Overall performance of Gazelle in comparison to HPLC– validated with local populations

Gazelle showed high accuracy (sensitivity and specificity) in detecting Beta Thalassemia Trait and Disease and Sickle Cell Trait and Disease when compared with HPLC.

(N=615)	DISEASE* VS. NORMAL***	DISEASE* VS. TRAIT**	TRAIT** VS. NORMAL***
TRUE POSITIVE	90	90	57
TRUE NEGATIVE	461	57	461
FALSE POSITIVE	0	0	7
FALSE NEGATIVE	0	0	0
SENSITIVITY	100%	100%	100%
SPECIFICITY	100%	100%	98.5%

Accuracy of Gazelle's Hb Variant test when compared with HPLC

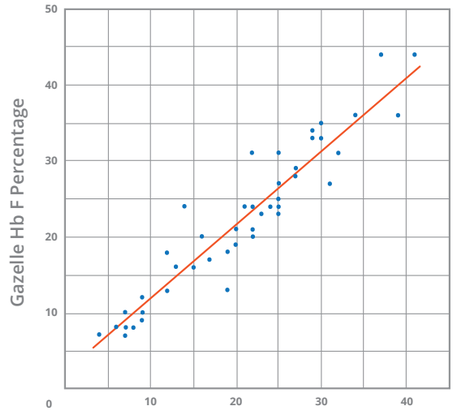
* Disease: HbSS, HbSC, β-Thalassemia major/intermedia
** Trait: HbAS, HbAC, HbA/ β-Thalassemia
*** Normal: HbAA

The average Pearson correlation coefficient for overall hemoglobin quantification comparing Gazelle to HPLC is 97.3%.

Source: GZL-S10-RPT-0027 r9 Gazelle Hb Variant Performance Characteristics Summary

Data from Korle Bu Teaching Hospital, Accra, Ghana

Gazelle Hb F quantification performance for hydroxyurea treatment monitoring



Gazelle results are with 95% confidence, on average, within 3.3% of HPLC Hb F quantification results. The average error for the 48 samples included in this report was 2.6%, with a standard deviation of 2.2%. The Hb F quantification data ranges from 3% to 43%, with a Pearson correlation coefficient of 95%. A scatter plot of comparing the Hb F quantification of Gazelle and HPLC can be seen in the figure above.

Source: GZL-S10-RPT-0048 Gazelle Clinical Accuracy Report

Data from Korle Bu Teaching Hospital, Accra, Ghana

Hemex Health

Creating affordable, life-changing medical diagnostics for people everywhere

contact@hemexhealth.com
www.HemexHealth.com

NAFDAC Reg. No. A3-100356
GZL-S10-MKG-0002-4 r2

Specifications

Principle
Electrophoresis

Time to Result
8 minutes

Sample Material
20 µL whole blood by fingerstick, heel prick, or venous draw

Limitations
Gazelle cannot be used to test children 6 months of age or younger for beta thalassemia.

May not be accurate for babies born before a 37-week gestation period. This test should be delayed until the baby's age plus the gestation period reaches 37 weeks or more.

Hb A2/C/E comigrate. Hb A2 is measured in combination with Hb C and Hb E, and therefore cannot be measured if Hb C or Hb E is present. In determining the presence of beta thalassemia trait, Hb A2 can be measured down to 2%.

Hemoglobin Variants and HbF limit of reporting:
SS, SE, SC, CC, EE, SA* 4%
AC, AE 10%
AA 15%
AS 35%

**Hb F detection was focused on these variants where the percentage of Hb F is significant at low levels, especially for hydroxyurea therapy.*

Data Storage
Reader stores up to 1500 tests, depending on type of test.

