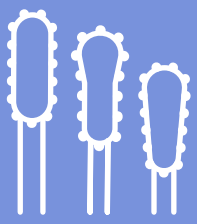
Scientific Booklet

Sars-CoV-2



Copan

innovating together

Acknowledgments:

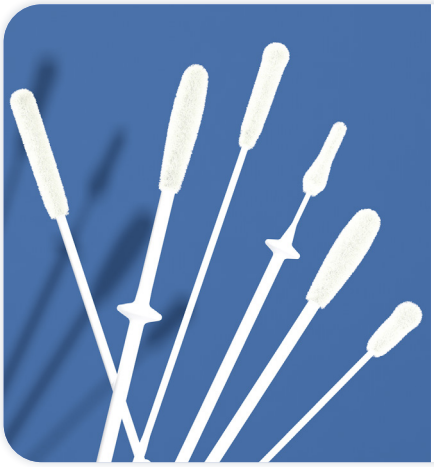
We would like to express our gratitude to the authors whose works have been arranged in this booklet: their insights and expertise greatly assisted this prime selection.
Secondly, we would like to thank all the experts throughout the world for the trust placed in our products in this emergency. Their esteem is the best acknowledgment ever.

We are dedicated to developing and providing high quality and cutting-edge biological sample collection products for human genomics, infectious diseases, environmental and forensic applications, along with automated workflow solutions. Copan's innovative approach enables an ever-expanding community of laboratories, scientists and institutions to benefit from an accessible sample collection that guarantees reliable quality performance.
Our goal is to continue this innovation by providing products, customized services, and prime solutions to improve patients' health and wellness.
Following the first reports of COVID-19 by China in December 2019, more than 121 millions of cases and 2 milions deaths have been reported globally, by March 2021. SARS-CoV-2, the virus responsible for the disease which has been declared a pandemic by the World Health Organization (WHO) on 11th March 2020, is the third coronavirus to cross species from animals to humans and cause a severe respiratory disease after SARS-CoV in 2003 MERS-CoV in 2012. Symptoms of SARS-CoV-2 infection vary in severity from mild flu-like upper respiratory symptoms to severe progressive respiratory failure, which requires intensive care and can lead to death. Asymptomatic individuals, representing a significant public health threat due to their unaware infectiousness, have also been reported.
It is clear how appropriate testing protocols are then crucial to track the spread of SARS-CoV-2 and to apply interventions as quarantine and clinical management of sick individuals. Thus, an accurate detection of the virus through respiratory sampling is the first essential step of this important diagnostic challenge.
Our products, specifically designed for the collection and transport of viruses and other micro-organisms, **have been approved by the WHO and the CDC for the sample collection from suspected cases of coronavirus disease**. In this booklet, you'll find a selection of the most interesting independent studies where these products are used in the screening and the control of the SARS-CoV-2 pandemic.

A patented technology

Why so special?

Copan conceived the FLOQ® technology in 2003, to answer the need of healthcare professionals for a more efficient sample collection. The main feature of this technology is the perpendicular arrangement of the short Nylon® fibers.



FLOQSwabs®

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UTM®

Universal Transport Medium™ is designed for the collection, transport, maintenance, and preservation of Viruses, such as SARS-CoV-2. Stable at room temperature, UTM® has been used successfully for Rapid Antigen Testing, DFA, Viral Culture, and for the primary Molecular-based Assays.

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We specifically designed eNAT®, our nucleic acid collection and preservation system, to stabilize and preserve microbial and human nucleic acids for applications such as pathogen detection, predictive genetics, pharmacogenomics, HLA typing, and microbiome analysis. With its lysis and inactivation features, eNAT® is the ready-to-use device to quickly inactivation your sample, for a high-quality and unbiased nucleic acid yield and fast turnaround time from the sample to the response.

eSwab®

The Liquid Amies-based multipurpose collection and transport system. Its formulation maintains the viability of aerobic, anaerobic, and fastidious bacteria and Chlamydia for up to 48 hours at room and refrigerator temperature. eSwab® is suitable for numerous downstream applications as gram stains, traditional culture, and molecular assays.

SL Solution™

Our SL Solution™ is the answer to the sputum processing problem, as its mucolytic activity rapidly liquefies sputum without affecting the vitality of bacteria and fungi. Easy and ready-to-use, SL Solution™ is suitable for manual use and automatic processing with WASP®

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An In-Well Direct Lysis Method for Rapid Detection of SARS-CoV-2 by Real Time RT-PCR in eSwab® Specimens

Rikke Lind Jørgensen et al.

J Virol Methods. 2021 Mar;289:114062

X

Genome Res. 2020 Dec; 30(12): 1781–1788

SARS-CoV-2

Sequencing Identifies Multiple Early Introductions of SARS-CoV-2 to the New York City Region

Matthew T. Maurano[1], Sitharam Ramaswami, Paul Zappile, Dacia Dimartino, Ludovic Boytard, Andre M Ribeiro-dos-Santos, Nicholas A Vulpescu, Gael Westby, Guomiao Shen, Xiaojun Feng, Megan S Hogan, Manon Ragonnet-Cronin[2], Lily Geidelberg[2], Christian Marier, Peter Mey, Yutong Zhang, John Cadley, Raquel Ordonez, Raven Luther, Emily Huang, Emily Guzman, Carolina Arguelles-Grande1, Kimon V. Argyropoulos, Margaret Black, Antonio Serrano, Melissa E. Call[1], Min Jae Kim[1], Brendan Belovarac, Tatyana Gindin, Andrew Lytle, Jared Pinnell, Theodore Vougiouklakis, John Chen, Lawrence H. Lin, Amy Rapkiewicz, Vanessa Raabe, Marie I. Samanovic, George Jour, Iman Osman, Maria Aguero-Rosenfeld, Mark J. Mulligan, Erik M. Volz2, Paolo Cotzia, Matija Snuderl, Adriana Heguy
Affiliation:[1] NYU School of Medicine, [2]MRC Centre for Global Infectious Disease Analysis and Department of Infectious Disease Epidemiology, Imperial College London

Keywords

UTM®	Viral Sequencing	Surveillance	Outbreak

Abstract

Effective public response to a pandemic relies upon accurate measurement of the extent and dynamics of an outbreak. Viral genome sequencing has emerged as a powerful approach to link seemingly unrelated cases, and large-scale sequencing surveillance can inform on critical epidemiological parameters. Here, we report the analysis of 864 SARS-CoV-2 sequences from cases in the New York City metropolitan area during the COVID-19 outbreak in spring 2020. The majority of cases had no recent travel history or known exposure, and genetically linked cases were spread throughout the region. Comparison to global viral sequences showed that early transmission was most linked to cases from Europe. Our data are consistent with numerous seeds from multiple sources and a prolonged period of unrecognized community spreading. This work highlights the complementary role of genomic surveillance in addition to traditional epidemiological indicators.

J Clin Microbiol. 2020 May 26;58(6):e00599-20

SARS-CoV-2

Clinical Evaluation of the Cobas SARS-CoV-2 Test and a Diagnostic Platform Switch during 48 Hours in the Midst of the COVID-19 Pandemic

Mario Poljak, Miša Korva, Nataša Knap Gašper, Kristina Fujs Komloš, Martin Sagadin, Tina Uršic, Tatjana Avšic Županc, Miroslav Petrovec
Affiliation:Institute of Microbiology and Immunology, Faculty of Medicine, University of Ljubljana, Ljubljana, Slovenia

Keywords

UTM®	Comparison	Diagnostics	FDA

Abstract

Laboratories are currently witnessing extraordinary demand globally for sampling devices, reagents, consumables, and diagnostic instruments needed for timely diagnosis of SARS-CoV-2 infection. To meet diagnostic needs as the pandemic grows, the U.S. Food and Drug Administration (FDA) recently granted several commercial SARS-CoV-2 tests Emergency Use Authorization (EUA), but manufacturer-independent evaluation data are scarce. Poljak et al. performed the first manufacturer-independent evaluation of the fully automated sample-to-result two-target test cobas 6800 SARS-CoV-2 (cobas), which received U.S. FDA EUA on 12 March 2020. The comparator was a standardized 3 hours SARS-CoV-2 protocol, consisting of RNA extraction using an automated portable instrument, followed by a two-target reverse transcription real-time PCR (RT-PCR). Cobas and the comparator showed an overall agreement of 98.1% and a kappa value of 0.95 on an in-house validation panel consisting of 217 well-characterized retrospective samples. The immediate perspective head-to-head comparative evaluation followed on 502 samples, and the diagnostic approaches showed an overall agreement of 99.6% and a kappa value of 0.98. A good correlation (r2 = 0.96) between cycle threshold values for SARS-CoV-2-specific targets obtained by cobas and the comparator was observed. These results showed that cobas is a reliable assay for the qualitative detection of SARS-CoV-2 in nasopharyngeal swab samples collected in the Universal Transport Medium System (UTM®) (Copan, Brescia, Italy). Under the extraordinary circumstances that laboratories are facing worldwide, a safe diagnostic platform switch is feasible in only 48 hours in the midst of the COVID-19 pandemic if carefully planned and executed.

