

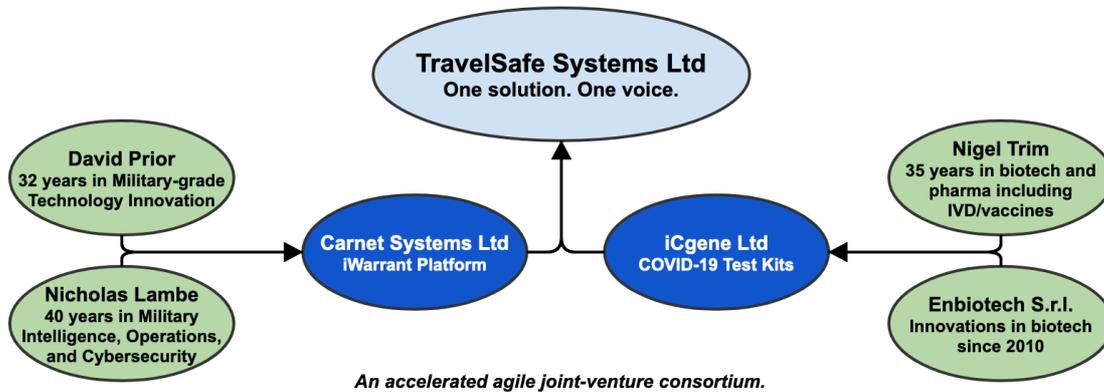
TRAVELSAFE SYSTEMS: IWARRANT AND ICGENE

BACKGROUND AND FAQ



ABOUT TRAVELSAFE SYSTEMS:

TravelSafe Systems Limited is an agile joint-venture consortium that has accelerated an integrated, holistic solution to the unprecedented challenges facing the travel sector as a result of the COVID-19 (SARS-CoV-2) coronavirus pandemic.



TravelSafe Systems brings together more than 100 years of relevant biopharma, technological, and operational experience, supported by world-class scientific and biotechnological expertise. Recognising that each of us held a part of the solution, the principals mobilised rapidly to create and realise an innovative approach to the detection, assignment, management, and monitoring of COVID-19 infection status for travellers, employees, and support personnel alike.

This approach integrates a fast, accurate, and field-deployable genetic test for SARS-CoV-2 with a Privacy First status management platform: delivering auditable and incontrovertible individual certification that provides a viable, affordable alternative to quarantine or other measures.

THE PRINCIPALS:

- **Nigel Trim (Joint CEO Chief Scientific Officer):**
 - With 35 years in bio and medical technology, including IVD/vaccine development, Nigel owns and operates an ISO17025 accredited lab for traditional and molecular biology testing. Nigel co-founded ICGENE Ltd with rights from Enbiotech S.r.l.
- **Nicholas Lambe (Joint CEO):**
 - A serial entrepreneur who, since leaving the RAF, has developed extensive experience in solutions for operations, logistics, and cybersecurity. Nick and David have collaborated on a number of ventures since 2003.
- **David Prior (Chief Technology Officer):**
 - David has delivered advanced, innovative technology solutions to a wide-range of commercial, military, and government organisations worldwide. David cofounded Carnet Systems with Nick to deliver the iWarrant platform.
- **Enbiotech S.r.l.:**
 - Formed in Italy in 2010 by a group of researchers with expertise in molecular biology, microbiology, chemistry, and biotechnology, Enbiotech develops and manufactures products and services for molecular diagnostics.



FREQUENTLY ASKED QUESTIONS:

iWarrant

1. How secure is the iWarrant software platform?

- The iWarrant software *platform* comprises a mobile app and the backend infrastructure that supports iWarrant functionality. All software is written to proven military-grade security standards and, on an ongoing basis, will be subject to penetration tests and red-teaming exercises to obtain and maintain certifications that evidence the safety, security, and resilience of the system.
- The personal security (Privacy First) design encrypts data at rest and in transit, adding multi-envelope encryption that ensures that even we cannot access our member's private data.

