Last updated 10th February 2021

Diagnostics Connectivity Solution Profile

GxAlert / Aspect

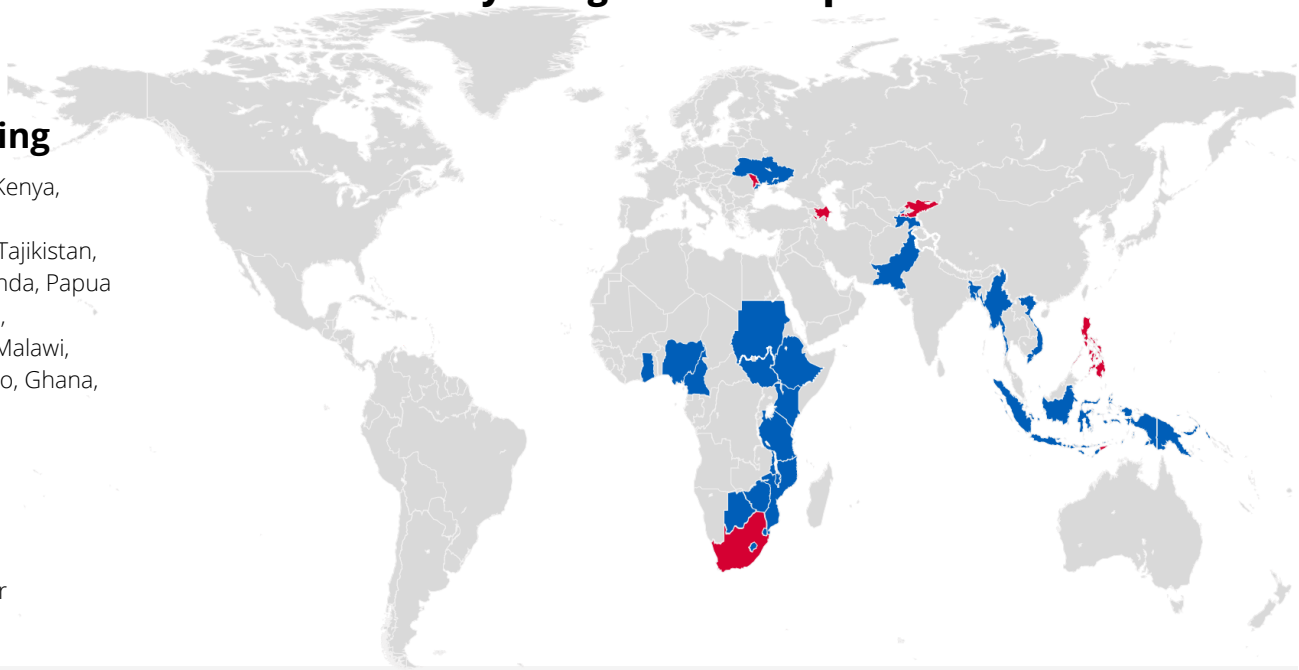
systemone

GxAlert is a software tool specifically for TB. Aspect is a multi-disease platform

No license fees for Ministries of Health

Over 3,300 installations
as of November 2020

Countries currently using GxAlert/ Aspect



Implementing

Nigeria, Mozambique, Kenya, Myanmar, Cameroon, Bangladesh, Tanzania, Tajikistan, Ethiopia, Pakistan, Uganda, Papua New Guinea, Swaziland, Botswana, Zimbabwe, Malawi, Ukraine, Sudan, Lesotho, Ghana, Vietnam, Indonesia

