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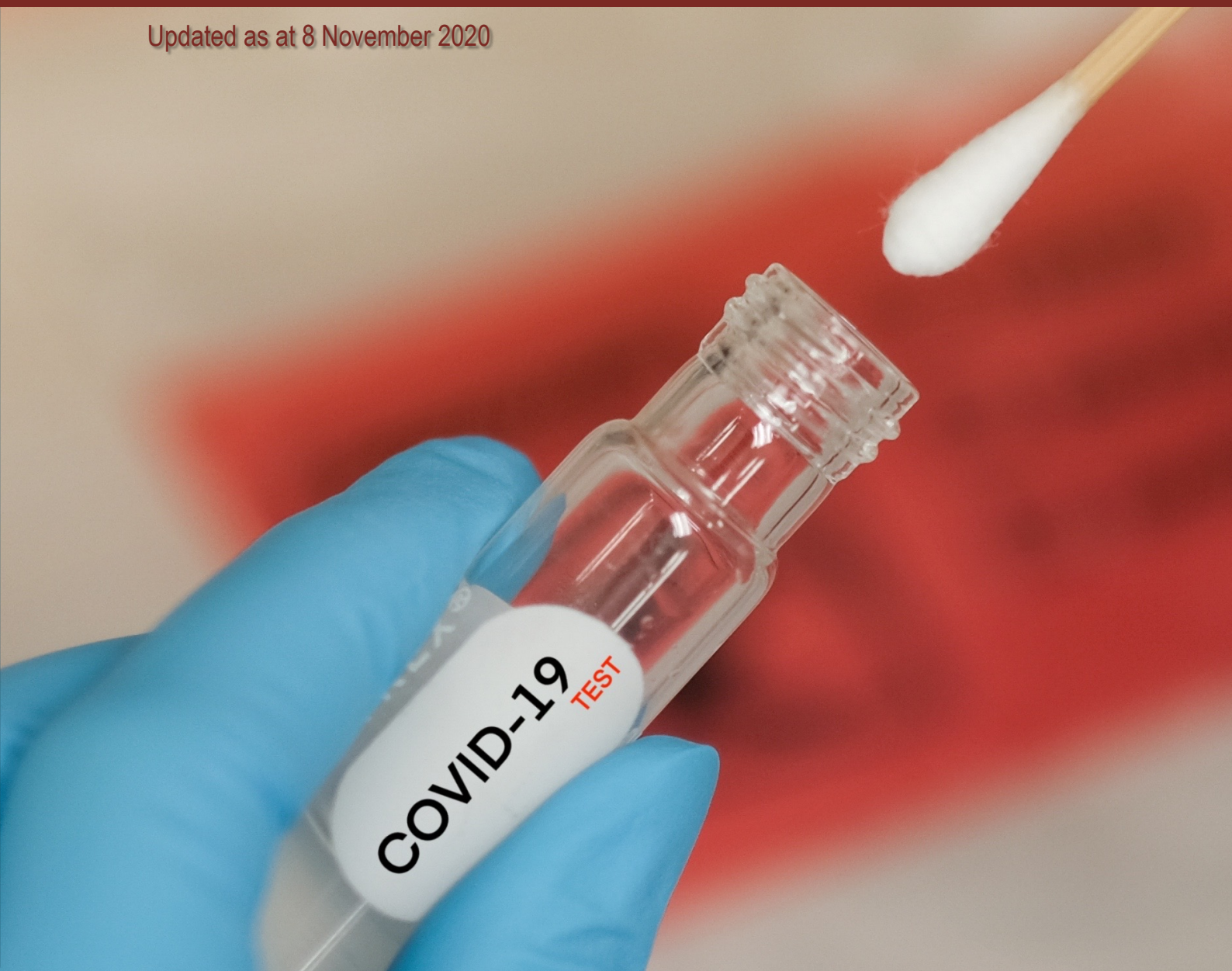
INTERIM TECHNICAL NOTE

Execution of diagnostic tests in the medical practices of primary care paediatricians and general practitioners

Updated as at 8 November 2020



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Execution of diagnostic tests in the medical practices of primary care paediatricians and general practitioners

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Istituto Superiore di Sanità - ISS

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This interim technical note provides the essential elements for safely performing rapid antigen tests in medical practices or at facilities identified in collaboration with the local health and civil authorities.

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Table of contents

1. Introduction

As a result of the rapid worsening of the epidemiological situation at national level and the criticalities that have emerged in the delivery of services at the local level in several Regions / Autonomous Provinces (APs) it is necessary to implement a local surveillance and diagnostic network for COVID-19 in order to reduce and contain the spread of SARS-CoV-2.

