LANDSCAPE OF
RDT-reading apps

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ABBREVIATIONS

Ab	Antibody
Ag	Antigen
AI	Artificial intelligence
BMGF	Bill & Melinda Gates Foundation
CE	Conformitè Europëenne
COVID-19	Novel coronavirus disease 2019
ELISA	Enzyme-linked immunosorbent assay
EUA	Emergency Use Authorization
FDA	United States Food and Drug Administration
ICMR	Indian Council of Medical Research
IFU	Instructions for use
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IVD	In vitro diagnostic
LAMP	Loop-mediated isothermal amplification
LMIC	Low- and middle-income country
MHRA	United Kingdom Medicine and Healthcare products Regulatory Authority
ML	Machine learning
NICE	United Kingdom National Institute for Health and Care Excellence
NIH	United States National Institutes of Health
PCR	Polymerase chain reaction
PrEP	Pre-exposure prophylaxis
RDT	Rapid diagnostic test
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2
SRA	Stringent regulatory authority
TPP	Target product profile
WHO	World Health Organization
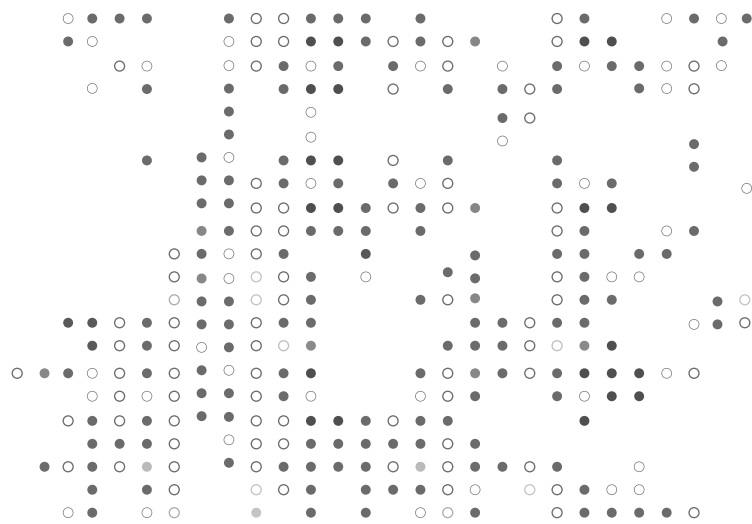
INTRODUCTION

Rapid diagnostic tests (RDTs) based on lateral flow assays have emerged as important diagnostic tools in the management of diseases such as malaria and COVID-19. However, errors can arise when individuals perform these tests and interpret their results. Mobile smartphone applications (apps) for reading RDTs offer a promising option to improve the accuracy of the interpretation of test results. This has been demonstrated with hardware RDT readers in low- and middle-income countries (LMICs). With apps, however, no additional hardware is needed, apart from a smartphone. Such smartphones are already becoming widely available, avoiding cost, supply chain, and maintenance concerns that would occur if new hardware needed to be deployed to read RDTs.

In 2019, FIND developed a target product profile (TPP) for a mobile app that helps users of RDTs to interpret as well as report the results of the assay. In addition to informing medical decisions, RDT-reading apps can transmit their results electronically for patient records, public health surveillance, monitoring, evaluation, and external quality assessment. Since 2020, the COVID-19 pandemic has accelerated the development of diagnostic tests, as well as mobile apps for use with these RDTs.

The aim of this report is to share a summary of publicly available information about mobile applications for reading RDTs. The focus is on RDT-reading apps that do not require additional hardware beyond a mobile device (meaning a smartphone or tablet) and the RDT kit. Apps for diseases of poverty and low-resource settings are of particular interest, but the report also includes other apps, to support an understanding of this industry overall.

ASSESSMENT METHODOLOGY

The list of apps included in this landscape was compiled from the following sources:
1. Literature searches
2. Online reports and news relating to the diagnostic industry (e.g. Fierce Biotech, Crunchbase, Genomeweb)
3. Submission to FIND of non-confidential information by relevant organizations

Nineteen products were reviewed in depth. Another 17 products were only briefly investigated because they required additional hardware, did not interpret tests, lacked a path to commercialization or provided insufficient information. Six more organizations that are developing a reader app were discovered too late in the compiling of this report to be reviewed. Therefore, a total of 42 products are reported below.

RESULTS

PRODUCTS REVIEWED IN DEPTH

The reviews of these products are not arranged alphabetically but by related topics and narrative flow, so it is recommended to read them in order, as shown in Table 1 below:

Table 1. Summary of RDT reader apps

Product and organization	Assay(s)	Market status	Accessories required
BBI Novarum	Calprotectin	Authorization by SRA	Scan card
IBDoc from Bühlmann	Calprotectin	Authorization by SRA	Scan card
QuantOn/SmarTest from Immundiagnostik / Preventis	Calprotectin	Authorization by SRA	Scan card
CalproSmart from Svar Calpro	Calprotectin	Authorization by SRA	Scan card
AppDx from Abingdon Health	Not stated	Bench studies	Unknown
IDA from iSTOC	COVID-19 Ag, HIV, malaria	Authorization by ICMR	None
NAVICA India from Abbott	COVID-19 Ag	Authorization by ICMR	None
On/go from Intrivo Diagnostics	COVID-19 Ag	Authorization by SRA	None
Exa Health	COVID-19 Ag	Submitted to SRA	Scan card
MagnifEye from Sensyne Health	COVID-19 Ag	Summarized clinical results	None
XRCOVID from xRapid Group	COVID-19 Ag	Bench studies	Phone stand
PocDoc from Vital Signs Solutions	COVID-19 Ag	Authorization by SRA	Unknown
Pragma Health	Malaria	Bench studies	None
RDTScan from the University of Washington	Malaria	Summarized clinical results	None
Global Health Labs	COVID-19 Ag	Summarized clinical results	None
HealthPulse DxA from Audere	COVID-19 Ag, HIV, malaria	Bench studies	None
TiraSpot from Spotlab	COVID-19 Ag, COVID-19 Ab	Bench studies	None
Global health scanner from Scanwell Health	Malaria	Authorization by SRA	None
BD Veritor At-Home with Scanwell Health	COVID-19 Ag	Authorization by SRA	Scan card

Ag, antigen; SRA, stringent regulatory authority

BBI Novarum

TECHNOLOGY OVERVIEW
The apps guide the use of the test, display the result to the user, and transmit the result for review by a physician.

KEY INSIGHTS
Novarum created the apps for faecal calprotectin testing from Bühlmann and Calpro, as profiled separately.

Company Background

Novarum is a software service provider to RDT companies. The company began as a spinoff from Albagaia after creating an app called Hydrosense to interpret lateral flow tests for *Legionella* in water supplies. In 2016, Novarum was acquired by BBI Solutions, a supplier to the diagnostics industry that was carved out of Alere and that, in June 2021, was acquired by Novo Holdings, the parent company of Novo Nordisk. Novarum created some of the first commercial RDT-reading apps.

The group worked for Bühlmann to create their IBDoc app, and the group has also been linked to Calpro's CalproSmart app. Both products are for patients with irritable bowel disease (IBD). In the global health field, in 2014 Novarum collaborated with Omega Diagnostics to develop an app for Omega's CD4 lateral flow test, although when Omega introduced the test several years later, no app or conventional reader was involved. Novarum has not announced any apps that read COVID-19 tests. Their publicly known COVID-19 work is limited to a feature for digital test certificates and participation in the UK Rapid Test Consortium led by Abingdon Health (also profiled in this landscape), which has not yielded any RDT-reading apps. Novarum holds patents for an overall interpretation system and for image processing.

Technology Overview

Both of Novarum's known apps (IBDoc and CalproSmart, both featured in this landscape) are quantitative self-tests for faecal calprotectin. A physician prescribes the test. The user performs the test according to the instructions in the app, scanning the code on the test with the smartphone camera to identify the test type and the lot number. The app prompts the user to scan the result. The app displays the result to the user and posts it to a web portal for review by the treating physician.

Summary of Evidence

Novarum had not published their own performance studies at the time of this report. Please see this landscape's entries on IBDoc and CalproSmart Home for details about studies of these apps.

IBDoc from Bühlmann

LOCATION: Schönenbuch, Switzerland
WEBSITE: ibdoc.net
MARKET STATUS: Authorization by SRA

TECHNOLOGY OVERVIEW
Like QuantOn/SmarTest and CalproSmart, this app provides instructions for use and delivers a quantitative result for a faecal calprotectin test; it also reports to a clinician portal.

KEY INSIGHTS
This and similar apps profiled later created a new market by enabling an existing test to be used in the home.