Connectivity
Wireless transfer (via Wi-Fi) of patient information and test results to Gazelle Cloud** or PC for access by clinician or lab. USB stick transfer to laptop

Report Printing
Transmits patient reports to Wi-Fi connected printer or to printer connected to a Wi-Fi accessible computer

Reader Weight
2.75 kg/ 6 lbs

Reader Size
15.24 cm x 19.56 cm x 25.40 cm
(6.0 inches x 7.7 inches x 10.3 inches)

Reader storage ranges
Reader storage temperature range:
-25°C to 60°C

Reader operating temperature range:
5°C to 45°C

Reader operating and storage relative humidity range: 5% to 95%

Multipack storage and transportation temperature range
5°C to 45°

Multipacks expire after one year and three months

**See https://www.HemexHealth.com for more information about availability of the Gazelle Cloud*

Gazelle™ Hb Variant Test

Point-of-Care Detection of Beta Thalassemia and Sickle Cell Disease

Hemex Health

Creating affordable, life-changing medical diagnostics for people everywhere

Convenient, Automated Testing For Beta Thalassemia and Sickle Cell Disease

Gazelle delivers rapid laboratory-quality results to facilitate early detection

Beta thalassemia and sickle cell disease (SCD) are life-threatening, genetic disorders that affect millions of people across the globe, many of whom could be helped with early testing. Gazelle enables affordable, convenient testing for newborns (SCD), patients, and marriage-age adults in at-risk population groups.

Gazelle reliably identifies and quantifies Hb A (normal), Hb S (sickle), Hb F (fetal) and Hb A2/C/E. The device offers interpretative statements for beta thalassemia disease (intermedia and major) and trait (beta-thalassemia minor) as well as sickle cell disease and trait.

The only point-of-care solution for detecting beta thalassemia

Populations at risk for beta thalassemia often lack access to or cannot afford expensive laboratory tests and may be misdiagnosed when symptoms begin to occur. Gazelle can detect beta thalassemia disease in persons over 6 months of age, before symptoms begin to manifest. Results are available at the time of visit, allowing treatment and education to begin immediately. Marriage age adults can be tested affordably and conveniently before making important life decisions.

Accurate quantification of Hb F

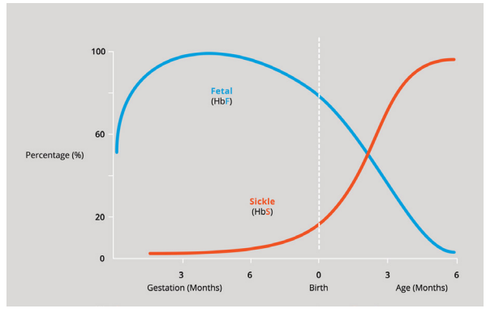
Gazelle's fetal hemoglobin accuracy can be useful for clinicians who are monitoring hydroxyurea therapy for sickle cell disease patients. Gazelle results are with 95% confidence, on average, within 3.3% of HPLC Hb F quantification results. The average error for the 48 samples included in this report was 2.6%, with a standard deviation of 2.2%. The Hb F quantification data ranges from 3% to 43%, with a Pearson correlation coefficient of 95%.*

**Source: GZL-S10-RPT-0027 r9 Gazelle Hb Variant Performance Characteristics Summary (Data from Korle Bu Teaching Hospital, Accra, Ghana; Study to be published later in 2022)*

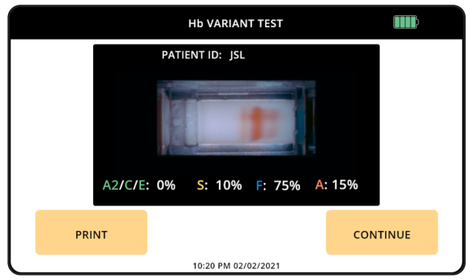
Newborn Screening

Early diagnosis of sickle cell disease is essential so that children can be started on affordable, life-saving treatments.

At birth, babies have only a small concentration of the abnormal hemoglobin (S) that causes sickle cell disease. The Gazelle Hb Variant point-of-care test can detect very low levels of hemoglobin S, enabling babies born as early as 37 weeks to be tested for sickle cell disease.



