BGResearch
....making innovation happen

ISO 13485 Medical Devices Quality Management

BioGene
.....innovative excellence

ISOQAR

UKAS

Università di Corsica
Pasquale Paoli

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

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« This reflects only the author's view and IMI2 JU is not responsible for any use that may be made of the information it contains »

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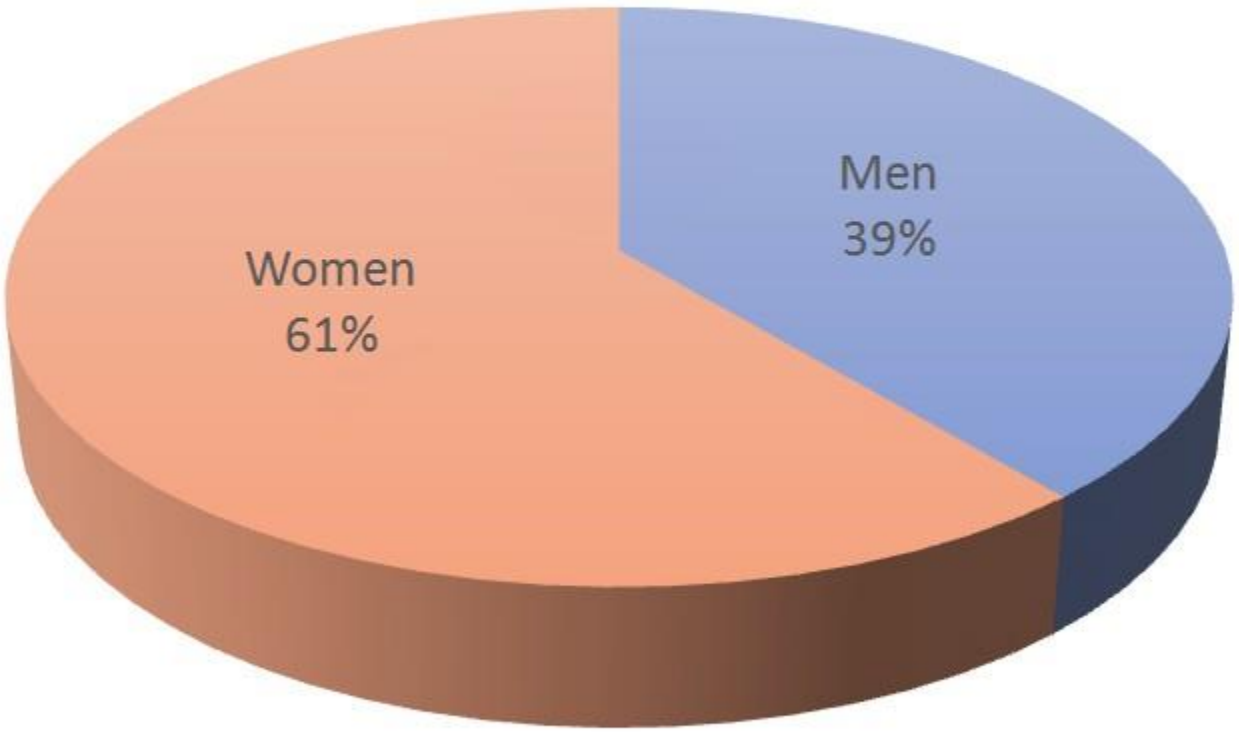
GENDER

- BGR/BG involve 100% of men (3)
- AMU involve 60% of women (3) and 40% of men (2)
- INMI involve 87,5% of women (7) and 12,5% men (1).
- UCPP involve 50% of women (1) and 50% of men (1)



KRONO

Evaluation of *a* production ready portable,, point-of-need platform {instrument and reagents).direct from nasal swab test for the moleculardiagnostic detection of COVI0-19 infection

Ongoing | IMI2 | Respiratory diseases, Infectious diseases, Coronaviruses, Diagnostics

Summary

Currently, COVI0 - 19diagnostic tests need to be processed by an expert in *a* laboratory, and patients often have to wait at least a day for their results. The KRONO project aims to change that by defivering *a* simple test that can *be* used at *a* doctor office or *a* patient s home (for example) and would deliverresults injust 40 minutes..

lhe diagnostickit is based on novel technology that can work with unprocessed samples *ol* bJood, saliva, or nose or throat swabs and can be operated by *anyone* with basic training in how to use the device. The software is based on algorithms trained on actual d inkal data, and allow'S users to easily interpret the results.

While the team is focusing ts efforts on the current C O V 119 outbreak. they also plan to ensure *the* system can *be* easily adapted to future outbreaks of new diseases in humans as well as animais..