SARS-CoV-2

Weak Association of Coinfection by SARS-CoV-2 and other Respiratory Viruses with Severe Cases and Death

Larissa Fernandes-Matano[1], Irma Eloisa Monroy-Muñoz[2], Luis Antonio Uribe-Noguez[3], María de los Angeles Hernández-Cueto[4], Brenda Sarquiz-Martínez[4], Héctor Daniel Pardav&eacute-Alejandre[4], Andrea Santos Coy-Arechavaleta[4], Julio Elias Alvarado-Yaah[4], Teresita Rojas-Mendoza[4], Clara Esperanza Santacruz-Tinoco[1], Concepción Grajales-Muñiz[5], Víctor Hugo Borja-Aburto[6], José Esteban Muñoz-Medina[1]
Affiliation: [1] División de Laboratorios de Vigilancia e Investigación Epidemiológica. Instituto Mexicano del Seguro Social, [2]Laboratorio de Genómica, Departamento de Genética y Genómica Humana, Instituto Nacional de Perinatología, Isidro Espinosa de los Reyes, [3]Laboratorio Central de Epidemiología, Instituto Mexicano del Seguro Social, [4]Laboratorio Central de Epidemiología, Instituto Mexicano del Seguro Social, [5]Coordinación de Control Técnico de Insumos, Instituto Mexicano del Seguro Social, [6]Dirección de Prestaciones Médicas, Instituto Mexicano del Seguro Social

Keywords

UTM®	Respiratory Viruses	Coinfection	Severe Cases

Abstract

COVID-19 ranges from asymptomatic to severe respiratory disease with multiorgan failure. Most severe cases of SARS-CoV-2 infections are associated with some comorbidities and old age. However, there are patients without those risk factors who still develop severe disease.
This study examines the presence of other respiratory viruses in Mexican positive cases of COVID-19, to determine if any coinfections were correlated with more severe manifestations of the disease. Analyzing with RT-qPCR 103 COVID-19 cases for the presence of 16 other respiratory viruses, the study found that of the 14 found cases of Coinfection, 92% never required hospitalization, even in advanced age patients. These results suggest that the Coinfection is not related to more severe COVID-19 symptoms. Moreover, depending on the virus involved, a coinfection status could even lead to a better prognosis.

Table 3a

Symptom	Total N=103 n(%)	Coinfection N=14 (%)	Single Infection by SARS-CoV-2 N=89 n(%)
Cough	87 (84.5)	11 (78.6)	76 (85.4)
Fever	84 (81.6)	12 (86.7)	72 (80.9)
Headache	84 (81.6)	12 (85.7)	72 (80.9)

Myalgias	72 (69.9)	11 (78.9)	61 (68.5)
Arthralgias	65 (63.1)	9 (64.3)	56 (62.9)
Odynophagia	57 (55.3)	8 (57.1)	49 (55.1)
Chills	55 (53.4)	10 (71.4)	45 (50.6)
Rhinorrhoea	51 (49.5)	10 (71.4)	42 (46.1)
Chest Pain	40 (38.8)	5 (35.7)	35 (39.3)
Dyspnoea	30 (29.1)	2 (14.3)	28 (31.5)
Diarrohea	23 (22.3)	6 (42.9)*	17 (19.1)
Abdominal Pain	22 (21.4)	3 (21.4)	19 (21.3)
Conjunctivitis	13 (12.6)	3 (21.4)	10 (11.2)
Adynamia	11 (10.7)	2 (14.3)	9 (10.1)
Coryza	6 (5.8)	2 (14.3)	4 (4.5)
Cyanosis	5 (4.9)	0 (0.00)	5 (5.6)
Polypnea	5 (4.9)	0 (0.00)	5 (5.6)
Dysphonia	0 (0.00)	0 (0.00)	0 (0.00)
Nasal Congestion	0 (0.00)	0 (0.00)	0 (0.00)
Low Back Pain	0 (0.00)	0 (0.00)	0 (0.00)

Table 4a

Symptom	Total N=103 n(%)	Coinfection N=14 (%)	Single Infection by SARS-CoV-2 N=89 n(%)
Obesity	21 (20.4)	4 (28.6)	17 (19.1)
Hypertension	19 (18.4)	4 (28.6)	15 (16.9)
Diabetes	16 (15.5)	3 (21.4)	13 (14.6)
Asthma	5 (4.9)	0 (0.00)	5 (5.6)
COPD	5 (4.9)	0 (0.00)	5 (5.6)
Chronic Kidney Disease	2 (1.9)	0 (0.00)	2 (2.2)
Chronic Liver Disease	0 (0.00)	0 (0.00)	0 (0.00)
Haemolytic Anaemia	0 (0.00)	0 (0.00)	0 (0.00)

N: total analysed samples; n: identified samples. * P<0.05.
a:The numbering of the tables has been taken from the original article

Clin Microbiol Infect. 2021 Feb;27(2):285.e1-285.e4

SARS-CoV-2

Saliva Sample as a Non-Invasive Specimen for the Diagnosis of Coronavirus Disease 2019: a Cross-Sectional Study

E. Pasomsub[1], S.P. Watcharananan[2], K. Boonyawat[2], P. Janchompoo[1], G. Wongtabtim[1], W. Suksuwan[2], S. Sungkanuparph[3], A. Phuphuakrat[2]
Affiliation:[1] Department of Pathology, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand [2]Department of Medicine, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand [3]Chakri Naruebodindra Medical Institute, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Samut Prakan, Thailand

Keywords

UTM®	Saliva	Non-Invasive	Patients

Abstract

Objectives: Amid the increasing number of pandemic coronavirus disease 2019 (COVID-19) cases, there is a need for a quick and easy method to obtain a non-invasive sample for the detection of this novel coronavirus (severe acute respiratory syndrome coronavirus 2; SARS-CoV-2). We aimed to investigate the potential use of saliva samples as a non-invasive tool for the diagnosis of COVID-19.
Methods: From 27 March to 4 April 2020, we prospectively collected saliva samples and a standard nasopharyngeal and throat swab in persons seeking care at an acute respiratory infection clinic in a university hospital during the outbreak of COVID-19. Real-time polymerase chain reaction (RT-PCR) was performed, and the results of the two specimens were compared.
Results: Two-hundred pairs of samples were collected. Sixty-nine (34.5%) individuals were male, and the median (interquartile) age was 36 (28-48) years. Using nasopharyngeal and throat swab RT-PCR as the reference standard, the prevalence of COVID-19 diagnosed by nasopharyngeal and throat swab RT-PCR was 9.5%. The sensitivity and specificity of the saliva sample RT-PCR were 84.2% (95% CI 60.4%-96.6%), and 98.9% (95% CI 96.1%-99.9%), respectively. An analysis of the agreement between the two specimens demonstrated 97.5% observed agreement (κ coefficient 0.851, 95% CI 0.723-0.979; $p < 0.001$).
Conclusions: Saliva might be an alternative specimen for the diagnosis of COVID-19. The collection is non-invasive, and non-aerosol generating. This method could facilitate the diagnosis of the disease, given the simplicity of specimen collection and good diagnostic performance.

J Korean Med Sci. 2020 Feb 24;35(7):e84

SARS-CoV-2

Virus Isolation from the First Patient with SARS-CoV-2 in Korea

Wan Beom Park[1,2] Nak-Jung Kwon[3] Su-Jin Choi[2] Chang Kyung Kang[1] Pyoeng Gyun Choe[1] Jin Yong Kim[4] Jiyoung Yun[3] Gir-Won Lee[3] Moon-Woo Seong[5] Nam Joong Kim[1,2] Jeong-Sun Seo[3,6] and Myoung-don Oh[1,2]
Affiliation:[1] Department of Internal Medicine, Seoul National University College of Medicine, Seoul, Korea. [2]Laboratory of Infection & Immunity, Seoul National University Hospital Biomedical Research Institute, Seoul, Korea. [3]Macrogen Inc., Seoul, Korea. [4]Department of Internal Medicine, Incheon Medical Center, Incheon, Korea. [5]Department of Laboratory Medicine, Seoul National University College of Medicine, Seoul, Korea. [6]Precision Medicine Center, Seoul National University Bundang Hospital, Seongnam, Korea.

