ACCESS to Life,
BIO for Hope
Life is precious regardless of nationality, race or religion. Access Bio saves lives and instills hope through advanced in vitro technology for the early diagnosis of diseases. Access Bio will serve as a bridge connecting science and life to promote health and wellbeing for all people.
Access Bio saves lives and instills hope through advanced \textit{in vitro} technology for the early diagnosis of diseases.

**History**

**2009 ~ 2011**
- Top performance in WHO RDT product evaluation results (ROUND 1, 2, 3, 4)
- Official publication of high quality mRDTs
- Landing an investment from STIC Investment
- Establishment of a production facility in Ethiopia
- Contracts to supply Malaria RDT - Ethiopia, Nigeria

**2006**
- U.S. Dept of Defense projects - Dengue, Scrub Typhus
- U.S. SBIR projects - Scrub Typhus, Leishmania

**2002**
- Establishment of Access Bio, Inc.

**2012**
- G6PD RDT achieved accuracy of $\geq 95\%$
- World’s first G6PD Biosensor development
- World’s first G6PD POCT commercialization
- Highlighted presentation of G6PD RDTs at the APMEN conference
- Won contracts of Malaria RDTs - Kenya, Uganda, Nigeria

**2013**
- $4$ million dollars malaria RDT order from Kenya
- Acquisition of a molecular diagnostic company
- Establishment of Korea R&D and production subsidiary
- Malaria RDT long-term contracts with John Snow Inc. and UNICEF
- $7.8$ million malaria RDT order from Ethiopia
- Ethiopian subsidiary started production
- Listed on Korean Stock Exchange (IPO)

**2014**
- KDFA certification of exportability for G6PD Biosensor

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“Each and every life is precious”
A healthy life, free of illness, is a long-held wish in society. Guided by the basic principles of cherishing life and health for all people, Access Bio has been dedicated to the research, development and quality improvement of the medical diagnosis industry. Through the development of in vitro diagnostics technology, Access Bio has successfully commercialized products of outstanding quality to battle malaria and other diseases that pose a serious health threat across the globe. Since our inception in 2002, we have built a strong presence in the global market for the diagnostic testing of malaria and instilled hope for a healthy life among those suffering from this deadly disease.

“Quality acknowledged by the WHO”
In accordance with the World Health Organization’s global fight against malaria, demand is steadily growing for high-quality rapid diagnostics tests (RDT) for prompt and accurate diagnosis. The superior quality of Access Bio’s CareStart™ has been verified through the malaria diagnostics kit testing by the U.S. Centers for Disease Control and Prevention upon request from the WHO. This has enabled Access Bio to forge partnerships with international agencies including the WHO, UNICEF, Global Fund, and MSF (Medecins Sans Frontieres, Doctors without Borders). Drawing from our solid footing in malaria diagnosis and accumulated R&D expertise, Access Bio strives to develop diagnostic tests in diverse fields and enhance the wellbeing and quality of life for people around the world.

“Global pioneer in diagnostic testing”
As we look toward the future, Access Bio will not merely respond to the changing environment, but move forward with a proactive stance. With efficient processes and a dynamic culture, we will harness our competitive advantage to develop next-generation technologies and sustain growth. As a world leader in medical diagnosis, Access Bio is committed in promoting hope for a healthy life and garnering the trust of all stakeholders.

Thank you.

Young H. Choi
President and CEO
Vision & Strategy

**Vision**

Global pioneer in *in vitro* diagnostic technology

**Mission**

Promote health and wellbeing of mankind via quality diagnosis of diseases

**Strategy**

- Reinforce market presence and diversify markets
- Strengthen quality control and customer management
- Develop value-added products
- Enhance sustainability of profits

**Products for LIfe**

Even at this very moment, malaria is taking the precious lives of young children. CareStart™ is shining a light of hope for children suffering from malaria.

**Facts on Malaria** (Source: WHO World Malaria Report 2012)

- Three major infectious diseases are AIDS, tuberculosis, and malaria
- 3 billion people in more than 100 countries are at risk of malaria infection
- Every year, over 200 million people are infected with malaria, resulting in 650,000 deaths
- Every 60 seconds, a child dies of malaria mostly in sub-Saharan Africa
Along with AIDS and tuberculosis, malaria is one of the world’s three major infectious diseases. Malaria is caused by Plasmodium parasites and transmitted to people through the bites of infected mosquitoes. It is prevalent in sub-Saharan Africa and Southeast Asia where sanitary conditions and healthcare infrastructure are lacking. In order to prevent side effects and drug resistance caused by the abuse of antimalarials, there is growing emphasis on prevention and early diagnosis of malaria. Accordingly, demands have increased for rapid diagnostic tests (RDT) with proven sensitivity and accuracy.