Achievements & News

A rapid ÔfiiiQIaostic test 'pipeline' b cwrent and futwe patlooga is

October 2020

KRONOs COVIcr 19 test technologywill make the world more prepared for new threats to human,animal and *even* plant health

Participants

9 Show participants on map

Universities, research organisations, public bodies, non-profit groups

- lstituto Nazionale Per Le Malattie Infettive Lazzaro Spallanzani-lstituto Di RicOlfero ECura A *Carattere* Scientilico, Rome, Italy
- Universite DAix Marseille,, Marseille, France
- Universite De *Corse* Pascal Paoli, Corte, France

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- 8 G Research LTD, Kimbolton. United Kingdom
- Biogene LTO, Kimbolton. United Kingdom

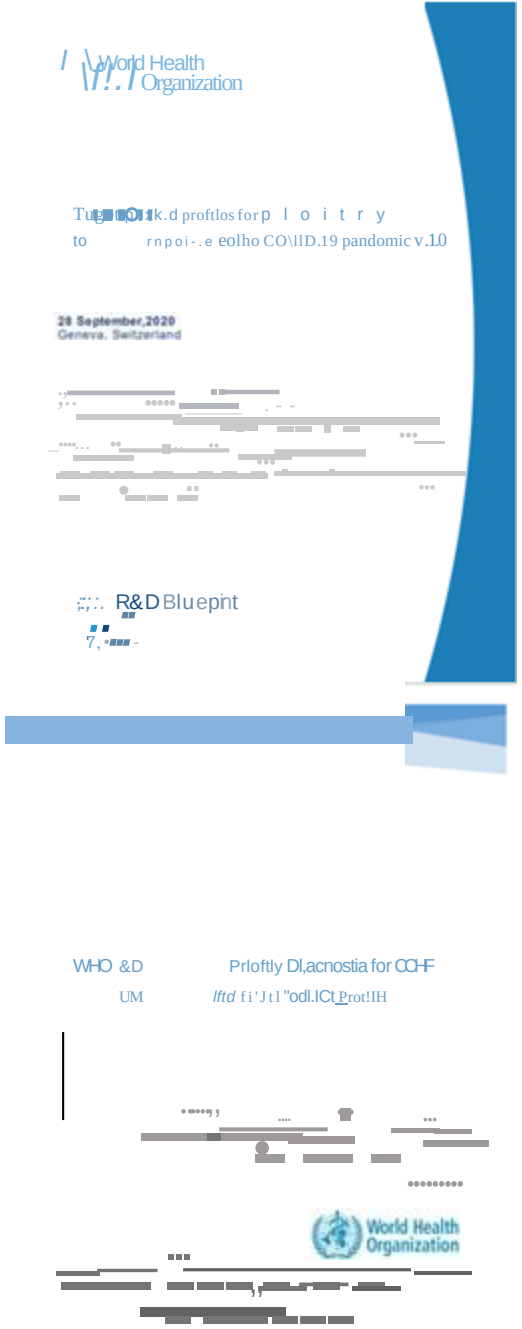
FACTS & FIGURES

Start *Date*	01/09/202()
End *Date*	31/1212021
Cali	IM12Call 21
Grant agreement number	101005075

Type of Action:
RIA(Research and Innovation Action)

Contributions	€
IMI Funding	784470
Other	1035494
ToealCOst	1819964

Project
Rémi Charrel
Universite DAix Marseille



KRONO KEY OBJECTIVES

- Meet the WHO R&D blueprint TPP of 10,000 virions/ml detection for simple to use, low cost tests for use in the developing world
- Ability to deploy tests for use without lab access in remote regions and used by anyone with simple training
- Drive the cost of goods to the point that assays can be sold at the price point of lateral flow but with sensitivity of molecular
- Advancement of the portable detection system from the existing lab based technology demonstrator to a portable validated production unit ready to be manufactured at scale to impact on bath the current pandemic and future outbreaks of emergent disease
- Development and validation of the SARS-CoV-2 assay, including internal positive control - latterly becoming a Duoplex test.
- Demonstration of rapid development and scaling to production of the lyophilised assays, including enzyme production, reagent and lyophilisation development

Bio

BGR

QuR ID· F

Application Areas

Ports of Entry and Travel

Proactive Pandemic Preparedness

Screening of Soldiers and FOBs

Border Control and Immigration

Humanitarian Efforts and Aid

Triaging and Treatment

Major Events (e.g. Sporting, Religious and Political)

