Guidelines for Aero-Medical Centres and Aeromedical Examiners regarding the examination and assessment of applicants

Guidelines in relation to the COVID-19 pandemic

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Revision record

Issue	Date of issue	Summary of changes
01		Initial issue
02		Changes limited to [brief description of changes]

Change Revision Summary

Paragraph no.	Description of change
	(brief description)

1. Purpose and applicability

This document provides guidance for Aero-Medical Centres (AeMCs), Aeromedical Examiners (AMEs), General Medical Practitioners (GMPs) and Occupational Health Medical Practitioners (OHMPs) in regard to performing examinations and assessments of applicants for an initial, revalidation or renewal of a medical certificate class 1, 2, 3 or LAPL, or of a cabin crew (CC) medical report, as applicable, during the COVID-19 pandemic.

The document aims to assist the AeMCs, AMEs, GMPs and OHMPs by providing guidelines and management recommendations able to identify aircrew and ATCO applicants, that in any way have been associated with the COVID-19. Furthermore, it aims at indicating suitable options and framework to consider, in order to identify the compatibility of the exposed candidate with the established framework of Part-MED concerning infectious diseases and, consequently, relevant also for COVID-19, in order to ensure flight safety.

Additionally, the document provides recommendations on the management of active infection cases of SARS-CoV-2 and to establish control measures to avoid new infections.

The medical assessors of the national competent authorities (NCA) should give proper consideration to the recommendations below when performing assessment of applicants following referrals, requests for secondary review, change of a competent authority or consultations, and when reviewing medical files for the purpose of continuous oversight of AMEs.

2. Background

The SARS-CoV-2 Pandemic has generated many publications and a great load of reports and information related to diagnosis, treatment and follow-up of patients with COVID19.

Since the beginning of the pandemic numerous aircrew members and ATCOS have been infected with SARS-CoV-2 virus, which led for many of them to the development of COVID-19 symptoms of various severity levels.

From a pure aeromedical view, we have to discuss how to manage and handle the return to flying duties and air traffic control operations of those applicants who suffered from the disease, those who might be considered asymptomatic carriers and hence to identify those who might be infected. Furthermore, some of the symptomatic COVID-19 patients reported medium- and long-term sequelae which, in case of aeronautical personnel, may interfere with the safe performance of their tasks.

Furthermore, Part-MED requires certain medical examinations such as pulmonary functional tests, which may pose additional risk for the applicant and for the medical practitioner performing it in the context of the pandemic. This has been considered as a risk of transmission for other applicants and for the medical staff performing the examinations and such examinations have been either stopped or performed only for exceptional situations.

At the time of the drafting, one SARS-CoV-2 vaccine was assessed and recommended by the European Medicines Agency (EMA). Once approved this may become available for use also by aviation personnel. In this regard certain recommendations are made to address the potential adverse reactions which may interfere with the safe performance of their tasks.

Already several EU Member States have started developing national guidelines in this regard. EASA has used as a starting point and reference the good work of AESA in Spain and DGAC and Percy AeMC in France in developing their national guidelines.

3. COVID-19 symptoms and characteristic features

The most common symptoms and signs in laboratory-confirmed COVID-19 cases include:

- fever
- dry or productive cough
- asthenia
- dyspnoea
- sore throat
- headache
- myalgia or arthralgia
- shivers
- nausea or vomiting
- nasal congestion
- diarrhoea
- haemoptysis
- conjunctival congestion

Some less frequent symptoms, but with high relevance for the medical fitness include:

- Neurological: dizziness, altered level of consciousness, stroke, ataxia, epilepsy, neuralgia and Guillain-Barré syndrome.
- Cardiological: heart failure or acute myocardial damage.
- Ophthalmological: dry eye, blurred vision, foreign body sensation and conjunctival congestion.
- Otolaryngology: facial pain, nasal obstruction, olfactory and taste dysfunction.
- Dermatological injuries.
- Haematological: thrombotic phenomena or bleeding.

