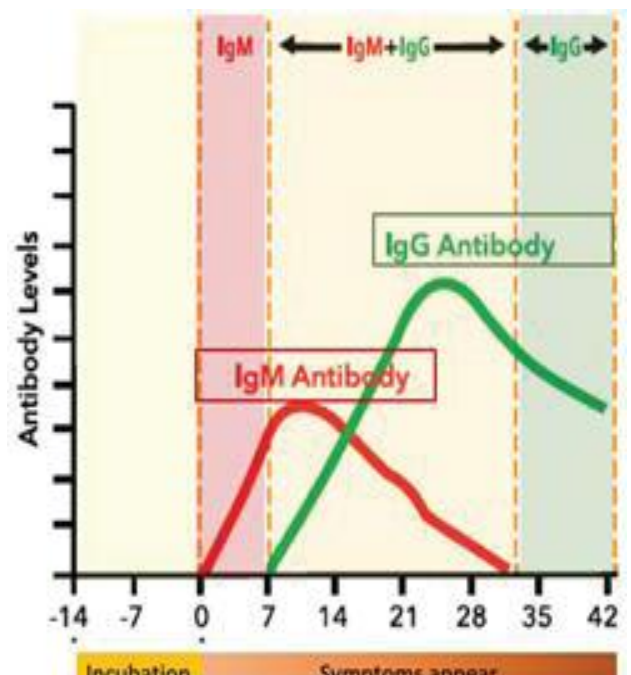


# COVID-19 IgM-IgG Immediate Mobile Diagnostics and Analytics Solution at Point of Care

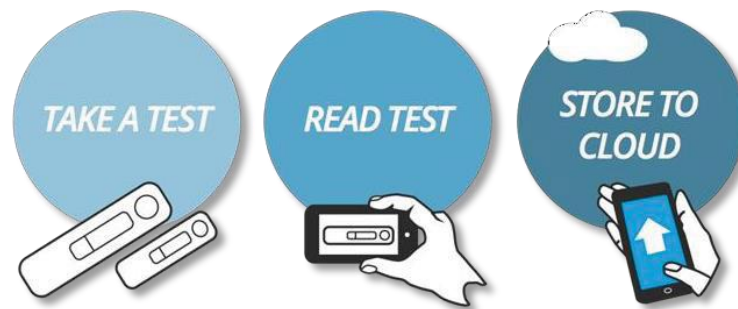
Immunoglobulin M (IgM) is found mainly in the blood and lymph fluid, is the first antibody to be made by the body to fight a new infection. IgM provides the first line of defense during viral infections. Next is the creation of the Immunoglobulin G (IgG) which is associated with long term immunity and immunological memory. Testing of COVID-19 IgM and IgG antibodies is an established and effective method for the rapid diagnosis of COVID-19 infection. The detection of COVID-19 IgM antibodies is an indication of a recent exposure to COVID-19, while the detection of COVID-19 IgG antibodies indicates a later stage of infection. Our combined antibody test is capable of providing information on COVID-19 stage of infection.

Test Results	
Sensitivity	97.60%
Specificity	100%
Test Accuracy	98.80%



## iSTOC Mobile Diagnostics Solution Description

- iSTOC's IDA (immediate diagnostics and analytics) IDR (infectious diseases reader) is a turnkey solution for healthcare professionals to be used in point-of-care (POC) diagnostics for infectious diseases. The IDA IDR solution consists of a smartphone mobile reader application and an IDA backend solution.
- The smart phone mobile reader application is used to digitize and analyze lateral flow tests(LFT), while the IDA backend solution provides analysis, support and dynamic configuration for the supported lateral flow tests.
- The mobile application can analyze data from the LFT designed to diagnose **COVID-19 IgM-IgG**
- With very minimal instructions to untrained staff, the IDA IDR solution can be deployed to capture digitized diagnostic data. The data can be verified and analyzed from LFTs tests in 3 simple steps:



1. **TAKE A TEST** Healthcare worker downloads the mobile application to a Smartphone and performs rapid diagnostics test
  2. **READ A TEST** Healthcare worker scans the test using the application
  3. **STORE RESULTS** The application makes a quick analysis to the test and send results to the IDA backend.
- The IDA IDR mobile application can be used by a healthcare worker at a point of care screening site or by a technician in the field.
  - After the scan has been performed the results of the LFT are available immediately on both the IDA IDR mobile application and the IDA backend service. This ensures the data is immediately available where it is actionable, either at the screening site or at a central care facility. IDA IDR solution can also communicate directly with legacy healthcare systems, laboratory systems or medical records systems through IDA API.

- Healthcare professionals at a central care facility, such as health center, can receive measurement results, treatments logs and any images describing potential problems or disease symptoms, via the IDA backend service. This enables a real-time consultation between the mobile application user and a
- healthcare professional at a central care facility.