Company Background

Bühlmann Laboratories is an in vitro diagnostic (IVD) manufacturer based near Basel, Switzerland; it was founded in 1976. In April 2015, Bühlmann announced the launch of IBDoc, one of the first CE-marked lateral flow tests that required a smartphone for interpretation. (Novarum, profiled earlier, created the smartphone app.) The app enables the routine, home use of a quantitative test for faecal calprotectin in the management of irritable bowel disease, as a convenient alternative to the delivery of stool samples to a laboratory. In June 2019, Bühlmann announced that the platform had been used by more than 1000 patients in 15 countries.
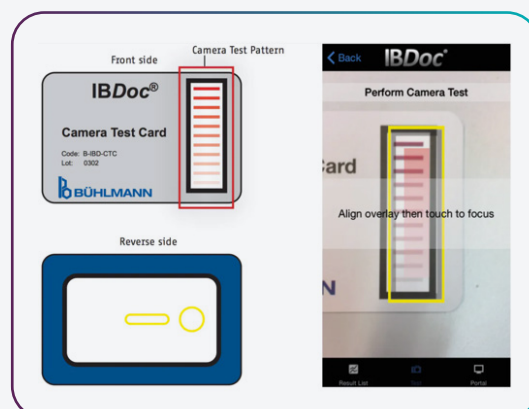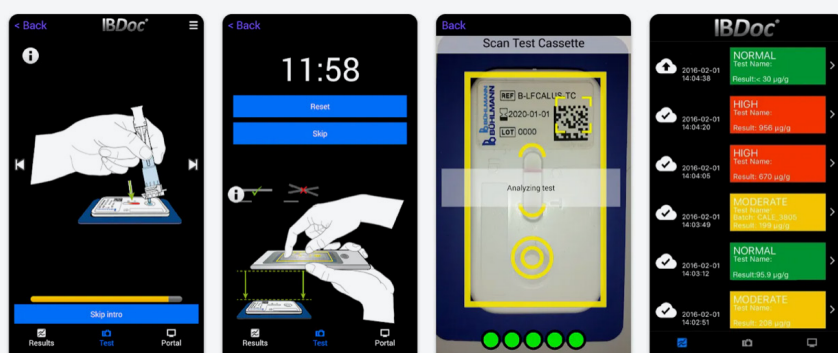
Technology Overview

As is customary for IVD apps, the use of IBDoc is limited to mobile devices that its manufacturer has validated. Each package of tests includes an optical reference, called a "camera test card", that enables the app to check the mobile device camera's performance, a step it requires every 30 days. The app provides brief instructions for use (IFU) of the test and a timer, all of which can be skipped. When the test is ready to be read, the user flips the camera test card over and places the test on it, ensuring a high-contrast background. The app turns on the phone's torch (flashlight), and the IFU instructs the user to avoid direct sunlight, strong sideways-light, and shadows. The app displays a quantitative result along with a history of recent results. According to the IBDoc website, the app integrates with a hospital remote monitoring system using the standard HL7 communication pathway.

Summary of Evidence

In 2017, the UK's National Institute for Health and Care Excellence (NICE) published a review of IBDoc and CalproSmart (a similar test, described below) that concluded that the apps performed comparably to laboratory tests. Other studies of IBDoc include a method comparison in 2017, in which 101 patients used IBDoc on their own phones and sent samples for reference testing by the same lateral flow test on a Qiagen reader. IBDoc readings at home correlated well with the laboratory's reader ($r = 0.94$), although at high levels of the analyte just 81% of pairs were within clinically relevant limits of agreement. The majority (87%) of survey respondents said the test was not difficult to perform. The other 13% found it challenging to hold the mobile phone in the correct position to scan the test. Another study that included IBDoc in a comparison with its competitors is described in the following profiles.

QuantOn/SmarTest from Immundiagnostik and Preventis

LOCATION: Bensheim, Germany
WEBSITE: immundiagnostik.com/en/technology
MARKET STATUS: Authorization by SRA

TECHNOLOGY OVERVIEW

Like IBDoc and CalproSmart, this app provides the IFU and delivers a quantitative result for a faecal calprotectin test, as well as reporting to a clinician portal.

KEY INSIGHTS

Smartphone models other than those qualified by the company can be used if they pass a photographic test.

Company Background

Like Bühlmann Laboratories (described above), Immundiagnostik and Preventis, a pair of related companies, have provided a CE-marked app-based faecal calprotectin self-test since at least 2016. Vitamin D, faecal immunochemical tests (FITs), and other self-tests have since been made available. Each of these tests is quantitative or semi-quantitative, based on the intensity of the test line(s), making the smartphone app the enabler of lay use. Preventis does provide tests for infectious diseases, such as tests for gonorrhoea and leptospirosis, but these are for professional use only and there is no app.
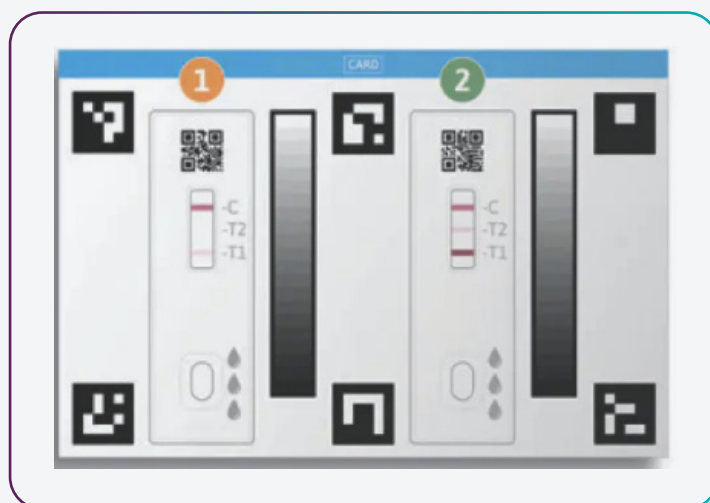
Technology Overview

Some smartphone models are prequalified, while users can attempt to qualify other models by using the app to photograph the provided camera test card. The image shown below, from the IFU, displays the strong and faint test lines on the card, as well as a stepped gradient.
Like the other calprotectin products profiled here, the app guides the administration of the test, shows a quantitative result to the user, and sends the result to the company's portal for the patient's physician to review.

Summary of Evidence

A head-to-head comparison was performed for the QuantOn faecal calprotectin test against similar smartphone-based home tests from Bühlmann, who funded the study, and Calpro. Instead of lay users, medical students with no laboratory training ran the apps, in a laboratory setting with four smartphone models, comparing each app-based result to a reference ELISA (enzyme-linked immunosorbent assay) from the same manufacturer. In terms of clinically significant thresholds, QuantOn was concordant in 79% of pairs, between Bühlmann (82%) and Calpro (73%), but with 8% categorized as a serious misclassification, a higher rate than from Bühlmann (5%) or Calpro (2%). In terms of the app being unable to read tests because of focus problems etc., the Bühlmann app had a lower rate (1.9%) than QuantOn (4.8%) or Calpro (5.8%).

CalproSmart Home from Svar Calpro

TECHNOLOGY OVERVIEW
Like IBDoc and QuantOn/SmarTest, this app provides the IFU and delivers a quantitative result for a faecal calprotectin test, as well as reporting to a clinician portal.

KEY INSIGHTS
In a comparison test, Calpro was found to have the most problems with focusing the camera compared with the other two apps.

Company Background
As a subsidiary of Svar Life Science, Svar Calpro focuses on calprotectin for IBD diagnostics. Calpro's product portfolio includes CalproSmart, one of three apps on the market for faecal calprotectin self-testing. The others, IBDoc and QuantOn, have been profiled above in this landscape.
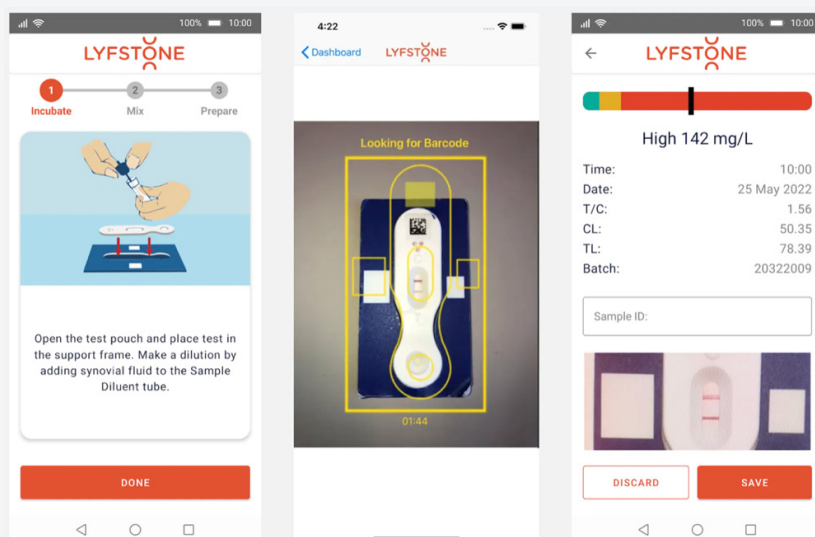
Technology Overview
Calpro offers iPhone and Android CalproSmart Home apps as part of the CalproSmart Home RDT. The app gives step-by-step guidance on how to perform the faecal calprotectin test, leading to quantitative results. The URL for the app's Google Play listing includes the name of Novarum, the app developer who created IBDoc. The CalproSmart app has several similarities to IBDoc, including the use of a card beneath the cassette, but the camera test is optional.

Calpro also offers Lyfstone, a similar app-based test for calprotectin but for professional use with synovial fluid extracted from joints, as shown below.

Summary of Evidence
As detailed in the QuantOn entry, the head-to-head comparison between Calpro, QuantOn and IBDoc faecal calprotectin tests found Calpro to have the lowest concordance of results (73% vs. 79% and 82% for QuantOn and IBDoc, respectively). However, the Calpro app had the lowest percentage of misclassifications (2% vs 8% and 5% for QuantOn and IBDoc, respectively). The comparison test also showed that the Calpro test had the most focus problems, making it difficult to read the tests (5.8% vs 4.8% for QuantOn and 1.9% for IBDoc).

