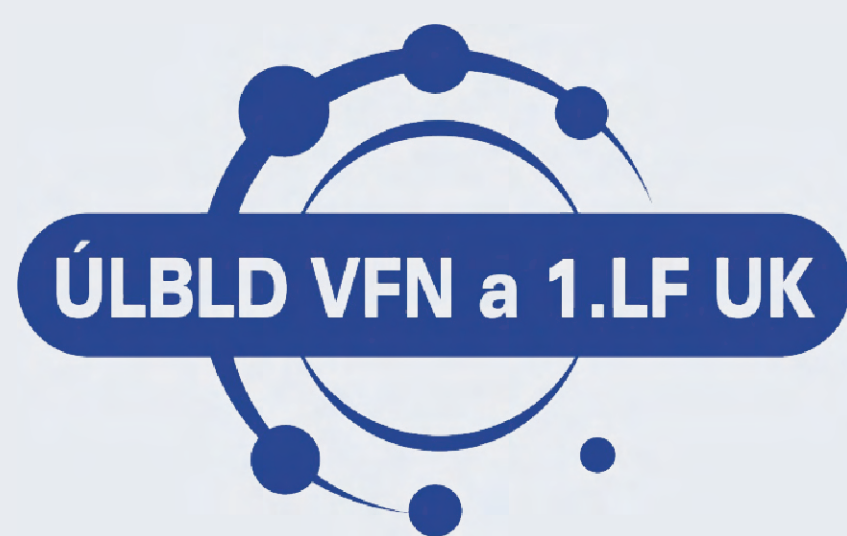


# External Quality Assessment (EQA) for Quantitative Fecal Blood in Stool (FIT)

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## SUMMARY

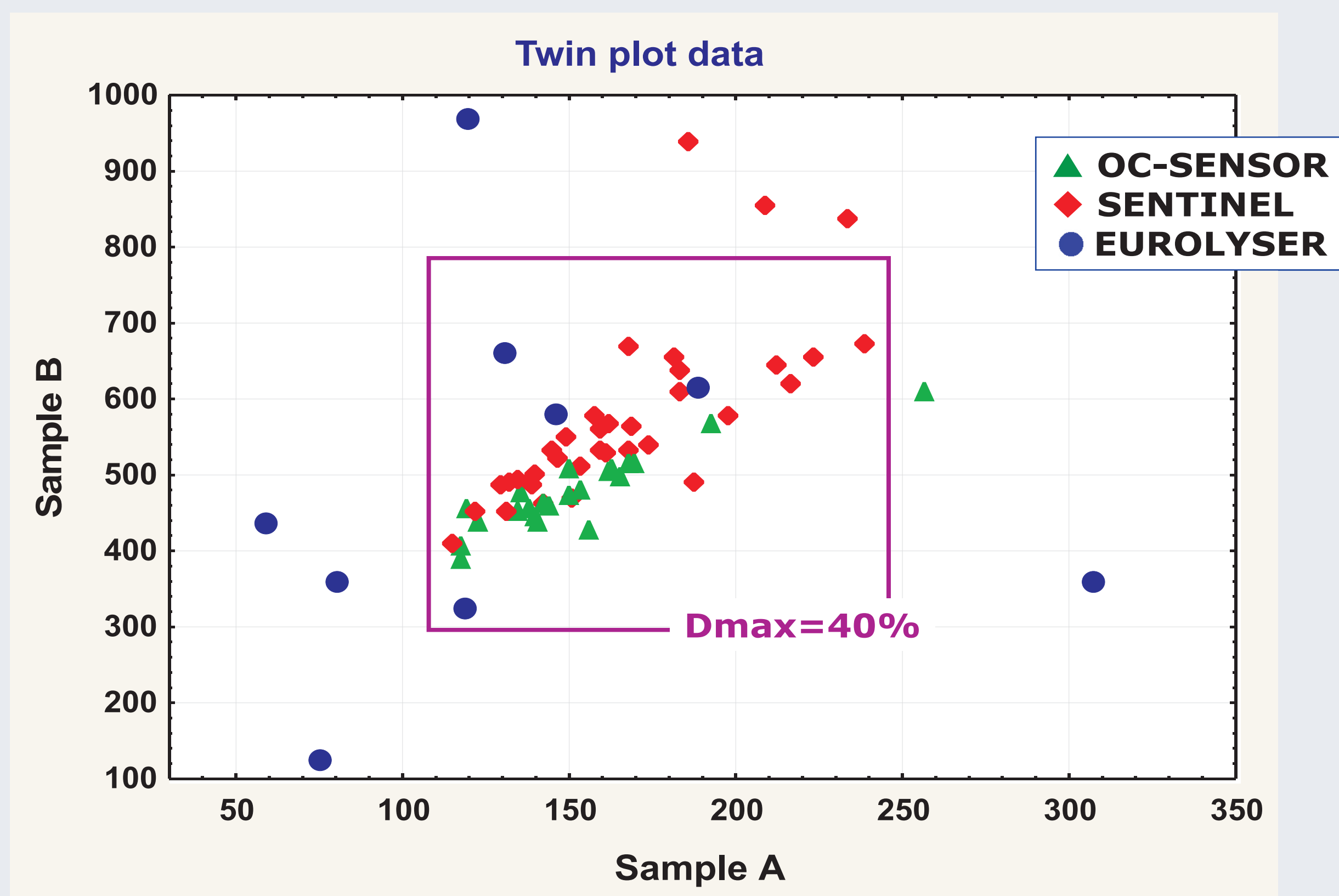
**Background.** Colorectal cancer (CRCA) is the second most frequent malignant disease in Europe. CRCA screening we began in the Czech Republic in 1994, and population-based national screening with FOBT was started in 2002, since 2009 with immunochemical test (FIT). External quality assessment (EQA) of haemoglobin determination in the stool has been started in January 2012 as a part of the national EQA. The aim was to improve the analytical quality of new, quantitative FIT for colorectal cancer screening. This EQA programme is provided by SEKK (member of EQALM) which is accredited according to ISO/IEC 17043:2010 and provides EQA programmes for Czech and Slovak republics. This study will compare our new Czech FOB EQA with 15 years running ECQS annual Eiken program for users of OC-Sensors.