Piloting

Philippines, Kyrgyzstan, Azerbaijan, Moldova, South Africa, East Timor

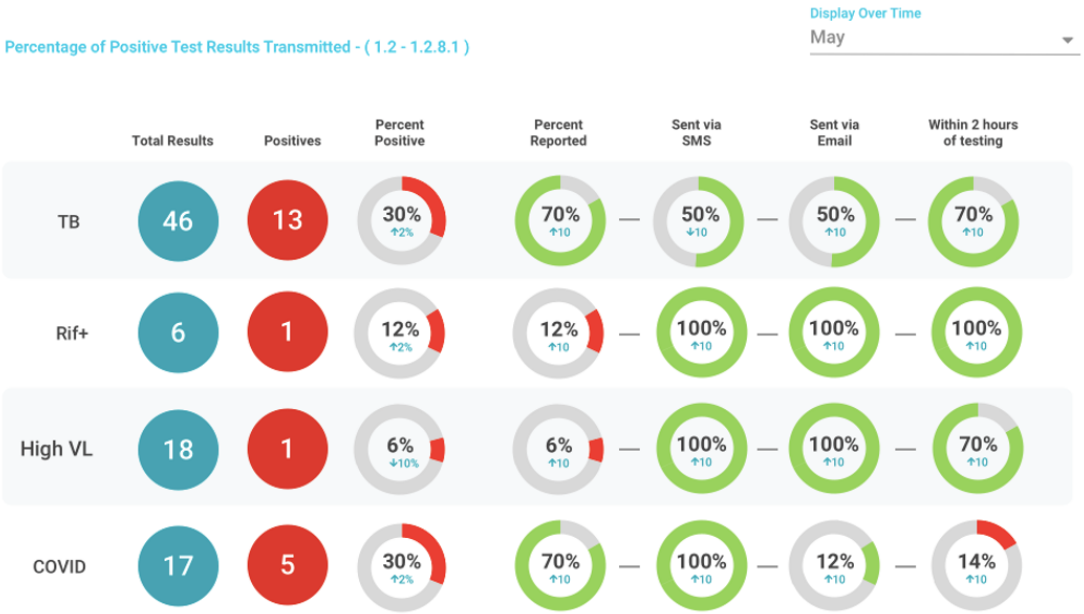
Assays currently supported:

- Xpert MTB RIF and Ultra
- Xpert HIV Qual (VL)
- Xpert HIV Quant (EID)
- Xpert CTNG
- Xpert RSV
- Xpert HCV Qual (VL)
- Xpert Sars CoV-2
- Xpert Ebola
- Abbott HIV-VL and TB
- Roche VL and TB
- PIMA CD4
- Alere Q / Abbott mPIMA HIV VL and EID
- MGIT Culture and DST
- Hain GenoScan (automated or manual)

Languages currently available in:

English, French, Portuguese, Kiswahili, Bahasa Indonesia, Russian, Ukrainian, Dutch, Vietnamese

Any language can be added with notice



Diagnostic Device Network Management

Device Usage Statistics

Dashboard shows a high level overview of all connected devices, error rates and issues. This can also be configured with dynamic KPI's, which are user customizable.

Device Utilization Rates

Dashboard shows high level utilization nationally, by region or laboratory. Utilization rates can be customized to country-specific indicators.

Dashboard

Built with responsive design and accessible from any connected device.

Display of Results

Dashboard shows disease results by result types, color coded. Results can also be exported to CSV or Excel, or embedded into notifications via email, SMS text, or API to another software.

Recommendations for Targeted Support

The system shows a national average, devices above/below the average as well as automatically generated "recommendations" to further investigate labs with significantly higher unsuccessful test results. The system can also provide these as automated reports, emails, Excel documents, PDF, SMS, etc.

Connectivity

The system indicates whether a device is connected- showing the current connectivity status of a router, modem or other communications device.
Upon request, the System can also show the current connectivity and billing status of SIM card.

Records and displays warranty information

The system tracks the date of warranty contracts and shows the end date. This data can also be configured in reports, emails, SMS notification and shared with the instrument manufacturer or service provider.

Network Maintenance and Calibration

Records and displays calibration dates

Automatically captures when a calibration has been completed on the GeneXpert instrument and forecasts the next calibration date. This data can also configured in reports, emails, or SMS notifications and shared with the instrument manufacturer or service provider.