There are four Plasmodium parasites that cause malaria in humans, namely P. falciparum, P. vivax, P. malariae, and P. ovale. After infection, the parasites travel through the bloodstream to the liver where they multiply and are released back to the bloodstream before infecting red blood cells. Symptoms of malaria include fever, chills, and vomiting. If untreated, malaria can lead to serious complications and even death.

Common in Africa, P. falciparum is highly virulent and associated with high mortality rates.

Access Bio offers an extensive lineup of 11 different malaria RDTs, including diagnosis of all 4 human malaria and pregnancy.
**CareStart™ G6PD**

True Point-Of Care Test for G6PD with > 99.9% Sensitivity*

*WHO classification I & II

CareStart™ G6PD RDT is a visual screening test that identifies G6PD deficient patients using whole blood sample. It can also be a semi-quantitative assay in conjunction with a CareStart™ RDT reader.

- Catalog Number: G0223
- Test Type: Qualitative point-of-care test
- Assay Method: Visual dye colorization method
- Interpretation: Normal vs. deficient
- Specimen: Whole blood
- Specimen volume: 2 μL
- Result Time: 10 min.
- Package Size: 25 or 50 tests/box
- Other Specifications:
  - Simple and easy to use
  - Fast and reliable
  - Broad range of assay temperature (18-32 °C)
  - Room temperature storage
  - Marked

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**Results of Access Bio’s G6PD Performance Test: Institute Pasteur, Cambodia**

<table>
<thead>
<tr>
<th>Test</th>
<th>Cutoff Value(%)</th>
<th>&lt;30%</th>
</tr>
</thead>
<tbody>
<tr>
<td>CareStart™ G6PD RDT</td>
<td>Sensitivity (95% CI)</td>
<td>100%</td>
</tr>
<tr>
<td></td>
<td>Sensitivity (95% CI)</td>
<td>97%</td>
</tr>
</tbody>
</table>


*Title: A field trial to evaluate the performance of a point-of-care diagnostic for screening G6PD Deficiency in a falciparum and vivax malaria endemic area of Western Cambodia.

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**Access Bio is preparing to introduce the world’s first commercial G6PD biosensor that enhances sensitivity and accuracy based on electrochemical analysis.**

**CareStart™ G6PD Biosensor**

- Catalog Number: TGB-E00181
- Test Type: Quantitative point-of-care test
- Measurement: Precise measurement of total G6PD activity
- Specimen: Whole blood
- Specimen volume: 5 μL
- Result Time: 4 min.
- Package Size: 25 strips/pack
- Other Specifications:
  - Assay Method: Automatic blood loading
  - Internal sensor for temperature calibration
  - Internal memory storing up to 1,000 test results

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Glucose-6-Phosphate Dehydrogenase (or G6PD) is one of key enzymes that helps the body process carbohydrates and turn them into energy. G6PD deficiency is a genetic disorder, resulting in no or low G6PD activity. People with G6PD deficiency should not take primaquine, a malaria drug, and other painkillers because it could cause serious illness, brain damage, or even death via high oxidative stress. Now, more countries are implementing G6PD screening as a part of their newborn screening program.

CareStart™ G6PD Biosensor gives quantitative measurement of total G6PD enzyme activity in just 4 minutes, which is suitable for neonatal and adult screening purposes.
Applications
■ Screening for congenital adrenal hyperplasia (CAH) mutations using allele-specific primer extension (ASPE) and bead-array hybridization
■ Detection of the 10 major point mutations and the 8 bp deletion at Chromosome 6p21.3
■ Detection of a large deletion between CYP21A1P and CYP21A2

Features
■ Semi-quantitative test with bead array for point mutation and agarose electrophoresis for a large deletion
■ Approximately 8 hours from DNA extraction to data reporting

Products for LIFE

CareStart™ HPV Genotyping/Screening Test

HPV Genotyping Test
■ CareStart™ HPV Genotyping kit-T
  Catalog Number : MVT-N10081
■ CareStart™ HPV Genotyping kit-O
  Catalog Number : MVO-N10081

HPV Screening Test
■ CareStart™ HPV genotyping kit-PNA
  Catalog Number : MVA-N10081

Other Products

Dengue Fever RDT
Access Bio’s Dengue fever RDT enables speedy and accurate diagnosis of dengue fever infection based on immunochromatography of NS1 and IgG/IgM detection. Dengue fever ROSGENE™ combines immunochromatography with gene amplification for enhanced sensitivity and accuracy.

Myocardial Infarction RDT
Prevention and early diagnosis is crucial for myocardial infarction (MI) which refers to the necrosis of myocardial muscle. The occurrence of arrhythmia after MI can be fatal. Access Bio’s myocardial infarction RDT can be used for early diagnosis in place of tests involving costly equipment such as the electrocardiogram, echocardiogram, and CT scan.

Pregnancy and Ovulation Test
Pregnancy and ovulation can be easily diagnosed with a urine sample.

Access Bio is pursuing product and market diversification through development of a wide range of diagnostic tests.