In this connection General Practitioners (GPs) and Primary Care Paediatricians (PCPs) need to be actively involved in the diagnosis of the SARS-CoV-2 infection for a better and rapid management of COVID-19 patients in compliance with the indications set forth by the NCA (National Collective Agreement).

This guide provides the essential elements for safely performing the rapid antigen tests that will be performed in the medical practices of physicians or at facilities identified jointly by the local health and civil authorities as being suitable for the purpose.

2. Rapid antigen tests

Just like the molecular tests, antigen assays are of the direct type, i.e. they directly identify the presence of the virus in the biological sample. The biological sample for both assays is the oro-nasopharyngeal swab, but prototypes using saliva are also being developed. Unlike molecular tests, however, antigen tests detect the presence of the virus not through its nucleic acid (RNA) but through its proteins (antigens).

These tests contain specific antibodies as substrate that binds to the viral antigens of SARS-CoV-2 and the result of the antigen-antibody reaction is directly visible to the naked eye or may be read using simple point-of-care equipment. Due to these characteristics, this type of diagnostic test can be performed in a doctor's office or in dedicated areas without the need to being sent to a laboratory.

The swab must be processed as quickly as possible, generally within one hour of collection. Operationally, the sample is immersed in a reagent that activates the viral antigen making it available for the antigen-antibody reaction. A few drops of the solution obtained are introduced into a “lateral flow” device (similar to a pregnancy test), in which antibodies against viral antigens are immobilized and capable of capturing the virions or protein components of the SARS-CoV-2 virus. A second revealing mixture is then applied, which binds the antigen-antibody complex, containing other antibodies conjugated with enzymes whose chromatographic reaction (for example with peroxidase or phosphatase) can be seen with the naked eye or with fluorophores whose emission is detected through a specific compact and portable fluorescence analyser. Overall, the results of these rapid antigen tests are obtained in a matter of 15-30 minutes.

The test result is negative if the antigen concentration is below the detection limit of the test. There may also be false positive results for problems of specificity. For this reason, a rapid antigen test that is positive needs to be confirmed by a molecular test, with some exceptions[1].

[1] Circular of the Ministry of Health 30/10/2020 “Test di laboratorio per SARS-CoV-2 e loro uso in sanità pubblica”

3. Requirements for performing rapid antigen tests in medical practices

In the medical practice a room, or at least a section of a room, needs to be reserved to this activity. In order to reorganizing the facility, the patients to be tested, potentially infected, need to be kept separate from the other patient population that frequents the medical practice. This means that either separate entry and exit paths, separate waiting rooms and separate testing rooms are to be provided or, alternatively, appointments are to be scheduled ensuring patient spacing taking into account patient history and symptoms and on the basis of phone triage. For instance, the rapid antigen tests could also be performed towards the end of the day, planning appointments to prevent patients from crossing each other and providing adequate time for sanitation of the areas frequented by the patients and those used for the execution of the test. This activity must be carried out ensuring patient privacy, possibly delimiting the dedicated area with a mobile screen that can be sanitized.

If medical premises with these characteristics are not available, the oral-nasopharyngeal swab and subsequent rapid antigen test could be performed in facilities identified in collaboration with the local Health or Civil Authorities or alternatively, if the season permits, outdoors in an area previously identified and adequately protected from weather interference, also using the drive-through mode.

For the sampling and testing operations, it is recommended to:

- use a trolley or in any case a suitable support for the “clean” material and a separate container for used material to be disposed of;
- maintain adequate distance among people to be tested in an area identified based on the location of the medical practice and logistics / availability of a facility (e.g. also a “drive-through” solution) in accordance with the health / local authorities.

Personal Protective Equipment (PPE) must be available for all operators involved in the sampling procedures (doctors and nurses) at the doctor's office, or in the place designated for performing tests (*see* point 5.3) provided by healthcare companies. The healthcare workers performing the procedures are to be appropriately trained with regard to the correct execution of the collection of biological material and the safety procedures for the management of the PPE and the disposal of the special waste (at risk of being a vehicle of infection) produced by this activity. The training may be provided also through distance learning.

4. General measures for the prevention and control of SARS-CoV-2 infection in the operational setting

4.1. Hand hygiene

Clean your hands with an alcohol-based hand rub (rub for 20 seconds) or wash with soap and water – if an alcohol-based sanitizer is not available or if your hands are visibly soiled (for 40 seconds) – before and after contact with a patient or with a potentially contaminated work surface (since SARS-CoV-2 is also transmitted through contact with contaminated surfaces or with other fomites) and always before and after visiting a patient.