Keywords

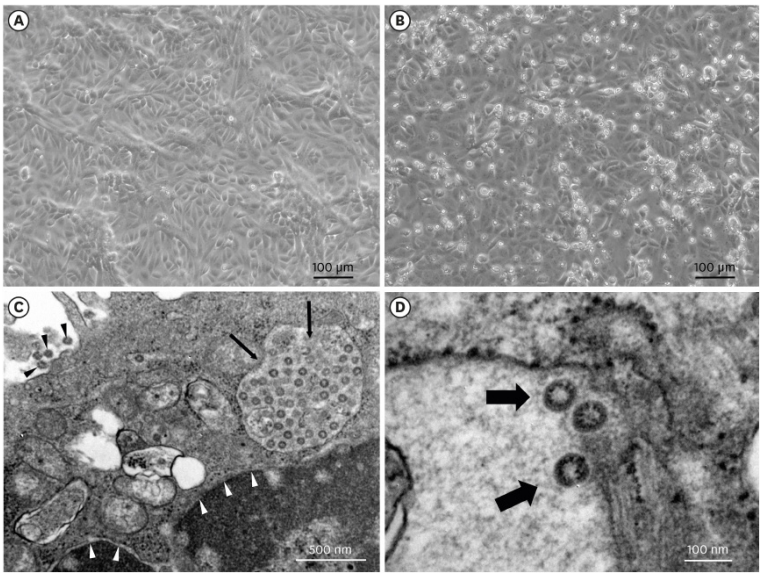
UTM®	Electron Microscopy	Viral Culture	First Patient

Abstract

The researchers isolated here SARS-CoV-2 from the oropharyngeal sample obtained from the patient with the first laboratory-confirmed SARS-CoV-2 infection in Korea. Cytopathic effects of SARS-CoV-2 in the Vero cell cultures were confluent three days after the first blind passage of the sample. This paper was one of the first to confirm the spherical shape of the virus, with a fringe reminiscent of a crown on transmission electron microscopy. Phylogenetic analyses of whole-genome sequences showed that it clustered with other SARS-CoV-2 reported from Wuhan.

Image

Cytopathic effects of SARS-CoV-2 in Vero cell cultures and electron microscopy image of SARS-CoV-2. Vero cells were inoculated with oropharyngeal swab sample.
(A) Vero cell cultures in negative control.
(B) Cytopathic effects consisting of rounding and detachment of cells in Vero cell cultures 3 days after the first blind passage.
(C, D) Transmission electron microscopy image of Vero cells infected with SARS-CoV-2. White arrow head denotes nuclear membrane, black arrow head extracellular virus particles, and thin black arrow cytoplasmic vesicle including virus components (C). Thick black arrow denotes magnified virus particles with crown-like spikes (D).
SARS = severe acute respiratory syndrome, CoV = coronavirus.



J Clin Microbiol. 2020 May 26;58(6):e00669-20

SARS-CoV-2

Comparison of Copan eSwab® and FLOQSwabs® for COVID-19 Diagnosis: Working around a Supply Shortage

Christie Vermeiren[1,2], Xavier Marchand-Senécal[3], Elena Sheldrake[1], David Bulir[4,5], Marek Smieja[4,5], Sylvia Chong5, Jessica D. Forbes[2] and Kevin Katz[1,2,3]
Affiliation: [1]Shared Hospital Laboratory, Toronto, Ontario, Canada [2]Department of Laboratory Medicine and Pathobiology, University of Toronto, Toronto, Ontario, Canada [3]Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada [4]Department of Pathology and Molecular Medicine, McMaster University, Hamilton, Ontario, Canada [5]Research Institute of St. Joe's Hamilton, Hamilton, Ontario, Canada

Keywords

UTM®	eSwab®	Transport	Collection

Abstract

A proper COVID-19 screening strategy relies on the availability of appropriate and validated collection and transport systems, to ensure the preservation of nucleic acids and the compatibility with downstream molecular testing. Vermeiren et al. investigate, using two downstream molecular testing methods (BD Max and Rotor-gene), the eSwab® collection device as a suitable alternative to the Universal Transport System™ (UTM®) for the collection and transport of COVID-19 specimens, to enhance global testing capacity. Sampling with both collection systems 94 COVID-19 patients across five hospitals, the positive percent agreement, negative percent agreement, and Cohen's kappa values were 100% (95% confidence interval [CI], 0.900 to 1.000), 100% (95% CI, 0.939 to 1.000), and 1.00 on the BD Max platform and 97.1% (95% CI, 0.847 to 0.999), 100% (95% CI, 0.939 to 1.000), and 0.98, on the Rotor-gene system. This work demonstrates that the eSwab® collection device is a suitable alternative to the UTM® collection system in the context of an international swab shortage.

Nature. 2020 Aug;584(7821):425-429

SARS-CoV-2

Suppression of a SARS-CoV-2 Outbreak in the Italian Municipality of Vo'

Enrico Lavezzo, Elisa Franchin, Constanze Ciavarella, Gina Cuomo-Dannenburg, Luisa Barzon, Claudia Del Vecchio, Lucia Rossi, Riccardo Manganelli, Arianna Loregian, Nicolò Navarin, Davide Abate, Manuela Sciro, Stefano Merigliano, Ettore De Canale, Maria Cristina Vanuzzo, Valeria Besutti, Francesca Saluzzo, Francesco Onelia, Monia Pacenti, Saverio G. Parisi, Giovanni Carretta, Daniele Donato, Luciano Flor, Silvia Cocchio, Giulia Masi, Alessandro Sperduti, Lorenzo Cattarino, Renato Salvador, Michele Nicoletti, Federico Caldart, Gioele Castelli, Eleonora Nieddu, Beatrice Labella, Ludovico Fava, Matteo Drigo, Katy A. M. Gaythorpe, Imperial College COVID-19 Response Team, Alessandra R. Brazzale, Stefano Toppo, Marta Trevisan, Vincenzo Baldo, Christl A. Donnelly, Neil M. Ferguson, Ilaria Dorigatti & Andrea Crisanti
Affiliation: University of Padova, Padua, Italy and Azienda Ospedale Padova, Padua, Italy with MRC Centre for Global Infectious Disease Analysis, Imperial College London, London, UK

Keywords

eSwab®	Asymptomatic	Public Health	Outbreak

Abstract

On 21 February 2020, a resident of the municipality of Vo', a small town near Padua (Italy), died of pneumonia due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection1. This was the first coronavirus disease 19 (COVID-19)-related death detected in Italy since the detection of SARS-CoV-2 in the Chinese city of Wuhan, Hubei province2. In response, the regional authorities imposed the lockdown of the whole municipality for 14 days3. Here we collected information on the demography, clinical presentation, hospitalization, contact network and the presence of SARS-CoV-2 infection in nasopharyngeal swabs for 85.9% and 71.5% of the population of Vo' at two consecutive time points. From the first survey, which was conducted around the time the town lockdown started, we found a prevalence of infection of 2.6% (95% confidence interval (CI): 2.1-3.3%). From the second survey, which was conducted at the end of the lockdown, we found a prevalence of 1.2% (95% CI: 0.8-1.8%). Notably, 42.5% (95% CI: 31.5-54.6%) of the confirmed SARS-CoV-2 infections detected across the two surveys were asymptomatic (that is, did not have symptoms at the time of swab testing and did not develop symptoms afterwards). The mean serial interval was 7.2 days (95% CI: 5.9-9.6). We found no statistically significant difference in the viral load of symptomatic versus asymptomatic infections (P = 0.62 and 0.74 for E and RdRp genes, respectively, exact Wilcoxon-Mann-Whitney test). This study sheds light on the frequency of asymptomatic SARS-CoV-2 infection, their infectivity (as measured by the viral load) and provides insights into its transmission dynamics and the efficacy of the implemented control measures.

PLoS One. 2020 Aug 5;15(8):e0237127

SARS-CoV-2

SARS-CoV-2 Detection in Setting of Viral Swabs Scarcity: Are MRSA Swabs and Viral Swabs Equivalent?

Daniel G. Federman, Shaili Gupta, Gary Stack, Sheldon M. Campbell, David R. Peaper, Louise M. Dembry, Ann Fisher, Asim F. Tarabar, Michael Kozal, Christopher B. Ruser
Affiliation: VA Connecticut Healthcare System, West Haven, CT, United States of America, Yale University School of Medicine, New Haven, CT, United States of America

Keywords

UTM®	eSwab®	Viral Transport Medium	Comparison

Abstract

Background: The global pandemic of Severe Acute Respiratory Syndrome-Related Coronavirus 2 (SARS-CoV2) has resulted in unprecedented challenges for healthcare systems. One barrier to widespread testing has been a paucity of traditional respiratory viral swab collection kits relative to the demand. Whether other sample collection kits, such as widely available MRSA nasal swabs can be used to detect SARS-CoV-2 is unknown.
Methods: We compared simultaneous nasal MRSA swabs (COPAN eSwabs® 480C flocked nasal swab in 1mL of liquid Amies medium) and virals wabs (BD H192(07) flexible mini-tip flocked nasopharyngeal swabs in 3mL Universal Transport Medium) for SARS-CoV-2 PCR testing using Simplexa COVID-19 Direct assay on patients over a 4-day period. When the results were discordant, the viral swab sample was run again on the Cepheid Xpert Xpress® SARS-CoV-2 assay.
Results: Of the 81 included samples, there were 19 positives and 62 negatives in viral media and 18 positives and 63 negative in the MRSA swabs. Amongst all included samples, there was concordance between the COPAN eSwabs® 480C and the viral swabs in 78 (96.3%).
Conclusion: We found a high rate of concordance in test results between COPAN eSwabs® 480C in Amies solution and BD H192(07) nasopharyngeal swabs in in 3 mL of Universal Viral Transport medium viral media. Clinicians and laboratories should feel better informed and assured using COPAN eSwabs® 480C to help in the diagnosis of COVID-19.

