Supplementary Appendix.Summary of FIT/FOBT Device Manufactures

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| --- | --- | --- | --- |
| Brand | Type | Manufacturer | Location |
| HemeSelect | FIT | SmithKline Diagnostics | San Jose, CA |
| OC-Hemodia | FIT | Eiken Chemical Co. | Tokyo, Japan |
| Monohaem | FIT | Nihon Pharmaceutical | Tokyo, Japan |
| Magstream HemSp | FIT | Fujirebio | Tokyo, Japan |
| FlexSure OBT | FIT | Beckman Coulter | Fullerton, CA |
| OC-Micro | FIT | Eiken Chemical Co. | Tokyo, Japan |
| OC-Light | FIT | Eiken Chemical Co | Tokyo, Japan |
| OC-Sensor | FIT | Eiken Chemical Co | Tokyo Japan |
| Ridascreen | FIT | R-Biopharm | Darmstadt, Germany |
| OC-FIT CHEK | FIT | Polymedco | Cortland Manor, NY |
| FOB Gold | FIT | Sentinel Diagnostics | Milan, Italy |
| Bionexia FOBplus | FIT | DIMA | Gottingen, Germany |
| ImmoCARE-C | FIT | CAREdiagnostica | Voerde, Germany |
| FOB advanced | FIT | Ulti med | Ahrensburg, Germany |
| QuickVue iFOB | FIT | Quidel | San Diego, CA |
| PreventID CC | FIT | Preventis | Bensheim, Germany |
| HM-Jack | FIT | Kiowa | Tokyo, Japan |
| InSure/Insure II | FIT | Enterix | North Ryde, NSW, Australia |
| Hemoccult ICT | FIT | Beckman Coulter | Fullerton, CA |
| Immudia-HemSp | FIT | Fujirebio | Tokyo, Japan |
| iChroma | FIT | Boditech | Chuncheon, South Korea |
| Hemosure | FIT | W.H.P.M Inc | Irwindale, CA |
| Hemoccult Sensa | FOBT | Beckman Coulter (formerly SmithKline Diagnostics) | Fullerton, CA |
| Hemofec | FOBT | Roche Diagnostics | Barcelona, Spain |
| Hemoccult II | FOBT | Beckman Coulter | Fullerton, CA |
| HemOccult | FOBT | Beckman Coulter | Krefeld, Germany |

Supplementary Table 1.Summary of Selected FIT Devices Cleared by the FDA for Use

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Brand(s) | Manufacturer/distributor | FDA approval document | Sampling device | Number of samples | Qualitative or quantitative | Detection threshold |
| OC-Micro and OC-Sensor Test System | Eiken/Polymedco | K041408 K092330 | Probe inserted into stool and then placed into collection vial | 1 sample | Quantitative | Adjustable but set by manufacturer to 20 *μ*g/g |
| i-Chroma iFOBT | Boditech | K132167 | Probe inserted into stool and then placed into collection vial | 1 sample | Quantitative | 8 *μ*g/g |
| Insure and Insure II | Enterix | K101831 K060930 | Brush surface of stool and apply water from brushing to test card | 2 sample | Qualitative | 50 *μ*g/g |
| QuickVue iFOB Test | Quidel | K021423 | Probe inserted into stool and then placed into collection vial | 1 sample | Qualitative | 50 *μ*g/g |
| Hemosure | W.H.P.M. Bioresearch and Technology, Inc | K041202 | Probe inserted into stool and then placed into collection vial | 1 or 2 samples | Qualitative | 50 *μ*g/g |
| OC-Light | Eiken Polymedco | K042197 | Probe inserted into stool and then placed into collection vial | 1 sample | Qualitative | 10 *μ*g/g |
|  |  |  |  |  |  |  |
| Clearview ULTRA FOB | Inverness Medical | K041297 | Probe inserted into stool and then placed into collection vial | 1 sample | Qualitative | 50 *μ*g/g |
| immoCARE | Care Diagnostics | K05298 | Sample stool using the provided collection stick, then puts the collection stick back into the bottle of buffer solution | 1 sample | Qualitative | 30 *μ*g/g |
| Consult IFOBT One Step+ | Consult Henry Schien | K060463 | Collect sample with stick and place on card | 2 sample | Qualitative | 50 *μ*g/g |
| Hema-screen SPECIFIC Rapid FOBT Rapid Response Immuostics Rapid | Immunostics CLIAwaived, Inc BTNX Teco | K061065 | Insert the stick into the fecal specimen, wipe excess off, replace the stick in the tube | 1 sample | Qualitative | 6 *μ*g/g |
| Forsure One Step Acutest Compliance Gold | Syntron Bioresearch Jant Pharmacal Germaine Lab | K063693 | Insert applicator into stool, wipe excess off and screw applicator into tube | 1 sample | Qualitative | 50 *μ*g/g |
| One Step FOBT | IND Diagnostics | K100031 | Cylindric tube, vial dipstick sampling, developed on a cassette | 1 sample | Qualitative | 50 *μ*g/g |
| Hemoccult ICT (also known as FlexSure OBT) | Beckman Coulter | K080812 | Use stick to collect a pea-size stool sample and apply to top window and repeat process to bottom window | 2-and 3-day screening kits | Qualitative | 300 *μ*g/g |

**Supplementary Table 2.**FIT Performance Characteristics Over Multiple Screening Rounds in an Average-Risk Population: PPV and Adenoma

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Study, year | FIT brand, cut-off | Screening round | Participation rate, % | Positivity rate, % | Colonoscopy completion rate, % | Positive predictive value for any adenoma, % |
| Denters et al,46 2012 | OC Sensor, 10 *μ*g/g | 1 | 57.0 | 8.1 | 82[*a*](#bookmark14) | 76.3 |
|  |  | 2 | 86.1 | 7.4 | 89 | 68.5 |
| Parente et al,49 2013 | HM-JACK, 250 *μ*g/g | 1 | 49.7 | 6.2 | NR | 36.6 |
|  |  | 2 | 54.4 | 5.8 | NR | 37.7 |
| Kapidzic et al,47 201 4 | OC Sensor, 10 *μ*g/g | 1 | 62.6 | 8.4 | 95.8 | 65.5 |
|  |  | 2 | 63.2 | 6.0 | 97.0 | 52.1 |
|  |  | 3 | 68.3 | 5.7 | 94.5 | 50.9 |
| McNamara et al,48 2014 | OC Sensor, 20 *μ*g/g | 1 | 50.7 | 10.1 | 81.5 | 36.7 |
|  |  | 2 | 47.5 | 8.0 | 82.4 | 34.9 |
| Jensen et al,52 2016 | OC FIT Chek, 20 *μ*g/g | 1 | 48.2 | 5.0 | 75.5 | 51.5 |
|  |  | 2 | 75.3 | 3.9 | 80.5 | 47.4 |
|  |  | 3 | 83.4 | 3.7 | 80.5 | 48.5 |
|  |  | 4 | 86.1 | 4.3 | 81.1 | 47.9 |

*a*Includes FOBT as well as FIT participants.