Records and displays maintenance performed per instrument

Provides alerts and warnings when instruments need maintenance. These can be packaged into a report for an Authorized Service Provider for the instrument.

Provides a report for instruments requiring calibration

The system can manually, or automatically, generate a report for all instruments with upcoming calibration in the next 30/60/90 days. Aspect can capture and report calibration activity automatically (requiring no manual entry).

Results of quality checks can be sent directly to manufacturers for troubleshooting

Notifications can be customized directly for Service and Support staff as well as login roles, which allows the service providers to log into the System and see the overall instrument operational overview without access to any patient or disease information.

System error logs are scanned and errors indicating module failure can be automatically sent to Cepheid.

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Improving Patient Management

Automated notification of healthcare workers

Notifications feature is flexible and allows single results, or reports of results (Excel, CSV, PDF) to be automatically populated and sent to patients, clincians or anyone else in the health system, including another software (e.g. EMR, LIS, eTB Manager, etc.). The companion Aspect Reporter app can send results to specific clinics or healthcare workers which enables linking to treatment.

Patient management features for clinicians:

- Clinicians can use the Aspect Reporter app to capture information such as diagnosis, treatment initiation, medication and treatment outcomes. Diagnosis can also be manually entered in the web application.
- Clinicians can order diagnostic tests via the Aspect Reporter mobile application.
- Aspect can assign unique IDs to patients as they are confirmed by positive diagnosis.
- System is able to merge duplicate patient IDs and preserve non-duplicates.

Captures patient demographic information for clincial care and follow-up

Users can specify additional information to be captured per test. On devices where user has no PC or option to input (abbott mPIMA, for example) they can add this information via a customized web-page to link this information to the test result.
The set of additional patient fields can be defined or updated centrally (at GxAlert server) and all instruments will automatically update to collect new fields.

Connection via API to Lab Information Management Systems, Electronic Medical Records and other case management tools.

All API's are supported and the System can be customized to customer requests including REST/JSON, HTTPS, HL7, Web-Hook, FTP/FTPS, etc. User interface available for creating web hook integrations with other systems in JSON format.

Examples in current use include: DHIS2, OpenMRS, OpenLDR, e-TB Manager, and more. Such integrations are currently live in Nigeria, Mozambique, Kenya, Ethiopia, Philippines, South Africa and Malawi.

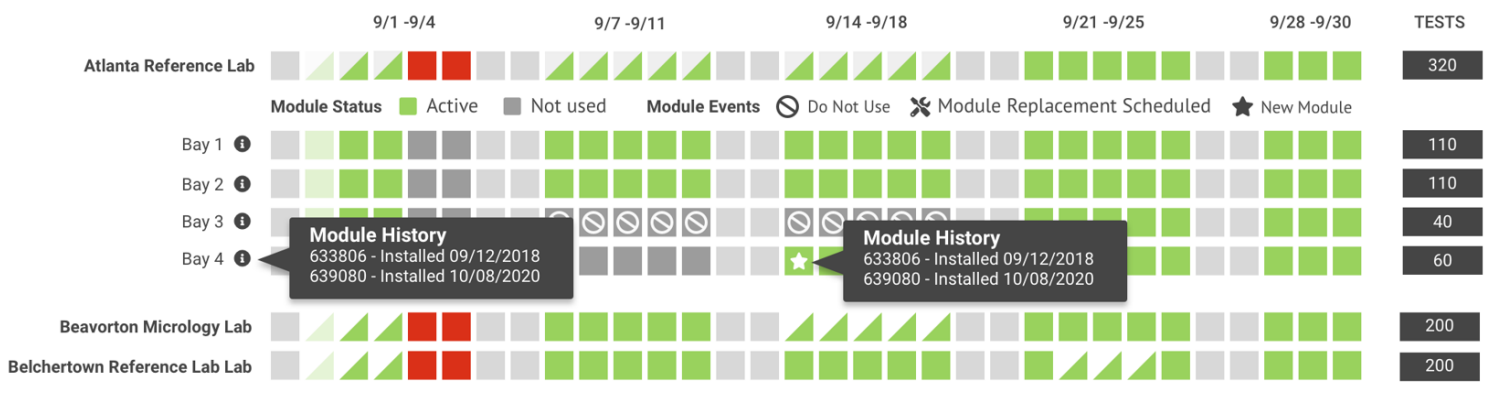
Connection with clinical results reporting systems

