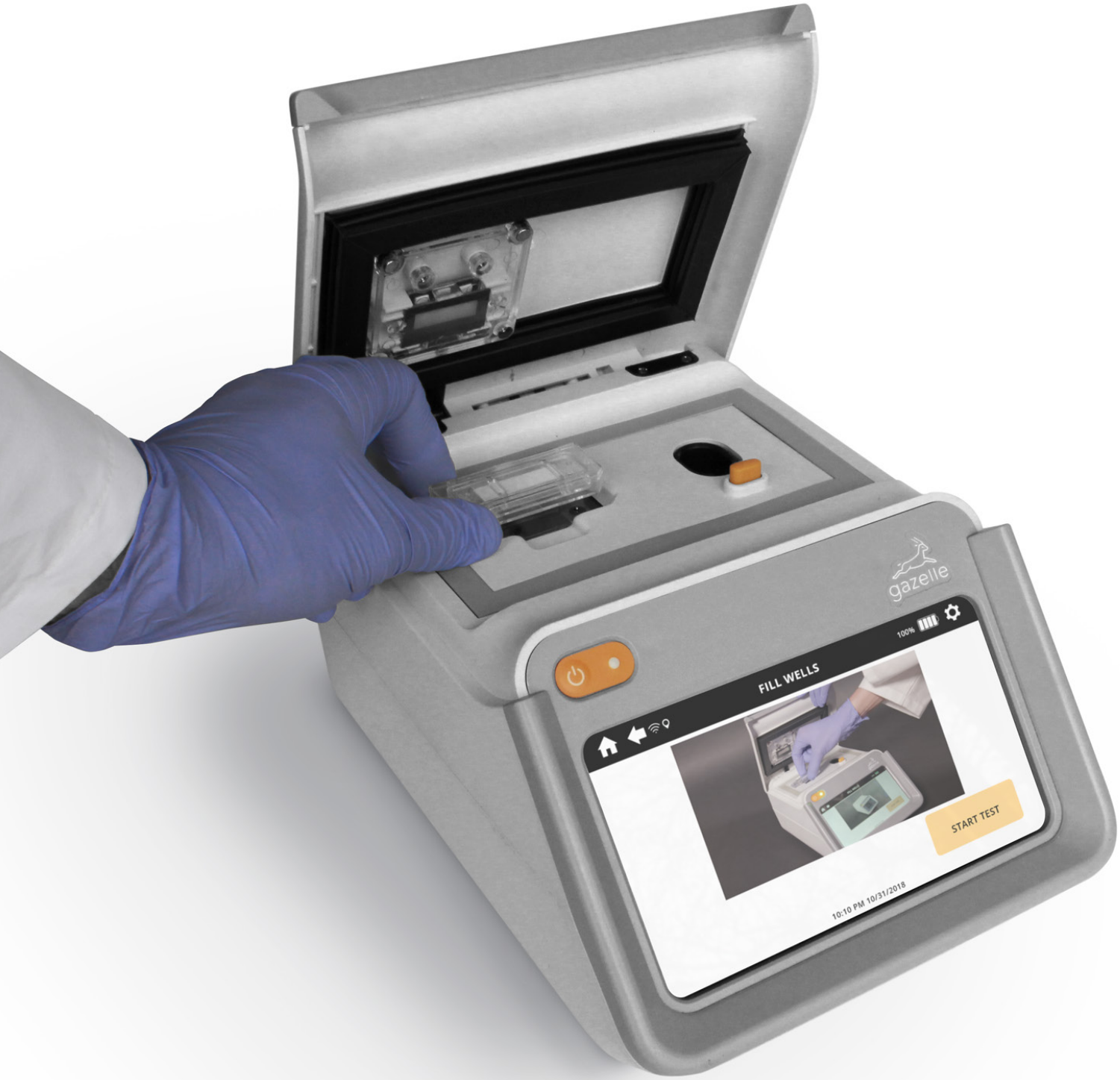
Gazelle™ Hb Variant Test

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



Hemex Health

Creating affordable, life-changing medical diagnostics

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.

A 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. Children over 6 months of age can be screened. Marriage age adults can be tested affordably and conveniently before making important life decisions.