AppDx from Abingdon Health

TECHNOLOGY OVERVIEW
The AppDx app uses machine learning (ML) and digital processing for the qualitative readout of RDTs.

KEY INSIGHTS
Customized apps fit within the company's provision of contract services and components for lateral flow tests.
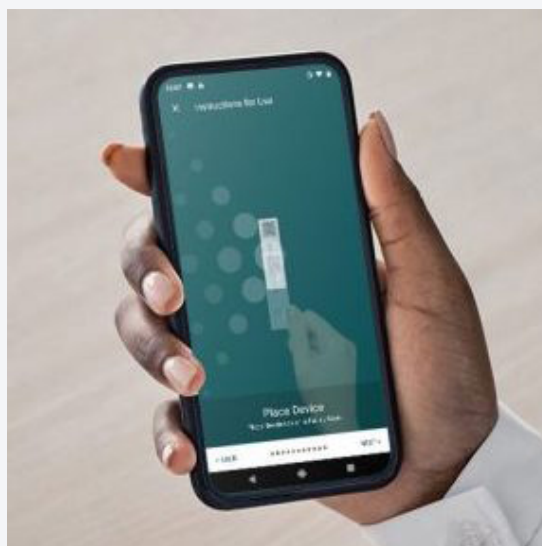
Company Background

Abingdon Health supplies components for and manufactures lateral flow tests. They also offer a white-label app that can be tailored to a client's test and requirements. The firm announced they received £1M in funding from Innovate UK in September 2020, to further develop their reader app. Bond Digital Health and Abingdon Health have collaborated in this field, with Abingdon Health supplying the RDT analyser and Bond Digital Health providing wrap-around features such as data management. Abingdon Health also led the UK Rapid Test Consortium, which included BBI's Novarum, profiled separately in this landscape.

Technology Overview

AppDx uses ML and digital processing to read lateral flow test results using a smartphone. Abingdon Health offers their analyser as a software development kit (SDK) that can be incorporated into customers' smartphone apps. A patent assigned to Abingdon Health claims the application of neural networks to read lateral flow tests.

Summary of Evidence

In a March 2022 release to investors, Abingdon Health briefly announced that the app demonstrated 98.15% sensitivity and 98.28% specificity with an unnamed blood-based lateral flow test.

IDA from iSTOC

TECHNOLOGY OVERVIEW

The IDA app shows its interpretation to the user and stores results in the cloud.

KEY INSIGHTS

iSTOC's app has been tailored to various RDTs and has been released in India for Premier Medical Corporation's COVID-19 home test.

Company Background

iSTOC developed the app IDA (immediate diagnostics and analytics) to digitize and analyse RDT results. iSTOC is providing Premier Medical Corporation's app for COVID-19 home tests in India.
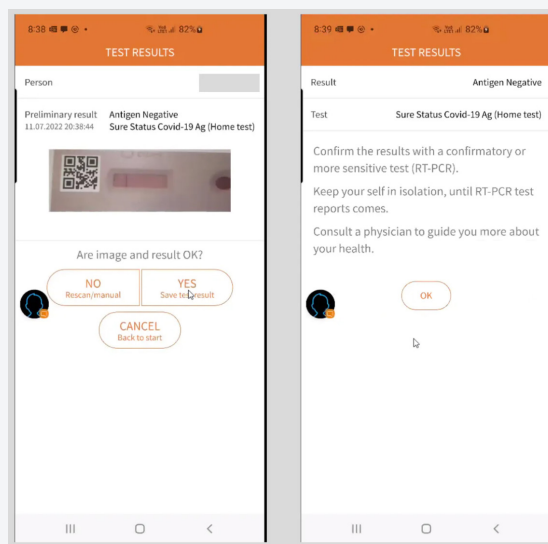
Technology Overview

The app includes a 15-minute assay timer to prompt the user at the right time to photograph the test. Machine interpretation of the result is performed on the device, with a preliminary result shown to the user for confirmation or manual correction. Results are reported as per Indian Council of Medical Research (ICMR) requirements.

According to iSTOC, supported diagnostic tests include those for COVID-19, malaria, dengue, HIV, hepatitis A virus (HAV), hepatitis B virus (HBV) and hepatitis C virus (HCV).

Summary of Evidence

No published performance data for the Premier Medical Corporation app in India have been found. iSTOC states on their website that, based on validations, their "reader accuracy is better than test result assessment by visual inspection." iSTOC was included in a comparative evaluation of RDT-reading instruments and apps for malaria tests and was found to have lower sensitivity than the other readers, none of which was as sensitive as the expert eye.

NAVICA India from Abbott

LOCATION: Jena, Germany
WEBSITE: globalpointofcare.abbott/en/product-details/panbio-covid-19-antigen-self-test.html?c=in
MARKET STATUS: Authorization by ICMR

TECHNOLOGY OVERVIEW
The NAVICA India app interprets the Panbio COVID-19 RDT and reports user data to the ICMR to fulfill authorization requirements for home testing.

KEY INSIGHTS
An active internet connection is required. Users must enter their personal information into the app every time, due to a government requirement that the app cannot retain any personal data.

Company Background

Abbott is a global medical technology company with products spanning diagnostics, pharmaceuticals, diabetes, nutrition, cardiovascular and neuromodulation applications. Abbott's portfolio includes lateral flow tests to diagnose malaria, HIV and COVID-19. One of Abbott's RDTs for COVID-19 is the Panbio COVID-19 Ag Rapid Test for qualitative detection of SARS-CoV-2 antigen (Ag). While the test is available in multiple countries, this NAVICA app is only available in India, where regulators have evidently required COVID-19 self-tests to have apps for machine interpretation and reporting. (In other markets, Abbott uses the NAVICA name for apps that do not interpret the test.)

Technology Overview

The user follows the paper IFU provided in the test kit. After the user performs the test, the app records the user's personal information and instructs the user to take a photograph of the result. The app then sends the photograph to a remote server for machine interpretation of the result, which is submitted to the ICMR and displayed to the user (the IFU also describes how to interpret the test visually). The manufacturer does not currently list any restrictions on the types of phones that can be used with the app.

Summary of Evidence

As shown in the first screenshot above, the NAVICA India app claims to have "demonstrated an ability to accurately identify test results at a rate that is equivalent to human read results". However, no information to support this statement has been found.
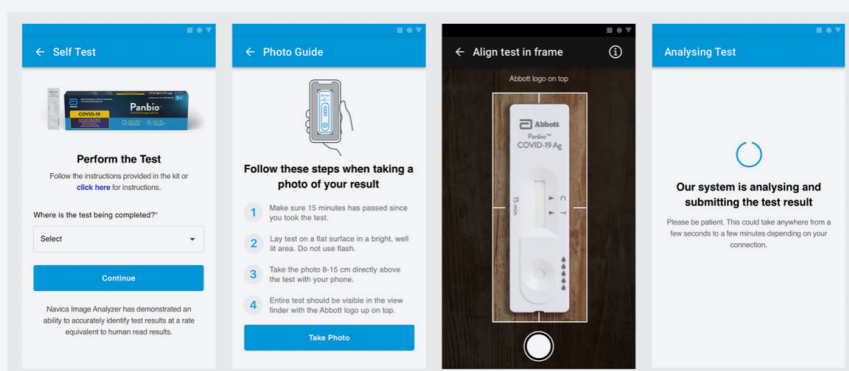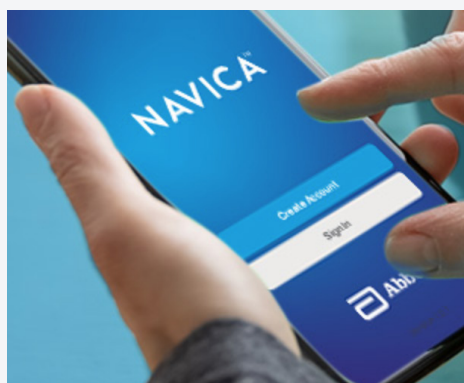
On/Go from Intrivo

LOCATION: Santa Monica, CA, USA
WEBSITE: letsongo.com
MARKET STATUS: Authorization by SRA

TECHNOLOGY OVERVIEW
The On/Go app provides instructions for testing, including guidance on visual interpretation.

KEY INSIGHTS
Although the app takes a photograph of the test, the user must interpret the test visually.