Figure 1

		MRSA Swabs		
		+	-	Total
Viral Swab	+	17	2	19
	-	1	61	62
	Total	18	63	81

Clin Infect Dis. 2020 Nov 3;ciaa1693

SARS-CoV-2

SARS-CoV-2 Infections Among Children in the Biospecimens from Respiratory Virus-Exposed Kids (BRAVE Kids) Study

Jillian H. Hurst[1], Sarah M. Heston[2], Hailey N. Chambers[1], Hannah M. Cunningham[1], Meghan J. Price[1], Lilianna Suarez[1], Carter Crew[2], Shree Bose[1], Jhoanna N. Aquino[2], Stuart T. Carr[2], S. Michelle Griffin[2], Stephanie H. Smith[2], Kirsten Jenkins[2], Trevor S. Pfeiffer[2], Javier Rodriguez[2], C. Todd Demarco[3], Nicole A. De Naeyer[3], Thaddeus C. Gurley[3], Raul Louzao[3], Coleen K. Cunningham[1], William J. Steinbach[1], Thomas N. Denny[3], Debra J. Lugo[1], M. Anthony Moody[1], Sallie R. Perma[1], Alexandre T. Rotta[1], Nicholas A. Turner[1], Emmanuel B. Walter[1], Christopher W. Woods[1], Matthew S. Kelly[1]
Affiliation: [1]Duke University School of Medicine; [2] Duke University; [3] Duke Human Vaccine Institute

Keywords

FLOQSwabs®	Children	Viral Load	Respiratory

Abstract

Background: Children with SARS-CoV-2 infection typically have mild symptoms that do not require medical attention, leaving a gap in our understanding of the spectrum of illnesses that the virus causes in children.
Methods: We conducted a prospective cohort study of children and adolescents (<21 years of age) with a SARS-CoV-2-infected close contact. We collected nasopharyngeal or nasal swabs at enrollment and tested for SARS-CoV-2 using a real-time PCR assay.
Results: Of 382 children, 293 (77%) were SARS-CoV-2-infected. SARS-CoV-2-infected children were more likely to be Hispanic (p<0.0001), less likely to have asthma (p=0.005), and more likely to have an infected sibling contact (p=0.001) than uninfected children. Children ages 6-13 years were frequently asymptomatic (39%) and had respiratory symptoms less often than younger children (29% vs. 48%; p=0.01) or adolescents (29% vs. 60%; p<0.0001). Compared to children ages 6-13 years, adolescents more frequently reported influenza-like (61% vs. 39%; p<0.0001), gastrointestinal (27% vs. 9%; p=0.002), and sensory symptoms (42% vs. 9%; p<0.0001), and had more prolonged illnesses [median (IQR) duration: 7 (4, 12) vs. 4 (3, 8) days; p=0.01]. Despite the age-related variability in symptoms, we found no differences in nasopharyngeal viral load by age or between symptomatic and asymptomatic children.
Conclusions: Hispanic ethnicity and an infected sibling close contact are associated with increased SARS-CoV-2 infection risk among children, while asthma is associated with decreased risk. Age-related differences in the clinical manifestations of SARS-CoV-2 infection must be considered when evaluating children for COVID-19 and in developing screening strategies for schools and childcare settings.

Clin Infect Dis. 2020 Nov 3;ciaa1693

SARS-CoV-2

Detection of SARS-CoV-2 on Hospital Surfaces

Cesira Pasquarella, Maria Eugenia Colucci, Assunta Bizzarro, Licia Veronesi, Paola Affanni, Tiziana Meschi, Ettore Brianti, Pietro Vitali, Roberto Albertini
Affiliation: University of Parma and University Hospital of Parma

Keywords

eNAT®	Transmission	Contamination	Surface

Abstract

The COVID-19 pandemic, affecting 213 countries, with more than 10 million cases and over 500,000 deaths is still causing serious health, social and economic emergency worldwide. Italian Northern regions are among the most badly affected areas. Surfaces represent matrices to which particular attention should be paid for prevention and control of SARS-CoV-2 transmission. A few studies have highlighted virus presence on surfaces. We report the evidence of its presence on hospital surfaces, in a single room hosting a patient whose nose-pharyngeal swab resulted positive for SARS-CoV-2 RNA at the admission. The surfaces sampling was carried out using pre-wetted swabs followed by extraction and amplification of viral RNA by reverse Real-Time Polymerase Chain Reaction (rRT-PCR). A total of 4/15 (26.66%) surfaces were positive for SARS-CoV-2 RNA: the right bed rail, the call button, the bed trapeze bar, the stethoscope; moreover, the patient's inner surgical mask was positive, showing the emission of the virus from the patient. This study is a further confirmation that the surfaces represent a potential vehicle of transmission. This supports the need for strict adherence to hand and environmental hygiene.

J Clin Microbiol. 2020 Jul 23;58(8):e00708-20

SARS-CoV-2

Evaluation of Transport Media and Specimen Transport Conditions for the Detection of SARS-CoV-2 by Use of Real-Time Reverse Transcription-PCR

Amy A. Rogers[1], Russell E. Baumann[1], Gwynngelle A. Borillo[1], Ron M. Kagan[1], Hollis J. Batterman[1], Marzena M. Galdzicka[2], Elizabeth M. Marlowe[1]
Affiliation: [1] Quest Diagnostics Infectious Disease, San Juan Capistrano, California, USA. [2] Quest Diagnostics, Marlborough, Massachusetts, USA

Keywords

UTM®	eSwab®	RNA Stability	Transport

Abstract

The global coronavirus (CoV) disease 2019 (COVID-19) pandemic has resulted in a worldwide shortage of viral transport media and raised questions about specimen stability. The objective of this study was to determine the stability of severe acute respiratory syndrome CoV 2 (SARS-CoV-2) RNA in specimen transport media under various storage conditions. Transport media tested included Copan UTM®, Copan UTM®-RT, Copan eSwab®, M4, and saline (0.9% NaCl). Specimen types tested included nasopharyngeal/ oropharyngeal swabs in the above-named transport media, bronchoalveolar lavage (BAL) fluid, and sputum. A high-titer SARS-CoV-2 remnant patient specimen was spiked into pooled SARS-CoV-2 RNA-negative specimen remnants for the various medium types. Aliquots of samples were stored at 18°C to 26°C, 2°C to 8°C, and 10°C to 30°C and then tested at time points up to 14 days. Specimens consistently yielded amplifiable RNA with mean cycle threshold differences of 3 over the various conditions assayed, thus supporting the use and transport of alternative collection media and specimen types under a variety of temperature storage conditions.

Emerg Infect Dis. 2020 Oct;26(10):2469-2472

SARS-CoV-2

Pooling Upper Respiratory Specimens for Rapid Mass Screening of COVID-19 by Real-Time RT-PCR

So Yeon Kim[1], Jaehyeon Lee[2], Heungsup Sung[3], Hyukmin Lee[4], Myung Guk Han[5], Cheon Kwon Yoo[5], Sang Won Lee[5], and Ki Ho Hon[6]
Affiliation:[1] National Medical Center, Seoul, South Korea. [2] Jeonbuk National University Medical School and Hospital, Jeonju, South Korea. [3] Asan Medical Center and University of Ulsan College of Medicine, Seoul. [4] Yonsei University College of Medicine, Seoul. [5] Korea Centers for Disease Control and Prevention, Cheongju. [6] Seoul Medical Center, Seoul

Keywords

eNAT®	Pooling Specimens	Rapid Mass Screening	PCR

Abstract

To validate the specimen-pooling strategy for real-time reverse transcription PCR detection of severe acute respiratory syndrome coronavirus 2, we generated different pools including positive specimens, reflecting the distribution of cycle threshold values at initial diagnosis. Cumulative sensitivities of tested pool sizes suggest pooling of <6 specimens for surveillance by this method.