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, robust, battery-powered device

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

Digital storage and printing

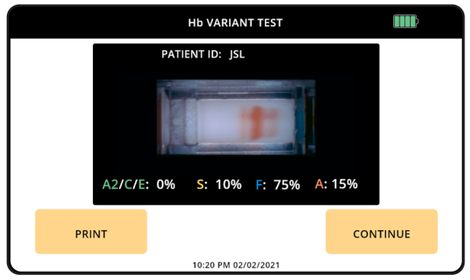
Gazelle stores over 2500 test results, along with patient data and GPS location. PDFs of patient reports can be printed or transmitted via USB stick to a laptop. Data can be uploaded to the Gazelle Cloud Application*, which can store data or connect to other databases.

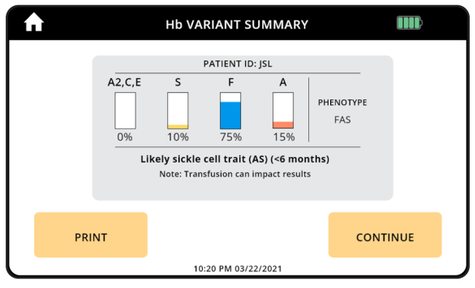
**See https://www.HemexHealthGazelle-Cloud for more information about availability.*

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 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.

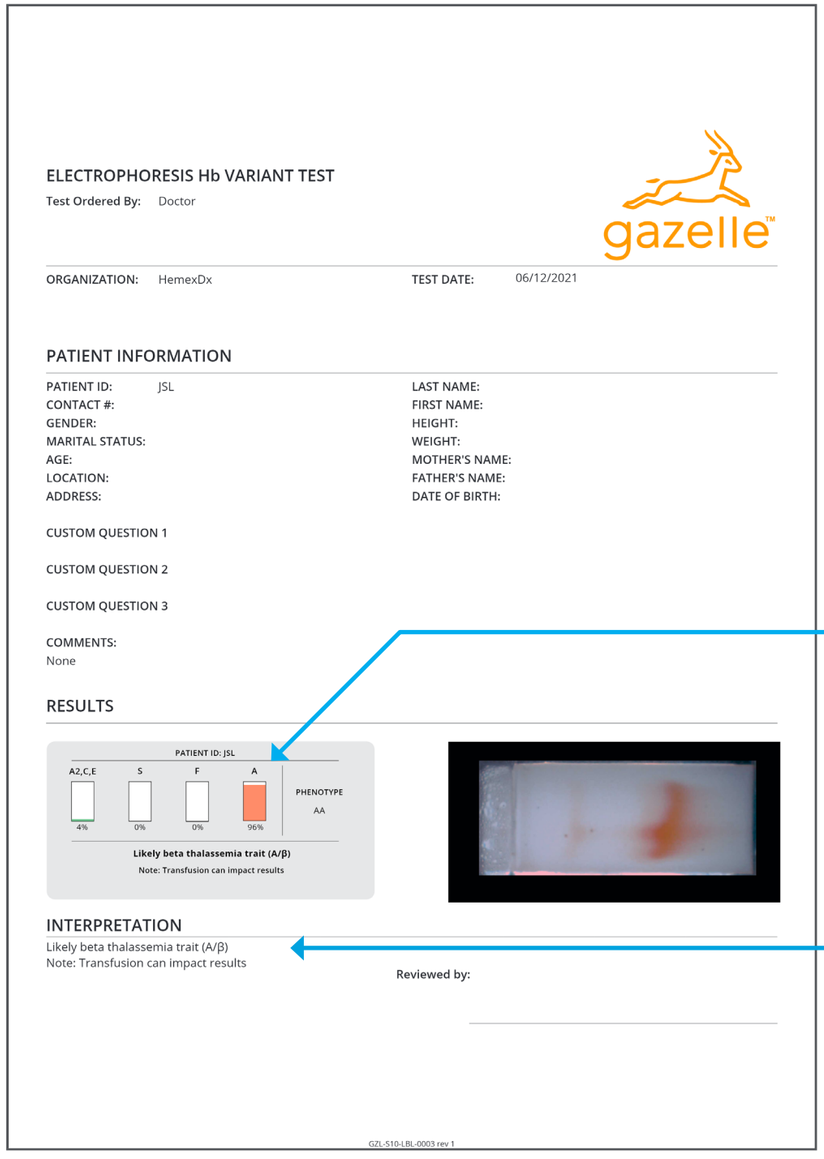




The images above show an example of a newborn with high fetal hemoglobin and sickle cell trait.