**Methods.** In the Czech Republic the Faecal Occult Blood (FOB) EQA programme is organised 2-times per year, in Japan EQCS once per year, with 2 liquid samples produced by Eiken. The results are collected using web application and evaluated according to the ISO13528. We use robust means of all results as the assigned value for each sample. Also group based statistics (based on manufacturers of kits) are evaluated.

**Results:** There ran 2 rounds of the new FOB EQA programme up to now. Participants in two rounds - May (n=34) and October (n=32) - analysed samples with OC-Sensor analyser (mean CV% were 10 and 8.7), Sentinel-Gold methods (mean CV% were 16 and 18) and Smart Eurolyser POCT (mean CV% were 52 and 76). Eiken ECQS data from 880 facilities indicating smaller CV% with OC-Sensor Diana (3.5 and 3.2), OC-Sensor Micro (5.2 and 3.7), other analysers (5.8 and 12).

**Conclusions.** The new FOB EQA programme that started in January 2012 was joined by 33 clinical laboratories analysing quantitative FIT samples. Our results confirm the importance of the newly implemented FOB EQA for the quantitative haemoglobin in the stool samples and support further activities aimed to improve quality and optimization of the colorectal cancer screening programme. The results obtained in the Czech EQA rounds show higher CV in comparison to the Eiken EQAS. It is probable that this behaviour is also influenced by the number of participants which is incomparably larger in the Eiken's EQAS.