## By using the IDA IDR solution

- ◆ The healthcare worker can perform a scan using the IDA IDR mobile application.
  - ◆ The testing site can send the results to the care facility.
  - ◆ The healthcare professional can deliver care instructions and facilitate care plans.
- The IDA IDR solution may circumvent the need to record LFT test information on paper. By eliminating the need for manual data recording the user can save time and be sure that the information gathered will be accurate. The solution is safe to use and the data is securely stored. The solution has been certified by FDA, CE and is HIPAA compliant.
  - The IDA IDR mobile application manages and records and then delivers critical and time sensitive information to the health centers. The IDA IDR solution provides real time communication between the mobile application user and the healthcare professional. This allows for real time patient follow up, which in the past has been problematic to many healthcare systems globally.
  - The health care professionals at the health center are able to message and communicate with the technicians in the field via messaging capabilities.
  - By using the IDA IDR solution all users involved can get access to relevant and timely data, thus helping the daily work and patient care to be executed smoothly.

## Features

### IDA IDR mobile application:

- The IDA IDR mobile application allows the smartphone user to rapidly record outcome of LFTs by using the smartphone camera. In addition to a digital storage of the measurement data, the IDA IDR mobile application provides a safely stored image of the LFT test outcome.
- The IDA IDR mobile application can provide additional data related to a LFT test scan. For example: pertinent and appropriate patient and GPS location information.
- All of this information is automatically sent to the IDA backend service and made available for the healthcare professionals at a central care facility.

### IDA IDR backend service

IDA IDR backend service is comprised of a set of web applications and services that can be used through a standard web browser – using either a PC/Mac or tablet devices.

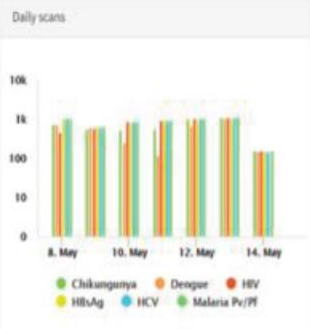
- These services enable the healthcare professional at a central care facility to view any data created during a LFT scanning process. It also allows the healthcare professional to collaborate in real time with the mobile application user.
- The backend service provides tools for visualizing both test results and different activities performed within the service. This helps to further analyze the LFT test scans and provides the foundation for data analytics.
- The IDA backend service is also used to configure additional supported LFT tests. The IDA IDR mobile application automatically synchronizes supported LFT test information. Automatic synchronization of the IDA IDR application increases functionality without the need to deploy new versions of the mobile application.
- Any personally identifiable data stored to the IDA backend is strongly encrypted. All data access services use SSL for encryption

### Map visualization; Number of LFT scans performed geographically

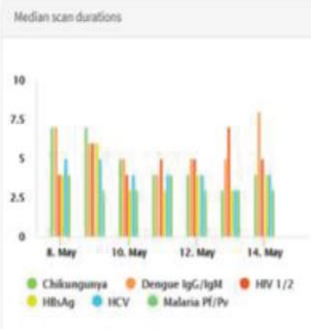


## Management Dashboards

### Daily Count



### Team Performance



### Interactive Pie Charts – Disease & Location Wise



### Interactive Screening Results – Trends & Monitoring



## Summary

IDA IDR solution provides real-time communication capabilities for a mobile application user and healthcare professionals at a central care facility, such as a health center. It converts diagnostic data into immediate and actionable information,

- Immediate diagnostics: only a smartphone is necessary
- Patient management: Web applications in the IDA backend service ensure real-time medical guidance back to the mobile application user
- No attachments: no additional hardware attachments are required
- Real-Time data and data analytics
- Interactive mapping: disease surveillance and real time epidemic alerts
- Data management: seamless integration into client/stakeholder information systems
- Quality assurance: lateral flow test quality control

## Approvals and Certifications

### FDA approval April 9, 2014

- Digital Analysis, Digital image, storage and communications, laboratory information system with the definition under NVV (Class I product).
- Intended for clinical laboratory analysis, image storage and communications.
- The device is for professional use only.

### CE approval May 23, 2013

- IVD class I device: A SW reader in mobile device and SW information system to read POC tests or test results displayed on POC device.
- The implemented relevant standards were: Quality management system (ISO 13485) Risk management system (ISO 14971) Software life-cycle processes (IEC 62304) and Usability engineering (IEC 62366).

### HIPAA compliance

- All data stored to the cloud that contain personally identified information (PII) is encrypted both when transmitted and at rest
- All traffic between the mobile app and the cloud service is encrypted (HTTPS)
- The HTTPS data stream is secured using standard secure SSL certificate (RSA encryption; key size 2048 bytes).
- All personally identifiable information (PII) is encrypted in the database using strong (AES512) encryption algorithm

**Velvira Certified, National Supervisory Authority for healthcare and welfare, Finland**

**Global Free Sales Certified, Finland**

## **iSTOC Technology Patents and FDA Registration**

iSTOC Oy holds 2 technology patents for its Immediate Diagnostics & Analytics (IDA) of Infectious Diseases platform,

- 1) US 2014/0240491 A1
- 2) US 2014/0247340 A1

## **iSTOC COVID-19 IgM/IgG Test Kit**

- ISO 1384 Certified
- CE Certified
- CE Certified, In-Vitro Diagnostics

Authorized distributor – Xenon Medical Technologies / Goliath Inc



Offices in: Beverly Hills, California  
Provo, Utah P:669-251-0983



Xenon