COVID 19 is a dynamic process that corresponds to a variable clinical course, but with a quite uniform syndromic expression. The disease course may vary from a mild evolution, treated at home and with phone follow-up, to a medical ambulatory /visit medical follow-up, to hospital admission or even to ICU care.

3.1. Laboratory diagnosis

There are three main types of detection assays relevant for COVID-19 diagnostic testing and screening, based on the target that is being detected:

- Nucleic acid tests detect the presence of viral RNA. Typically, these are RT-PCR and RT-LAMP. Both types use an amplification-based process. The gold standard so far has been the RT-PCR due to its very good sensitivity and specificity. RT-LAMP tests demonstrated sensitivity and specificity levels close to RT-PCR for patients with high viral load, however it had lower performance in patients with low viral load. RT-LAMP tests are being considered for validation as diagnostic tests in several Member States.

- Antigen tests detect the presence of a viral antigen, typically part of a surface protein. They are also known as Rapid Antigen Detection Tests (RADT). Several RADTs manage to achieve sensitivity and specificity performances close to RT-PCR for patients with high viral load, however it had lower

performance in patients with medium and low viral load. Several RADTs have been validated by Member States for use in health care facilities. Currently RADTs are not recommended for use in low prevalence populations.

- Antibody tests detect the presence of antibodies generated against SARS-CoV-2. The three most used assays are enzyme-linked immunosorbent assays (ELISA), chemiluminescence assays (CLIA) and lateral flow assays (LFA). In addition, virus neutralisation tests are used, which can specifically detect neutralising antibodies, but this is mainly used for assay validation and research. Preliminary reports on ELISA assays have shown good correlation of antibody titration results with virus-neutralising antibodies.

Apart from these main detection assays, whole genome sequencing can also be performed to determine the sequence of the SARS-CoV-2 virus in a sample, with possible quasi-species variants.

The Figure 1 below presents the transmissibility periods depending on the severity of the disease and the average detection periods by various testing methods based on current evidence.