Deployment in Local GP Surgeries and Care Homes

Containment and Quarantine

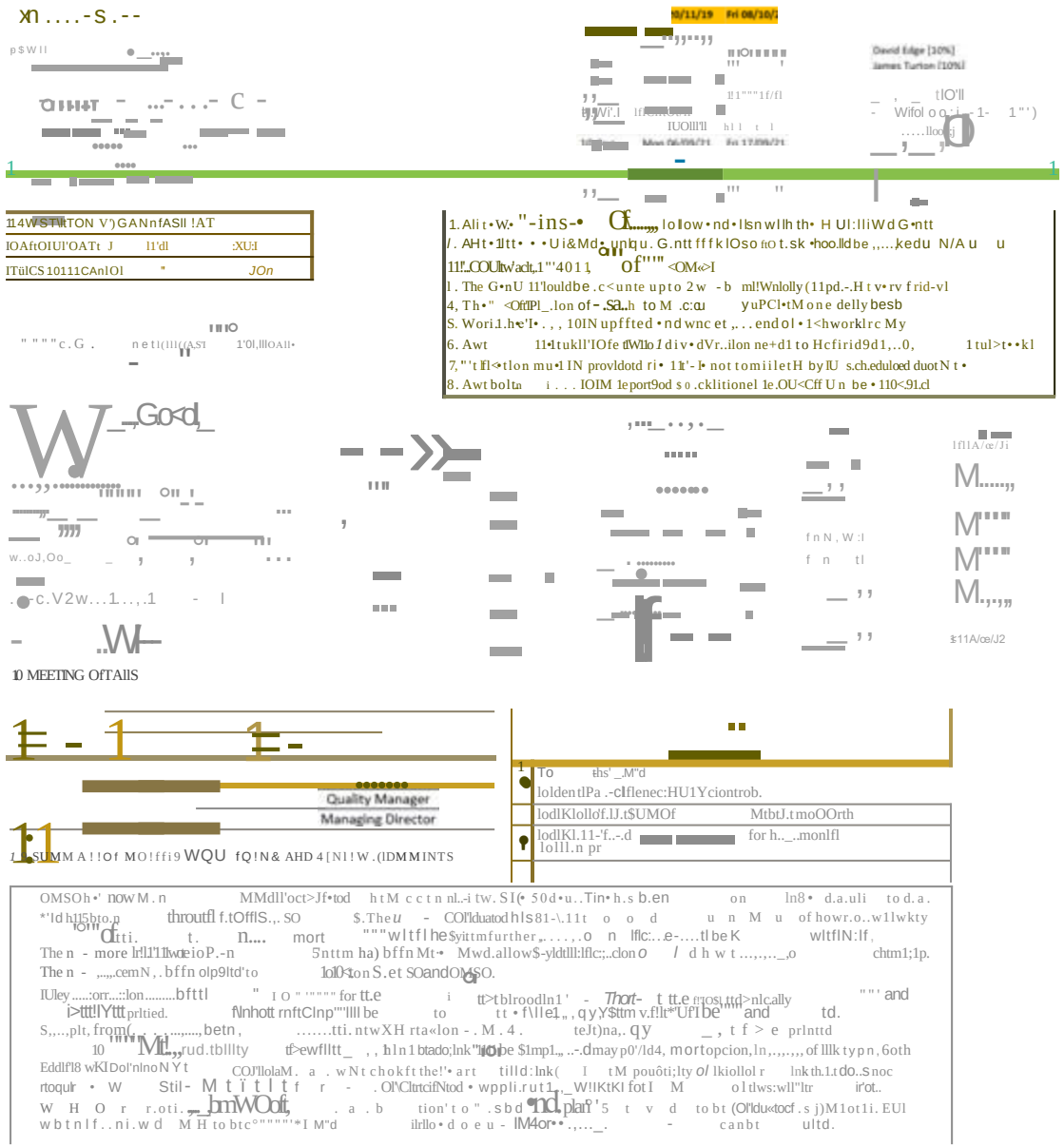
Biosecurity and Biowarfare

[redacted]rinary

Homeland Security

PLANNING AND PROJECT MANAGEMENT

- The ISO 13485 QMS gives BG Research a strategic capability in planning and management of projects
- Each project has its own dedicated Design and Development Plan (DDP) where key milestone deliverables and required resources are documented
- A master project Gantt is used to ensure tasks are clearly defined, assigned and completed within specified time frames
- The Gantt is updated on an ongoing basis and a weekly forecast issued each week (forecasted tasks integrated into assigned personnel's daily worksheets)
- Monthly documented team meetings (biology, mechanical and quality) are scheduled at the end of each month (used to summarise work, identify any bottlenecks/risks and plan objectives)

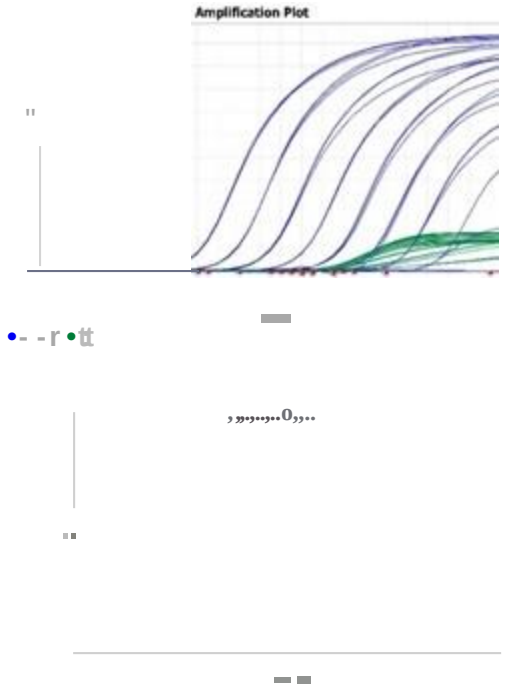


First batch of reagents Experiments to compare BGR reagents vs Altn. A. H.