Company Background

On/Go is a COVID-19 Ag self-test manufactured by Access Bio, a major manufacturer of lateral flow tests for global health. The On/Go test and all CareStart COVID-19 Ag self-tests on the United States market under emergency use authorization (EUA) are sold by Pure Blue Medical, incorporated in 2020 and doing business as Intrivo Diagnostics.
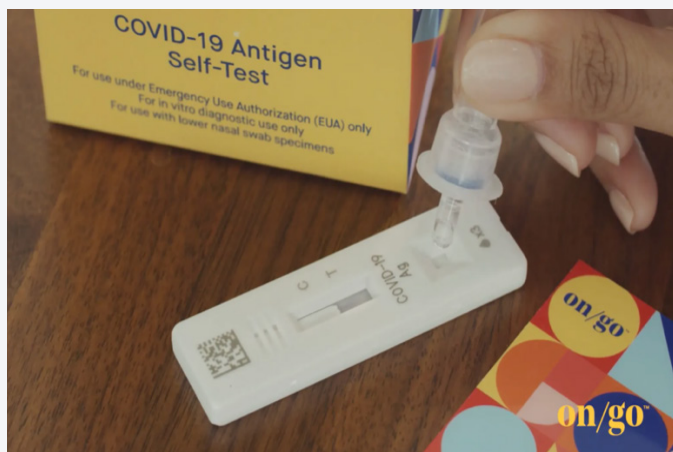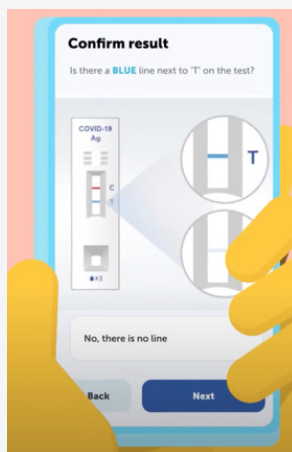
Technology Overview

The On/Go app provides step-by-step instructions for performing tests as well as help in the interpretation of visual results of the Intrivo COVID-19 test. The user is required to take a photograph of the test device, then look at the test cassette and answer questions about the interpretation of the result. Despite the app having this step that involves the camera, the IFU states that the test is interpreted conventionally: "visual reading following the in-app interpretation instructions or provided Quick Reference Instructions". The camera step may have nothing to do with the lateral-flow strip but instead with the Data Matrix two-dimensional code found on each cassette. The test's US Food and Drug Administration (FDA) authorization explains that the app can inform the user if a test is invalid because it has expired (using the test's lot information) or has been previously used (using a serial number), a safeguard against false results and reports.

Summary of Evidence

In a study for FDA authorization, the On/Go COVID-19 Ag home test had 87% positive agreement and 98% negative agreement compared with polymerase chain reaction (PCR) results in an evaluation of 153 individuals who used the test, but the Ag tests were interpreted visually, meaning the performance of the app, if it does interpret the test, has not been disclosed. A subsequent version of the test, called On/Go One, appears to use the same app as the original.

MagnifEye from Sensyne Health

LOCATION: Oxford, UK
WEBSITE: sensynehealth.com/magnifeye (page not found at time of publication; archive.org snapshot of previous content)
MARKET STATUS: Summarized clinical results

TECHNOLOGY OVERVIEW
The app helps the user take a photograph of the test and uses cloud-based artificial intelligence (AI) to interpret the results.

KEY INSIGHTS
The company claims that the app's algorithm can detect lines too faint to be seen by eye.

Company Background

MagnifEye is an app from Sensyne Health, a digital health and clinical AI company. Sensyne Health advertises that they have developed a very high-performing interpretation app that is based on ML. In February 2021, Sensyne Health announced an exclusive licence for all lateral flow tests, starting with COVID-19, to another British firm, Excalibur Healthcare Services. Excalibur Healthcare Services is a medical products reseller whose products include a COVID-19 Ag RDT manufactured by Boson, a Chinese company. In 2022, Sensyne Health restructured, and at time of writing neither Sensyne Health's website nor that of Excalibur Healthcare Services mention RDT apps. As of May 2022, archive.org showed Excalibur Healthcare Services' site for the product to be TestToGoApp.com, which was not reachable either.

Technology Overview

The MagnifEye app helps the user take a photograph of a lateral flow test using a smartphone. The app then uses deep-learning AI, running in the cloud, to interpret the lateral flow test results. The company claims that the algorithm can detect lines that are too faint to be visible to the human eye, to potentially improve interpretation of test results. In a January 2021 press release, Sensyne Health stated that the app operated "beyond the human visible spectrum".

Summary of Evidence

A study published in September 2022 found that the use of the MagnifEye app when compared with interpretation by trained operators, with 59 450 Innova COVID-19 Ag RDTs, led to an increase in sensitivity from 92.08% to 97.6%, as well as an increase in specificity from 98.86% to 99.99%. Among a similarly sized sample of self-testers, MagnifEye improved sensitivity from 16.00% to 100% and specificity from 99.15% to 99.40%. The study used the interpretation of the photograph by a panel of experts as its ground truth, although among the tests read as negative by the app and by their user a random sample of just 1% were checked by the experts (other pairs of app-read versus user-read results were checked more thoroughly).
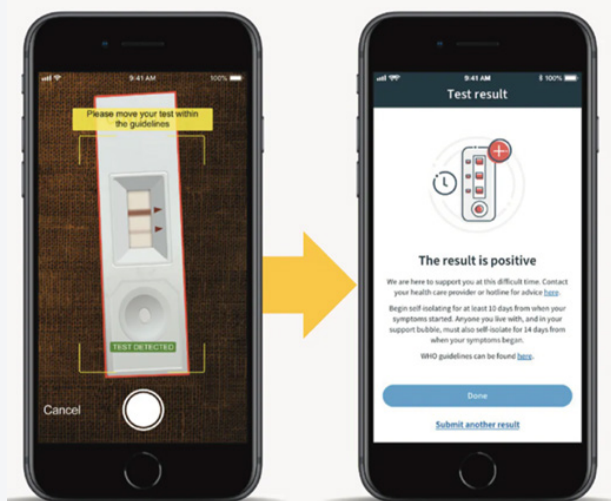
Exa Health

LOCATION: Los Altos, California, USA
WEBSITE: exahealth.com
MARKET STATUS: Submitted to SRA

TECHNOLOGY OVERVIEW
The app includes step-by-step video instructions and interpretation of results of a SARS-CoV-2. RDT

KEY INSIGHTS
The app features AI-monitored sample collection.

Company Background

Exa Health is a company that was spun out of Gauss Surgical in October 2021 following the acquisition of Gauss Surgical by Stryker. Exa Health's inception arose from a partnership between Cellex, which manufactures an Ag RDT, and Gauss Surgical, which makes medical computer-vision apps, to enable home testing for COVID-19 in the US. Gauss Surgical announced partnerships with three groups to market the test: Truepill, Ro, and Kroger, a major grocery store in the US. In October 2020, Gauss Surgical announced a $30M funding round, in part to support this product, while also mentioning a COVID-19 antibody (Ab) study. Exa Health's website states that the company has raised $3M.

Technology Overview

After the user scans the test's QR code, the app displays step-by-step instructional videos. The company's website shows a white scan card with a QR code in each corner, graded intensity bars, and colour samples. The RDT itself shows no barcodes. No human-readable serial number is shown, but the result screen shows a serial number that could be encoded in the scan card. Sample collection is assisted by an AI, with feedback to the user on the proper technique to use, based on action-recognition. The results are interpreted by the AI.

Summary of Evidence

Exa Health lists 95% positive agreement and 98% negative agreement of their SARS-CoV-2 Ag RDT with a high-sensitivity, emergency-use-authorized PCR test.

XRCOVID from xRapid Group

LOCATION: Marseille, France

WEBSITE: xrapid-group.com/xrcovid-en (not reachable at the time of publication; archive.org snapshot of previous content)

MARKET STATUS: Bench studies

TECHNOLOGY OVERVIEW
The app uses AI to interpret qualitative tests and uploads results for public health surveillance.

KEY INSIGHTS
Using an iPhone on a stand, xRapid demonstrated excellent agreement with visual interpretation of COVID-19 Ab RDTs.

Company Background
XRCOVID is an app developed by xRapid Group for analysing and monitoring results from COVID-19 RDTs. xRapid Group was formed in 2015 and has locations in France, USA, UK and China. In 2015, the company launched an app for malaria detection (xRapid-Malaria) that used ML to read blood smears for malaria. In addition to software, xRapid is also developing a home system for performing complete blood counts (xRblood). In December 2020, xRapid launched a Kickstarter campaign to fund the development of a powered mask for protection from COVID-19 (xHale).

Technology Overview
The XRCOVID app uses a smartphone camera to take a photograph of an RDT and then uses AI to read the test and interpret the result for the user. The result is displayed as positive, negative or inconclusive. Data from tests are sent to a server that can be accessed by a public health authority.

Summary of Evidence
xRapid published bench results showing 98.9% positive agreement and 99.7% negative agreement when using recent iPhones placed on a stand and comparing their results with visual interpretation of COVID-19 Ab RDTs.
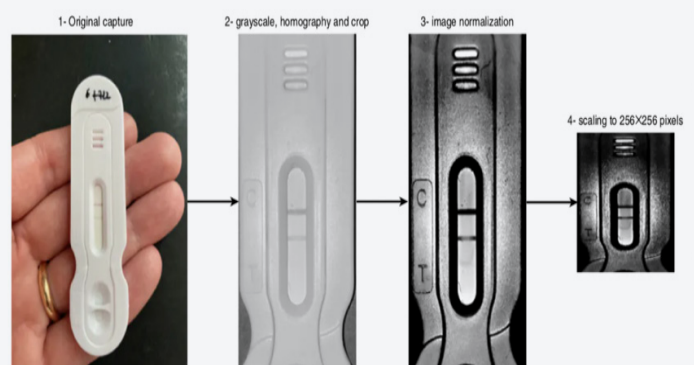
PocDoc from Vital Signs Solutions

LOCATION: Cambridge, England, UK
WEBSITE: mypocdoc.co.uk
MARKET STATUS: Authorization by SRA

TECHNOLOGY OVERVIEW
For COVID-19 RDTs, the app is only used to record the result after the user makes a visual interpretation.

KEY INSIGHTS
The PocDoc app works with multiple lateral flow tests and appears to have an interpretation technology; however, for the COVID-19 application, the user is asked to make a visual interpretation and input the results in the app.

