

**Appendix H**

**Clinical Study Information**

**Fecal Occult Blood Rapid Test (Cassette)**

**(Feces)**

**Purpose:**

To evaluate the clinical performance of Fecal Occult Blood Rapid Test Cassette (Feces).

**Materials:**

Clinical samples

Fecal Occult Blood (FOB) Rapid Test Cassette(Feces)

Cassette Lot 1:100301a, Lot2: 100302a, Lot 3: 100303a

**Method:**

532 clinical feces specimen were collected from hospital. They were tested both by Orient Gene Fecal Occult Blood (FOB) Rapid Test Cassette(Feces) and a commercial FOB rapid test according to the insert.

**Device:**

- 1.Place the test cassette on a clean and level surface.
- 2.Transfer 3 drops of samples to the sample well of the test device, then start the timer.
3. All results will be interpreted according to the standard color card at 5 mins and record the background.

**Results:****1. Cassette Lot 1:**

Method		Commercial FOB rapid test		Total
FOB rapid test		Positive	Negative	Results
	Positive	245	3	248
	Negative	2	282	284
Total Results		247	285	532

Relative Sensitivity:99.2%

Relative Specificity:98.9%

Accuracy: 99.1%

**2. Cassette Lot 2:**

Method		Commercial FOB rapid test		Total
FOB rapid test		Positive	Negative	Results
	Positive	245	3	248
	Negative	2	282	284
Total Results		247	285	532

Relative Sensitivity:99.2%

Relative Specificity:98.9%

Accuracy: 99.1%

3. Cassette Lot 3:

Method		Commercial FOB rapid test		Total
FOB rapid test		Positive	Negative	Results
	Positive	245	3	248
	Negative	2	282	284
Total Results		247	285	532

Relative Sensitivity:99.2%

Relative Specificity:98.9%

Accuracy: 99.1%

Conclusion:

According to the limited samples above, the Fecal Occult Blood (FOB) Rapid Test Cassette(Feces) has higher accuracy with the commercial FOB rapid test.