Int J Environ Res Public Health. 2020 Nov 4;17(21):8142

SARS-CoV-2

COVID-19 Emergency Management: From the Reorganization of the Endoscopy Service to the Verification of the Reprocessing Efficacy

Beatrice Casini[1], Benedetta Tuvo[1], Fabrizio Maggi[1,2], Giuliana Del Magro[3], Alessandro Ribechini[4], Anna Laura Costa[1], Michele Totaro[1], Angelo Baggiani[1], Giulia Gemignani[5], Gaetano Privitera[1]
Affiliation: [1] Department of Translational Research, N.T.M.S., University of Pisa, 56126 Pisa, Italy. [2] Virology Division, University Hospital of Pisa, 56126 Pisa, Italy. [3] Endoscopy Service Division, University Hospital of Pisa, 56126 Pisa, Italy. [4] Thoracic Endoscopy Division, University Hospital of Pisa, 56126 Pisa, Italy. [5] Medical Direction, University Hospital of Pisa, 56126 Pisa, Italy.

Keywords

eSwab®	Endoscopy	Surface	Collection

Abstract

Microbiological surveillance carried out in order to verify the effectiveness of endoscope reprocessing does not include the research of viruses, although endoscopes may be associated with the transmission of viral infections. This paper reports the experience of the University Hospital of Pisa in managing the risk from severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) during an endoscopy. A review of the reprocessing procedure was conducted to assess whether improvement actions were needed. To verify the reprocessing efficacy, a virological analysis was conducted both before and after the procedure. Five bronchoscopes and 11 digestive endoscopes (6 gastroscopes and 5 colonoscopes) were sampled. The liquid samples were subjected to concentration through the use of the Macrosep Advance Centrifugal Devices (PALL Life Sciences, Port Washington, NY, USA) and subsequently analyzed using the cobas® SARS-CoV-2 Test (Roche Diagnostics, Basel, Switzerland), together with eSwab® 490 CE COPAN swab (COPAN, Brescia, Italy), which were used to sample surfaces. In accordance with the first ordinance regarding the coronavirus disease 2019 (COVID-19) emergency issued by the Tuscany Region in March 2020, a procedure dedicated to the management of the COVID-19 emergency in endoscopic practices was prepared, including the reprocessing of endoscopes. The virological analysis carried out on samples collected from endoscopes after reprocessing gave negative results, as well as on samples collected on the endoscopy column surfaces and the two washer-disinfectors that were dedicated to COVID-19 patients. The improvement in endoscope reprocessing implemented during the COVID-19 emergency was effective in ensuring the absence of SARS-CoV-2, thus reducing the risk of infections after an endoscopy on COVID-19 patients.

Clin Microbiol Infect. 2021 Apr;27(4):656-657

SARS-CoV-2

Saliva Collected in Universal Transport Media is an Effective, Simple and High-Volume Amenable Method to Detect SARS-CoV-2

Byron M. Berenger[1,2], John M. Conly[2,3,4,5], Kevin Fonseca[1,3], Jia Hu[6,7], Thomas Louie[3,4,5], Angela R. Schneider[4], Takshveer Singh[4], William Stokes[1], Linda Ward[5], and Nathan Zelyas[1,8]
Affiliation: [1] Alberta Public Health Laboratory, Alberta Precision Laboratories, Calgary, Canada. [2] Department of Pathology and Laboratory Medicine, University of Calgary, Calgary, Canada. [3] Department of Microbiology, Immunology and Infectious Diseases and Snyder Institute for Chronic Diseases, University of Calgary, Calgary, Canada. [4] Department of Medicine, Cumming School of Medicine, University of Calgary and Alberta Health Services, Calgary, Canada. [5] Infection Prevention and Control, Alberta Health Services, Calgary, Canada. [6] Department of Community Health Sciences, University of Calgary, Calgary, Canada. [7] Communicable Diseases, Public Health, Alberta Health Services, Calgary, Canada. [8] Department of Laboratory Medicine and Pathology, University of Alberta, Edmonton, Canada

Keywords

UTM®	Saliva	Non-Invasive	Collection

Abstract

During the Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-Co-V-2) pandemic we have encountered unprecedented testing volumes and constant supply chain disruptions, including swabs. These challenges could be somewhat alleviated by using saliva as a sample type because it is easy to collect, does not use swabs and is amenable to high-volume collection. Crude saliva added to universal/viral transport media (Copan UTM®) at the point of collection is amenable to high volume automated processing because the saliva arrives at the laboratory suspended in liquid form. participants accumulated saliva for 1e2 min (no specific volume) and spat into an empty urine container, and then 3 mL of Copan Italia UTM®-RT (Code 330C) was immediately added. Study samples were tested upon receipt at the laboratory using an E gene RT-PCR. Although collection of NP swab alone (or with an OP swab) and saliva in UTM® may provide higher sensitivity than saliva alone, saliva in UTM® offers many advantages over a NP swab because it is non-invasive, convenient (especially for children), involves minimal labour and lends itself well to mass screening programmes.

Sci Rep. 2020 Oct 30;10(1):18764

SARS-CoV-2

Assessment of the Direct Quantitation of SARS-CoV-2 by Droplet Digital PCR

Michela Deiana[1], Antonio Mori[1,2], Chiara Piubelli[1], Salvatore Scarso[1], Mosè Favarato[3], Elena Pomari[1]
Affiliation:[1] Department of Infectious Tropical Diseases and Microbiology, IRCCS Sacro Cuore Don Calabria Hospital, Via Don A. Sempreboni, 5 37024 Negrar di Valpolicella, Verona, VR, Italy. [2] Department of Diagnostics and Public Health, University of Verona, Verona, Italy. [3] Laboratory Medicine, ULSS3 Venetian, Venice, Italy

Keywords

eSwab®	Droplet Digital PCR	Comparison	Direct Quantification

Abstract

Droplet digital PCR (ddPCR) is a sensitive and reproducible technology widely used for quantitation of several viruses. The aim of this study was to evaluate the 2019-nCoV CDC ddPCR Triplex Probe Assay (BioRad) performance, comparing the direct quantitation of SARS-CoV-2 on nasopharyngeal swab with the procedure applied to the extracted RNA. Moreover, two widely used swab types were compared (UTM® 3 mL and eSwab® 1 mL, COPAN). A total of 50 nasopharyngeal swabs (n= 25 UTM 3 mL and n= 25 eSwab® 1 mL) from SARS-CoV-2 patients, collected during the pandemic at IRCCS Sacro Cuore Don Calabria Hospital (Veneto Region, North-East Italy), were used for our purpose. After heat inactivation, an aliquot of swab medium was used for the direct quantitation. Then, we compared the direct method with the quantitation performed on the RNA purifed from nasopharyngeal swab by automated extraction. We observed that the direct approach achieved generally equal RNA copies compared to the extracted RNA. The results with the direct quantitation were more accurate on eSwab® with a sensitivity of 93.33% [95% CI, 68.05 to 99.83] and specifcity of 100.00% for both N1 and N2. On the other hand, on UTM® we observed a higher rate of discordant results for N1 and N2. The human internal amplifcation control (RPP30) showed 100% of both sensitivity and specifcity independent of swabs and approaches. In conclusion, we described a direct quantitation of SARSCoV-2 in nasopharyngeal swab. Our approach resulted in an efcient quantitation, without automated RNA extraction and purifcation. However, special care needs to be taken on the potential bias due to the conservation of samples and to the heating treatment, as we used thawed and heat inactivated material. Further studies on a larger cohort of samples are warranted to evaluate the clinical value of this direct approach.