Company Background

PocDoc is a digital healthcare company owned by Vital Signs Solutions. PocDoc's app is designed to work with Vital Signs Solutions' set of proprietary, quantitative blood tests focused on cardiovascular disease and diabetes. The PocDoc platform is also able to integrate with existing rapid tests, enabling the company to partner with multiple organizations. Vital Signs Solutions has collaborated with BioSure for COVID-19 RDTs, while in July 2021 it began collaborating with PATH to develop a screening test for primary immunodeficiency diseases related to polio vaccination. In addition, in May 2022, PocDoc partnered with Dears Pharmacy chain to develop a lipid test (not a lateral flow test) that uses colour, referenced by an app against colour standards on the test.

Technology Overview

The PocDoc app supports the user in performing their RDT and understanding what the result means. When using the app as a companion to the BioSure COVID-19 RDT, the user is asked to scan the test's QR code, which tracks the batch number and expiry date of the test. The user then follows the IFU in the test kit and, when ready, the app activates the camera of the mobile device to take a photograph of the completed test, but the user makes the visual interpretation of the results instead of the app. The app is only used to record the data from the test. When using the lipid panel, the app does interpret the test, displaying the results along with a health assessment.

Summary of Evidence

The company performed a study among staff at Edinburgh airport but has yet to share the performance data. In March 2022, PocDoc announced that their "universal" digital reader of lateral flow tests, with over 98% accuracy, had received a CE mark, but did not share any additional details.
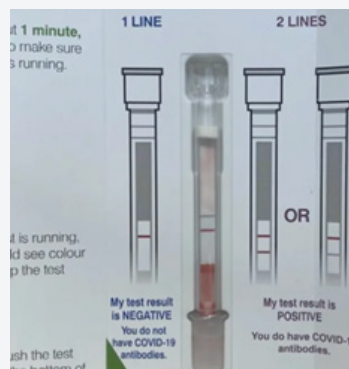
Pragma Health

TECHNOLOGY OVERVIEW
Smartphone photographs of standard and custom lateral flow tests are analysed on a server.

KEY INSIGHTS
Pragma Health was spun off from research conducted at Vanderbilt University, USA.

Company Background

Pragma Health was established to develop digital health products, beginning with RDT-reading apps. CEO Thomas Scherr is also a researcher at Vanderbilt University, USA. Currently the Pragma Health webpage states the mission of "reimagining communication tools so patients can get more while doctors do less".

Technology Overview

In 2016, Scherr and colleagues published details of their development of a software reader for existing malaria RDTs. Using a mobile phone in their laboratory, the researchers took photographs of RDTs used to test spiked, pooled blood. The photographs were uploaded to a server and then analysed. The server software had the potential to be ported to phones. The following year, Scherr and colleagues published details of the development of a lateral flow test in which the typical control line had been replaced by a QR code that enabled an app to collect test-specific information once the control had developed, alongside a typical test line. (Earlier, researchers at Simon Fraser University, Canada, and Taiyuan University of Technology, China, published details of a lateral flow assay that produces a one-dimensional barcode which incorporates the test's result, so that a positive or negative result can be interpreted as "+" or "−" by standard barcode readers.) In 2021, Scherr and colleagues published details of their development and evaluation of a web app on iOS and Android phones that uploads photographs of malaria RDTs for cloud-based machine interpretation. Scherr was also part of Vanderbilt teams that published two papers about an app they developed in 2020 for COVID-19 contact tracing (not testing).

Summary of Evidence

In their 2016 publication with existing malaria RDTs, their app's limit of detection using an iPhone 5S camera was 20.6 malaria parasites per microlitre of blood, compared with 64.4 parasites per microlitre for a commercial RDT reader and 12.5 parasites per microlitre for users making a visual interpretation. Their 2021 publication showed 91.9% positive agreement and 91.4% negative agreement of their mobile web app when compared with tests read by eye in 14 rural health clinics in Zambia.

RDTScan from the University of Washington

TECHNOLOGY OVERVIEW
The app automatically captures an image of the RDT and determines the result, without ML.

KEY INSIGHTS
Studies showed (1) that, with faint positive results, users were less sensitive when viewing unadjusted smartphone photographs of the RDTs than when viewing the RDTs directly and (2) that the app's PCR-referenced accuracy was slightly better than that of the eye.

Company Background

While no company is known to be commercializing RDTScan, the maturity of this project and the background of the laboratory that produced it make this project notable. In 2017, the University of Washington (UW) received a grant from the Bill & Melinda Gates Foundation (BMGF) to develop RDT-reading apps and related smartphone sensing approaches. The grant included funding for the UbiComp laboratory of Prof. Shwetak Patel, who had spun-off previous research to form several companies, including one bought by Google that was developing a smartphone app to analyse a newborn's skin colour for the detection of jaundice. The RDTScan team published their results, and the open-source code is available on GitHub. However, according to an email from the team in June 2022, the project is no longer active, although the technology has been used by GH Labs (see profile below). The RDTScan project was separate from an earlier RDT-reading app from UW, details of which were published by Nicola Dell and colleagues in 2013 and 2014. ODK Diagnostics, named for its connection to the Open Data Kit project at UW, required a stand that held a phone over an RDT. The project was taken up by the nonprofit GSID but is also no longer active.

Technology Overview

The RDTScan app uses Android's Camera2 application programming interface (API) to direct the camera to activate its torch (flashlight) and set its exposure and focus at the centre of an image, where the RDT is expected to be, so that it will not be thrown off by the background. The app also determines when the camera appears to be properly focused. The algorithm runs image quality checks in real-time to provide feedback to the user on camera positioning, automatically grabbing the definitive photograph for interpretation once the checks have been passed. The app identifies the RDT by correcting its perspective and template-matching to a single reference photograph. To determine the result, the app enhances the contrast locally within the strip, calculates the sum of all pixels within each row (rows being perpendicular to the direction of the lateral flow test), and searches among these sums for peaks corresponding to the control and test lines.

Summary of Evidence

RDTScan's 2020 publication, in collaboration with the Muso and Medic digital health organizations, showed 96.3% positive agreement and 99.1% negative agreement of the app when compared with tests read by eye from 775 malaria RDTs run by laboratory technicians in Mali. No reference tests were involved. When the laboratory technicians interpreted the RDTs by viewing photographs they had taken earlier using a basic smartphone, they identified 7 fewer positives (out of 107, for 93.5% positive agreement) than they did when viewing the RDTs directly. The authors attributed this to "faint lines that were even more difficult to read when they were digitized," noting that one technician, in an un-blinded review, could identify some tests as positive on a computer screen after thinking they were negative when viewed on a smartphone. When the app was used to provide a contrast-enhanced image, positive agreement improved to 98.1%. In a follow-up publication in 2021, the UW team, together with the Ona digital health organization and other researchers, described the performance of a refined app used in conjunction with malaria RDTs in Kenya. The users were experienced community health workers (CHWs) at a health clinic. From 228 samples, the app showed 95.5% positive agreement and 98.7% negative agreement with the eye. Referenced against PCR, the app was slightly less sensitive but more specific than the eye, with the app having slightly better overall accuracy (85.5% app vs. 84.6% eye).

Global Health Labs

TECHNOLOGY OVERVIEW
The RDTScan app (profiled above) was adapted for a new RDT, with usability and signal detection revisions.

KEY INSIGHTS
This app is an open-source companion for an open-access SARS-CoV-2 Ag RDT developed by the same organization.

Company Background

Global Health Labs (GH Labs), formerly the Global Good division of Intellectual Ventures Laboratory, develops technologies that seek to address unmet healthcare needs, with a focus on LMICs, to advance the priorities of BMGF. With a focus on diagnostics and reproductive, maternal, neonatal and child health, as well as primary healthcare tools and equipment, GH Labs have developed multiple innovations. The GH Labs app came about as part of their work on an open-access SARS-COV-2 Ag-detection lateral flow assay, which they validated against commercially available assays. GH Labs developed their app based on the RDTScan app described above.

Technology Overview

The GH Labs app, like its underlying code, is open source. The app requires special, low-resolution two-dimensional codes on the RDT as part of its detection system for GH Labs-developed cartridges, which lack the ink that the RDTScan app relies on. The GH Labs app requires the camera be held within 5° of level with respect to gravity, a tight range that could complicate usability. GH Labs has also revised the algorithm for peak detection. It is unclear how these changes may have affected the app's performance.

Summary of Evidence

In December 2020, in California, the app's performance was clinically studied with 155 RDTs from individuals who had COVID-19 symptoms for a duration of 7 days or less; it showed about 65% visual positivity. The specific model of phone used was not mentioned. A major limitation was that the positive–negative threshold was optimized by the researchers after the photographs were analyzed. There was "a single discordant case that appeared to stem from an improper visual interpretation." This was not explained further, but apparently the PCR result matched that of the app for the discordant case, as overall the PCR-referenced accuracy was slightly better for the app than the eye.

HealthPulse DxA from Audere

LOCATION: Seattle, WA, USA
WEBSITE: healthpulsenow.org/dxa
MARKET STATUS: Bench studies

TECHNOLOGY OVERVIEW
The app incorporates step-by-step instructions for performing RDTs and uses AI to interpret a photograph of an RDT.

KEY INSIGHTS
The app is intended to be adaptable to any RDT for any health condition. Studies are underway with RDTs for malaria, HIV and COVID-19.