## SEKK FOB - EHK 2011/2012



## COLORECTAL CANCER SCREENING

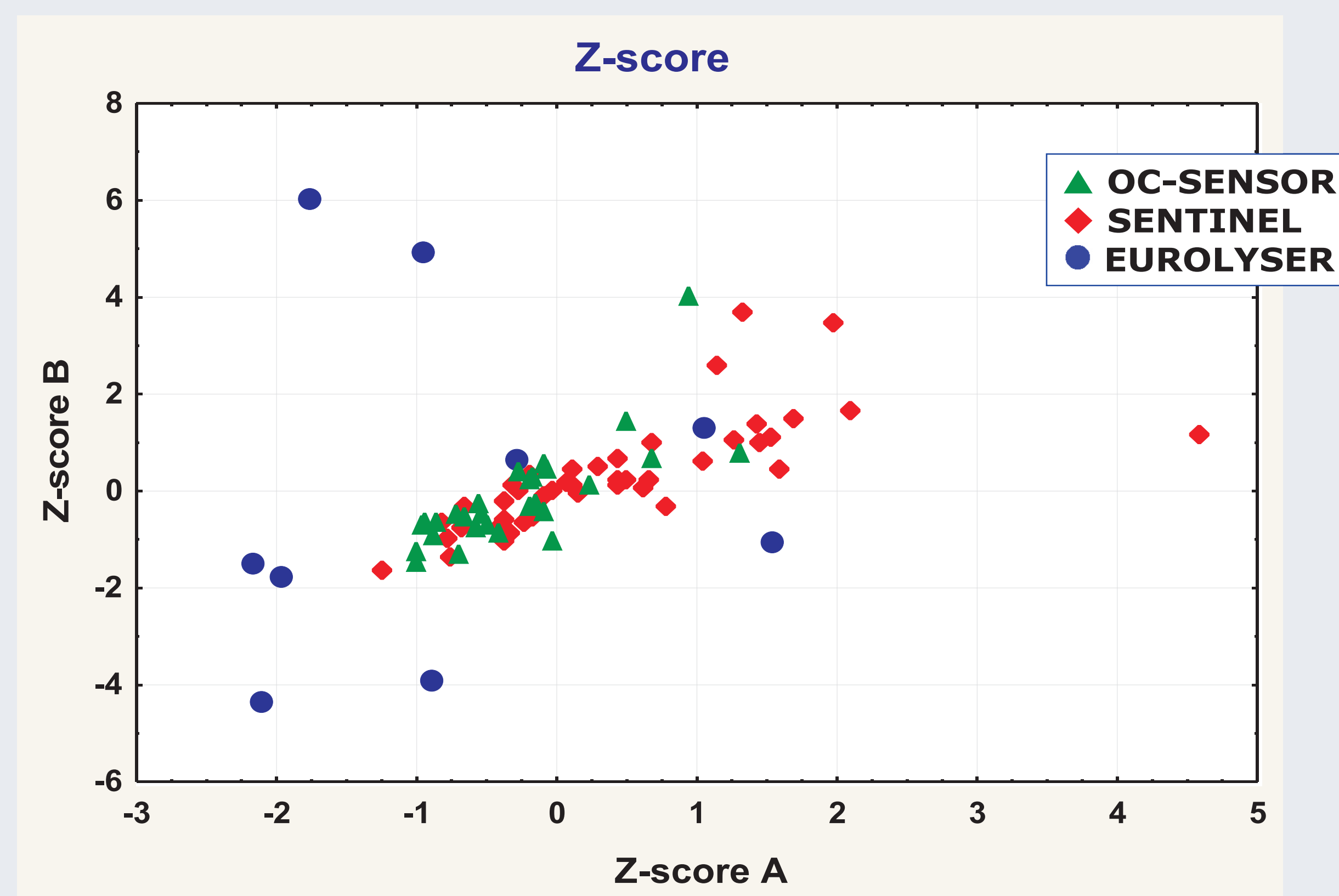
**Colorectal cancer (CRCA)** is the second most frequent malignant disease in Europe. Every year, 412 000 people are diagnosed with this condition, and 207 000 patients die of it. The introduction of population-wide national screening programs is a priority for the healthcare policies of individual nations, and this is also being addressed at the highest levels by European Union (EU) administrators. A national screening program, of one sort or another, has been implemented in 19 out of 27 European countries. The most frequently applied method is testing the stool for occult bleeding (faecal occult blood test, FOBT). In the Czech Republic we began CRCA screening programs in 1994, and population-based national screening with FOBT was started in 2002. The involvement of GPs has been found to improve patient compliance with bowel cancer screening.

**The first level of FOBTs** tested were guaiac based gFOBT methods, which are still used as traditional methods of screening with a high significance of Evidence-based-medicine. The sensitivity of gFOBT for colorectal cancer is lower than 30%, and these methods of FOBT will soon be changed to immunological FIT in most countries.

**The second level of FOBTs** tested were qualitative immunochemical based, which uses an antibody against human globin and are more sensitive than the gFOBT methods. These methods have very different accuracies and sensitivities, ranging from 29 - 72%, using different sampling devices and different stabilities of the sampling buffer.

**The third level of FOBTs** tested are now quantitative methods of faecal haemoglobin determination with automated analysers (qiFOBT), increasing the accuracy to 90 - 95%, enabling the setting to country-specific optimal cut-offs, and most importantly to be controlled by the External Quality Assurance Services (EQAS) programs. The European Group on Tumour Markers recommends the use of a quantitative iFOBT with an adjustable cut-off point to all new centres undertaking FOBT for colorectal neoplasia; and organized faecal immunochemical test screening has been associated with an increase in annually detected CRC. The pilot study with OC-Sensor qiFOBT recommended 75 ng Hb/ml as the optimal cut-off value for screening in the Czech Republic.

## SEKK FOB - EHK 2011/2012



## SEKK - EQA - FOB quality, programme design

**SEKK is EQA/PT provider** accredited according to ISO 17043. SEKK started in 1996 and currently operates in Czech and Slovak Republics and offers EQA programmes in the fields of clinical chemistry, haematology, immunology, nuclear medicine, transfusion medicine, and pathology. The 5 year history of statistical evaluations of all EQA rounds is freely available at [www.sekk.cz](http://www.sekk.cz).

