

# Gazelle™ Hb Variant Test



## Hemex Health

Creating affordable, life-changing medical  
diagnostics for under-served  
people everywhere

## Convenient, Automated Testing For Sickle Cell Disease

## Gazelle delivers rapid laboratory-quality results to facilitate early detection



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

## Gazelle's Microchip Electrophoresis

Reliably identifies and quantifies Hb A (normal), Hb S (sickle), Hb F (fetal) and Hb A2/C/E.\* The device offers interpretative statements for conditions such as Sickle Cell Disease and Trait and certain thalassemias.

## Accurate Results Available At The Patient Visit

Gazelle eliminates the wait time between testing and delivery of results, allowing treatment and education to begin at the time of initial screening.

## Automated Interpretation

Gazelle steps you through preparation of the sample, then automatically analyzes the sample for hemoglobin types and quantities. Results are displayed onscreen in 8 minutes.

## Lightweight, Battery-Powered Reader Tested 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 over 2500 test results, along with patient data and GPS location. PDFs of patient reports can be printed or transmitted via USB stick to a laptop. Data can be uploaded to the Gazelle Cloud Application\*\*, which can store data or connect to other databases.

*\*Hb A2 alone is below the limit of detection, therefore some beta-thalassemias will not be detected.*

\*\*See <https://www.HemexDx.com/Gazelle-Cloud> for more information about availability.

## Automated, Microchip Electrophoresis

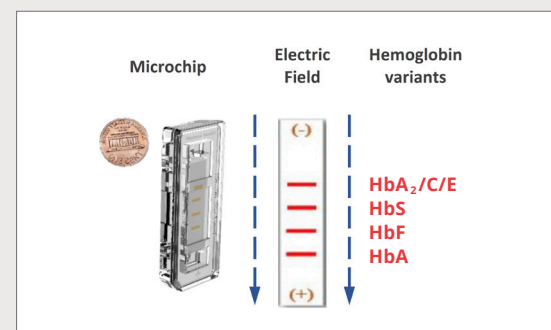
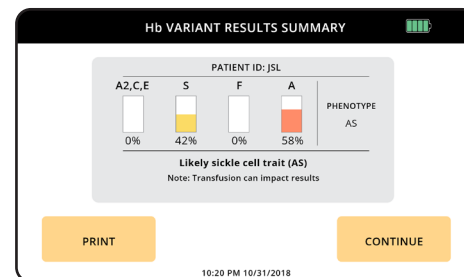
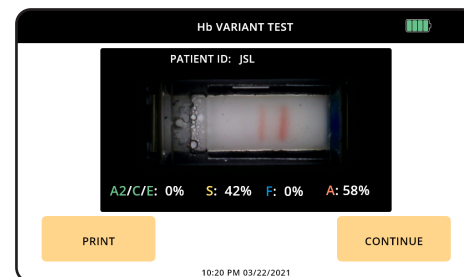
Gazelle uses a miniaturized version of the gold standard test known as electrophoresis. When the disposable cartridge containing a lysed blood sample is inserted into the reader, the hemoglobin types are separated according to their charge. In less than 8 minutes, the types and percentages of hemoglobin as well as the interpretation (normal, trait, disease) are displayed on the screen and stored digitally.

# Gazelle Microchip Electrophoresis Operation

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



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



## Sample Hb Variant Report PDF

(for digital storage or print)



## ELECTROPHORESIS Hb VARIANT TEST

Test Ordered By:

ORGANIZATION:

TEST DATE:

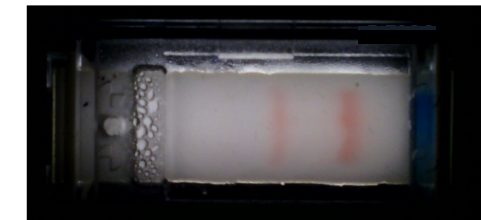
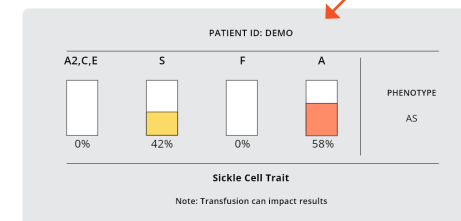
## PATIENT INFORMATION

PATIENT ID:  
CONTACT #:  
GENDER:  
MARITAL STATUS:  
AGE:  
LOCATION:  
ADDRESS:

LAST NAME:  
FIRST NAME:  
HEIGHT:  
WEIGHT:  
MOTHER'S NAME:  
FATHER'S NAME:  
DATE OF BIRTH:

COMMENTS:  
None

## RESULTS



- Hemoglobin types and percentages

## INTERPRETATION

Sickle Cell Trait  
Note: Transfusion can impact results

Reviewed by:

GZL-S10-LBL-0003 r1



For more information, please contact:

Email: [contact@hemexhealth.com](mailto:contact@hemexhealth.com)

Website: <https://www.HemexDx.com>

# Laboratory Performance Validated With Local Populations

Gazelle showed high accuracy (sensitivity and specificity) in detecting SCD (Hb SS) and Sick Cell Trait (Hb AS) when compared with standard screening tests.

Category N=1063	Hemoglobin Type	Accuracy
Sickle Cell Disease (70/70)	HbSS/HbSC	100%
Sickle Cell Trait (293/301)	HbAS/HbAC	97.3%
Normal (682/692)	HbAA	98.6%
Total (1045/1063)	-	98.3%

Table 1: Accuracy of Gazelle Hb Variant compared with HPLC/electrophoresis as gold standard.\*

	Sickle Cell Disease HbSS/HbSC vs. HbAA	Sickle Cell Disease HbSS/HbSC vs. HbAS/HbAC	Sickle Cell Trait HbAS/HbAC vs. HbAA
True Positive	70	70	293
True Negative	682	293	682
False Positive	1	2	9
False Negative	0	0	6
Sensitivity	100% (94.9-100)	100% (94.9-100)	98.0% (95.7-99.3)
Specificity	99.9% (99.2-100)	99.3% (97.6-99.9)	98.7% (97.5-99.4)
PPV	98.6% (90.8-99.8)	97.2% (89.8-99.3)	97.0 (94.5-98.4)
NPV	100%	100%	99.1% (98.1-99.6)

Table 2: Sensitivity and Specificity of Gazelle Hb Variant test compared with HPLC/electrophoresis as gold standard.\*

\* Combined results from the following studies:

1. Gazelle Hb Variant Clinical Accuracy Report - NIRTH 1 (Hemex Health #GZL-S10-RPT-0003 r11), all ages excluding newborns
2. Interim Gazelle Clinical Accuracy Report - Korle Bu Ghana (Hemex Health #GZL-S10-RPT-0048 r1), primarily newborns.

The Gazelle platform also includes a highly sensitive test for detecting all species of malaria\* in just one minute.

\* Check [www.HemexDx.com](http://www.HemexDx.com) for availability

## Specifications

### Principle

Electrophoresis

### Time to Result

8 minutes

### Sample Material

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

### Limitations

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 quantified in combination with Hb C and Hb E. Hb A2 alone is below the limit of detection.

### Data Storage

Reader stores over 2500 tests

### Connectivity

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

### Report Printing

Transmits PDF 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 Operating & 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°C  
Multipacks expire after one year and three months

\*See <https://www.HemexDx.com/Gazelle-Cloud> for more information about availability of the Gazelle Cloud

Gazelle has CE Mark for Hb Variant and Malaria, not yet approved in all countries. Please check [www.HemexDx.com](http://www.HemexDx.com) for the latest information.