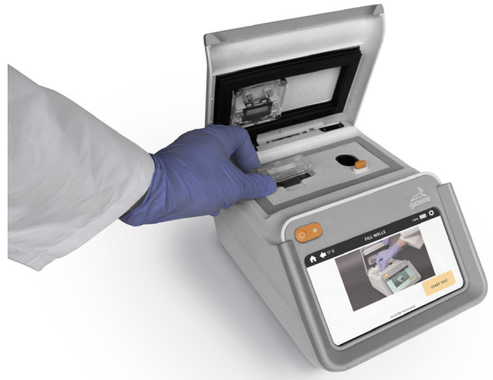
Hemoglobin production during prenatal and postnatal periods



The images above show an example of a newborn with high fetal hemoglobin and sickle cell trait.

Gazelle Microchip Electrophoresis Operation

A 20 µL blood sample is lysed and applied to the cartridge, which is then placed into the reader for analysis.



In 8 minutes, the reader displays hemoglobin types, percentages, and an interpretation on the screen. Test results can be printed, stored in the reader, or uploaded to the Gazelle Cloud Application* at the touch of a button.

Automated interpretation and ease-of-use features

Gazelle steps the user through the preparation of the sample, then automatically analyzes the sample for hemoglobin types and quantities. The interpreted results are displayed onscreen in 8 minutes.

Lightweight, battery-powered device designed for tropical environments

The easily carried device can withstand high temperatures and humidity. No cold chain management is required.

Digital storage and printing

Gazelle stores up to 1500 test results, along with patient data and GPS location. PDFs of patient reports can be printed or transmitted via USB stick to a laptop via Wi-Fi or USB drive. Data can be uploaded to the Gazelle Cloud Application**, which can store data or connect to other databases.

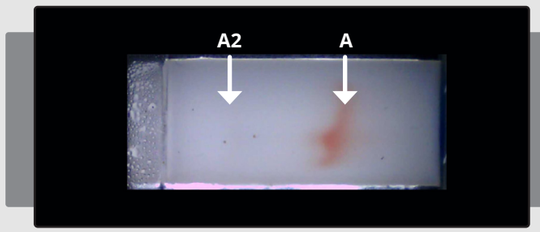
***See https://www.HemexHealth.com for more information about availability.*

Sample Hb Variant Report

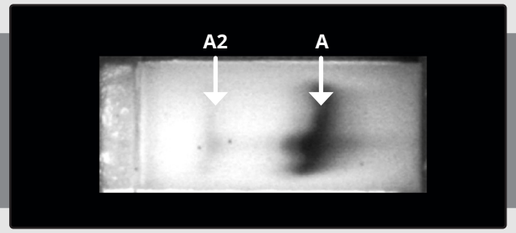
(for digital storage or print)

Microchip Electrophoresis with Multispectral Imaging

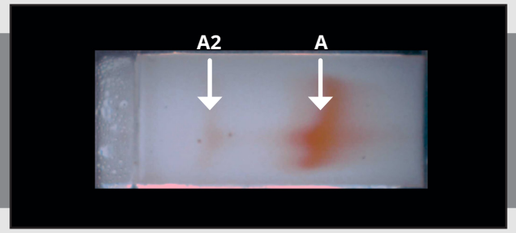
Gazelle is a microchip-based cellulose acetate electrophoresis test. When a disposable cartridge containing a lysed blood sample is inserted into the reader, an electric field is applied to separate the hemoglobin types according to their charge. Gazelle uses white light and UV light to identify even low-concentration variants. Gazelle AI automatically tracks, detects, identifies, and quantifies the electrophoretically separated variants. Results appear onscreen in 8 minutes, are stored digitally in the Reader, and can be printed.



Under white light, low concentrations of hemoglobin types are invisible.



When illuminated by UV light, the low concentration of HbA2 is detected by Gazelle, allowing determination of beta thalassemia trait.



UV and white light images are combined and displayed on the screen and printed report, allowing users to see low concentration hemoglobin variants invisible in white light.