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SISTEMA SANITARIO REGIONALE
IRCCS LAZZARO SPALLANZANI

Aix*Marseille université

KRONO

Evaluation of a production ready portable, Point of Need Platform (instrument and reagents), direct from nasal swab test for the molecular diagnostic detection of COVID-19 infection

Communication and dissemination

Publications

☐ This project does not currently have any scientific publication

Suggested publications from OpenAIRE (1 publications)

No.	Type	Title	Authors	Title of the Journal/Proc./Book
1	Article in Journ	Virological and Serological Characterisation of SARS-CoV-2 Infections Diagnose	Francesca Colavita; Silvia Meschi; Cesare Ernes	Frontiers in Medicine

Project publications (6 publications)

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No.	Type	Title	Authors	Title of the Journal/Proc./Book
1	Article in Jour	SARS-CoV-2 Early Screening at the Point of Entry: Travelers From Bang	Rueca M, Di Caro A, Gruber CEM, Messina	Frontiers in Genetics
2	Article in Jour	Effective screening strategy against SARS-CoV-2 on self-collected saliv	Effective screening strategy against SARS-	The journal of infection
3	Article in Jour	COVID-19 Rapid Antigen Test as Screening Strategy at Points of Entry:	Colavita F, Vairo F, Meschi S, Valli MB, Lalle	Biomolecules
4	Article in Jour	Saliva Is a Valid Alternative to Nasopharyngeal Swab in Chemiluminesce	Amendola A, Sberna G, Lalle E, Colavita F,	Journal of Clinical Medecine
5	Article in Jour	Investigation of Nasal/Oropharyngeal Microbial Community of COVID-1	Rueca M, Fontana A, Bartolini B, Piselli P,	International Journal of Environmental Research and Pu
6	Article in Jour	16S rRNA gene sequencing of rectal swab in patients affected by COV	Mazzarelli A, Giancola ML, Farina A, Marcl	Plos One

PLOS ONE

RESEARCH ARTICLE

16S rRNA gene sequencing of rectal swab in patients affected by COVID-19

Antonio Mazzarelli[1☯], Maria Letizia Giancola[1☯], Anna Farina[1], Luisa Marchioni[1], Martina Rueca[1], Cesare Ernesto Maria Gruber[1], Barbara Bartolini[1], Tommaso Ascoli Bartoli[1], Gaetano Maffongelli[1], Maria Rosaria Capobianchi[1], Giuseppe Ippolito[1], Antonino Di Caro[1]*, Emanuele Nicastri[1‡], Valerio Pazienza[2‡], INMI COVID-19 study group[¶]

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¶ Membership of the Collaborators Members of the National Institute for Infectious Diseases (INMI) COVID-19 study group is provided in the acknowledgments.
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biomolecules

MDPI

Article

COVID-19 Rapid Antigen Test as Screening Strategy at Points of Entry: Experience in Lazio Region, Central Italy, August–October 2020

Francesca Colavita [1], Francesco Vairo [1], Silvia Meschi [1], Maria Beatrice Valli [1], Eleonora Lalle [1], Concetta Castilletti [1], Danilo Fusco [2], Giuseppe Spiga [2], Pierluigi Bartoletti [3], Simona Ursino [4], Maurizio Sanguinetti [5], Antonino Di Caro [1], Francesco Vaia [1], Giuseppe Ippolito [1] and Maria Rosaria Capobianchi [1,*]

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frontiers in Genetics

BRIEF RESEARCH REPORT
published: 09 February 2021
doi: 10.3389/fgene.2021.625607

Check for updates

SARS-CoV-2 Early Screening at the Point of Entry: Travelers From Bangladesh to Italy–July 2020

Martina Rueca, Antonino Di Caro, Cesare Ernesto Maria Gruber, Francesco Messina, Emanuela Giombini, Maria Beatrice Valli, Eleonora Lalle, Simone Lanini, Francesco Vairo, Maria Rosaria Capobianchi and Barbara Bartolini*

National Institute for Infectious Diseases, INMI (Istituto Nazionale per le Malattie Infettive), "Lazzaro Spallanzani" IRCCS (Istituto di ricovero e Cura a Carattere Scientifico), Rome, Italy

We report phylogenetic and mutational analysis by NGS of six SARS-CoV-2 strains from patients flying from Bangladesh to Italy (July 2020). Data suggest that no further circulation of such imported strains occurred in Italy, stating the efficacy of early screening at the point of entry and supporting the importance of molecular epidemiology in monitoring the efficacy of control measures.