Notifications can be sent to any customizable end-point

Contact list of MOH staff, supervisors, lab personnel, clinicians, patients, NTP and NRL is established as part of the setup process

Scheduled reporting of Rifampicin-resistant TB cases

Can be done on a per-test basis- as soon as a single test registers Rif+ it triggers SMS/ email/ API notification- or, on a scheduled basis (weekly, monthly, etc). Aspect Reporter app also assists with this workflow to manage via mobile application to ensure all Rif+ cases are confirmed on appropriate treatment.



Facilitating Supply Management

Records currently available inventory in an instrument site

This can be configured per-site or by national and regional level warehouses.

Automatically alerts lab and stock managers when inventory is running low

Alerts are by SMS, email, API or other custom mechanism.

Forecasting model can be customized per country

Forecasts stockouts and cartridge expiration

Based on the individual lab utilization and stock levels with associated expiration dates in the system - can provide accurate predictions of laboratory stockouts.

Recommends stock reallocation to reduce stockouts and cartridge expiration

Recommends that cartridges be re-allocated but does not specify to where.

Enhancing Connectivity and Data Management

Integration with diagnostic devices

Brands of diagnostic instruments currently connected:

- Cepheid GeneXpert
- Abbott m2000
- Roche Cobas (series)
- BD MGIT Culture and DST
- Hain Genoscan (automated and manual)
- Alere PIMA and Q/Abbott mPIMA.

Any device can be connected on request within 60 days.

App can capture non-digital results (microscopy, TB-LAMP,etc) as well as screening from digital X-ray or other case finding methods.

System also supports all APIs and can be customized to requests for integrating with other systems.

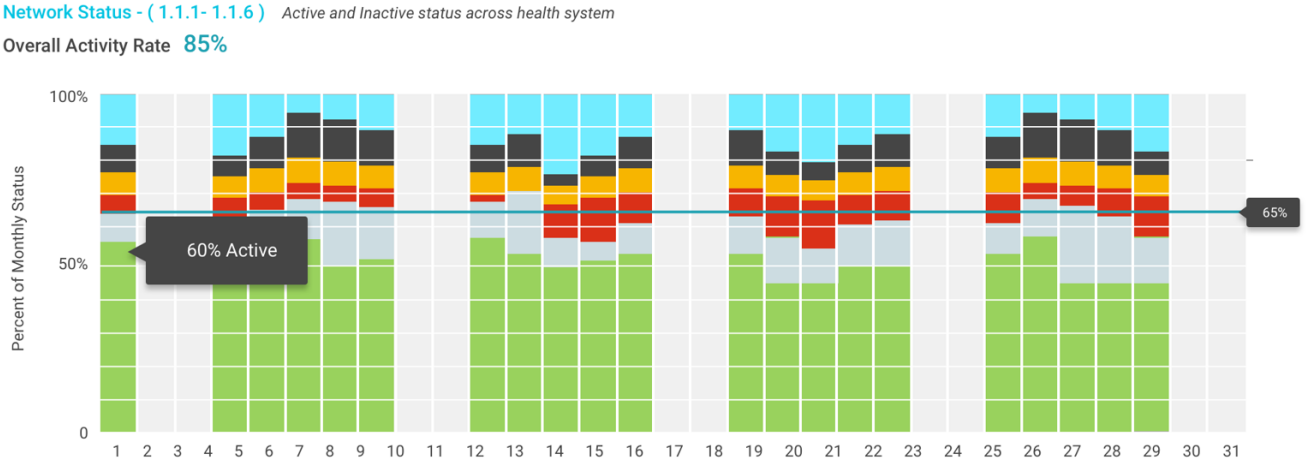
Ability to perform in settings with poor connectivity

Offline data is stored until there is a connection. The app functions offline and syncs when network is available.

