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Analytical performance of the new Sentinel CALiaGold® pierce Tube and Quantitative Calprotectin latex immunoassay on the SENTiFIT®270 analyzer

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Introduction

Inflammatory Bowel Disease is a chronic inflammation of the intestines and is diagnosed by a combination of colonoscopy and measurement of fecal calprotectin.
Recently, Sentinel Diagnostics developed a new CALiaGold® pierce Tube in combination with a new latex immunoassay for calprotectin measurement on the SENTiFIT® 270 analyzer. The new tube has been developed with the advantage that patients can store the tube at room temperature instead of 2-8°C prior to fecal sampling.

The aim of the study was to evaluate the stability of the new CALiaGold® pierce Tubes (Sentinel Diagnostics, REF 1151300) and the analytical performance of the new Calprotectin latex immunoassay (Sentinel Diagnostics, REF 1151000), compared to the current Calprotectin latex immunoassay (Sentinel Diagnostics, REF 1159000).

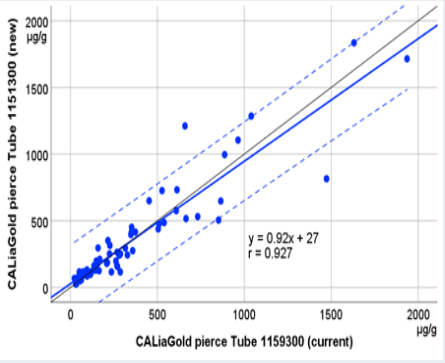

Figure 1: Comparison study
Linear regression results of new CaliaGold® pierce Tubes and reagents with current CaliaGold® pierce Tubes and reagents. The blue dashed lines respresent the 95% CI. The black line represents Y=X. Stool collection in the CaliaGold® pierce Tubes was performed by patients at home (n=100).

Reproducibility		within tube	between tube	day-to-day		
stool (µg/g)		CV (%)	CV (%)	level (µg/g)		CV (%)
1	75	1.2	6.7	C-1	75	5.9
2	165	1.2	6.3	C-2	320	4.1
3	800	1.6	6.9			
4	1100	2.1	7.6			

Table 1: Results of the reproducibility tests
Fecal sampling for within tube and between tube precision (n=15) was performed by a lab technician. Measurements were performed at one day in duplicate. Day-to-day precision (n=20) was performed with CALiaGold® Control level 1 and level 2 (REF 1151200, lot 10103).

Methods

- **Reproducibility**: Fecal sampling for within tube and between tube precision (n=15) was performed by a lab technician. Calprotectin was measured in each tube in duplicate with the new Calprotectin latex immunoaasay (REF 1151000) on the SENTiFIT® 270 analyzer. For day-to-day precison (n=20) Sentinel Calprotectin Control level 1 and level 2 were used (REF 1151200, lot 10103).
- **Stability of the new Sentinel CALiaGold® pierce Tube before fecal sampling** (REF 1151300): in a laboratory setting tubes without stool were incubated at 2-8°C, 21°C, 28°C and 35°C. After a maximum of 28 days of incubation, all tubes were sampled with stool by one laboratory technician and measured on the same day with the new Quantitative Calprotectin latex immunoassay (REF 1151000) on the SENTiFIT® 270 analyzer.
- **Stability of the new Sentinel CALiaGold® pierce Tube after fecal sampling** (REF 1151300): Tubes sampled with stool by a laboratory technician were incubated at 2-8°C, 21°C, 28°C and 35°C and measured at day 0, 1, 4, 7, 11 and 14.
- **Comparison study with stool collection at home**: patients received the current (REF 1159300) and the new tube (REF 1151300) along with the instruction protocol for stool collection at home. Within two days after fecal sampling, calprotectin was measured with the corresponding Quantitative Calprotectin latex immunoassays (current-REF 1159000 or new-REF115100) on the SENTiFIT® 270 analyzer.

Results

1 **Reproducibility:** Within tube (n=15, duplicate measurements), between tube (n=15) and day-to-day (n=20) precision yielded appropriate results (Table 1).
2 **Stability new Sentinel CALiaGold® pierce Tube (REF 1151300):**
- Before fecal sampling (= preservation of stability): Table 2
- After fecal sampling (= conservation of functionality): Table 3

3 **Comparison study with stool collection at home:**
Linear regression analysis with 100 at home collected stool samples is determined as CALiaGold® new = 27 + 0.92x CALiaGold® current (r=0,928). The results for incept and slope meet the criterion that the 95% Confidence Interval for intercept and slope must include 0 and 1.

Tube stability – before fecal sampling

	stool 1 (160 µg/g)				stool 2 (1100 µg/g)			
% decrease	2-8°C	21°C	28°C	35°C	2-8°C	21°C	28°C	35°C
day 0 - day 7	-3.4	9.5	10.7	4.3	-2.5	0.0	-4.7	5.5
day 0 - day 14	2.5	7.2	5.5	-2.5	-7.9	-6.6	-2.0	-3.4
day 0 - day 21	4.0	9.5	-7.8	0.6	-6.0	-4.7	-3.2	-1.2
day 0 - day 28	-3.5	0.0	-1.3	0.0	3.2	-5.2	-7.6	-2.7

Table 2: Stability of the new Calprotectin pierce Tube when kept at 2-8°C, 21°C, 28°C and 35°C prior to fecal sampling
Percentage decrease or increase of calprotectin at day 7, 14, 21 and 28 compared to the result at day 0.

Tube stability – after fecal sampling

	stool 1 (160 µg/g)				stool 2 (1100 µg/g)			
% decrease	2-8°C	21°C	28°C	35°C	2-8°C	21°C	28°C	35°C
day 0 - day 1	-0.5	-0,5	0.7	0.3	0,6	2.6	-1.2	-1.8
day 0 - day 4	-1.6	-2,3	-3.6	5.2	0,8	-3.8	-2.6	-2.3
day 0 - day 7	1.2	-8,3	-10.4	-10.9	0,2	-12.1	-9.9	-14.5
day 0 - day 11	-2.5	-13,6	-15.6	-16.6	-1,5	-16.4	-19.1	-25.1
day 0 – day 14	-2.0	-19,6	23.6	-30.5	-1,9	-23.0	24.9	-29.0

Table 3: Stability of the new Calprotectin pierce Tube when kept at 2-8°C, 21°C, 28°C and 35°C after fecal sampling
Percentage decrease or increase of calprotectin at day 1, 4, 7, 11 and 14 compared to the result at day 0.

Conclusion

- The **preservation of stability** and the **conservation of functionality** of the new Sentinel CALiaGold® pierce Tube (REF 1151300) in a laboratory setting has been approved and is more user-friendly for fecal sampling by patients at home:
  - 4 weeks storage at room temperature (21-35°C) prior to fecal sampling instead of storage at 2-8°C
  - 14 days storage at 2-8°C or 4 days at room temperature (21-35°C) before calprotectin measurement instead of 5 days at 2-8°C
- The **analytical performance** of the new Sentinel CALiaGold® Immunoassay (REF 1151000) on the SENTiFIT®270 analyzer meets the requirements for quantitative determination of calprotectin in human stool.

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