Company Background

HealthPulse DxA is an app developed by Audere, a nonprofit organization that focuses on digital solutions for global health applications. Audere was founded in 2018 and has received more than $21M in grants from BMGF. In March 2022, Audere announced a collaboration with Medical Diagnostech to pair Audere's app with Medical Diagnostech's SARS-CoV-2 Ag RDT in South Africa, with the intention of making it more broadly available in Africa. The goal is to have the app provide instructions on how to use the RDT and AI-powered interpretation of results. Other collaborations have included a December 2021 announcement of Audere's participation in a study into the development and evaluation of an ePharmacy platform for HIV pre-exposure prophylaxis (PrEP) delivery in Kenya. In this study, Audere's app is involved with HIV self-testing to qualify for PrEP. Audere and FIND are also collaborating on a WhatsApp chatbot for COVID-19 self-testing, which does not include machine interpretation but does include instructions and a reporting facility.

Technology Overview

The HealthPulse DxA app's features include step-by-step instructions for performing RDTs and capturing results using a phone camera, with artificial intelligence to interpret the photograph (Audere holds a patent in this area). In some settings, the machine-interpreted result will not be shown to the user but will be reported to local public health authorities.

Summary of Evidence

Audere conducted studies of malaria RDTs in Kenya and Nigeria, the results of which are yet to be published. In March 2022, Audere and collaborators published a study of the 2019–2020 flu@home project in the USA and Australia that used visible RDTs. There was no description of machine interpretation, but previously, in a September 2020 meeting of Digital Solutions for Malaria Elimination, Audere stated that their software correctly interpreted RDTs for influenza 98% of the time, compared with 95% correct visual interpretation by self-testers.
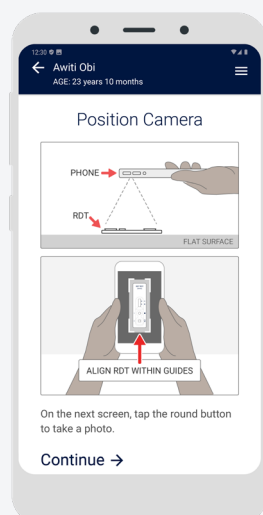
TiraSpot from Spotlab

LOCATION: Madrid, Spain
WEBSITE: spotlab.ai
MARKET STATUS: Bench studies

TECHNOLOGY OVERVIEW
TiraSpot captures the user's interpretation of an RDT and a photograph of the RDT for interpretation by cloud-based AI as part of a web platform.

KEY INSIGHTS
TiraSpot is focused on quality assurance rather than clinical diagnostic results.

Company Background
TiraSpot is an app from Spotlab, a telemedicine company that started out manufacturing automated microscopy products and now, since the advent of COVID-19, focuses on digitizing medical images from smartphones for AI-based interpretation and analysis. Spotlab develops their products under an ISO 13485-certified process. FIND has collaborated with Spotlab on a project related to Chagas disease that does not include machine interpretation.

Technology Overview
The TiraSpot app records a user's interpretation and captures a photograph of the completed RDT. It then sends these to a Spotlab server that uses AI to interpret the test (on-phone AI is under development). Currently, TiraSpot is not intended to present its interpretations for clinical use but to improve the diagnostic process by informing a supervisor of any cases with suspected errors in the visual reading. In addition, Spotlab offers TiraSpot as a web platform for analysing data collected throughout a geography.

Summary of Evidence
Spotlab's work on COVID-19 Ab RDTs and a small number of Ag RDTs was presented at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) 2021. For the identification of the immunoglobulin G (IgG) band, the algorithm demonstrated sensitivity of 96.6% and specificity of 99.9%, while for the immunoglobulin M (IgM) band, sensitivity was 90.9% and specificity was 93.3%. Spotlab has released preprints of additional studies into SARS-CoV-2.

Customizable acquisition forms — Create the case

Adaptable system to any **rapid diagnostic test** — Record the observed **test result** — Capture the test

Record the result

Data is **stored securely** on the platform — Upload to the cloud
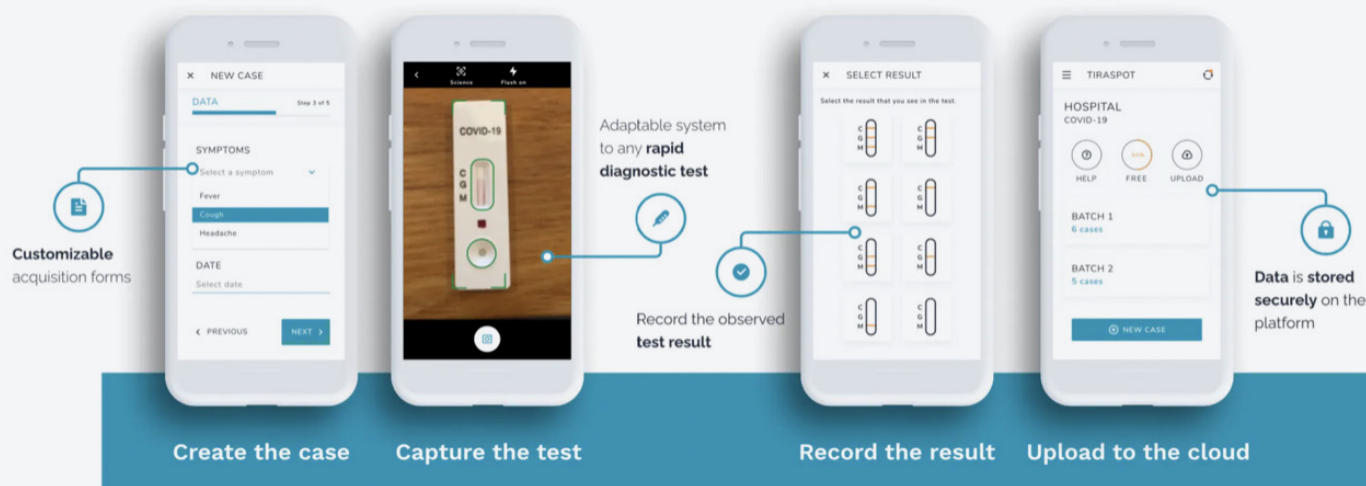
Global health scanner from Scanwell Health

Scanwell

LOCATION: Los Angeles, CA, USA
WEBSITE: www.scanwellhealth.com/global-health
MARKET STATUS: Authorization by SRA

TECHNOLOGY OVERVIEW
Scanwell's software library uses computer vision to read RDTs, while Dimagi's RDToolkit Android app adds testing instructions, a timer, and data export facilities.

KEY INSIGHTS
Clinical studies with malaria tests showed PCR-referenced accuracy equal to that of expert visual interpretation.

Company Background

A spin-off from Teco Diagnostics, Scanwell Health created the first FDA-cleared product that employs a smartphone app to interpret urinalysis strips used for self-testing. In 2019, FIND began a project with Scanwell Health to create a software library that can interpret three World Health Organization (WHO)-prequalified malaria RDTs and that could be expanded to interpret other tests. FIND also collaborated with Dimagi to create the open-source RDToolkit, which includes Scanwell's proprietary scanning algorithm in an Android app. Ministries of Health in LMICs can also directly integrate Scanwell's library into their own mobile apps. The RDToolkit can be used, without automatic interpretation, for some additional RDT models beyond those that Scanwell supports, while Dimagi is open to incorporating additional algorithms. In June 2021, Scanwell announced a $1.6M grant from the United States National Institutes of Health (NIH) to develop a smartphone-enabled, at-home test for chronic kidney disease. In December 2021, Becton, Dickinson and Company (BD), who had collaborated with Scanwell on COVID-19 self-tests as profiled separately below, acquired Scanwell Health and continue to offer the software library described here.

Technology Overview

The Scanwell library is designed to be adaptable to most cassette-style RDTs that have one or two test lines. The accompanying RDToolkit app provides a user interface that includes test instructions, a timer, and a data export facility. When photographing a test, the user is instructed to fit the test approximately to an on-screen outline; the user then taps a button when they are ready to capture the photograph. By default, the RDToolkit does not show the app's computer-vision interpretation to the user, instead asking the user for their visual interpretation and reporting both interpretations to a health programme. However, the RDToolkit can be configured to display the app's interpretation if a health programme has validated it for this use. If the Scanwell library cannot deliver a positive, negative or invalid result from a photograph, the app tells the user what the problem is, either photographic (e.g. too dark or too blurry) or related to the test itself (e.g. the zone of the test line being obscured by too much blood); the app then suggests a solution.

Summary of Evidence

In clinical studies that were presented in September 2021, FIND and research partners in Indonesia, Rwanda and Sudan evaluated the Scanwell library's performance with 1637 malaria tests that used two WHO-prequalified RDTs, using a mid-grade Samsung Galaxy A10 mobile phone. The app's agreement with results from expert interpretation by eye, comprising a panel of three experienced laboratory staff, was 98.9% overall, with lower agreement among those positive by eye (96.4%). Most disagreements between eye and app stemmed from faint or patchy test lines that were positive by eye but negative by the app. PCR results for these were negative as often as they were positive, yielding identical overall accuracies for app and eye of 91.1%. As a demonstration, Scanwell self-certified the app for the CareStart Malaria Pf/Pv test under the CE In Vitro Diagnostic Medical Devices Directive (IVDD), although this CE mark is no longer active since the In Vitro Diagnostic Medical Devices Regulation (IVDR) came into force.