SystemOne deploys Smart routers with global sims able to connect to any in-country network,e xternal antennas, and smart-routing infrastructure. Globally, SystemOne manages the network for over 3,000 devices obtaining >90% monthly uptime.

Upon request the system can send patient and medical information to the national server via SMS- but this is not recommended due to GDPR regulations.

System can also support manual upload of .GXX files. Integrates with Dropbox to manage file sizes.



Data Control and Ownership

Data hosting can occur in-country or in a private cloud

SystemOne provide private web-server hosting or can support local-cloud and private web-hosting as per the MoH request.

Multiple levels of data access can be granted upon permission by the NTP

Data can be configured by users, roles and geography.

Data on the system is owned by the Ministry of Health

Data Use Agreement (DUA) is used to define permitted use of data

- DUA requires destruction of the data within 30 days of the revocation of data access via the system.
- DUA is compliant with South Africa's Privacy of Personal Information (POPI) law and GDPR from the EU.

Sample DUA can be provided upon request to the developer

Availability of Support

22 staff dedicated to developing this specific software

Works on all major operating systems (Windows, Linux, Mac OS X)

Provides a Service Level Agreement (sample available upon request)

Available software support includes:

- GxAlert SysAdmin Certification Course
- Monthly webinars on system features
- Online help desk and knowledge base
- Email and WhatsApp support
- User guides, training materials and technical documentation

Components required to support the software

Ubuntu operating system for Aspect and Windows Server
Server specs:

- Computer Hardware minimum 8GB RAM, 100GB Hard drive, I5 processor or better, Ethernet.
- Networking publicly accessible IP number open on port 22, 80, 443 and 3000.

SystemOne can provide any components (including physical server and operating system). All items included in a bundle, unless a country has specific legislative requirements to switch to local service provider.

11 staff dedicated to training and implementation

The dedicated team spans each continent with primary support running out of the office in South Africa. Large implementations typically involve the hiring of an in-country manager which is seconded to work with the NTP.

Available installation and implementation support

1-week in-country TOT with the MOH, NTP and implementing partners. The team jointly installs the solution at 4/5 labs.
SystemOne facilitates completion of the rollout, provides remote support and ongoing training via webinar or in-country visits per the selected SLA for a given country.
The global SIMS and smart routers enable much of the support to be provided remotely, thereby greatly reducing long-term support costs and improving sustainability.

All training material and installation files are included in roll-out. Support is provided to connect instruments in remote areas and SystemOne can conduct all local installations (where requested).

Last updated 10th February 2021

Software Updates

Code is updated on a weekly basis

As one project contributes new functionality, it is tested, relased in limited fashion, and then released to the global GxAlert/ Aspect community so that everyone benefits.

External contributors are welcome to contribute feature ideas or code

How is the software updated?

Server is updated centrally (cloud or in-country) which then automatically updates all the client installations on the diagnostic instruments so no additional installations/ site visits are required. Any customer requests/ tickets are managed via a helpdesk.

Planned product updates for diagnostic device management:

1. Display of weekly and monthly instrument plunger maintenance and maintenance history for the instrument
2. History of daily status-utilization if tests performed, reasons why not if tests performed. Can be broken down to the model level.
3. Report Cepheid AccessCare SLA indicators.

Planned product updates for patient management:

1. Additional tracking of care cascade for a single patient's GeneXpert, MGIT (Culture and DST), Smear, LPA results to see full history of tests per case.

Other short and mid-term activities planned for software updates:

1. Molbio TrueNat and Cepheid Xpert XDR integration pending.
2. Integration with Cepheid ASP's for proactive notifications on failed modules, instruments and specific errors.

Further updates can be added upon request