4.2. Cleaning and disinfecting devices

After patient examination, all medical devices (e.g., stethoscope, otoscope) and any other object used (telephone, PC keyboard and mouse) need to be accurately cleaned using an approved disinfectant or biocide, after verifying that the product is compatible with the surfaces and materials to be treated. If these products are not available, a 70% ethyl alcohol solution can be used.

The PC keyboard may be suitably protected by applying a transparent film, to be sanitized and replaced at the end of the procedure.

4.3. Organizing access to medical practices

- Display a notice at the entrance to the practice providing clear instructions as to access (indicating the entry, waiting area and exit route) and how to book an appointment for the test (by telephone, e-mail, text messaging), specifying the days and time slots when rapid antigen tests are performed. Testing is available by appointment only.
- Take samples by appointment and allow for a predetermined interval between one person and the next to ensure adequate sanitation of the surfaces of possible contact. In case of children or individuals who are unable to comply, longer time slots are to be envisaged in order to avoid the presence of more than one person in the waiting room and hence avoid contact between people.
- It is preferable to set a time frame at the end of the day for the rapid antigen tests, to avoid contact between the patients who may have a SARS-CoV-2 infection and the patients who come to the doctor’s office for other reasons. If a patient is unable to go to the doctor's practice, provision must be made to perform the rapid antigen test at the patient’s home.
- Establish, where possible, an alternative route of entry and exit.
- Set up signs recommending hand hygiene and physical distancing in the waiting area.
- Make alcohol-based hand rub solution available at the entrance to the waiting room and in the doctor's office / sampling room.
- Have surgical masks available for unequipped patients and thermal scanners or infrared thermometers to control body temperature.

- Set up, where possible, physical barriers to reduce staff exposure (e.g. glass or Plexiglas screens in the areas of patient reception/ staff desk).

4.4. Guidance on the cleaning and disinfection (sanitization) of premises

Special attention must be paid to the application of ordinary cleaning and disinfection measures in common areas (bathrooms, halls, corridors, elevators, etc.) as a general preventive measure throughout the duration of the COVID-19 epidemic. These measures must also be applied to the ordinary activities in the doctor's practice.

In addition, objects and surfaces that are touched frequently, such as elevator buttons, handrails, switches, door handles, chair backs and armrests, etc. must be properly and frequently sanitized.

Regarding the specific rooms or areas made available to the patients, the following conditions must be implemented:

- Make sure the rooms are adequately aired through natural ventilation by periodically opening the windows several times a day for about 5-10 minutes. Thoroughly clean the flat surfaces of the rooms and furnishings at least once a day with a neutral detergent or a detergent-disinfectant product (an approved disinfectant or biocide).
- Disinfect surfaces potentially contaminated with respiratory secretions or other body fluids, such as toilets, sinks and taps using a germ-killing disinfectant (an approved disinfectant) or sodium hypochlorite containing 0.1% active chlorine (equivalent to 1000 ppm).
- Rinse with clean water after ten minutes of contact with sodium hypochlorite.
- Alternatively use detergent-disinfectant products without rinsing.
- Use an approved disinfectant or biocide or, if not available, a 70% ethyl alcohol solution, taking into consideration compatibility with the material to be disinfected (e.g., for telephones, electronic instruments and remote-control equipment, use a 70% ethyl alcohol solution).
- Use only disposable cleaning materials.
- • Properly disinfect non-porous cleaning products and equipment with a sodium hypochlorite solution containing 0.5% active chlorine or in accordance with the manufacturer's instructions before using them in other environments.
- • Remove visible contamination from porous surfaces such as carpets and rugs, and clean them with appropriate detergents and disinfectants according to the manufacturer's instructions.
- Use disposable paper towels and sheets. If linen is still used, the dirty linen must be collected in closed containers (bags), wearing disposable gloves without shaking it in the environment before placing it in the bag and sending it to a qualified cleaning company for washing and sanitizing. Choose companies that have a UNI EN 14065: 2016 certification - Textiles treated in laundries. If the linen is washed in-house, wash all the fabrics (towels, curtains, etc.) with hot water (60°C or more, for at least 30 minutes) and with the addition of common washing powder. If hot water cannot be used because of the characteristics of the fabrics, specific chemical products for washing need to be added (e.g., laundry products containing sodium hypochlorite or decontamination products developed specifically for being used on fabrics).

