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Positioning Document: TravelSafe Systems Solution**BACKGROUND:**

SARS-CoV-2 is a new strain of coronavirus, belonging to the Betacoronavirus family, first identified in humans in Wuhan (China) in December 2019. This virus is highly transmissible and occurs with severe symptoms in one out of five patients. To date, there have been 19.67 million confirmed cases and 727.5 thousand deaths globally, with infection rates continuing to rise.

With the closing of international borders, lock-downs, self and enforced isolation, social distancing, and the closure of many aspects of society, the SARS-CoV-2 pandemic has had the most profound socioeconomic effect on the global population in the last 150 years and will continue to do so. Moreover, current research indicates that vaccination programmes may only confer relatively short periods of immunity to the disease and that the virus will continue to present challenges to society for the foreseeable future.

A major challenge to controlling the spread of the disease is that carriers can remain asymptomatic spreaders for up to 10 days prior to exhibiting symptoms: rendering temperature checks at airports etc. ineffective in controlling the spread. Indeed, the United States Centres for Disease Control and Prevention (US-CDC) forecast in July 2020 that up to 40% of people infected with SARS-CoV-2 are asymptomatic. That same forecast, however, also reported that the chance of onward transmission of the virus from asymptomatic individuals is still 75% of that of onward transmission from a symptomatic individual.

Widespread implementation of a rapid and robust test, with high specificity and the sensitivity to allow earlier detection of and intervention in SARS-CoV-2 cases, is clearly recognised as being essential to the management and control of the SARS-CoV-2 pandemic.

RESPONSE:

TravelSafe Systems (TSS) supplies an integrated testing solution for SARS-CoV-2. The TSS testing solution for SARS-CoV-2 is a molecular genetic test that employs Loop-mediated Isothermal Amplification (LAMP) technology to detect the presence of SARS-CoV-2 viral RNA in samples taken from human subjects or surfaces. LAMP technology, which has a 20-year history of use in molecular genetics testing for pathogens, is described by the European Commission as '*an isothermal variant of PCR (Polymerase Chain Reaction)*' testing.

The TSS test as provided is fully CE/IVD certified for use in human diagnostics, with such certification recording 100% diagnostic specificity, 100% exclusivity, and 100% inclusivity. With 12 points of attachment to SARS-CoV-2 viral RNA, plus 6 internal controls, per test, the analytical sensitivity (or Level of Detection) of the test has been confirmed as 1 copy of viral RNA per microliter of sample. Attachment to a conserved (or stable, as in not subject to mutation) section of the SARS-CoV-2 genome provides for application to all current mutations of the virus, including the proliferating D614G mutation. Real-time results mean that analysis outcomes are normally produced in under 40 minutes.

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Full data sheets on the TSS testing solution, as well as copies of the CE/IVD certification documents, can be provided but it is worth noting here that the sensitivity of the TSS test allows the detection of infected individuals well in advance of the point at which they are able to infect others. This is clearly illustrated in Figure 1, below.

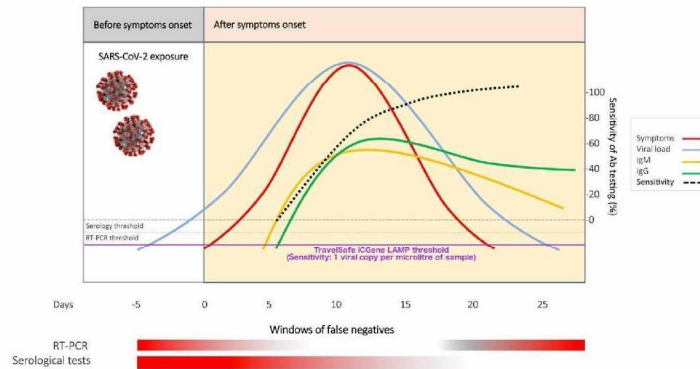


Figure 1: Viral Kinetics of SARS-CoV-2 and Detection Thresholds (Adapted)¹

The TSS testing solution allows performance of a qualitative, rapid, and specific test for SARS-CoV-2 using oropharyngeal or nasopharyngeal swabs. Each test kit includes all reagents required for rapid RNA extraction, amplification, and SARS-CoV-2 virus detection. Unless otherwise requested and negotiated, the kits do not include swabs or disposable Eppendorf pipette tips. The use of saliva testing as an alternative sampling method is currently under evaluation. Once evaluated, recommendations and supporting data for the use of saliva samples will be released as guidance to end-user communities.

The TSS testing solution is designed for use as a 'Point-of-Need' / 'Point-of-Care' (PoN/PoC) system rather than requiring that samples be taken to a central laboratory facility. As such, the TSS testing solution includes robust, small form factor analysis machines that are able to process either 12 or 48 tests simultaneously using single test gene amplification through loop-mediated isothermal amplification (LAMP) technology.