Eur J Clin Microbiol Infect Dis. 2021 Mar 20;1-6

SARS-CoV-2

Clinical Performance of the Abbott Panbio with Nasopharyngeal, Throat, and Saliva Swabs Among Symptomatic Individuals with COVID-19

William Stokes[1,2,3], Byron M. Berenger[1,4], Danielle Portnoy[5], Brittney Scott[5], Jonas Szelewicki[5], Takshveer Singh[6], Allison A. Venner[1,4], LeeAnn Turnbull[1], Kanti Pabbaraju[1], Sandy Shokoples[1], Anita A. Wong[1], Kara Gill[1], Tracy Guttridge[1], Dustin Proctor[1,4], Jia Hu[7,8], Graham Tipples[1,2,9]
Affiliation:[1] Alberta Public Health Laboratory, Alberta Precision Laboratories, Alberta, Canada. [2] Department of Pathology and Laboratory Medicine, University of Alberta, Edmonton, Alberta, Canada. [3] Division of Infectious Diseases, Department of Medicine, University of Alberta, Edmonton, Alberta, Canada. [4] Department of Pathology and Laboratory Medicine, University of Calgary, Calgary, Alberta, Canada. [5] Faculty of Medicine & Dentistry, University of Alberta, Edmonton, Alberta, Canada. [6] Cumming School of Medicine, University of Calgary, Calgary, Alberta, Canada. [7] Department of Community Health Sciences, University of Calgary, Calgary, Alberta, Canada. [8] Public Health, Alberta Health Services, Alberta, Canada. [9] Li Ka Shing Institute of Virology, University of Alberta, Edmonton, Alberta, Canada

Keywords

UTM®	CLASSIQSwabs™	Abbot Panbio	POC Testing

Abstract

SARS-CoV-2 antigen tests used at the point-of-care, such as the Abbott Panbio, have great potential to help combat the COVID19 pandemic. The Panbio is Health Canada approved for the detection of SARS-CoV-2 in symptomatic individuals within the first 7 days of COVID-19 symptom onset(s). Symptomatic adults recently diagnosed with COVID-19 in the community were recruited into the study. Paired nasopharyngeal (NP), throat, and saliva Copan CLASSIQSwabs™ were collected, with one paired swab tested immediately with the Panbio, and the other transported in universal transport media (Copan UTM®) and tested using real-time reverse-transcriptase polymerase chain reaction (RT-PCR). We also prospectively evaluated results from assessment centers within the community. For those individuals, an NP swab was collected for Panbio testing and paired with RT-PCR results from parallel NP or throat swabs. One hundred and forty-five individuals were included in the study. Collection of throat and saliva was stopped early due to poorer performance (throat sensitivity 57.7%, n=61, and saliva sensitivity 2.6%, n=41). NP swab sensitivity was 87.7% [n=145, 95% confidence interval (CI) 81.0–92.7%]. There were 1641 symptomatic individuals tested by Panbio in assessment centers with 268/1641 (16.3%) positive for SARS-CoV-2. There were 37 false negatives and 2 false positives, corresponding to a sensitivity and specificity of 86.1% [95% CI 81.3–90.0%] and 99.9% [95% CI 99.5–100.0%], respectively. The Panbio test reliably detects most cases of SARS-CoV-2 from adults in the community setting presenting within 7 days of symptom onset using nasopharyngeal swabs. Throat and saliva swabs are not reliable specimens for the Panbio.

medRxiv. 2021 Jan 20;2021.01.15.21249891

SARS-CoV-2

Inactivation of SARS-CoV-2 Virus in Saliva Using a Guanidium Based Transport Medium Suitable for RT-PCR Diagnostic Assays

Sukalyani Banik[1], Kaheerman Saibire[1], Shraddha Suryavanshi[1], Glenn Johns[2], Soumitesh Chakravorty[2], Robert Kwiatkowski[2], David Alland[1], Padmapriya Banada[1]
Affiliation: [1] Public Health Research Institute, 225 Warren Street, Newark, NJ 07103. [2] Cepheid, Sunnyvale, CA

Keywords

eNAT®	Inactivation	Saliva Specimens	PCR

Abstract

Background: Upper respiratory samples used to test for SARS-CoV-2 virus may be infectious and present a hazard during transport and testing. A buffer with the ability to inactivate SARS-CoV-2 at the time of sample collection could simplify and expand testing for COVID-19 to non-conventional settings.
Methods: We evaluated a guanidium thiocyanate-based buffer, eNAT® (Copan) as a possible transport and inactivation medium for downstream RT-PCR testing to detect SARS-CoV-2. Inactivation of SARS-CoV-2 USA-WA1/2020 in eNAT® and in diluted saliva was studied at different incubation times. The stability of viral RNA in eNAT® was also evaluated for up to 7 days at room temperature (28°C), refrigerated conditions (4°C) and at 35°C.
Results: SARS-COV-2 virus spiked directly in eNAT® could be inactivated at >5.6 log10 PFU/ml within a minute of incubation. When saliva was diluted 1:1 in eNAT®, no cytopathic effect (CPE) on vero-E6 cell lines was observed, although SARS-CoV-2 RNA could be detected even after 30 min incubation and after two cell culture passages. A 1:2 (saliva:eNAT®) dilution abrogated both CPE and detectable viral RNA after as little as 5 min incubation in eNAT®. SARS-CoV-2 RNA from virus spiked at 5X the limit of detection remained positive up to 7 days of incubation in all tested conditions.
Conclusion: eNAT® and similar guanidinium thiocyanate-based media may be of value for transport, preservation, and processing of clinical samples for RT- PCR based SARS-CoV-2 detection.

J Clin Microbiol. 2021 Feb 12;JCM.00110-21

SARS-CoV-2

eNAT® Transport System to Address Challenges in COVID-19 Diagnostics in Regions with Limited Testing Access

Melissa Richard-Greenblatt[1,3], Courtney E. Comard[4], Laurence Flevaud[5], Marina Berti[5], Rebecca M. Harris[1,3], Susan R. Weiss[4], Laurel Glaser[1,2]
Affiliation: [1] Department of Pathology and Laboratory Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, USA. [2] Clinical Microbiology Laboratory, Hospital of the University of Pennsylvania, Philadelphia, Pennsylvania, USA St. Joseph's Healthcare, Hamilton, Ontario, Canada. [3] Infectious Disease Diagnostics Laboratory, Children's Hospital of Philadelphia, Philadelphia, Pennsylvania, USA. [4] Department of Microbiology, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, USA. [5] Médicins Sans Frontières (MSF), Geneva, Switzerland

Keywords

eNAT®	Stability	Inactivation	Rural Area

Abstract

Community-based healthcare clinics and hospital outreach services have the potential to expand coronavirus disease 2019 (COVID-19) diagnostics to rural areas. However, reduced specimen stability during extended transport, the absence of cold chain to centralized laboratories, and biosafety concerns surrounding specimen handling has limited this expansion. In the following study, we evaluated eNAT® (Copan Italia, Brescia, Italy) as an alternative transport system to address the biosafety and stability challenges associated with expanding COVID-19 diagnostics to rural and remote regions. In this study, we demonstrated that high titer severe acute respiratory virus syndrome coronavirus 2 (SARS-CoV-2) lysate placed into eNAT medium cannot be propagated in cell culture, supporting viral inactivation. To account for off-site testing in these settings, we assessed the stability of contrived nasopharyngeal (NP) specimens stored for up to 14 days in various transport medium (eNAT®, eSwab®, viral transport media [VTM®], saline and phosphate-buffered saline [PBS]) at 4°C, 22-25°C, and 35°C. Molecular detection of SARS-CoV-2 was unaffected by sample storage temperature over the 2 weeks when stored in eNAT® or PBS (change in cycle threshold [ΔCT] ≤ 1). In contrast, variable stability was observed across test conditions for other transport media. As eNAT can inactivate SARS-CoV-2, it may support COVID-19 diagnostics at the point-of-care (POC). Evaluation of compatibility of eNAT® with Cepheid Xpert Xpress SARS-CoV-2 assay demonstrated equivalent diagnostic accuracy and sensitivity compared to VTM®. Taken together, these findings suggest that the implementation of eNAT® as a collection device has the potential to expand COVID-19 testing to areas with limited healthcare access.

PeerJ. 2021 Jan 21;9:e10801

SARS-CoV-2

Evaluation of Two Fluorescence Immunoassays for the Rapid Detection of SARS-CoV-2 Antigen-New Tool to Detect Infective COVID-19 Patients

Lorena Porte[1], Paulette Legarraga[1], Mirentxu Iruretagoyena[1], Valeska Vollrath[1], Gabriel Pizarro[1], Jose Munita[2,3,4], Rafael Araos[2,3,4], Thomas Weitzel[1,3]
Affiliation:[1] Laboratorio Clínico, Clínica Alemana, Universidad del Desarrollo, Santiago, Chile. [2] Servicio de Infectología, Clínica Alemana de Santiago, Facultad de Medicina Clínica Alemana, Universidad del Desarrollo, Santiago, Chile. [3] Instituto de Ciencias e Innovación en Medicina (ICIM), Facultad de Medicina Clínica Alemana, Universidad del Desarrollo, Santiago, Chile. [4] Millennium Initiative for Collaborative Research on Bacterial Resistance (MICROB-R), Santiago, Chile

Keywords

UTM®	Rapid Diagnostic Test	Antigen Detection	Fluorescence

Abstract

Background: Real-Time Reverse-Transcription Polymerase Chain Reaction (RT-PCR) is currently the only recommended diagnostic method for SARS-CoV-2. However, rapid immunoassays for SARS-CoV-2 antigen could significantly reduce the COVID-19 burden currently weighing on laboratories around the world.
Methods: We evaluated the performance of two rapid fluorescence immunoassays (FIAs), SOFIA SARS Antigen FIA (Quidel Corporation, San Diego, CA, USA) and STANDARD F COVID-19 Ag FIA (SD Biosensor Inc., Gyeonggi-do, Republic of Korea), which use an automated reader. The study used 64 RT-PCR characterized clinical samples (32 positive; 32 negative), which consisted of nasopharyngeal swabs in universal transport medium (Copan UTM®).
Results: Of the 32 positive specimens, all from patients within 5 days of symptom onset, the Quidel and SD Biosensor assays detected 30 (93.8%) and 29 (90.6%) samples, respectively. Among the 27 samples with high viral loads (Ct ≤ 25), the two tests had a sensitivity of 100%. Specificity was 96.9% for both kits.
Conclusion: The high performance of the evaluated FIAs indicates a potential use as rapid and PCR-independent tools for COVID-19 diagnosis in early stages of infection. The excellent sensitivity to detect cases with viral loads above ~106 copies/ mL (Ct values ≤ 25), the estimated threshold of contagiousness, suggests that the assays might serve to rapidly identify infective individuals.