Keywords: SARS-CoV-2, next generation genome sequencing, mutations, phylogenetic analysis, COVID-19, molecular epidemiology, early detection at point of entry

OPEN ACCESS

Edited by:
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Reviewed by:

frontiers in Medicine

BRIEF RESEARCH REPORT
published: 20 January 2022
doi: 10.3389/fmed.2021.815870

Virological and Serological Characterisation of SARS-CoV-2 Infections Diagnosed After mRNA BNT162b2 Vaccination Between December 2020 and March 2021

OPEN ACCESS

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International Journal of
Environmental Research and Public Health

MDPI

Article

Investigation of Nasal/Oropharyngeal Microbial Community of COVID-19 Patients by 16S rDNA Sequencing

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Journal of
Clinical Medicine

MDPI

Article

Saliva Is a Valid Alternative to Nasopharyngeal Swab in Chemiluminescence-Based Assay for Detection of SARS-CoV-2 Antigen

Alessandra Amendola [1,†], Giuseppe Sberna [1,†], Eleonora Lalle [1], Francesca Colavita [1], Concetta Castilletti [1], Giulia Menchinelli [2,3], Brunella Posteraro [3,4], Maurizio Sanguinetti [2,3], Giuseppe Ippolito [5], Licia Bordi [1,*], Maria Rosaria Capobianchi [1] and on behalf of INMI COVID-19 Study Group [‡]

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‡ The participating members of INMI COVID-19 study group are acknowledged at the end of the article.

Citation: Amendola, A.; Sberna, G.; Lalle, E.; Colavita, F.; Castilletti, C.;

Journal of Infection 83 (2021) e8–e10

Contents lists available at ScienceDirect

Journal of Infection

journal homepage: www.elsevier.com/locate/jinf

Letter to the Editor

Effective screening strategy against SARS-CoV-2 on self-collected saliva samples in primary school setting: A pilot project

Dear Editor,

of the Saint Camillus Hospital, as well as pre-testing clerical work were performed by skilled health care worker teams named USCAR (Special Rehabilitation Care Continuity Units). Samples were registered on the local Laboratory Information System (LIS) and processed as follows:

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Rose Kelleher, for the IMI communications team

A rapid diagnostic test 'pipeline' for current and future pathogens

KRONO's COVID-19 test technology will make the world more prepared for new threats to human, animal and even plant health

The KRONO project is working to deliver an ultra-fast COVID-19 diagnostic test that will provide results within 40 minutes. It will be used to detect pre-symptomatic and asymptomatic cases, when and where it is needed, without the need for a lab or trained technicians. Rapid testing carried out while the disease is in the early stages allows quick triaging of subjects. Testing can be carried out in doctors' surgeries, schools, care homes, transit points of entry (airports, ship ports), and even in people's own homes.

The technology is adaptable to a large number of pathogens; the aim is to be able to detect not only human pathogens, but also those that threaten animal and plant health. The project's aim is to build up a generic platform technology pipeline that can be operational within weeks of the appearance of a new disease-causing agent in the population.

The KRONO Project is on schedule and the project partners expect to have the system validated for emergency use and ready for production scale-up in under 16 months. The core technology, developed by British SME BG Research, detects viruses without the need for nucleic acid extraction or laboratory equipment. It is an UltraRapid PCR-based molecular test ('RT-QPCR') deploying a novel type of custom reagent that breaks open the virus, with a single enzyme system that is resistant to being inhibited by compounds that can be found in crude samples of blood, saliva and nose or throat swabs.

How it will work

The sample is placed into a tube that contains the buffer agent, and then a fixed amount of the sample is transferred into another tube that contains the freeze-dried reagent. The test is run and the result is displayed in the form of a traffic light, which simplifies the interpretation of the results. This whole operation can be carried out by a trained non-expert user or by a trained technician in care-homes, doctors' offices, schools, as well as dental clinics and hospitals. The entire process will take about 40 minutes, which will be critical in places like airport testing centres or at other points of entry, where people will only be permitted to transit if they can be shown not to pose an infection risk to others.