These analysis machines are connected to a small Android tablet computer, which runs the analysis, provides automatic visualisation and interpretation of results, and relays results to a suite of upstream digital services for wider scale analysis and dissemination of results. Each tablet may control two analysis machines and, where circumstances and protocols permit, up to 4 samples may be pooled in each test.

¹ Original chart: La Marca et al. Testing for SARS-CoV-2. <https://doi.org/10.1016/j.rbmo.2020.06.001>

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At maximum capacity, therefore, a single testing station controlling two 48-well analysis machines is capable of processing 384 samples simultaneously and delivering accurate results in 45 minutes or less. As noted above, the TSS testing solution is designed for PoN/PoC use and, therefore, testing stations may be deployed where needed without the requirement for clean room laboratory conditions. This includes deployment within vehicles and, even, in the open air: connected via cellular or satellite networks and helping create a nation-scale biosecurity fabric in response to the SARS-CoV-2 pandemic.

FORWARD BIOSECURITY AND KNOWLEDGE TRANSFER:

As observed above, the TSS testing solution for SARS-CoV-2 combines a proven test methodology (LAMP) with a novel primer construct for the molecular genetic detection of SARS-CoV-2 viral RNA. This is wrapped in a digital services layer that provides wider scale analysis and dissemination of results.

While this is a compelling solution for the detection and control of SARS-CoV-2, a simple change of test allows the same analysis machines – and the same digital services layer - to be used against a broader range of pathogens, both on surfaces and in humans. Additionally, as and when new pathogens emerge and are genetically sequenced, new tests can be rapidly produced to detect and control those also. In short, investing in the TSS testing solution now delivers a solution for SARS-CoV-2 but also lays the foundations for the development of national-scale biosurveillance and biosecurity strategies.

The robust, reliable, and straightforward nature of the TSS testing solution lends itself to the creation of a distributed infrastructure that operates at Point-of-Care / Point-of-Need and, therefore, that can operate in concert with other, more centralised, biosecurity capabilities.

This represents a sustainable forward opportunity for TSS customers. In order to facilitate that opportunity, upon first order, TSS provides a ‘train-the-trainer’ programme is provided to customers. This will allow TSS customers to train ‘swab’ takers, sample preparers, and analysis machine operators: creating a sovereign capability in respect of the use of molecular genetics for pathogen detection and diagnosis.

Such sovereign capability, supported by the robustness and quality of the TSS testing solution, can be applied to the detection of ‘everyday’ pathogens – such as giardia, norovirus, campylobacter, legionella, and more – as well as forming a rapid reaction force in the face of future disease outbreaks due to both known and as yet unknown organisms.

Additional options in support of the development of sovereign capabilities with regard to biosurveillance and biosecurity include, but are not limited to, collaboration on biosurveillance observatories and the development of associated analytical skills, as well as direct Knowledge Transfer of the skills and procedures required to conduct annual maintenance and recalibration operations for the analysis machines.

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Undertaking such programmes would provide for additional skilled worker positions that would reinforce the provision of sustainable sovereign capability while ensuring the continued quality of the biosecurity services provided.

BASIS OF SUPPLY:

Supply of the TSS testing solution includes both analysis machines and test kits. Analysis machines are delivered with all ancillaries, including the required Android tablet preloaded with the testing station software.

Test kits are delivered with all reagents required for rapid RNA extraction, amplification, and SARS-CoV-2 virus detection. Test kits also include all costs for access to the suite of upstream digital services for wider scale analysis and dissemination of results. Unless requested and negotiated as additional items, the test kits do not include swabs or disposable Eppendorf pipette tips.

In order to meet specific client requirements for privacy, security, and integration, the suite of upstream digital services (known as 'iWarrant') can be deployed inside national borders, integrated with existing systems of record, or otherwise customised. Specific requirements will need to be discussed with TSS and may result in an additional cost.

Unless otherwise requested and negotiated, supply is ex-factory (Italy), with all onward costs (including but not limited to freight charges, import duties, and sales taxes) being the responsibility of the buyer.

REGIONAL RETAIL PRICING AND BUNDLING:

TSS supplies its testing solution on the basis of a defined Regional Retail Pricing model. Such pricing is available on request. Where applicable, reseller discounts (which create reseller margin) are available to be negotiated on qualification of opportunities.

We understand and appreciate that the TSS Price per Test will be compared to the price per test for current PCR mass testing services. We would, however, observe that the PCR Price per Test often excludes the capital expenditure costs of establishing, maintaining, and staffing the laboratory facilities that PCR testing requires. We would also observe that PCR requires a number of additional reagents, some of which are in volatile supply.

For transparency of both capital and operating expenditure, creating a blended effective price per test that delivers both infrastructure and consumables, TSS offers bundled pricing options that deliver the both the analysis machines and the test kits: creating a distributed, rapid, robust, and accurate testing response to SARS-CoV-2 that also provides a sovereign foundation for future national biosecurity strategies.

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