**SEKK is full member of EQALM organisation** and closely cooperates with other EQA providers (e.g. RfB - Germany, ECAT - The Netherlands, UK NEQAS - Great Britain).

**The FOB (Faecal Occult Blood) programme** started in 2011 (pilot study) and it is focused to the quantitative determination of the haemoglobin concentration in the stool. The qualitative tests are not covered by this programme. We had only 19 participants in the pilot study in 2011.

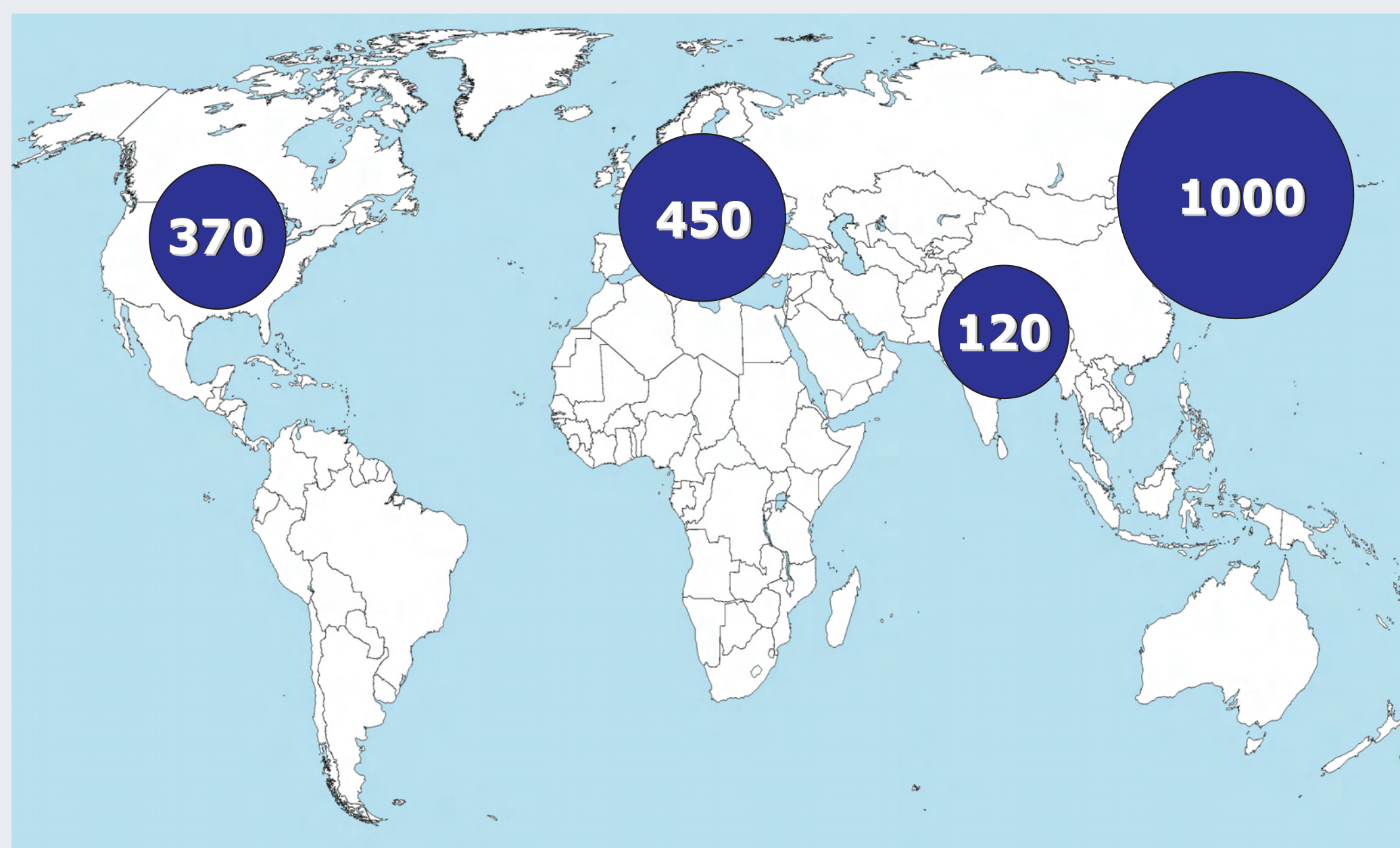
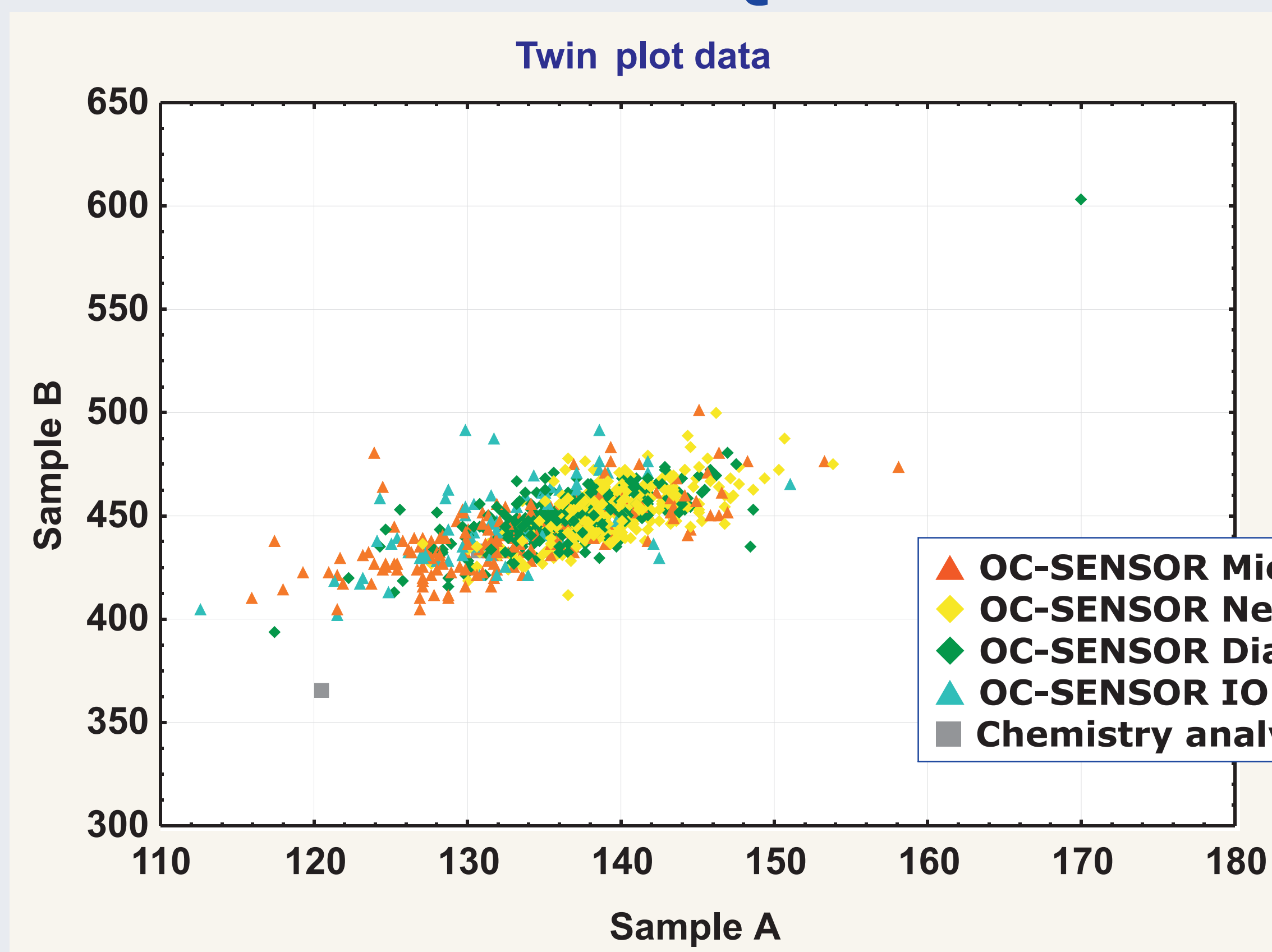
**Now(2013) we have 65 participants.** We organise 2 rounds of this programme in the year (spring and autumn). We are sending 2 samples to the participants and they have 9 days to finish the measurement and send us their results.

**Assigned values (AV)** are calculated as the robust means according to the ISO 13528. The results of the participant are compared to the AVs and maximal allowed deviation (Dmax) is set to the 30 % (thus the result of the participants must be within  $\pm 30$  % around the AV to be evaluated as successful).

**The participants of the EQA** round receive the final report that consists of:

- Supervisor's comment.
- Confirmation of attendance.
- Result sheet.
- Complex statistics, includes Youden plot, history of results, and general statistics

## EIKEN EQCS 2011



## OC SENSORS ON THE WORLD

## EIKEN EQCS 2011