2. Who owns the data and where is it stored?

- All data in iWarrant is owned by the individual who has full control over how, why, and with whom they share their data and any claims arising from that data.
- iWarrant stores all private data in a resilient "translucent" database, and the claims arising from that data in an immutable (can't be changed) record that is distributed across Tier 3+ data centres worldwide. Data storage locations may be defined by jurisdiction, geographic location, or personal preference as required by the individual and/or pertinent laws.

3. Is iWarrant compliant with GDPR and equivalents?

- Individual data in iWarrant is owned and controlled by that individual and TravelSafe Systems has no access to, or means of identifying the individual behind, that data. This exceeds GDPR requirements. (See 2 above).

4. Can I download iWarrant from my app store?

- The iWarrant app is released to the Apple and Android app stores for evaluation and authorisation for sale. It is expected that iWarrant will be fully accessible at the same time as the ICGENE test becomes available for bulk orders end of Jun 2020.

5. Is iWarrant available globally to match the demand of air travel?

- Yes iWarrant will be available at no cost on the Apple Appstore and Android Google Play store. If these can be accessed in a passenger's jurisdiction they can download and use iWarrant

TRAVESAFE SYSTEM (TSS)

1. When are tests to be taken on a passengers journey.

- Tests are only required out and back at the airport of departure (some countries may differ from this process) (2 tests per journey) and any additional tests, if required at arrival at destination are by national regulation.
- If it is a short duration journey e.g. under 3 days and a bilateral national agreement is in place you could travel out and back on a single green pass (1 test).



2. *Would the tests be taken by all passengers or would this be by exception, i.e. those that develop symptoms or are flagged by temperature screening.*

- While this is a Government regulation decision, TSS **do not recommend** that this is an effective method.
- **All passengers and airport staff, crew** etc should be tested. So that best endeavours are made to ensure a **“green zone”** is created around the passengers. 100% testing can of course be reduced as the risk and infection levels in a region or state decline.
- **The same process can be applied to any confined area where people naturally interact such as care homes, schools, restaurants, theatres etc**
- Asymptomatic cases significantly reduce the effectiveness of temperature and visual checks.
- Citizens may be asked to undertake an arrival quarantine process, depending on local requirements, but could still be a “silent spreader” if quarantine is not fully adhered to. TSS substantially addresses the issue, as all people are tested at the commencement of their travel journey.
- TTS suggest this is the type of approach that the public is looking for (evidenced by independent survey results), to give them confidence.
- There are clear reports indicating that aviation has significantly contributed to fast multi country virus spreading. There is a duty of care for the industry to address this risk and create **“decontaminated zones”** for customers and employees on the ground and in the air.
- Evidence suggests that zones and/or “bridges” will eventually become “green (infection free)” and therefore the solution can be deployed as a shield where needed. As shields are lifted it may be an option to take smaller and smaller sample sizes and become more of an “adjustable shield” to meet individual government requirements.
- An international protocol for any future surges or pandemics that creates shields, green zones and agreed testing levels can be created as a future defence. This can avoid the wholesale shut down of the travel economy that we are experiencing in the event of future medical emergencies.

3. *Should we[sic] be suggesting tests for everyone on arrival at the airport?. As an example, some countries have looked at a test taken at least 48 hours prior to travel:*

- TTS clinical advisors state that *“to minimize risk its best to test close to departure”*. If a country wants to adopt a 48 hour procedure that can be accommodated. E.G. Frankfurt International and other airports may adopt a 24 hour protocol.

4. *How saleable is the solution?*

- The near-term scalability is approximately 2.5M per month being achievable but there is engagement to improve this through licensed manufacture and dedicated resources to build out the medical testing capability. This can scale to 10M per month quite quickly. Beyond that will depend on cross government collaboration and licence manufacture which is in plan and achievable.



5. What is the cost?

- A cost per test is less than €40. However, depending on volumes and local requirements the price could be significantly less than this. TTS is also sourcing specialist testers to support airports if an airport requires additional local personnel support. (This was discussed at Frankfurt).

6. Do the tests fit the criteria expressed, as needed in the market?

- TTS believes that it **does** meet many of the criteria including subject data security, it can be integrated into the boarding pass flow, the test is fast, accurate and affordable.

7. What is the business model?

- This is the decision of the government, regulators, airports and airlines in any given location; however, TSS believes that a tariff or fee added to the price of a ticket or charged at the departure airport is the most likely (and attractive) model.

