510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k110309

B. Purpose for Submission:
New device

C. Measurand:
Human hemoglobin (hHb) in human feces

D. Type of Test:
Qualitative

E. Applicant:
Orient Gene Biotech

F. Proprietary and Established Names:
FOB One Step Rapid Test

G. Regulatory Information:

1. Regulation section:
   21 CFR 864.6550, Occult blood test
2. Classification:
   Class II
3. Product code:
   KHE, Reagent, Occult blood
4. Panel:
   Hematology (81)

H. Intended Use:

1. Intended use(s):
   The FOB One Step Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of human occult blood in human fecal specimens as an aid in the diagnosis of gastrointestinal disorders. The device is suitable for use in laboratories and physician's offices as well as for over the counter use.
2. Indication(s) for use:
   Same as intended use
3. Special conditions for use statement(s):
   Prescription and over-the-counter use
4. Special instrument requirements:
   Not applicable

I. Device Description:
The FOB One Step Rapid Test device consists of a sample well and a testing pad that employs double antibody-sandwich chromatographic immunoassay technology to detect the presence of FOB in human feces. The sample is collected in a tube containing collection buffer fluid.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   INSTANT-VIEW® Fecal Occult Blood Rapid Test

2. Predicate 510(k) number(s):
   k070660
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended use	Qualitative detection of occult blood in feces	Same
Sample Type	Feces	Same
Assay	Lateral flow chromatographic immunoassay	Same
Detection Level	50 ng/mL hHb in fecal extraction buffer	Same
Users	Healthcare professionals and lay persons (OTC)	Healthcare professional use and lay persons (OTC)
Differences		
Item	**Device**	**Predicate**
Format	Cassette only	Dip Strip and Cassette

K. Standard/Guidance Document Referenced:

None

L. Test Principle:

The FOB One Step Rapid Test is a rapid qualitative test detecting the presence of human hemoglobin (hHb) in a fecal sample at 50 ng/mL and above. The tube is shaken to mix the fecal sample in the extraction buffer. Then, 3 drops (about 75µL) of the mixed sample solution is added onto the sample well of the test device. After the sample has been dispensed into the sample well, the extracted sample migrates into the pad containing detector antibody conjugated dye label. The hHb in the sample will bind to the detector antibody and migrate onto the membrane where the test and control lines are located. On the membrane, immobilized capture antibodies form the invisible Test line. When the complex of hHb and detector antibodies reaches the Test line, the complex binds to the capture antibodies to form a visible red Test line indicative of a positive result; i.e., hHb is present. When no hHb is present in the sample, no red Test line forms. In addition to the Test line, a Control line on the membrane provides an internal quality control of the test device. Anti-species specific IgG antibodies are immobilized at the Control line. These antibodies will capture any unreacted/excess antibody-gold conjugates, forming a distinct red Control line. The Control line serves to demonstrate that: lyophilized antibodies in the dye pad have been hydrated; sufficient sample has been applied to allow for migration to the Test line and beyond; chemicals are working properly; and the proper procedure was followed. If a Control line does not appear within the designated incubation time, the test result is invalid and the test should be repeated using a new test device.

M. Performance Characteristics:

1. Analytical performance:
   a. Precision/Reproducibility:

Human stool samples in collection buffer were spiked with hHb at the following concentrations: 0, 37.5, 50, 62.5, and 2000 ng/mL. In the intra-run, intra-day precision studies, 10 samples were tested at each concentration with 3 lots of the FOB One Step Rapid Test. In the inter-site reproducibility studies, 15 samples were tested at each concentration with 3 lots of the FOB One Step Rapid Test. All samples with concentrations below 50 ng/mL hHb tested negative with the candidate device while samples at and above 50 ng/mL tested positive, as expected.

b. *Linearity/assay reportable range*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Internal Control: Procedural controls are included in the test device. A red line appearing the control region is considered as the internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External Control: Controls are not provided with this kit. It is recommended that positive and negative controls be performed to verify proper test performance.