- Place disposable items (paper towels, gloves, masks, handkerchiefs) in a container with a lid and dispose of them according to the facility's procedures and national waste management regulations.
- Extraordinary cleaning of public areas is not required when a confirmed COVID-19 case has spent a minimum amount of time there (e.g., climbing the stairs or walking down a corridor).
- If the cleaning service is provided by external personnel, make sure medical devices and PPE are used: surgical masks; uniform and overalls or disposable gown; gloves; safety goggles or face shield (if there is a risk of splashing of organic matter or chemicals).
- Perform hand hygiene each time gloves or face masks are removed. Waste materials produced during cleaning should be placed in a separate, tightly closed bag, to be disposed of in the unsorted waste bin.

4.5. Management of waste

Medical practices are to be equipped with the correct waste collection containers, including the PPE used.

A suitable space accessible only to authorized personnel is to be reserved for the temporary storage of containers pending collection.

Therefore, there must be special containers for medical waste containing Category B (UN 3291) infectious substances, which must be periodically removed from the medical practices and disposed of by authorized companies in accordance with the legislation in force.

Regarding the procedures for disposing of reagents and consumables used for the performance of the test and for the maintenance and sanitization of the devices used for reading the test results, refer to the manufacturer's instructions.

5. Procedures for performing diagnostic tests

5.1. Organizational and prevention measures for safely collecting swabs

Compared to the general precautions referred to in the previous points, some organizational and preventive measures are specifically necessary for safely collecting swabs.

- Choose an area of the practice that is to be dedicated specifically to diagnostic testing. The ventilation must be ensured and it must not be a passageway. There should be few high-frequency contact surfaces that can be disinfected rapidly using special an approved disinfectant or biocide.
- Ensure adequate ventilation of the rooms where this activity takes place by keeping a window open before, during, and after collection of the sample. Airing the room frequently, even if for short spells, is more effective than opening windows longer but less frequently. Where possible, it is recommended to position the swab collection stations in such a way as to make sure that staff and patients are not directly exposed to air draughts.
- Do not turn on ventilation and air conditioning systems, such as heat pumps or fan coils during visiting hours, because they recirculate the same air and could possibly spread the virus. Any heat pumps or fan coils that cannot be turned off, should be set to a minimum and the air flow that is generated should not be directed towards the area where the swabs are collected nor towards the areas where patients station (as this would cancel the effect of distancing between patients). The ventilation / air conditioning terminals and the grids must be regularly cleaned according to the instructions provided by the manufacturer and sanitized when the system is stopped. Use clean microfiber cloths moistened with water and common detergents, or with a 70% (v/v) ethyl alcohol solution, and then wipe dry. Avoid spraying cleaning products and detergents / disinfectants directly onto the filter to avoid inhaling pollutants during the cleaning operation. It is recommended to schedule filter cleaning regularly on the basis of the actual use of the ventilation / air conditioning terminal and the activities performed.
- When scheduling appointments, consider also the time required to process the samples.
- Patients taking the test are not to be accompanied into the testing room except minors or persons unable to cooperate or not self-sufficient. In this case, the presence of one carer is allowed who must be equipped with a surgical face mask or an FFP2 / FFP3 mask without a filter. If the carer were to have an active role in the collection procedure, he/she should wear the PPE envisaged for the procedure.
- In performing the test, priority should be given to:
  - people at risk of developing severe forms of the disease and frail individuals, such as the elderly with co-morbidities and the people they live with.
  - pupils / school staff who are in contact with children and with school-aged students in order to make sure they can attend school regularly.
- Avoid scheduling appointments back-to-back as this may result in queues or in having several people in the waiting room without physical distancing and sanitation through appropriate devices between one appointment and the next. Perform the swab collection procedure in compliance with the rules applied on the premises where the medical practice is located. In particular, the common areas of

the structure are not to be used as a waiting room or as a sampling site. Where possible, recommend that people accessing the doctor's practice use the stairs instead of the lift.

- When making an appointment for the diagnostic test the patients are to be adequately informed about the correct behaviour, about the technique used to perform the swab test, and about how they will be given the test result. If required, they are to provide any informed consent in advance so as to reduce to a minimum the time they spend in the clinic.
- Prefer electronic means for the results delivery to limit the time spent by patients in the medical practice.
- Process the samples according to the manufacturer's instructions to ensure the analytical quality and reliability of the tests.
- Make sure that patients over the age of 6 access the room wearing a face mask which is to be removed only when the sample is taken and repositioned immediately afterwards.
- Sanitize before and after collection of the swab sample: the chair the patients sit on for the oral-nasopharyngeal swab and anything the patient touches is to be disinfected with an approved disinfectant or biocide or, if not available, with a 70% ethyl alcohol solution before the next patient is admitted.