ICGENE TEST

1. What is the ICGENE test?

- The ICGENE test uses LAMP (RNA)ⁱ analysis on a sample taken from a nasal swab.

2. How fast and accurate is the ICGENE test?

- Current clinical outputs show a sensitivity of 2 copies of the SARS-CoV-2 virus per millionth of a litre of sample with zero false positives when tested against 6 other common coronaviruses.
- **With up to 48 simultaneous tests, results are typically delivered in 45 minutes or less. The test is able to detect 2 copies per micro litre enabling identification of the virus before any major viral shedding occurs.**
- The specificity of the test has been checked against six commonly found human corona viruses including SARS and MERS with zero percent cross reactivity.
- Because TSS is using LAMP technology the accuracy is very high thereby reducing the risk of false positives and negatives to the extent that it is almost eliminated.

3. Is the ICGENE test certified?

- The ICGENE received CE IVD certification in early July 2020 and is being fast tracked for FDA approval. The CE IVD certification provides the formal assessment of the safety and efficacy of the test and associated equipment using real world patient derived sensitivity and specificity data.

4. When will the ICGENE test be available?

- The test is available now and orders have been placed in Germany, Italy, South Africa and the USA. Immediately after receiving its certification the test was deployed to the Italian Island of Lampedusa to test thousands of migrants that arrived there in July.



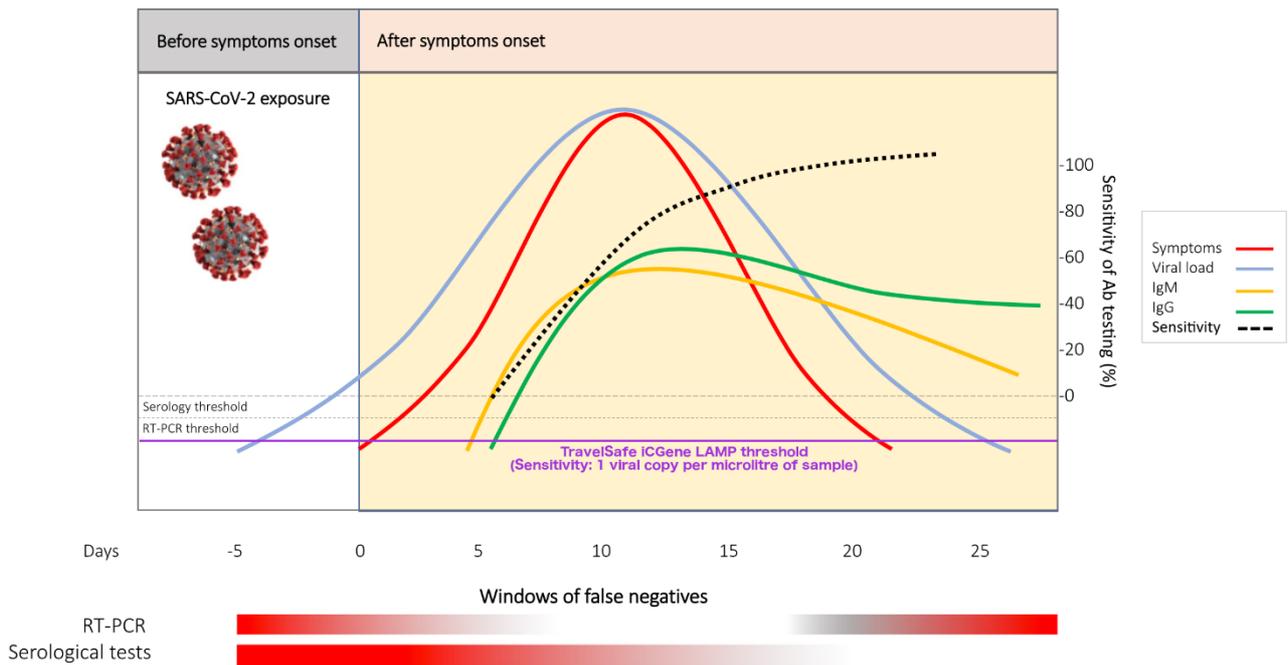
5. Where are the test kits manufactured and are they available at scale?