Sample Hb Variant Report PDF

(for digital storage or print)



ELECTROPHORESIS Hb VARIANT TEST

Test Ordered By: Doctor

gazelle™

ORGANIZATION: HemexDx TEST DATE: 06/12/2021

PATIENT INFORMATION

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

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

CUSTOM QUESTION 1

CUSTOM QUESTION 2

CUSTOM QUESTION 3

COMMENTS:
None

RESULTS

PATIENT ID: JSL

A2,C,E	S	F	A	PHENOTYPE
4%	0%	0%	96%	AA

Likely beta thalassemia trait (A/β)
Note: Transfusion can impact results

INTERPRETATION

Likely beta thalassemia trait (A/β)
Note: Transfusion can impact results

Reviewed by:

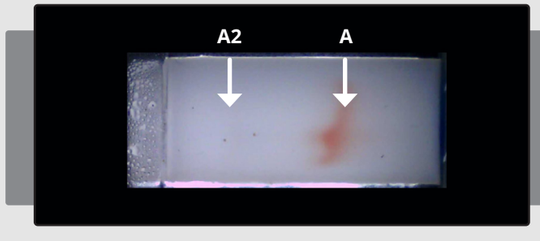
GZL-S10-LBL-0003 rev 1

Hemoglobin types and percentages

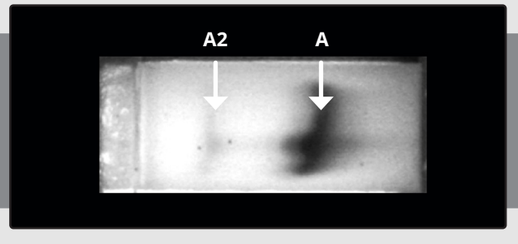
Gazelle interpretation

Microchip Electrophoresis with Multispectral Imaging

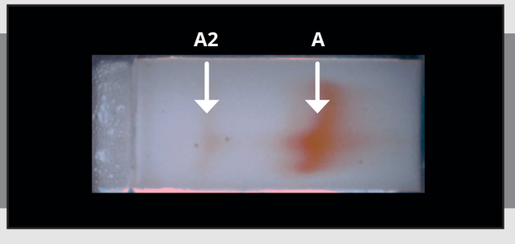
Gazelle is a microchip-based cellulose acetate electrophoresis test. When a disposable cartridge containing a lysed blood sample is inserted into the reader, an electric field is applied to separate the hemoglobin types according to their charge. Gazelle uses white light and UV light to identify low-concentration variants. Gazelle artificial intelligence (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, resulting in an interpretation of beta thalassemia trait.



UV and white light images are combined and displayed on the screen and printed report.

CURELEADS
Email: info@cureleads.com
Website: https://www.cureleads.com

Laboratory Performance 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=595)	DISEASE* VS. NORMAL***	DISEASE* VS. TRAIT**	TRAIT** VS. NORMAL***
TRUE POSITIVE	76	76	54
TRUE NEGATIVE	458	54	458
FALSE POSITIVE	0	0	7
FALSE NEGATIVE	0	0	0
SENSITIVITY	100%	100%	100%
SPECIFICITY	100%	100%	98.5%

TABLE 1: Accuracy of Gazelle's Hb Variant test when compared with HPLC[1]

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

[1] Data on file: *GZL-S10-RPT-0027 r7 Gazelle Hb Variant Performance Characteristics Summary*

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Creating affordable, life-changing medical diagnostics

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CU-GAZ-007

GZL-S10-MKG-0002-5 r1

Gazelle will grow in testing capability with easy-to-install software upgrades.

* Check www.HemexHealth.com for availibility

For more information, please contact:

CURELEADS

Email: info@cureleads.com
Website: https://www.cureleads.com

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%.

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 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°C

Multipacks expire after one year and three months

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

Gazelle has CE Mark for Hb Variant. Please check www.HemexHealth.com for the latest information.

CE

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