5.2. Recommendations for the medical practices of primary care paediatricians

- Take great care in keeping separate the access of paediatric patients coming in for check-ups or vaccinations from the patients coming in for the SARS-CoV-2 diagnostic test which should preferably be scheduled at the end of the day's work.
- Recommend that children undergoing the test be accompanied by only one person.
- When booking appointments remember to inquire about the health of the person accompanying the child.
- Give priority to immunocompromised children, to children with previous diseases and to those who attend kindergartens.
- Consider different approaches to the collection of the biological material in relation to the age and compliance of the child: for infants, envisage the presence of a nurse for the execution of the nasopharyngeal sampling, while a parent could provide support for the simpler nasal swab.

5.3. Personal protection equipment for physicians and staff

Disposable waterproof gowns, shoes, gloves, face shields (if not available, protective goggles), and face masks (FFP2 / FFP3) are to be worn when performing the tests. In addition to using the appropriate PPE, hand hygiene is always of the utmost importance.

Gloves are to be replaced after each patient.

PPE that cannot be reused must be disposed of in an appropriate waste container and hand hygiene must be performed before putting the protection equipment on and after removing it.

The respirator must cover the nose, mouth and chin well and must fit snugly against the sides of your face. However, it must be replaced immediately if damaged, contaminated or damp. The use of an FFP2 or

FFP3 by men with a beard is not recommended. The mask must adhere perfectly to the sides of your face even when you move your face.

Masks, respirators and gloves cannot be reused and are to be disposed of properly.

A disposable waterproof apron can be used in the absence of a disposable waterproof gown.

5.4. Operational guidance for performing the tests

For the execution of the tests follow the manufacturer's instructions, both for the collection and processing of the samples, being careful to comply with the timing between the time of sampling and the reading of the results and the comparison with the control band.

For infants (0-3 years) preferably use swabs for paediatric use or, if not available and only if required by the test, perform a pharyngeal sampling (using a tongue depressor) as an alternative to the nasopharyngeal swab.

A video on the correct execution of the anterior nasal swab is available at: https://www.youtube.com/watch?v=DYRz3j6HNag&feature=youtu.be.

Other tutorials will be made available at the Epicentro portal of the Istituto Superiore di Sanità (ISS, the National Institute of Health in Italy).

6. Management of patients in relation to test results

The results of the test are to be communicated to the Prevention Department in accordance with the organizational methods of one's Region and in accordance with the operational guidelines of the Circular of the Ministry of Health dated 3/11/2020 "Operational guidelines for carrying out rapid antigen tests by general practitioners and primary care paediatricians".

The management software of GPs and PCPs must include a specific function for recording the results of the swabs and for transmitting them to the electronic health record.

In this regard, the Decree-Law no. 137 of 28 October 2020, "Additional urgent measures in the area of health protection, support for workers and businesses, justice and security, regarding the COVID-19 epidemiological emergency", provides in Article 19 that the functionalities of the Health Card System are to be used for transmitting the test results. General practitioners and primary care paediatricians draw up electronic reports on the swabs performed, indicating the results of the tests and providing the information required by the epidemiological surveillance system.

The Health Card System will allow you to:

- enter the report into the electronic health record.
- transmit the information to the competent Prevention Department, to the Extraordinary Emergency Commissioner and report the number of rapid antigen swabs performed, aggregated by Region or Autonomous Province.
- transmit to the platform set up at the ISS in pursuance of Order no. 640 of 27 February 2020 of the Head of the Department of Civil Protection, the number of rapid antigen swabs and the number of rapid swabs carried out by type of patient, indicating the number of positive and negative results for subsequent transmission to the Ministry of Health so that the latter can carry out its functions in the field of prevention and control of infectious diseases and, in particular of COVID-19.

Positive results of the rapid antigen test are to be notified to the competent Hygiene and Public Health Service (*Servizio di Igiene e Sanità Pubblica,* SISP) or to the Department of Prevention and in any case to a competent health authority, and the people who tested positive must undergo to a molecular test for confirmation and after they are followed up through telemonitoring and remote surveillance tools.

People who have tested negative will be given care according to their specific needs.

7. Training activities

In order to facilitate the start of activities related to the execution of rapid swabs by the GPs and the PCPs, a training course with CME (Continuing Medical Education) credits will be set up on the online training platform of the ISS, EDUISS.

In addition, a video-tutorial on how to put on and take off PPE correctly is already available at: https://www.epicentro.iss.it/coronavirus/sars-cov-2-ipc-video-vestizione-svestizione