



Unique Features of BioMedomics Sickle SCAN® Rapid Test

The purpose of this paper is to document some of the unique features and benefits of the Sickle SCAN rapid test that distinguish it from other point-of-care tests for the diagnosis of sickle cell disease and trait. Below is a table summarizing these features, followed by more details for each one:

Feature	Sickle SCAN™	Competitor A
Test Design	Traditional lateral flow design where lines appear in order to qualify sample	Atypical design where lines disappear in order to qualify sample
Strip Architecture	Sandwich immunoassay ideal for diluted Hb solution, using two antibodies to capture Hb molecules ensures good test sensitivity	Competitive assay not ideal for larger molecules like Hb (mw~64K), can result in protein aggregation that can compromise assay sensitivity
Test Result Visualization	Blue nanoparticles provide strong visual contrast of test result, adding to assay sensitivity	Red colored nanoparticles can result in background interference with red blood cells, thus reducing assay sensitivity
Antibody Linkage Process	Antibodies chemically bond to blue bead surface, results in highly stable bonding in biological samples	Antibodies passively absorbed on gold particle surface, can result in less stable bonding in biological samples
Complete Test Duration ¹	6 minutes	20 minutes ²
Buffer Solution	Pre-packaged stable liquid buffer included in kit	Powdered buffer requires use of whatever water source is available
Packaging / Environmental Stability	Individually foil-sealed tests.	Single sealed bottle containing 25 loose test strips
Limits of Detection	~1% Hb proteins	<2.7% HbA, <3.3% HbS, <1.3% HbC ²
Time Used In Market	2 years +	< 4 months
Test Handling / Disposal	Blood/Buffer Solution contained in sealed bottle.	Blood/Buffer solution in open vial.

¹Including preparation time

²Quinn TC, et al., *British Jour Haem*, 2016, 175:724-732

Test Design

BioMedomics Sickle SCAN is one of the simplest, easy-to-use tests on the market but still provides reliable, accurate results. Unlike some competitive tests, Sickle SCAN does not require a visual “key” to interpret the test results, since each individual test is clearly labeled. In addition, Sickle SCAN works in a similar way to other commonly-used POC tests where indicator lines will visibly appear to indicate a result instead of disappearing. This intuitive, user-friendly design reduces training time and potential user errors.



Strip Architecture

BioMedomics Sickle SCAN uses a lateral flow strip designed as a “sandwich” immunoassay, which uses two antibodies to capture hemoglobin molecules from a patient’s blood sample. This ensures excellent test sensitivity. While true that some sandwich assays are susceptible to something called the prozone effect, the Sickle SCAN test is not since the whole blood specimen is combined with a liquid buffer at 200x dilution. Some other sickle cell rapid tests use a “competitive” assay design, which uses only a single antibody and is typically used for molecules that are much smaller than hemoglobin. This kind of assay is not ideal for larger molecules like Hb (mw~64K) because it can result in protein aggregation that can compromise assay sensitivity. As a result, Sickle SCAN’s sandwich assay design can provide results that are more reliable and accurate.

Test Result Visualization

BioMedomics Sickle SCAN uses blue stripes for a strong visual contrast to any reddish hue on the white strip background caused by the liquid blood/buffer sample. Tests that use traditional red lines can make interpretation more difficult when using test samples containing red hemoglobin. As a result, Sickle SCAN can be easier to interpret than competitive tests using red lines.

Antibody Linkage Process

BioMedomics Sickle SCAN uses antibodies that chemically bond to the blue nanoparticles that signal the presence of the targeted hemoglobin. This can produce less variability in test results and stands up well to a wide range of environmental conditions versus gold beads, which have less stable bonding characteristics. Utilizing these covalent chemical bonds gives Sickle SCAN tremendous stability and reliability.

Test Duration

BioMedomics Sickle SCAN is designed to provide the fastest test results possible, while maintaining a high degree of accuracy. Each test cartridge comes with a bottle of pre-mixed buffer solution, so no preparation is needed before adding the blood sample. Additionally, the buffer/blood mixture is ready to apply to the cartridge with only three inversions of the bottle. There is no need to wait several minutes for a blood sample to diffuse with water. Finally, the resolve time for Sickle SCAN is five minutes instead of ten for some competitive tests. Overall, Sickle SCAN takes approximately half as long, or less, to conduct. This allows a clinician to conduct more tests in a given amount of time, which is more economically efficient.



Buffer Solution

BioMedomics Sickle SCAN tests come with bottles of pre-packaged buffer solution--one for each individual test cassette. No separate sourcing of vials or dispensing of liquid is required, which can reduce the time needed to conduct each test. In addition, some competitive tests require the use of whatever water source might be available, which could compromise test results if the source water has a ph level or impurities that could interfere with results.

Packaging / Environmental Stability

BioMedomics Sickle SCAN tests are individually-sealed in airtight foil pouches which ensures long-term shelf life and stability until the test is needed. Because some competitive tests are bulk-packaged in non-airtight vessels, once the entire vessel is removed from the foil pouch all of the test strips inside become susceptible to humidity and airborne impurities that drastically shorten the shelf-life and could result in the need to discard unused tests if they are not used within the shortened shelf-life period. Worst case, test results could be compromised by environmental conditions if test strips are not used immediately after opening the entire kit. Sickle SCAN's individual foil pouches with desiccant ensures that each test will last as long as the expiration date printed on the outer box.

Time Used in Market

BioMedomics Sickle SCAN has been used to help diagnose hundreds of thousands of patients around the world since 2016. Also, the test has been used on over 5,500 test subjects as part of peer-reviewed research by several different sickle cell experts globally. No sickle cell rapid test on the market today has such a successful and lengthy track record of proven success in both clinical practice and research.

Test Handling / Disposal

BioMedomics Sickle SCAN uses a sealed bottle to contain unused blood/buffer solution, and the test strip is contained inside a plastic cartridge for easy and safe disposal, unlike some competitive tests that utilize an open vial containing the test strip and blood/buffer solution. Depending on laboratory or facility protocols, this arrangement can more easily expose health care workers to blood-borne pathogens and make disposal of used test materials more difficult.