Influenza A & B RDT
The use of immunochromatography to distinguish between influenza types A and B enables the best course of treatment depending on the symptoms. With outstanding sensitivity and specificity, Access Bio’s Influenza RDT is expected to generate new demand around the world, and it will facilitate Access Bio’s diversification into global markets.

Influenza A & B ROSUS™
ROSUS™ improves the immunochromatographic method with the adoption of fluorescent europium for enhanced signal-to-noise ratios, which eventually lead to higher sensitivity and specificity. Therefore, our Influenza A & B and ROSUS™ kits enable rapid and accurate diagnosis of influenza A and B.

Strep A RDT
Access Bio’s Strep A RDT detects Streptococcus pyogenes Aureus Group A infection based on immunochromatography and requires just a small amount of pathogen antigens. It is a cost-competitive strip test providing higher sensitivity and specificity than the earlier version.

Products in the Pipeline

Products in the Pipeline

Access to Life, BIO for Hope

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Technology for HOPE

A healthy life is a long-held wish in society. CareStart™ is paving the way toward healthy and hopeful future.

Extraordinary progress is being made in the field of medical diagnosis thanks to the convergence of bio, information, nano and electronic technologies. With a firm commitment to sustainable values, Access Bio continues to pioneer advances in *in vitro* diagnosis to protect precious lives, bringing hope to future generations.

Research & Development

Access Bio is combining immunochromatography with nanotechnology to develop diagnostic tests with enhanced sensitivity and accuracy. We have added G6PD and dengue fever RDT kits to our existing lineup of products for malaria and myocardial infarction. In addition, research is underway for the development of tests to diagnose strep throat and influenza. Our R&D pipeline also includes ROSUS™, which labels antibodies and antigens with europium to increase sensitivity and detection range, and ROSGENE™ that combines genetic diagnosis with RDT technology for shorter testing times.
The quality of CareStart® RDT has been proven in numerous clinical trials of international agencies and research institutes (WHO, Pasteur Institute, MSF, University of Toronto, Malaria Consortium, etc.). This has elevated the brand value of Access Bio products. Currently, Access Bio is preparing to launch the world’s first G6PD biosensor based on electrochemical analysis.

**Key Patents**
- Unique technology for sample extraction and storage
- Chromatography-based measuring system
- Nucleic acid detection system
- A single-pad lateral flow system for enhanced liquid flow

**Countries of Patent Registration**
- U.S.A.
- Europe
- Japan
- China
- Canada
- Korea

**International Certification**
- ISO 13485:2003 (quality management systems in the field of medical devices including in vitro diagnostics)
- CE (compliance with the European Union in vitro diagnostics directive 98/79/EC)
- FDA Certificate of Exportability (compliance with the U.S. FDA GMP guidelines and product stability standards)
- FDA 510(K) (U.S. FDA notification for stability and performance of diagnostic tests)

**Access Bio’s Genotyping Platform Technology**

**Unique Design**
**SBS (Specific-Bulging-Specific Oligonucleotide)**
SBS is a unique primer designed for MULTIPLEX PCR. It allows amplification of multiple target sequences in a single reaction with high sensitivity and specificity.

- Regular Primer

![SBS Primer Diagram](chart)

**Innovative Technology**
1 PCR in 2-Step Amplification
SBS primers amplify multiple target analytes simultaneously in a single tube using step-wide increase of temperature.

- ~45°C (Low Temperature)
- ~65°C (High Temperature)
With technology and quality recognized by international organizations and global research institutes, Access Bio is pioneering the field of in vitro diagnosis.

**Business Partners**
- International Organization: WHO (World Health Organization), UNICEF (United Nations Children’s Fund), UNDP (United Nations Development Programme), UNOPS (United Nations Office for Project Services), MSF (Médecins Sans Frontières), KIOCA (Korea International Cooperation Agency), UNOPS (United Nations Office for Project Services), CHAI (Clinton Health Access Initiative), etc.
- Government: 55 nations including Kenya, Nigeria, Madagascar, Cambodia, Ethiopia, India, etc.
- Private Corporation: Premier Medical Corporation, Microgene, SGV Medical Supplies, etc.

**R&D Partners**
- U.S.A.: U.S. Department of Defense, U.S. Army Research Institute, U.S. Naval Research Laboratory, Tulane University, PATH, etc.
- Korea: Medisensor, KIAT (Korea Institute of Advancement of Technology), KCDC (Korea Centers for Disease Control & Prevention), etc.
- Others: Pasteur Institute (Cambodia), Shoklo Malaria Research Unit (SMRU, Thailand), Eijkman Institute (Indonesia), Kintampo Health Research Center (Ghana), etc.

**Production Network**
- Access Bio, Inc., U.S.A. (Headquarters in New Jersey)
- Access Bio, Inc., Korea
- Access Bio, Inc., Ethiopia
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