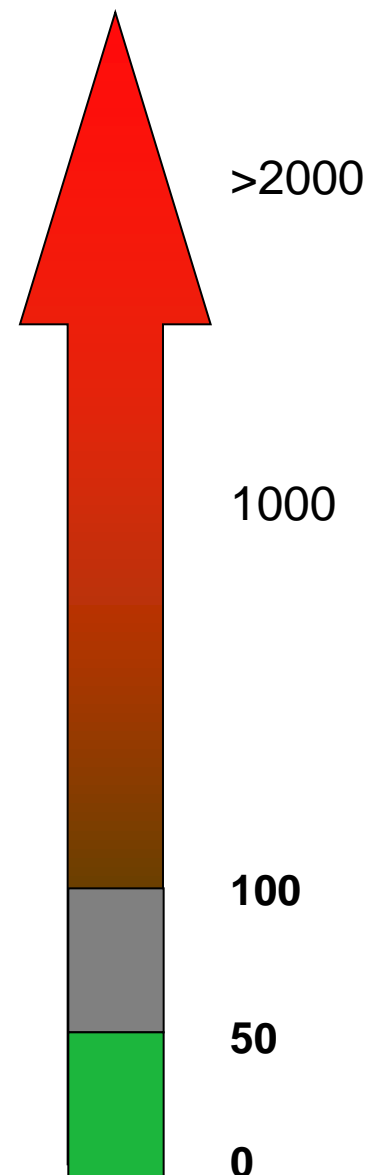
# May 2013

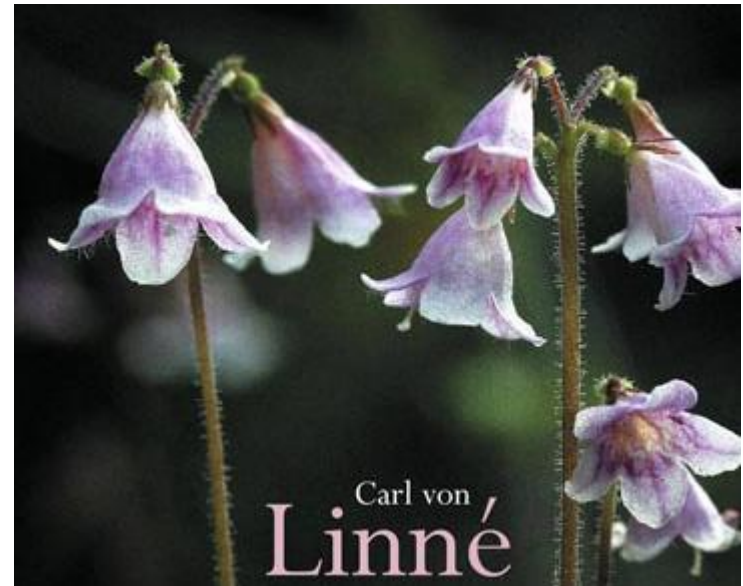


Supplier	Sample A (variation in results – mg/kg)	Sample B (variation in results – mg/kg)
BÜHLMANN ELISA	49 - 107	396 - 862
CALPRO ELISA	31 - 84	185 - 666
IMMUNDIAGNOSTIK ELISA	53 - 79	373 - 638
EliA/Phadia	23 - 46	244 - 488

# EQA for Calprotectin Reflections

- Test material: feces or extracted feces
  - Extracted feces in different buffer
  - Transportation conditions
  - Non extracted feces material more stable
  - Non extracted feces material includes extraction in the scheme
  - Do the participants conduct the calprotectin analysis according to the suppliers instructions?
- Results:
  - Discrepancy in results from different manufacturers
  - Large variation within the methods
  - A need for standardisation – same cut off





# Thank you