HEMOSURE®

Instructions for Hemosure® Accu-Reader® A100 Test Kit

Product Name
Hemosure® Accu-Reader® A100

Packaging Specifications
50 test cartridges/box (P/N: AR01-CT50)
100 sample collection tubes/box (P/N: AR01-TB100)

Intended Use
The Hemosure® Accu-Reader® A100 is an automated immunochemical fecal occult blood test system intended for the qualitative detection of fecal occult blood in human feces by clinical laboratories. The Hemosure® Accu-Reader® A100 is comprised of Hemosure® Accu-Reader® A100 Reader with Sample Tray, Hemosure Accu-Reader® A100 Test Cartridge, Sample Collection Tube, Hemosure® Accu-Reader® A100 Controls and Hemosure® Accu-Reader® A100 Calibration Cartridge Kit. For in vitro diagnostic use. For Prescription use.

Test Principle
Hemosure® Accu-Reader® A100 is a qualitative, sandwich dye conjugate immunoassay and employs a unique combination of monoclonal and polyclonal antibodies to selectively identify hemoglobin in test samples with a high degree of sensitivity. As the test sample flows up through the absorbent device, the labeled antibody-dye conjugate binds to the hemoglobin in the specimen forming an antibody-antigen complex. This complex binds to anti-hemoglobin antibody in the positive test reaction zone and produces a pink-rose color band. In the absence of hemoglobin, there is no line in the positive test reaction zone. The pink-rose color bands in the control reaction zone demonstrate that the reagents and devices are functioning correctly.

Components
Hemosure® Accu-Reader® A100 test cartridges and sample collection tubes: The test cartridge is a polystyrene plastic case that contains a test strip composed of a plastic plate, a water absorption plate, a nitrocellulose film, colloidal gold, and water absorption paper; The nitrocellulose membrane consists of a control line (line C) coated with sheep anti-mouse polyclonal antibody and a reaction line (line T) coated with mouse anti-human hemoglobin monoclonal antibody 1. Colloidal gold is prepared by labeling mouse anti-human hemoglobin monoclonal antibody 2.
- Each test cartridge is individually sealed in a foil pouch including desiccant.
- The sample collection tube contains 2 ml of extraction buffer. Sample collection tubes are packaged in a separate box.

Storage Conditions and Validity Period
- The test cartridge has a validity of 24 months while sealed in the foil pouch. The test cartridge is to be stored at 4°C~30°C and kept away from direct light. Please refer to the packaging label for the production date and service life.
- The test cartridge is to be used as soon as possible after the foil pouch is unsealed.
- The sample collection tube has a validity of 24 months. The sample collection tube is to be stored at 4°C~30°C and kept away from direct light. Please refer to the packaging label for the production date and service life.
- It is recommended to use the sample collection tube immediately after sampling. Otherwise the sample collection tube with fecal samples may be stored up to fourteen (14) days at room temperature and up to thirty (30) days in refrigeration at 2°C~8°C.

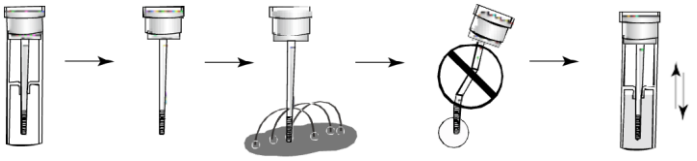
Applicable Instruments
Product Name: Hemosure® Accu-Reader® A100 Reader

Sample Collection
- Method 1: Sample collection paper. Patient defecates directly onto sample collection paper and collects fresh stool sample following the sample collection tube procedure.
- Method 2: Stool collection container. Patient collects fresh stool sample using a clean and dry collection container. Follow stool sample collection tube procedure to prepare sample for testing.

Note: Patients will receive a Hemosure® Accu-Reader® A100 "patient mailer" that contains a set of instructions for use and the following: (1) 1 sample collection tube; (2) sample collection paper; and (3) a specimen pouch with absorbent pad included. Please note that the test cartridge is not included in the patient mailer, only the sample collection tube.

Test Method
Check all the items in the box before using this product. Do not tear open the aluminum foil bag before getting ready for the test.

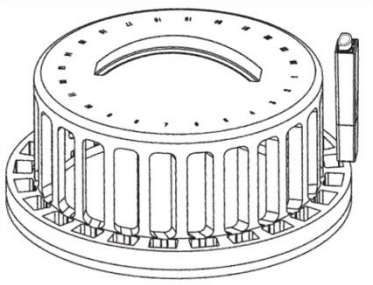
1. Sample Collection Tube Procedure
a) Remove the rubberized cap and connected stool collection rod from the main sample collection tube. Be careful not to spill the solution in the sample collection tube.
b) Use stool collection rod to collect stool by inserting the rod into 6 different sites of the stool sample (it is advisable to completely cover the spiral groove at the distal end of the stool collection rod).
c) Place the sample into the sample collection tube by inserting the stool collection rod back into the main sample collection tube. Press down to ensure the rubberized cap is firmly in place and has sealed the sample collection tube. Lightly shake the stool sample to ensure it is fully mixed with the buffer solution.