BD Veritor At-Home COVID-19 Test with Scanwell Health

Scanwell

TECHNOLOGY OVERVIEW
The app includes step-by-step instructions, a timer, and an automatic interpretation shown to the user and also reported to public health authorities.

KEY INSIGHTS
The test's paper instructions warn against visual interpretation. The app can only be run on smartphone models that BD and Scanwell have determined to be compatible, and a supplied scan card must be placed under the test.

Company Background

Please see Scanwell Health's profile (above) regarding their global health reader. In early 2021, BD and Scanwell announced their collaboration on the Veritor At-Home COVID-19 Test, which effectively replaced BD's Veritor professional-use reader with Android and iOS apps on ordinary phones. In August 2021, BD and Scanwell announced their app had received US FDA EUA, the first for a smartphone-interpreted COVID-19 Ag RDT. The test was made available through Amazon. As noted earlier, BD acquired Scanwell Health in December 2021, with plans to deliver at-home tests for influenza, group A streptococcus, and more.

Technology Overview

The Scanwell app serves as an essential component of the test. The app provides the only step-by-step instructions for running the test. The paper instructions only state that the app's instructions should be followed, with a warning against attempting to interpret the test visually. BD advertised that the app meant that "No human interpretation needed", describing competing COVID-19 tests as having "unclear lines, subject to interpretation". (Unlike most SARS-CoV-2 Ag tests, this test has a sample adequacy line which must pass a threshold, in addition to test and control lines, none of which are labelled. Some early reviews on Amazon claimed that this test could be read just like other COVID-19 tests, when in fact a negative result using the BD test could show two lines, the way a positive result appears on most brands.)

The app can only be run on mobile device models that BD has demonstrated to be compatible, a list that initially was brief and omitted the newest iPhone but has expanded in a year to include many Apple, Samsung, Google, LG, Motorola and OnePlus devices. The user is guided by the app's timers, text, and videos with spoken instructions. The app confirms a phone's photographic capability in the current lighting conditions by having the user point the camera at a supplied scan card featuring optical targets. Once the test is ready, the user places the cassette on the scan card before pointing the camera at both. The user does not need to press a button to take the photograph, and the app will provide feedback about any image problems. The app presents the result to the user and reports it to relevant public health authorities, along with the tested person's legal name and address, which must be entered at the start of the test.

Summary of Evidence

Clinical performance stated in the healthcare provider IFU was 84.6% sensitive and 99.8% specific among 597 symptomatic patients compared with a high-sensitivity PCR reference, similar to the previously studied performance of the instrumented Veritor Plus test (84% sensitive, 100% specific). In a usability study involving 768 home users, the lowest success rate (85.7%) occurred when rotating the swab five times in the first nostril. Clinical performance was not reported for this study, so it is not known how adherence problems may have affected the results.
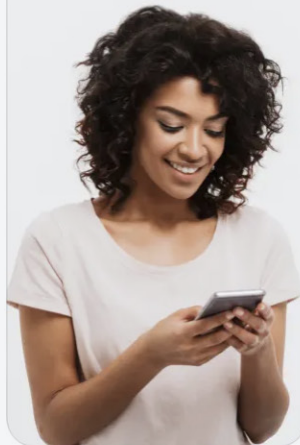
At-home tests with results in 15 minutes or less

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Convenient and private

Test from the comfort of your home.

Step-by-step video instructions

Follow along with the app.

9:41

Follow along with the video to collect your own sample.

Continue with the test as soon as possible after swabbing both sides of the nose. You must begin the next step within 1 hour.

Continue
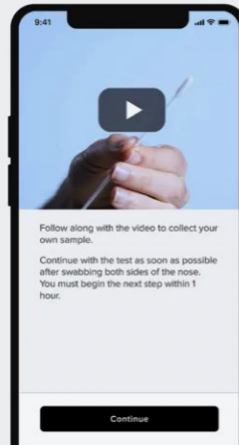
Reliable and clear digital results

Know your next steps.

9:41   Result   ✕

Brian Thompson
COVID-19 Antigen

Test Date: Jan 27, 2022 | 12:23 pm
DxID: dx_1q4KHWdSMxXmwxo3tXvtDKJr

NEGATIVE

If you have COVID-19 symptoms
You should self-isolate from others and contact a healthcare provider for medical advice about your symptoms.

If you do not have COVID-19 symptoms and this is your first test
You must perform a second test (this is called serial testing). Your second test should be taken at least 24 hours and no more than 48 hours after the first test.

Share Result

PROJECTS BRIEFLY REVIEWED

There were 17 entries that were briefly reviewed; they are listed alphabetically by organization in Table 2.

Table 2. Projects briefly reviewed

Organization	Product	Summary
BacTrace BioTec	Racordiax	This professional-use COVID-19 Ab test used cloud-based interpretation. The app is no longer available.
Bond Digital Health	Transform	Bond provides apps for RDTs, for professional or lay use, but does not create interpretation software, instead relying on partners for that.
Cellmic (previously Holomic)	HRDR	Founded in 2011 as a spinoff from the University of California, Los Angeles, this company made optical add-ons to enable phones to read RDTs. In 2018, Cellmic sold this technology to NOW Diagnostics; however, this technology is not currently listed on NOW Diagnostics' website.
Columbia University & BioMedomics	CoV-SCAN	In a publication, graduate students from Columbia University mentioned an app that reads a COVID-19 self-test, but the test seems to have moved forward without any app.
Cornell University	Unknown	A research team developed an optical reader (not a mobile app) to interpret their custom lateral flow assays for malaria and typhoid.
Dropshippers, Germany	My Rapid Test	This app does not have an interpretation capability; however, it does demonstrate a novel way to establish that an individual's self-test result was their own and was photographed at a stated time.
éclateral	Unknown	This start-up company announced the development of an RDT-reading app but now is developing a reader for electrochemical detection of infectious diseases.
Imperial College London, University College London, and other researchers	ALFA	According to their publication, this research project involved more than half a million images of COVID-19 Ab self-tests.
Laipac Technology	LooK Spot	Although this reader has CE-IVDD, it relies on a phone add-on to hold the matching RDT.
Meril	CoviFind	As with Abbott NAVICA India, this app is part of an authorized home-use test in India.
Midge Medical	Unknown	Midge Medical is developing a blood-collection device with integrated Ag detection (although it is not an RDT), with interpretation by a phone camera.
MyLab	CoviSelf	As with Abbott NAVICA India, this app is part of an authorized home-use test in India.

Organization	Product	Summary
R-Biopharm	Rida Smart	R-Biopharm's agricultural testing app for mycotoxins does not list support for phones introduced since 2018, but in 2022 a representative said that they were developing an app for clinical diagnostics.
Safe Health	HealthCheck	The company advertises RDT-reading apps as part of their white-label digital platform, although no details or recent news could be found.
Techcyte	NanoSpot	A company that initially focused on ML and computer vision for medical microscopy, Techcyte is developing a phone app to interpret a COVID-19 Ab test in a blood-spot test format rather than a lateral flow test.
University of Glasgow	Unknown	A research team published details of their AI lateral flow test reader on a smartphone-based instrument, but it interprets a custom LAMP (loop-mediated isothermal amplification) assay.
University of Washington students	SCIÖ	As a master's degree project sponsored by Microsoft and PATH, a group of students prototyped a universal RDT-reading app. The project has concluded.

Late during the compiling of this landscape, the six organizations listed in Table 3 were discovered to be working in this field.

Table 3. Projects discovered late during the compilation of this landscape

- BTNX
- Platform Kinetics & Microlab Devices
- Primary Health
- ProDiag
- Rapigen
- UnifAI Technology

DISCUSSION

Within this landscape's focus of RDT-reading apps that run on ordinary smartphones and tablets, a diverse range of approaches was found to have been taken by the organizations profiled, with impacts on their potential for success.

The physical components of RDT-reading apps are one area of divergence. Many of these apps aim for handheld use of a phone while photographing the test, but a few rely on a stand to control the phone's parallel placement at a fixed distance above the test. While no stand is needed for the SRA-authorized apps (including apps with temporary authorizations, for COVID-19) that display results to the user, almost all of these apps require placement of a special card underneath the test. The use of a stand and a card likely ease the technical challenges involved with machine interpretation, potentially improving usability and diagnostic performance by reducing the impact of user technique. However, in most situations in LMICs, these physical accessories, although simple, may create barriers to successful implementation. A stand must be delivered and retained, as must a card unless one is included with every test kit, adding a potentially considerable cost; even $0.01 would be considerable, given that a WHO-prequalified malaria RDT on its own currently sells for as little as US$0.25. Apps that require no physical add-ons continue to be the ideal for global health purposes.

Intended use is another area of divergence. As often happens in the life cycle of a technology, the role that people initially hoped these apps would fulfil—replacing the human eye in the interpretation step—has proven difficult to achieve, particularly in global health. Ensuring that a camera-based app works well enough to be an IVD device is a challenge even with just one smartphone model. Doing so across thousands of smartphones and tablets in LMICs is another matter. The technical challenges, however, may not be as difficult as the regulatory process, which has led mostly to apps that can only be run on mobile device models that the app maker has demonstrated to perform properly. This approach ensures quality in a straightforward manner, and it may be economically viable in a high-income country where test prices are high and the number of phone models is low, but it is unlikely to work in a global health context. This difficulty is probably a factor in the increasing interest in non-medical uses of these apps. An app that does not provide its interpretation to its user can still serve a useful purpose by reporting its result for epidemiology, surveillance, monitoring, evaluation, and external quality assessment purposes.

