

## Hemosure® Accu-Reader® A100 FIT System Performance Characteristics

### Device Description

The Hemosure® Accu-Reader® A100 is a fully automated FIT system intended for the in vitro qualitative detection of fecal occult blood in feces by professional laboratories. With a throughput of 100 tests per hour, the test system is comprised of FIT test cartridges, fecal sample collection tubes (with buffer), QC controls, a calibration cartridge set, and a benchtop analyzer with sample tray. The principle of measurement is a sandwich dye conjugate immunoassay that employs a combination of monoclonal and polyclonal antibodies to selectively identify and provide qualitative determination of human hemoglobin in feces. As the test sample flows up through the immunoassay, if human hemoglobin is present, the labeled antibody-dye conjugate will bind to form an antibody-antigen complex. The complex then binds to anti-hemoglobin antibody in the test reaction zone and produces a signal that is detected by the analyzer. In the absence of human hemoglobin, an antibody-antigen complex will not form, and no signal will be present in the test reaction zone. The test assay includes an internal control to ensure the proper performance of each individual test prior to reporting the result. The samples may be collected by the patient at home or in a clinical setting with the sample collection tube. The sample collection tube and test cartridge are then assembled and placed into a slot on the Accu-Reader® A100 sample tray. The laboratory operator initiates testing using the touchscreen interface. Results are reported immediately after sample reading and are displayed on the device. Test result may also be printed by the on-board printer or transferred to the Laboratory Information System (LIS) via LIS-HL7 connectivity.



### Clinical Performance: Method Comparison Study

A clinical method comparison study was performed in order to demonstrate the equivalency between the Hemosure® Accu-Reader® A100 and an FDA cleared predicate device. A total of 377 clinical fecal samples were collected from individuals who were undergoing physician ordered fecal occult blood screening. The Accu-Reader® A100’s capability and consistency were evaluated through comparative testing against a widely used automated immunoturbidimetric latex-agglutination predicate device. Real world patient samples were tested for the presence of human hemoglobin in side-by-side comparison of the Accu-Reader® A100 and the predicate.

**Table 1: Number of clinical fecal samples tested during clinical method comparison study of Accu-Reader® A100**

Study Site	Clinical samples tested by site & unique operator											
	Operator 1			Operator 2			Operator 3			Operator 1+2+3		
	Positive	Negative	Total	Positive	Negative	Total	Positive	Negative	Total	Positive	Negative	Total
Site 1	31	11	42	17	6	23	13	40	53	60	58	118
Site 2	36	29	65	25	25	50	19	5	24	80	59	139
Site 3	2	38	40	5	35	40	0	40	40	7	113	120
Total										147	230	377

**Table 2: Statistical analysis of clinical method comparison study of Accu-Reader® A100 FIT**

Study site	Predicate System	Accu-Reader® A100 System			Overall Percent Agreement	Positive Percent Agreement (95% CI)	Negative Percent Agreement (95% CI)
		Positive	Negative	Total			
Site 1	Positive	59	1	60	98.31% (94.03%~99.54%)	98.33% (91.15%~99.70%)	98.27% (99.69%~100%)
	Negative	1	57	58			
	Total	60	58	118			
Site 2	Positive	78	1	79	97.84% (94.21%~98.90%)	97.5% (90.14%~99.31%)	93.22% (91.01%~99.70%)
	Negative	2	58	60			
	Total	80	59	139			
Site 3	Positive	7	0	7	100% (96.23%~100%)	100% (56.96%~100%)	100% (96.01%~100%)
	Negative	0	113	113			
	Total	7	113	120			
Total	Positive	144	2	146	98.67% (96.93~99.43%)	98.63% (93.51%~99.97%)	98.71% (96.87%~99.76%)
	Negative	3	228	231			
	Total	147	230	377			

Following comparative evaluation of 377 patient samples the overall percent agreement (OPA) was 98.67% (CI95: 96.93%-99.43%), with a Clinical Sensitivity (PPA) of 98.63% (CI95: 93.51%-99.97%), and a Clinical Specificity (NPA) of 98.71% (CI95: 96.87%-99.76%).

### Sample Collection Usability Study

Twenty laypersons were recruited to collect test samples from negative (Hemoglobin-free) and positive (known Hemoglobin concentration: 1000ng/mL) contrived fecal specimens with the Accu-Readers® A100 fecal sample collection tube by following the Instructions for Use (IFU). Five positive and five negative samples were collected by each layperson for a total of 200 samples (100 positive and 100 negative). The sample collection tubes loaded with the fecal sample were tested on the Accu-Reader® A100 after weighing and calculating the weight of feces in the sample collection tubes. The sample collection usability study demonstrated a high degree of result reproducibility and consistency of the amount of stool collected by all participants.

### Patient Sample Stability Studies

Stool samples were spiked with different concentrations of human hemoglobin and stored in the sample collection tubes at different temperatures for up to 30 days. Twenty-one (21) replicates of each of the following hemoglobin concentrations were tested: 0, 80, 100, 110, 120, 140 and 1000 ng/mL.

The samples stored at 30°C and 40°C were tested on days 0, 6, 11, 14 and 15. The samples remained stable when stored in the sample collection tube for up to 14 days. For refrigerated conditions, two temperature conditions were tested. Samples were stored at 2°C to 8°C and -10°C to -20°C and testing was performed at 0, 30 and 32 days. Based on the results, the fecal sample in the sample collection tube can be stored for up to 30 days under refrigerated conditions.

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.

### Test Cartridge Stability Studies

The real time stability study was conducted to verify the test kits are stable up to 24 months when stored at temperatures between 4°C and 30°C. The study was conducted with 3 different lots of Hemosure® Accu-Reader® A100 test kits (test cartridge and sample tube). Measurements were performed at day 0, after 12 months, 18 months, 24 months, and 30 months using stool samples spiked with the seven known concentrations of human hemoglobin (0, 80, 100, 110, 120, 140, and 1000 ng/ml). The samples were measured in 21 replicates. The test results demonstrated that the Hemosure® Accu-Reader® A100 test kits (test cartridge and sample tube) are stable for up to 24 months at 4°C - 30°C.