Pull out the stool-collection rod. | Stool-collection Rod. | Insert the rod into 6 different sites of the stool sample. | Be sure not to bend the stool-collection rod. | Lightly shake up and down for 10 second

2. Test Cartridge
a) Tear and open the foil pouch, remove the test cartridge from the pouch and firmly hold the cartridge.
b) Insert the sample collection tube into the test cartridge and lightly press down until the bottom of the rubberized cap is in line with the top edge of the test cartridge.

c) **ATTENTION!** Be careful not to push the sample collection tube down into the test cartridge to the point that the foil seal on the bottom of the sample collection tube is ruptured. In the event the foil is ruptured during sample preparation the result of the test is considered invalid.
d) Place the test cartridge containing a sample collection tube into the Hemosure® Accu-Reader® A100 sample tray.



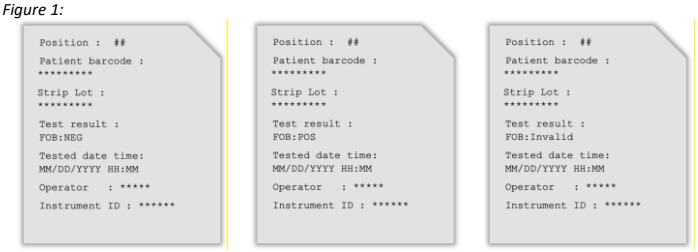
e) Follow the instructions of the Hemosure® Accu-Reader® A100 during operation of the testing. Please refer to the operating instructions of the instrument for specific steps.

Interpretation of Test Results

This product is used in conjunction with the Hemosure® Accu-Reader® A100 manufactured by W.H.P.M., Inc. The results may be printed out by Hemosure® Accu-Reader® A100, an example of the printout is shown in Figure 1.

- Hemosure® Accu-Reader® A100 automatically calculates the test results and displays the human hemoglobin concentration of samples in terms Positive or Negative results.
- Results reported as "Invalid" should be retested with a new fecal sample and new Hemosure® Accu-Reader® A100 cartridge. Do not reuse test cartridge.
- The Hemosure® Accu-Reader® A100 should be considered as a screening tool only. Please consult a physician to discuss the test results.

Figure 1:



Negative Positive Invalid

Quality Control

This product is specifically designed for the Hemosure® Accu-Reader® A100. The test strip within the cartridge contains an internal control line to determine for the operator whether or not the test has run properly.

The Hemosure® Accu-Reader® A100 Controls set can be purchased separately and used to run daily controls for the Hemosure® Accu-Reade® A100 as an external quality control. The Hemosure® Accu-Reader® A100 Controls external quality control should be run daily before using the Hemosure® Accu-Reader® A100 for sample testing to ensure accurate results during testing.

Limitations of Test Method

1. This product qualitatively detects the presence of human hemoglobin in human stool samples.
2. The test results of this reagent are for reference use only and shall not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients shall be comprehensively considered in combination with their symptoms, signs, medical history, other laboratory examinations, and treatment reactions.

Product Performance Index

The capability of the Hemosure® Accu-Reader® A100 to detect variants of human hemoglobin has been tested against Hemoglobin-S (HbS) and has been found to be equally sensitive to HbS as to hHb.

The upper limits of detection capability of the Hemosure® Accu-Reader® A100 have also been evaluated to ensure sensitivity to hHb at abnormally high concentrations, namely against the Hook Effect. The Accu-Reader® A100 is not susceptible to the Hook Effect up to a concentration of fecal occult blood up to 3.0 µg/mL or 3000 ng/mL.

1. Interference Testing & Specificity

Interference Testing for the Hemosure® Accu-Reader® A100 was performed by spiking human fecal samples with the following non-human hemoglobin (Hb) at concentration of 500 ug/ml. Hb from bovine, equine, goat, porcine, rabbit, sheep, and fish were added to normal human stool containing 0 ng/ml, 80 ng/mL, 100 ng/ml, 110 ng/ml, 120 ng/ml, 140 ng/ml and 1,000 ng/ml hHb. These extracts showed no interference with the Hemosure® Accu-Reader® A100. In addition to hemoglobin, meat extracts of the animals listed above were tested against the Hemosure® Accu-Reader® A100 for cross-reactivity in a similar fashion. They exhibited no significant interference.

Dietary substances and vegetables such as iron, sodium L-ascorbate, broccoli, cantaloupe, cauliflower, horseradish, parsnip, radish, and turnip samples were similarly tested and were found to have no interference with the Hemosure® Accu-Reader® A100.

The Hemosure® Accu-Reader® A100 was also tested against toilet water contaminants such as lime-a-way, Clorox, Lysol bleach, Lysol cleaner, and scrubbing bubbles at a concentration of 5 mg/mL. Bisacodyl Enteric-coated tablets (25 mg/mL), Sennoside tablets (25 mg/mL), Glycerol enema (25 mg/mL), and Hydrogen peroxide enema (25 mg/mL). These substances were found to not have significant interference.