- ICGENE test kits are designed and manufactured in Italy. A full production manufacturing process is already in place and can be readily scaled to meet demand.
- The near-term scalability is approximately 2.5M per month being achievable but there is engagement to improve this through licensed manufacture and dedicated resources to build out the medical testing capability. This can scale to 10M per month quite quickly. Beyond that will depend on cross government collaboration and licence manufacture which is achievable.

6. Why is LAMP testing more effective than other tests?

- Testing has been the cornerstone of most countries response to COVID-19 containment. The current most used technique is Polymerase chain reaction (PCR). The issue is it can take 4-24 hours to get a result, requires laboratories, skilled staff and lots of reagents and can cost north of \$100 a test. Blood, or serology based testing, looks for antibodies. Results can be faster, 20 minutes, and can provide an indication that the person being tested had the virus in the past but does not indicate active infections. The costs are more modest, around \$30 per test, but have been discarded by some due to low levels of accuracy.
- The Loop-mediated isothermal amplification (LAMP) test is a single-tube technique for the amplification of DNA. Developed by a Japanese group of researchers at the Osaka University Medical School in Japan two decades ago, LAMP is performed in a single tube, at a constant temperature for very little cost, to detect DNA. The technique amplifies DNA quickly—with high specificity and efficiency.
- It is more accurate than PCR can be conducted on-site at an airport, pharmacy or point of care without the need for labs, delivers results in under 40 minutes and costs, with TravelSafe Systems (TSS), around €40 per test or less on volumes. This provides a real alternative for mass testing that protects travelers, airport staff and flight crews, care homes, schools and multiple other use cases.
- The ICGENE system uses portable machines that weigh less than 1Kg and can be carried anywhere and used by almost anyone. ICGENE analysis follows a three-stage process in which nucleic acid is extracted from the test sample; the extract is amplified using the LAMP technology (with any SARS-Cov2 RNA subject to a 12-point attachment by the ICGENE primers), and the fluorescence of the extract is analysed for the presence of the virus. The results are clearly expressed as either positive or negative and are either displayed on a local tablet app or uploaded for onward processing by iWarrant.
- The 12 point attachment enables the test to detect 2 copies per micro litre enabling identification before any major viral shedding occurs.
- **This is key as the diagram below shows. The TSS property test, due to its sensitivity and specificity has the widest range of detection from pre-symptomatic (almost the day after infection), symptomatic, asymptomatic and post-symptomatic**

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- TSS have taken this a step further by integrating test results into a secure immutable application to provide a certificate of test results that can be used in the flow through security and boarding an aircraft or entering any area where people naturally mix.
- The business model can be simple whereby the Airport provides the testing facility and holding areas and charges the airlines with a mark-up on their current contract. Airlines can then decide if they wish to pass on the costs to the travelers through their own pricing. Alternatively Governments that are keen to get the travel economy moving can underwrite the costs.
- Either way TSS have a vision to “Make Travel Safe Again” and they are very close to achieving it.



Background to LAMP technology

¹ LAMP technology allows rapid amplification of genetic material at constant temperatures using small sample quantities obtained from a nasopharyngeal or environmental swab. ICGENE analysis follows a three-stage process in which nucleic acid is extracted from the test sample; the extract is amplified using the LAMP technology (with any SARS-Cov2 RNA subject to a 12-point attachment by the ICGENE primers), and the fluorescence of the extract is analysed for the presence of the virus. The results are clearly expressed as either positive or negative and are either displayed on a local tablet app or uploaded for onward processing by iWarrant.

Binding with absolute precision to 12 unique points means that ICGENE very accurately identifies the RNA of the virus with a sensitivity of up to 2 viruses per μl of fluid. With a focus on minimal operator burden, the ICGENE test is simple and robust: occurring in one small tube to deliver high specificity results in approximately 45 minutes. The only other molecular test used for COVID-19 is a Polymerase Chain Reaction (PCR) test which requires laboratory conditions; has fewer binding points, and requires analysis equipment to cycle through a range of temperatures, often taking more than 2 hours to produce results. Additionally, PCR requires experienced, trained laboratory staff and additional reagents.