GMS Hyg Infect Control. 2021 Jan 19;16:Doc03

SARS-CoV-2

Comparison of Pre-Analytical Characteristics for Molecular and Serological Diagnostics of COVID-19

Ralph Wendt[1], Olaf Nickel[2], Sven Kalbitz[1], Jasmin Fertey[3], Sebastian Ulbert[3], Johannes Wolf[2,4], Christoph Lübbert[1,5,6], Stephan Borte[2,4,7]
Affiliation: [1] Department of Infectious Diseases/Tropical Medicine, Nephrology and Rheumatology, Hospital St. Georg, Leipzig, Germany. [2] Department of Laboratory Medicine, Hospital St. Georg, Leipzig, Germany. [3] Fraunhofer Institute for Cell Therapy and Immunology (IZI), Leipzig, Germany. [4] ImmunoDeficiencyCenter Leipzig (IDCL) at Hospital St. Georg Leipzig, Jeffrey Modell Diagnostic and Research Center for Primary Immunodeficiency Diseases, Leipzig, Germany. [5] Division of Infectious Diseases and Tropical Medicine, Department of Medicine II, Leipzig University Hospital, Leipzig, Germany. [6] Interdisciplinary Center for Infectious Diseases, Leipzig University Hospital, Leipzig, Germany. [7] Department of Laboratory Medicine, Division of Clinical Immunology, Karolinska Institute, Stockholm, Sweden

Keywords

eSwab®	Pre-Analytics	Pharingeal Specimens	Nasopharyngeal

Abstract

Background: The diagnosis of SARS-CoV-2 infection relies on RT-PCR from nasopharyngeal swabs. The pre-analytical value of different methods of material harvesting for SARS-CoV-2 are unknown.
Methods: We conducted a comprehensive investigation of the pre-analytical performance for different pharyngeal sampling procedures, using Copan eSwab® and dry swabs, in hospitalized patients with confirmed SARS-CoV-2 infection. In addition to swabs taken simultaneously from different locations, saliva and pharyngeal lavages were also analyzed using RT-PCR.
Results: In 10 COVID-19 patients, standard nasopharyngeal swabs detected 8 out of 10 positive patients, whereas swabs taken from the palatoglossal arch resulted in 9 correct-positive results. Brushing the posterior pharynx wall with swabs resulted in detection of 9 out of 10 positive patients with no difference using either dry swabs or liquid Amies medium. A strong correlation between Ct values of both swab materials was observed. Pharyngeal lavages yielded 6 out of 10 positive results in concordance with 85% of nasopharyngeal swabs in late-stage COVID-19 patients. Investigating 23 patients with early SARS-CoV-2 infection, pharyngeal lavages showed a concordance rate of 100% compared to nasopharyngeal swabs.
Conclusions: The diagnostic performance of swabs taken from the palatoglossal arch in detecting SARS-CoV-2 infection is similar to that of specimens taken from the nasopharyngeal region. However, the former sampling method is associated with less discomfort and much easier to perform. Pharyngeal lavages may replace swabs for mass screening in early stages of SARS-CoV-2 infection. The predictive values are comparable, and the procedure is performed without exposing healthcare workers to transmission risks.

BMC Microbiol. 2021 Jan 22;21(1):31

SARS-CoV-2

Combined Oropharyngeal/Nasal Swab is Equivalent to Nasopharyngeal Sampling for SARS-CoV-2 Diagnostic PCR

Tania Desmet[1], Peter De Paepe[1], Jerina Boelens[2], Liselotte Coorevits[2], Elizaveta Padalko[2], Stien Vandendriessche[2], Isabel Leroux-Roels[2,3], Annelies Aerssens[3], Steven Callens[4], Eva Van Braeckel[5], Thomas Malfait[5], Frank Vermassen[6], Bruno Verhasselt[2] Affiliation:[1] Emergency Department, Ghent University Hospital, Ghent, Belgium. [2]Department of Medical Microbiology, Ghent University Hospital, 9000 Ghent, Belgium. [3] Department of Infection Control, Ghent University Hospital, Ghent, Belgium. [4] Department of Internal Medicine & Infectious diseases, Ghent University Hospital, Ghent, Belgium. [5] Department of Respiratory Medicine, Ghent University Hospital, Ghent, Belgium [6] Department of Thoracic and Vascular Surgery, Chief Physician and Head of COVID-19 task force, Ghent University Hospital, Ghent, Belgium.

Keywords

UTM®	Flexibile Minitip	Oropharyngeal Swab	Nasal Swab

Abstract

Background: Early 2020, a COVID-19 epidemic became a public health emergency of international concern. To address this pandemic broad testing with an easy, comfortable and reliable testing method is of utmost concern. Nasopharyngeal (NP) swab sampling is the reference method though hampered by international supply shortages. A new oropharyngeal/nasal (OP/N) sampling method was investigated using the more readily available throat swab (Copan FLOQSwabs® in Copan UTM® medium).

Results: 35 patients were diagnosed with SARS-CoV-2 by means of either NP or OP/N sampling. The paired swabs were both positive in 31 patients. The one patient who tested negative on both NP and OP/N swab on admission, was ultimately diagnosed on bronchoalveolar lavage fluid. A strong correlation was found between the viral RNA loads of the paired swabs ($r = 0.76$; $P < 0.05$). The sensitivity of NP and OP/N analysis in hospitalized patients ($n = 28$) was 89.3% and 92.7% respectively.

Conclusions: This study demonstrates equivalence of NP and OP/N sampling for detection of SARS-CoV-2 by means of rRT-PCR. Sensitivity of both NP and OP/N sampling is very high in hospitalized patients.

Emerg Infect Dis. 2021 Jan;27(1):329-331

Postmortem Stability of SARS-CoV-2 in Nasopharyngeal Mucosa

Fabian Heinrich, Kira Meißner, Felicia Langenwalder, Klaus Püschel, Dominik Nörz, Armin Hoffmann, Marc Lütgehetmann, Martin Aepfelbacher, Eric BibizaFreiwald, Susanne Pfefferle, Axel Heinemann
Affiliation: University Medical Center Hamburg-Eppendorf, Hamburg, Germany

Keywords

eSwab®	Postmortem Stability	Swab	Nasopharyngeal Mucosa

Abstract

Analyses of infection chains have demonstrated that severe acute respiratory syndrome coronavirus 2 is highly transmissive. However, data on postmortem stability and infectivity are lacking. Our finding of nasopharyngeal viral RNA stability in 79 corpses showed no time-dependent decrease. Maintained infectivity is supported by virus isolation up to 35 hours postmortem.