{by using SARS-CoV-2 extracted RNA)

Aitona

	et
10A7 cp/reaction	15.129
10A7 cp/reaction	15.012
10A6 cp/reaction	18.410
10A6 cp/reaction	18 373
10A6 cp/reaction	18.492
10A5 cp/reaction	21.783
10A5 cp/reaction	21.659
10A5 cp/reaction	21.778
10A4 cp/reaction	25 095
10A4 cp/reaction	25.032
10A4 cp/reaction	25.106
10A3 cp/reaction	28.481
10A3 cp/reaction	28.397
10A3 cp/reaction	28.318
10A2 cp/reaction	32.421
10A2 cp/reaction	31.925
10A2 cp/reaction	31.745
10 cp/reaction	35.183
10 cp/reaction	35.153
10 cp/reaction	35.182
1 cp/reaction	38.857
1 cp/reaction	Undetermined
1 cp/reaction	38.910
neg	Undetermined
neg	Undetermined
neg	Undetermined

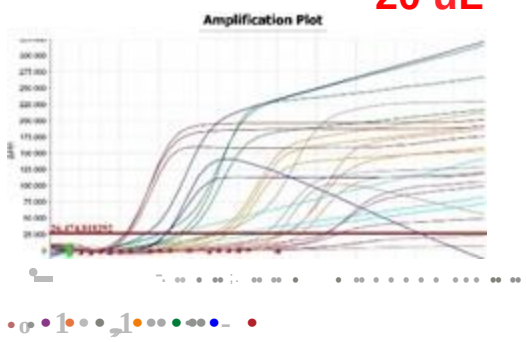


Slope = -3,378
Efficiency = 97,716

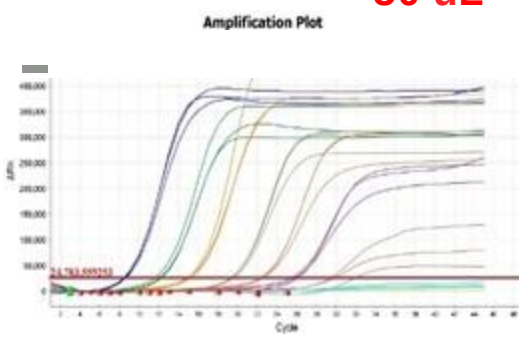
BGR (First batch of reagents)

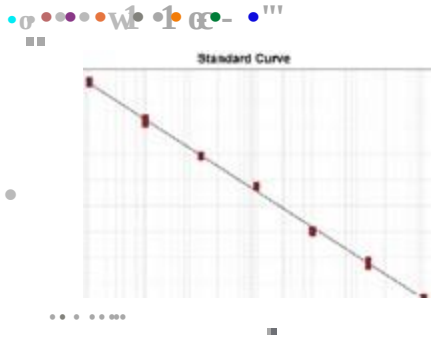
	20 ul et	50 ul et
10A7 cp/reaction	8,585	8,611
10A7 cp/reaction	8,955	8,525
10A6 cp/reaction	10,775	12,220
10A6 cp/reaction	12,785	11,551
10A6 cp/reaction	12,802	12,020
10AS cp/reaction	12,271	14,853
10AS cp/reaction	14,705	15,192
10AS cp/reaction	14,094	14,955
10A4 cp/reaction	19,109	19,535
10A4 cp/reaction	17,418	19,256
10A4 cp/reaction	18,135	19,286
10A3 cp/reaction	22,788	22,393
10A3 cp/reaction	24,049	22,462
10A3 cp/reaction	17,898	22,239
10A2 cp/reaction	26,486	25,772
10A2 cp/reaction	24,727	26,031
10A2 cp/reaction	24,993	25,358
10 cp/reaction	29,082	29,293
10 cp/reaction	28,749	31,755
10 cp/reaction	30,352	29,689
1 cp/reaction	Undetermined	Undetermined
1 cp/reaction	Undetermined	Undetermined
1 cp/reaction	Undetermined	Undetermined
neg	22,875	Undetermined
neg	13,748	Undetermined
neg	19,581	Undetermined

20 uL



50 uL





With BGR: Detection up to 10 cp/reaction
Best final reaction volume is 50 ul