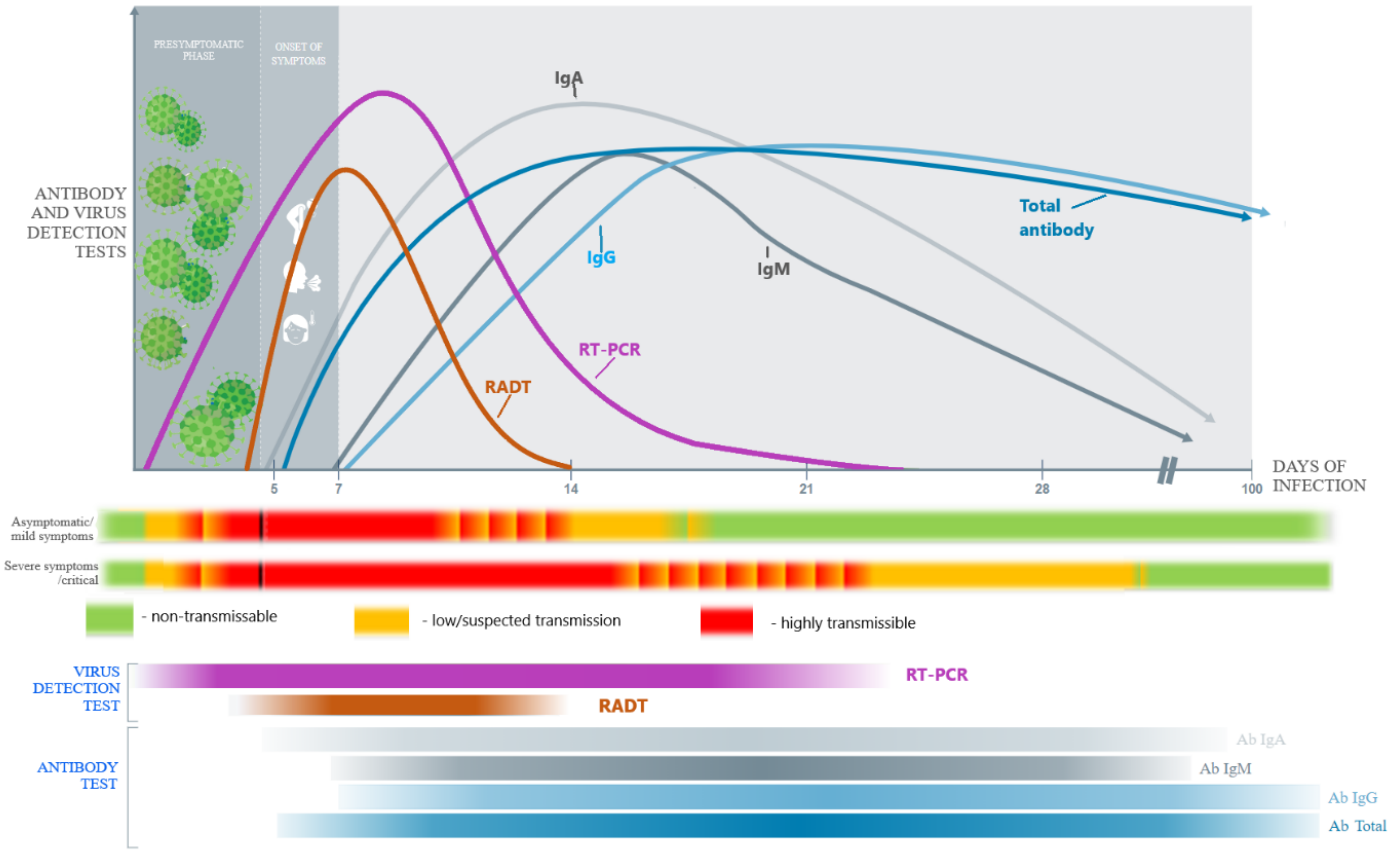


Figure 1 Transmissibility and detection periods of SARS-CoV-2[1]

[1] Figure 1 is based on the scientific information provided by the Ministry of Health of Spain on their website updated on 12 Nov 2020 - https://www.mscbs.gob.es/profesionales/saludPublica/ccayes/alertasActual/nCov/documentos/ITCoronavirus.pdf, and on the internal evidence presented by Synlab on their web-page https://www.synlab.es/es/Noticias/Noticias.aspx?idc=1786 as well as on other existing evidence on testing and transmissibility

4. Aero-medical examination and assessment

In the context of the characteristics detailed in section 3 of COVID-19 the AMEs should give proper consideration to the following Part-MED and Part ATCO.MED requirements and their corresponding AMC/GM:

- **MED.A.020 Decrease of medical fitness**
- **MED.A.050 Referral**
- **ATCO.MED.A.020 Decrease of medical fitness**
- **MED.B.015 Respiratory System**
- **ATCO.MED.B.015 Respiratory system**
- **MED.B.040 Infectious diseases**
- **ATCO.MED.B.040 Infectious Diseases**
- **MED.B.095 Medical examination and assessment of applicants for LAPL medical certificates**
- **MED.C.025 Content of aero-medical assessments**

Taking into account the symptoms and signs enumerated in section 3 AMEs should specifically ask to the applicant about items displayed in the application form which could be associated to COVID 19:

- 101 (Eye trouble)
- 105 (Other respiratory diseases)
- 106 (Heart or vascular trouble)
- 112 (Nose, throat disorder)
- 115 (Dizziness)
- 117 (Neurological disorders)
- 127 (Musculoskeletal illness)
- 128 (Other diseases)
- 129 (Hospitalization)
- 130 (medical visit)

In order to ensure a proper assessment, the AME should aim at:

- Collecting all medical reports provided by the applicant and asking about their occupational health status;
- Identifying details regarding the diagnosis, course of treatment and hospital admission, and in case of mild disease, what kind of preventive measures has been followed, including quarantine and possible confirmed contacts;
- Comprehensively reviewing all medical reports in terms of the clinical data, complementary testing, including laboratory and image diagnosis, and treatment provided, including oxygen therapy or assisted ventilation.
- Giving proper consideration to the presence of comorbidity and complications.