Rose Kelleher, for the IMI communications team (suite)

"The test can be carried out in the home," according to KRONO project coordinator, Nelson Nazareth, CEO of BG Research. As for how innovative it is, he says, "RT-QPCR-based systems already exist but the reagent system is unique in that it allows processing direct from raw samples. The instrument is innovative in that it is an UltraRapid, compact, off-grid powered, field-portable device that is designed to work in resource and economically poor regions. The software will allow for easy interpretation of complex results through algorithms based on actual clinical data, correlated with current gold standard tests to calibrate the results." Higher throughput systems are also being designed."

The fast-changing landscape of the pandemic poses risks that are beyond anyone's ability to predict, but Mr. Nazareth is optimistic that the system will deliver KRONO's objectives in the required timeframe. "Time is an issue for scale-up, as our supply chain and manufacturing partners may be affected by the pandemic. At each step of the project we might experience delays and potential roadblocks, as some of this work is fundamental research, but we have worked to mitigate these risks by preparing alternative options and look to have tight control of key resources and services."

This is the first time that BG Research has been involved in an IMI project. "The requirements for the project and our core technology was a good fit,' says Mr Nazareth. "The partners, with their own extensive experience and knowledge in communicable diseases, were very receptive once they were introduced to the unique benefits of the platform technology."

8th ESWI Influenza Conference Scientific

Contribution Details
272
Submission Type / Conference Track: ***8th ESWI Influenza Conference Scientific and SPI Programme abstract submission***

Development of a method and system for the rapid, portable, cold-chain free detection of viral pathogens direct from crude biological samples at the point of need

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8th ESWI Influenza Conference: Diagnostic testing in the management of acute respiratory infections in primary and secondary care
Keywords: diagnostics, rapid testing

2 pages

The KRONO project - Development of a method and system for the rapid, portable, cold-chain free detection of viral pathogens direct from crude biological samples at the point of need.

Background:

KRONO is a European Horizon 2020 IMI2 project funded to develop portable, extraction free, low cost diagnostics for detection of viral pathogens from unprocessed biological samples including blood, saliva and respiratory samples at the point of need. KRONO demonstrates direct from nasal swab and saliva diagnostic tests for SARS CoV-2 and Flu on a newly developed portable platform including diagnostic kit and portable equipment. Collaborators Aix Marseille University (AMU), University of Corsica (UCPP) and the National Institute of Infectious Diseases in Roma (INMI) will validate the instrument and assays on clinical samples, generating data for registration on the WHO Emergency Use List (EUL) through demonstration ability to detect < 10,000 virions/ml sensitivity.

Methods:

KRONO had to adapt to the COVID crisis through integration of unexpected needs such as emergence of variants of concerns, alternative clinical specimens, supplementary clinical needs that required upgrading the diagnostic assay from frozen single-plex Generation 1 to lyophilized Duo-plex Gen4. KRONO had dealt with (i) in silico studies for targets in the N and RdRp genes, (ii) *in vitro* evaluation of assays using Accuplex standard, (iii) development of stable Armoured RNA as controls, (iv) suitability of different matrices (nasal, naso-pharyngeal, breath, saliva), (v) impact of virus transportation media (VTM) on assay performance, (vi) sensitivity, (vii) specificity, (viii) LoD, (ix) LLoD95, (x) and clinical studies with contrived and clinical specimens. All these steps were done through access to >10,000 stored nasal swab and >350 saliva samples collected during the pandemic and stored in INMI and UCPP biobanks with the proper authorization for use. All results are analysed with a comparator allowing the consortium to generate the data necessary for WHO EUL approval for a SARS CoV-2 duoplex assay

Results:

A lyophilised reagent can be delivered that meets the required sensitivity of 100% at 10,000 virions/ml nasal swab eluate. The performance of frozen and cold-chain free reagents are the same and that the assay detects VOCs. The process renders the pathogen non-infectious, with minimally a 5 log titre reduction. Clinical studies and real-life assessment in three laboratories are on-going and results will be delivered soon.

KRONO has also demonstrated that both the XF1 and the assay technology are flexible and can be adapted to other targets in <3 months to provide point-of-need diagnostic solutions adapted to emerging viruses.

Conclusions:

The BG Research XF1 instrument and SARS CoV-2 assay can deliver, portable, cold-chain free diagnostics meeting the WHO TPP for SARS CoV-2. Tests are performed directly on VTM or saliva, require minimal training and provide results <40 minutes directly to the user as a sample pos/neg and use of the system should allow portable testing to take place, assisting outbreak management in remote regions or points of entry.