New analyzer SENTiFIT®270 and SENTiFIT® - FOB Gold® latex Fecal Immunoassay Test (FIT) evaluation and comparison with SENTiFOB® analyzer.

T. Lamacchia, S. Brenna, P.G. Gesu
Clinical Analysis Laboratory, Niguarda Hospital, Milan, Italy

Background
Fecal Immunoassay Testing (FIT) is an important step in colorectal cancer (CRC) screening programs. This study evaluates a new analyzer launched at IFCC 2013 by Sentinel CH.

Materials and methods

**Materials**

- **Reagents**
- **Fecal Specimens**

**Methods and results for SENTiFIT® - FOB Gold® latex**

- **Limit of Blank (LoB)**
- **Limit of Quantification (LoQ)**
- **Imprecision**
- **Linearity**
- **Comparison vs SENTiFIT®**

**Comparison of SENTiFIT® 270 vs SENTiFOB®. All values below LoB have been set with the dedicated LoB respectively: SENTiFOB® (x) = 15 ng/mL; SENTiFIT® 270 (y) = 5 ng/mL. Our study was separated in 2 sessions**

**First study:** 134 fecal samples per 2 runs, (total results 268).

**Second study:** 12 samples x 3 reps, 12 samples x 3 reps, 12 samples x 3 reps. (total results 372).

**Slope:** r = 0.5706; y = 0.972x (Graph 3).

**Regression:** y = 0.83 + 0.02x (Graph 4).

**Conclusion:** SENTiFIT®270 is reliable and suitable for automated Fecal Immunoassay Testing (FIT). In this study SENTiFIT® - FOB Gold® latex reagent application confirms all manufacturer claims. FIT method comparison by regression is affected by pre-analytical issues, with respect to cut-off values all patients were correctly classified.

Bibliography

- **CLSI EP17-A – Protocols for determination of Limits of Detection and Limits of Quantitation.** Vol. 24 No. 34
- **CLSI EP5-A – Evaluation of Precision of Quantitative Measurement Methods.** Vol 24 No. 25