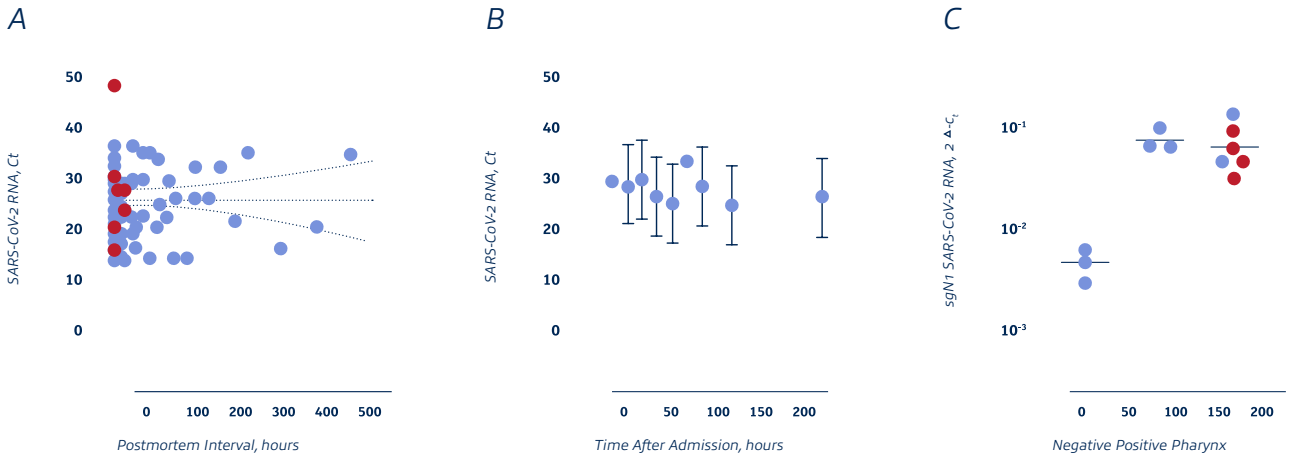


Figure: Postmortem stability of SARS-CoV-2 in nasopharyngeal mucosa. A) Correlation of SARS-CoV-2 RNA loads of the pharynx (at corpse admission to the Department of Legal Medicine) with the postmortem interval (time of death until cooling at 4°C) in 79 matched datasets. Red indicates patients in the longitudinal cohort. Spearman R = –0.07; 2-tailed p = 0.5. B) Median SARS-CoV-2 RNA loads with 95% CIs (error bars) in a series of 9 sequential pharyngeal swab samples (time points 0, 12, 24, 36, 48, 60, 72, 96, and 168 hours after admission) for 11 corpses. C) sgN1 RNA loads of SARS-CoV-2 in pharyngeal tissue of 6 corpses. Negative and positive controls from SARS-CoV-2 cell cultures. Red indicates samples with successful virus isolation from pharyngeal tissue (S. Pfefferle, unpub. data, https://doi.org/10.1101/2020.10.10.334458). Negative results are reflected by Ct 50. Ct, cycle threshold; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; sgN1 RNA, subgenomic RNA loads of the N1-gene.

J Clin Virol. 2021 Apr 1;138:104817

SARS-CoV-2

Performance of the RT-LAMP-Based Eazyplex® SARS-CoV-2 as a Novel Rapid Diagnostic Test

Renate Egerer[1], Birgit Edel[1], Bettina Löffler[1], Andreas Henke[2], and Jürgen Rödel[1]
Affiliation: [1] Institute of Medical Microbiology, Jena University Hospital, Jena, Germany. [2] Section of Experimental Virology, Institute of Medical Microbiology, Jena University Hospital, Jena, Germany

Keywords

SLSolution™	RT-LAMP	POC Test	Rapid Test

Abstract

Background: Diagnostic assays for severe acute respiratory syndrome Coronavirus-2 (SARS-CoV-2) that are easy to perform and produce fast results are essential for timely decision making regarding the isolation of contagious individuals.
Objective: We evaluated the CE-approved eazyplex® SARS-CoV-2, a ready-to-use real time RT-LAMP assay for identification of the SARS-CoV-2 N and ORF8 genes from swabs in less than 30 min without RNA extraction.
Methods: Oropharyngeal and nasal swabs from 100 positive and 50 negative patients were inoculated into 0.9% saline and tested by NeuMoDx™ RT-PCR. An aliquot was diluted fivefold in Copan sputum liquefying (SLSolution™) solution and directly analyzed by eazyplex® SARS-CoV-2. In addition, 130 patient swabs were prospectively tested with both methods in parallel. Analytical sensitivity of the assay was determined using virus stock dilutions.
Results: Positive percent agreement (PPA) between the eazyplex® SARS-CoV-2 and RT-PCR was 74% for samples with Ct values < 35. When using a Ct cut-off ≤ 28 the PPA increased to 97.4%. In the prospective part of the study overall PPA of the eazyplex® kit was 66.7% but increased to 100% when only Ct values ≤ 28 were considered. There were no false positive results. The median time to positivity was 12.5 min for the N gene and 16.75 min for ORF8. Analytical sensitivity was 3.75 TCID50/ml. 105 virus copies/ml were reproducibly detected.
Conclusion: The eazyplex® SARS-CoV-2 is a rapid assay that accurately identifies samples with high viral loads. It may be useful for near-patient testing outside of a molecular diagnostic laboratory.

J Mol Diagn. 2021 Apr;23(4):407-416

SARS-CoV-2

Comparison of Two Commercial Platforms and a Laboratory-Developed Test for Detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) RNA

Laura Mannonen[1], Hannimari Kallio-Kokko[1], Raisa Loginov[1], Anu Jääskeläinen[1], Pia Jokela[1], Jenni Antikainen[1], Paula Väre[1], Eliisa Kekäläinen[1,2], Satu Kurkela[1], Hanna Jarva1,2, and Maija Lappalainen[1]
Affiliation: [1] HUSLAB, Clinical Microbiology, University of Helsinki and Helsinki University Hospital, Helsinki; [2] Translational Immunology Research Program and Department of Bacteriology and Immunology University of Helsinki, Helsinki, Finland

Keywords

UTM®	Cobas SARS-CoV-2	Amplidiag COVID19	Respiratory

Abstract

Mitigation of the ongoing coronavirus disease 2019 (COVID-19) pandemic requires reliable and accessible laboratory diagnostic services. In this study, the performance of one laboratorydeveloped test (LDT) and two commercial tests, cobas SARS-CoV-2 (Roche) and Amplidiag COVID19 (Mobidiag), were evaluated for the detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA in respiratory specimens. A total of 183 specimens collected from suspected COVID-19 patients were studied with all three methods to compare their performance. In relation to the reference standard, which was established as the result obtained by two of the three studied methods, the positive percent agreement was highest for the cobas test (100%), followed by the Amplidiag test and the LDT (98.9%). The negative percent agreement was lowest for the cobas test (89.4%), followed by the Amplidiag test (98.8%), and the highest value was obtained for the LDT (100%). The dilution series of positive specimens, however, suggests significantly higher sensitivity for the cobas assay in comparison with the other two assays, and the low negative percent agreement value may be due to the same reason. In general, all tested assays performed adequately. Clinical laboratories need to be prepared for uninterrupted high-throughput testing during the coming months to mitigate the pandemic. To ensure no interruption, it is critical that clinical laboratories maintain several simultaneous platforms in their SARS-CoV-2 nucleic acid testing.

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An In-Well Direct Lysis Method for Rapid Detection of SARS-CoV-2 by Real Time RT-PCR in eSwab® Specimens

Rikke Lind Jørgensen[1], Martin Schou Pedersen[1], Alisha Shazad Chauhan[2,3], Louise Munkholm Andreasson[2,3], Gitte Qvist Kristiansen[1], Jan Gorm Lisby[1], Maiken Worsøe Rosenstierne[4], Kristian Schønning[1,5]
Affiliation:[1] Department of Clinical Microbiology 445, Hvidovre Hospital, Hvidovre, Denmark. [2] Research Laboratory for Stereology and Neuroscience, Bispebjerg-Frederiksberg Hospital, University Hospital of Copenhagen, Copenhagen, Denmark. [3] Copenhagen Centre for Translational Research, Bispebjerg-Frederiksberg Hospital, University Hospital of Copenhagen, Copenhagen, Denmark. [4] Virus Research and Development Group, Department of Virus and Microbiology Diagnostics, Statens Serum Institut, Copenhagen, Denmark. [5] Department of Clinical Microbiology, Copenhagen University Hospital, Rigshospitalet, Copenhagen, Denmark

Keywords

eSwab®	Direct PCR	IGEPAL-CA-630	Rapid Detection

Abstract

Background: Diagnostic real time reverse transcription PCR (rRT-PCR) is usually done using nucleic acid (NA) purified from the sample. In the SARS-CoV-2 pandemic reagents and utensils for NA purification has been in short supply. This has generated interest in methods that eliminate the need for NA purification.
Objectives: To investigate if addition of detergent to rRT-PCR master mix (MM) enabled in-well direct lysis and detection of SARS-CoV-2 in clinical eSwab® specimens. Study design: IGEPAL-CA-630 (IGEPAL) was added to SARS-CoV-2 MM to 0.3 % final concentration and crude sample was added directly to the PCR well containing MM. Cycle of positivity (Cp) and categorical agreement was compared in samples tested in standard rRT-PCR after NA purification and in in-well lysis, direct rRT-PCR.
Results: In-well lysis direct rRT-PCR detected SARS-CoV-2 in 27/30 previously SARS-CoV-2+ samples with an average bias of 3.26 cycles (95 %CI: 0.08–6.43 cycles). All 30 previously test negative samples remained negative when tested in in-well lysis, direct PCR.
Conclusions: Supplementation of detergent to MM was shown to be useful for the detection of SARS CoV-2 in eSwab specimens (COPAN) by direct rRT-PCR without prior NA purification.

Note

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@copangroup

Copan Italia s.p.a.
Via Francesco Perotti 10,
25125 Brescia, Italy

t | f +030 2687211
@ | info@copangroup.com
www.copangroup.com