RDT compatibility is a further area of divergence. Similar to the challenges presented by the variety of mobile devices, regulatory issues confound efforts to deliver a "universal" reader that replaces the eyes for any RDT, as controlled performance of the diagnostic system (test plus reader) must be shown. The December 2021 guidance from the UK Medicine and Healthcare products Regulatory Agency (MHRA) relating to COVID-19 tests stated outright that the agency would not accept "test agnostic" readers. Universality aside, some companies seek for their apps to be compatible with several brands of tests, spreading out the investment in the development of the core technology, but nearly all the apps that have reached market only support one brand or even model of test. This might be considered a streamlined experience for users of that one test but represents a fragmented experience for users of multiple tests and the administrators who must integrate the platforms into their health programmes. (Further aspects of this with regards to markets are discussed below.)

Machine-based interpretation technology is a notable divergence as well. Artificial intelligence and machine learning (AI/ML) have been employed by some developers, while classic computer vision and signal processing have been used by others, while still others have used some of each in their development process. AI/ML has enabled impressive performance in medical imaging, but chest x-rays and computed tomography (CT) scans present images that are far less structured and more difficult to interpret than do RDTs. Developers who have done without AI/ML have achieved high diagnostic performance and regulatory authorizations, with various benefits claimed: the regulatory review required is conventional, and new RDT models can be supported without requiring the large photographic datasets typically needed for training and testing AI/ML algorithms. Given the broader industry push in the field of AI/ML and the emergence of large datasets of RDT photographs, e.g. the more than half a million photographs obtained during a COVID-19 self-test study in the UK, it will be interesting to see how this field progresses.

DIAGNOSTIC PERFORMANCE AND USABILITY

On top of these differences in approach to the product, organizations have taken different approaches to diagnostic performance goals and evaluation. Among apps for qualitative interpretation (only a few quantitative apps have been launched, and these were not for global health purposes), some have aimed or claimed to provide better-than-human detection of faint lines in the quest for improved sensitivity. With a good enough camera and appropriate illumination, software may indeed find subtle signals that no human could see, but this is only useful if the detected signal is a true positive result. Manufacturers of visually interpreted tests use visual limits as their threshold for design of the assay and control of manufacturing. If greater sensitivity is to be afforded by the detection of lines invisible to the human eye, without worsening specificity or lot-to-lot variability, the diagnostic system, as already mentioned, of test-plus-reader must be designed, validated and managed for that capability, as fluorescence-based lateral flow tests and all other instrumented diagnostics are.

This is not to say that RDT-reading apps cannot improve real-world diagnostic performance. Avoidance of common mistakes in interpretation, such as judging a faint line to be negative, ignoring an obscuring artefact that may hide a faint line, overlooking a missing control line, or confusing which line of a multiplex test was positive, can help all individuals to interpret tests as well as experts can, reducing the risk of errors that even the most skilled humans may make. An objective, consistent and connected app also removes the possibility of biased interpretation (a test's result should factor into a clinical diagnosis, not the other way around) and mistakes and delays in reporting.

That organizations have varying ideas about performance goals, combined with the fact that some apps are being developed independently of the lateral flow tests they are to be used with, has led to varied methods of evaluation. Some systems of test-plus-app are evaluated for sensitivity, specificity, and limit of detection by referencing a gold-standard method such as ELISA or PCR. This is a rigorous, widely accepted route for qualitative diagnostics, but when an app reads a test that was originally intended for visual interpretation, it is natural to ask how well the app agrees with the eye, particularly considering the perils of seeking greater sensitivity, as already discussed. Some comparisons of interpretations by app and by eye are described with the terms sensitivity and specificity, confusingly, as if the eye were the gold standard, when positive and negative percentages of agreement would be the correct terms to use. Semantics aside, these percentages are useful. A further difficulty arises from the fact that visual interpretations, in themselves a complex matter, are sometimes made not by viewing the test, as the clinical user would and as test manufacturers intend, but by viewing a photograph of the test, often taken by the mobile device running the app. Strong-positive tests without artefacts are easy enough to interpret from photographs taken on basic phones even in less-than-ideal lighting conditions. However, an observer of a photograph, especially a photograph taken using a modest camera, is at a disadvantage compared with a live observer in cases of tests that exhibit faint lines and flow artefacts that transiently resemble positive results. Direct observation is therefore optimal, but even then, a single observer should not be considered sufficiently reliable, so a panel of multiple skilled observers is preferred in performance evaluations of apps with visually read RDTs.

As RDT-reading apps have reached the market, their users—mostly self-testers so far—have probably paid less attention to sensitivity and specificity than to usability, judging from product reviews on app store and test merchant websites. Diagnostic performance is of little concern if people cannot or will not use the app. The camera step has proven stressful for some users who could not figure out how to satisfy the app's quality requirements while the timer ticked towards result expiration. Apps that rely on remote interpretation of results introduce another possibility for wastage of a test, if loss of internet connectivity occurs during the test. Not surprisingly, one outcome from all of these issues is that some users resort to running a test without the app, even when the test kit provides no other instructions for performing and interpreting the test. The success of RDT-reading apps depends not only on being easy to use but also being worth using. An app that requires data entry is inherently more work than running a test without an app at all, and an app that only benefits the public health authority recipients of the data may leave users, especially self-testers, wondering why they should bother. Apps that interpret the test result for the user provide a reason for their use, but beyond that, stakeholders who want testers to use apps must show how the apps will help the users.
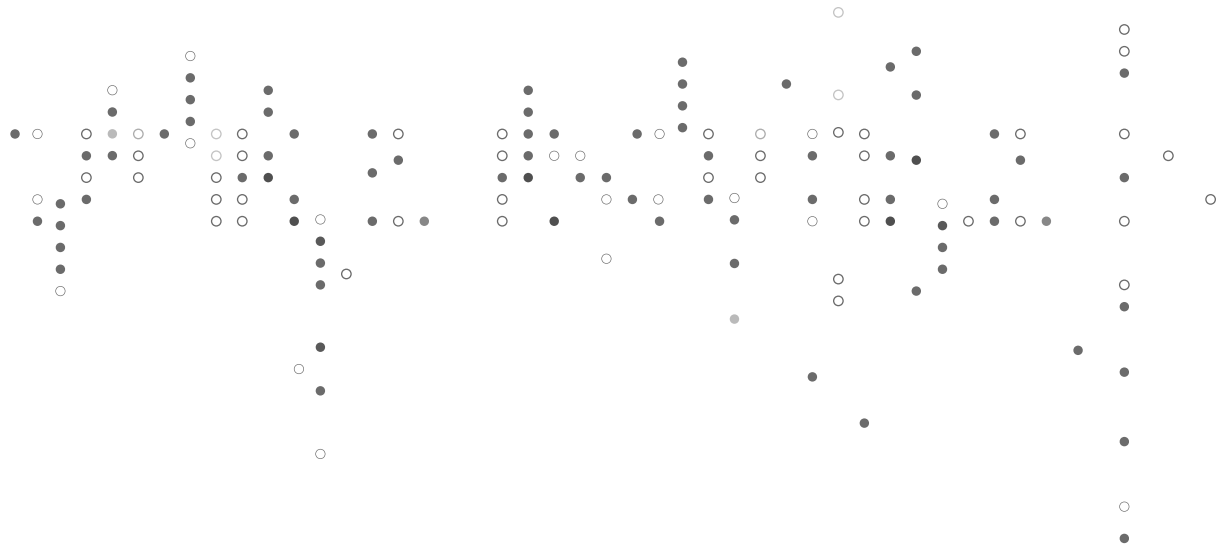
A NASCENT MARKET

Interest in RDT-reading apps continues to be strong, due to the opportunity they provide in helping RDTs work as well everywhere and for everyone as they do in the hands of experts and to ensure that results are reported. Since the first apps were authorized by SRAs in the mid-2010s, however, the pace of deployments and further authorizations has not been what their proponents might have hoped. More recently, the COVID-19 pandemic has accelerated growth in this sector, as it did for many fields in diagnostics, prompting new entrants, temporary authorizations, and at least one acquisition.

The question remains, however, as to why these apps have not become common and what will happen next. In addition to their usability challenges, market challenges will need to be addressed. An RDT-reading app may avoid the costs associated with the deployment of physical RDT readers, but the app must still be developed, tested and supported, incurring costs above and beyond those of visual tests. The apps must also demonstrate value, both to end-users and health programmes.

Stakeholders in global health often see these apps as a way to improve the use of existing, visually interpreted RDTs. The first commercialized apps followed a different strategy: they facilitated the sale of existing RDTs to new users. Expanding the market for a test from professional-use only to include self-testing offers the potential for increased margins and volumes for the RDT manufacturer and lower overall costs for healthcare systems. This certainly holds appeal, although this segment has not yet seen any major successes. As smartphones continue to be more widely used and their cameras improve, the potential for easy-to-use, high-performing RDT-reading apps will only increase. What is less certain is how they will fit into healthcare systems and cost structures.

LIMITATIONS

This landscape report presents a static snapshot of information found to date. As noted where applicable, some websites were unreachable at the time we published this report. We did not attempt to reach those organizations nor any others to confirm the information we have reported here. We also acknowledge that it is likely there are other RDT-reading app efforts underway of which we are unaware.

CONFLICT OF INTEREST

The authors declare no conflicts of interest. As noted where applicable, FIND has collaborated with several of these organizations on development, evaluation or both.

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