AnemoCheck® HOME

A simple over-the-counter test for determination of hemoglobin levels

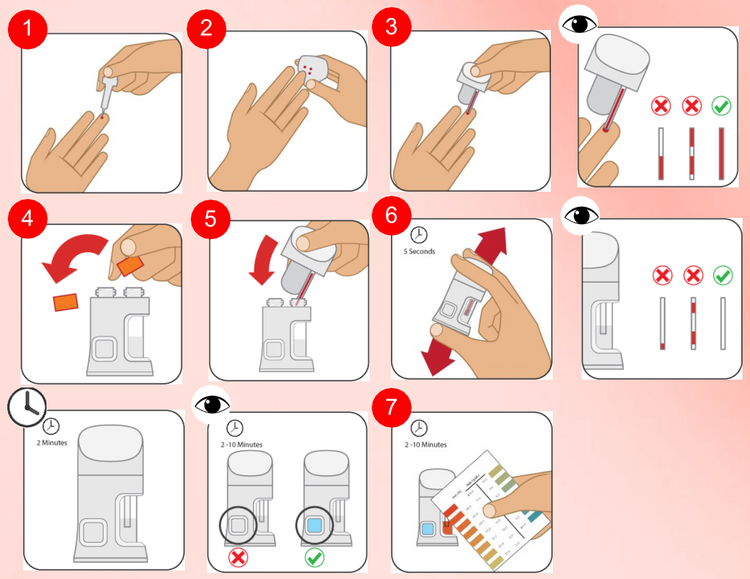
Developed by Sanguina®

Anemia is a worldwide problem

Caused by low hemoglobin (Hgb) levels, anemia affects over **2 billion people** annually and causes fatigue, dizziness, lost productivity, lower quality of life and in severe cases, cardiovascular collapse and death. The problem is anemia is only screened for and monitored clinically.

AnemoCheck can change that.

How It Works



1. User performs finger stick.
2. Wipe away first drops of blood.
3. Collect next drop into blood collection tube. Check to make sure the tube is filled all the way with no bubbles.
4. Uncap test.
5. Mate cap with test body, lock shut.
6. Shake up and down. Make sure blood has been mixed with test solution.
7. Wait 2 minutes, check control indicator and interpret result.

Current Progress

Sanguina is testing **Anemo**Check HOME in the hands of end users, as necessary for FDA over the counter evaluation. Specifically, we will obtain 300+ data points on end users to determine test accuracy, precision, control method validation, usability and human factors testing, as required for an over the counter FDA 510(k) submission. We expect to enter the market in 2020.

If you would like to become a beta tester, contact us at: anemocheck_info@sanguina.com

AnemoCheck HOME

Is a simple, single use, disposable test for hemoglobin level determination. The test:

- Is completed in 2-3 minutes
- Will be over-the-counter for home use

FDA-Cleared Technology

Our **Anemo**Check technology was cleared for clinical indication in 2017 (**K163215**). As part of the submission, precision and accuracy studies were completed. **Anemo**Check HOME will use the same technology and aims for OTC clearance in 2020.

ACCURACY

Results of comparison studies between AnemoCheck and a commercially available hemoglobin test are summarized in the table below. The study was performed at 3 sites. Both capillary and venous blood in K2EDTA, heparin or citrate was used.

Accuracy					
	Number of Tests	Min. Hgb (g/dL)	Max. Hgb (g/dL)	Regression Line	Correlation Coefficient (R Value)
AnemoCheck Study	262	4.0	17.7	y = 1.00x -0.05	0.98

PRECISION

Total precision was determined by performing repeated testing on control material. Testing was done at 3 sites, with 2 operators per site, using 1 lot of control material. Commercially available controls were tested at 2 levels. Hemoglobin level was measured 10 times per level on 5 different days.

Total Precision				
Level (g/dL)	Number of Determinations	Mean (g/dL)	Standard Deviation (g/dL)	CV (%)
5.9	900	5.7	0.36	6.4
17.5	900	17.3	0.54	3.1

Partners