2. Precision

The repeatability and precision of the Hemosure® Accu-Reader® A100 were evaluated in a series of studies including evaluation between test kit lots (one instrument and different lots), between instruments (one test kit lot and different instruments), between sites (different instruments and lots), and between runs with different operators. Testing included 21 replicates across 7 hHb concentrations at 0 ng/mL, 80 ng/mL, 100 ng/mL, 110 ng/mL, 120 ng/mL, 140 ng/mL, and 1000 ng/mL. The study results are summarized in Table 1.

Table 1.

Type of Precision Study	Observed Results	Expected Results			Overall Percent Agreement	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
		Positive Results	Negative Results	Total Results			
Repeatability	Positive Results	87	1	88	98.63%	98.86% (93.84%~99.80%)	98.31% (90.91%~99.70%)
	Negative Results	1	58	59			
	Total Results	88	59	147			
Between-run Reproducibility	Positive Results	266	2	268	99.09%	99.25% (97.33%~99.91%)	98.84% (95.89%~99.86%)
	Negative Results	2	171	173			
	Total Results	268	173	441			
Between Instrument Reproducibility	Positive Results	264	2	266	99.09%	99.25% (97.31%~99.78%)	98.86% (95.93%~99.86%)
	Negative Results	2	173	175			
	Total Results	266	175	441			
Lot-to-Lot Reproducibility	Positive Results	268	2	270	99.32%	99.63% (97.92%~99.93%)	98.84% (95.86%~99.69%)
	Negative Results	1	170	171			
	Total Results	269	172	441			
Between-site Reproducibility	Positive Results	356	2	358	99.32%	99.44% (98.00%~99.93%)	99.13% (96.89%~99. 89 %)
	Negative Results	2	228	230			
	Total Results	358	230	588			

3. Comparison Studies

The Hemosure® Accu-Reader® A100 was compared to the commercially available OC Auto® Micro 80. The two instruments detect the same cut-off level of human hemoglobin (hHb) and were compared in three different locations, two in China and one in the USA. The Hemosure® Accu-Reader® A100 was found to have an overall agreement ≥ 98% with positive agreement ≥ 98% and negative agreement ≥ 98%.

Warnings and Precautions

1. For in vitro diagnostic use only.
2. For professional use only.
3. When the test result is positive, the false positive caused by non-gastrointestinal hemorrhage, such as latent hemorrhage caused by aspirin stimulating intestinal tract, should be excluded in combination with clinical practice.

4. Normal people may suffer from physiological blood loss. For example, false-positive results may occur where the tested person is in menstrual period, suffering hematuria, oral and/or nasal hemorrhage, etc.

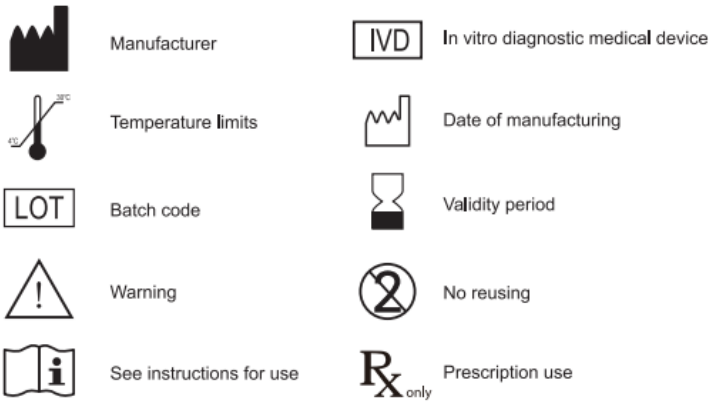
5. Hemoglobin may be degraded or destroyed by gastric acid or enzymes secreted by intestinal bacteria due to its long retention time in the digestive tract, which makes the immunogenicity of hemoglobin weaken or disappear, thus losing the binding ability with antibodies, which may further lead to weakened positive or false negative results, and need to be comprehensively judged in combination with clinical practice.

6. This method can only be used for screening or auxiliary diagnosis, and cannot replace gastroscopy, rectal endoscopy, endoscopy and X-ray examination.

7. This disposable kit should be used within the validity period.

8. Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

Interpretation of logo



References

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4. Ribet, A., Frexinos, J., and Escourrou, J. “Occult-blood test and Colorectal Tumors.” Lancet, Vol. I (1980):417.

5. Allison JB, Takawa IS, Ransom LJ, Adrian AL. A comparison of fecal occult blood test for colorectal -cancer screening. N Engl J Med 1996; 334:155-159.

Basic Information

EC REP
Lotus NL. B.V.
Koningin Julianaplein 10,
1e Verd, 2595AA.
The Hague, Netherlands

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CE
IVD

Rx Only

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For *in vitro* diagnostic device