Stability of the Assay

Real time stability of the device (cassette and collection buffer solution vial) was tested with 3 lots of the device. Devices were stored at 20 - 30ºC for 20 months. Nine devices from each lot were tested at 0, 3, 6, 9, 12, 15, 18 and 20 months. All test devices showed positive results when tested with an external positive control and showed negative results when tested with hemoglobin negative aqueous fecal samples. The expiration date of this device is set at 20 months when stored between 20ºC - 30ºC.

Sample Stability: Samples were stored in a refrigerator at 2- 8ºC and tested with 10 cassettes at 0, 12, 24, 48 and 72 hours. Two concentrations of hHb - 12.5 ng/mL and 62.5 ng/mL- spiked into aqueous stool samples were tested. Based on these studies, the sample stability is determined to be 72 hours when stored between 2- 8ºC.

Temperature Stress Study: Five test devices were tested after storing them in 4ºC, 10ºC, 25ºC, 30ºC, 37ºC, 45ºC, 50ºC, 55ºC and 60ºC for 4 hours. Five test devices tested with hemoglobin concentration of 10 ng Hb/mL tested negative for the storage temperature limit of 50ºC. The results for storage temperature above 50ºC were invalid. Five test devices tested with hemoglobin concentration of 50 ng Hb/mL tested positive for the storage temperature limit of 50ºC. The results for storage temperature above 50ºC were invalid. The test device (cassette and buffer) showed acceptable performance after being stored for 4 hours in temperatures ranging from 4ºC to 50ºC.

d. *Detection limit:*

The detection limit of the device was determined by spiking 100 hemoglobin-free stool samples with varying concentrations (0, 37.5, 50, 62.5 and 2000 ng hHb/ml) of human hemoglobin. The test showed a cut-of 50 ng hHb/mL and no prozone effect was seen up to 2000 ng hHb/mL.

The minimal detection limit of the device is 50 ng/mL of hHb in collection buffer.

e. Analytical specificity:

Positive and negative stool samples were spiked with the following substances: horseradish peroxidase (20 mg/mL), extract of red radish, extract of raw turnip, extract of cauliflower, extract of broccoli, dietary supplements with chlorine, fluoride, and iron, dietary supplements with Vitamin C and toilet water with and without cleaner and deodorizer. Animal hemoglobin from beef, chicken, fish, horse, goat, pig, rabbit, and sheep was also used in these studies. Addition of these substances had no effect on the test results.

g. Assay cut-off:

The assay cut-off is 50 ng/mL of hHb in buffer.

2. Comparison studies:

a. Method comparison with predicate device:

The FOB One Step Rapid Test was evaluated in comparison with a commercially available predicate device in foreign as well as US sites.

The foreign sites consisted of 3 physician office sites (POL) and 1 reference laboratory site. In the POL study, five different sample concentrations (0, 37.5, 50, 62.5, and 500 ng hHb/mL) were tested using the FOB One Step Rapid Test device and the predicate device using 20 replicates for each concentration, for a total of 100 samples. All samples were blind labeled. Results obtained from 3 sites agreed 99.0% with the expected results and 98.0% with the results obtained with the predicate device. In the reference laboratory site study (study of non-technical personnel), 30 participants tested 5 samples (1 at each concentration) with the two FOB devices. A total of 150 samples were tested in this study. There was 98.7% agreement with the expected results and 98.0% agreement with the results obtained with the predicate device.

The US study was a lay-user study conducted in two POL sites and one scientific laboratory site. Twenty lay-users per site participated in these studies by using their own specimens. The overall agreement of the test device with the predicate device when tested by lay-users was 95.0% (95% CI: 91% -100%). The overall agreement between the results obtained by lay-users and professional users was 98.3% (95% CI: 91% - 100%). In the study using spiked samples (12 per concentration), the overall agreement with the predicate device was 93.3% (95% CI: 84% - 97%).

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:
   Results are negative when <50 ng/mL of hHb in collection buffer solution and positive when ≥ 50 ng/mL of hHb in collection buffer solution are present.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports substantial equivalence decision.