Once this data has been collected, the AME should assess the quality and usability of the information received for a comprehensive aeromedical assessment or if any additional testing might be necessary, which may include, but not limited to: temperature, TC/TCAR, thoracic echography, pulmonary

function test, SpO2 follow-up, dyspnoea scale (MRC) & quality of life, 6 min walk test, ECG (QT/QTc), echocardiography, comorbidity, target organs involvement and specialist report.

In accordance with MED.B.015(b) and ATCO.MED.015(b), class 1 and class 3 applicants are required to undertake pulmonary functional tests during their initial examination. This was seen as difficult to achieve in the first months of the pandemic and Member States had to either suspend the initial class 1 and class 3 examinations or to find suitable alternatives. As the RT-PCR test became readily available and the turn-around time for the results has shortened to 24 hours or less, this is expected to enable the restart of relatively normal pulmonary functional tests. Consequently, AeMCs should consider requesting the initial applicants for class 1 and class 3 medical certificates to present a RT-PCR test performed withing 24 hours prior to the relevant aero-medical examination to reduce the risk of contamination for other users and for the medical professionals performing the test. Furthermore, the symptomatic applicants should not be allowed to continue the examination until a potential COVID-19 will not be excluded, and the equipment should be cleaned and disinfected after each examination in accordance with the recommendations of the equipment manufacturer.

As a SARS-CoV-2 vaccine was approved for use in Europe, AMEs should inform their applicants that subject to national prioritisation, when SARS-CoV-2 vaccines become available for various categories of aeronautical personnel. Under EU aviation medicine rules, as detailed in Annex IV – Part-MED of Regulation (EU) 1178/2011 and Annex IV – Part ATCO.MED of Regulation (EU)2015/340, there are no regulatory restrictions preventing aviation personnel subject to medical certification to get inoculated with the vaccine currently approved by EMA.

The knowledge regarding the adverse reactions to the vaccines or the potential impact on medical fitness and flight safety will continue to improve once the vaccination process will advance. More scientific information will become available supporting the aero-medical risk assessment which could also require adjusting the recommendations below. Notwithstanding, vaccinated applicants shall be informed about the requirement to immediately seek aero-medical advice if they experience adverse reactions to the vaccines.

5. Conclusions and recommendations

The SARS-CoV-2 infection is a dynamic process, that corresponds to a variable clinical course, but with a quite uniform syndromic expression.

Disease course may vary from a mild evolution, treated at home and phone follow-up, to medical ambulatory /visit medical follow-up, to hospital admission or ICU care.

In addition to the clinical expression of the actual COVID-19, AMEs should take into account psychological and mental status changes as a consequence of family or acquaintance mourning, long stay in ICU, and financial consequences due to loss of employment, changes in working schedule etc. Sudden changes in the wellbeing and mindset of the applicants may have a negative impact on the aeronautical environment. Such scenario should be explored during the mental health interview for all applicants.

The ever-changing nature of this illness means that AMEs need to keep their focus on the effect of the infection on the physiology of their applicants and potential implications on flight safety. Furthermore, the AMEs should continuously monitor the scientific evidence and the epidemiological situation at the time of the applicant examination.

To limit the risk of medium- and long-term complications, medical assessors of the NCAs could consider the necessity of additional investigations and/or follow-up by shorts periods of time for selected applicants.

There are two main scenarios where the AMEs will be requested to provide their aero-medical expertise due to the identification of a decrease of medical fitness:

1. The first one, when the aircrew/ATCO, during the validity of their medical certificate, notices a decrease of his medical fitness and communicates it to their AME.
2. The second one, where the AME receives or identifies the issue during the examination of an aircrew/ATCO for the initial issue, renewal or revalidation of a medical certificate or a cabin crew medical report, as applicable.

In both cases, the AME should evaluate the applicant and inform them of their obligations in accordance with MED A.020. In case of disease identification or risk of being contagious, the AME should direct the applicant to the appropriate health care professionals and proceed to deny the issuance of a new or suspend the currently valid medical certificate. The withdrawal of the suspension or the issuance of the medical certificate should be considered only after coordination with appropriate health care professionals.

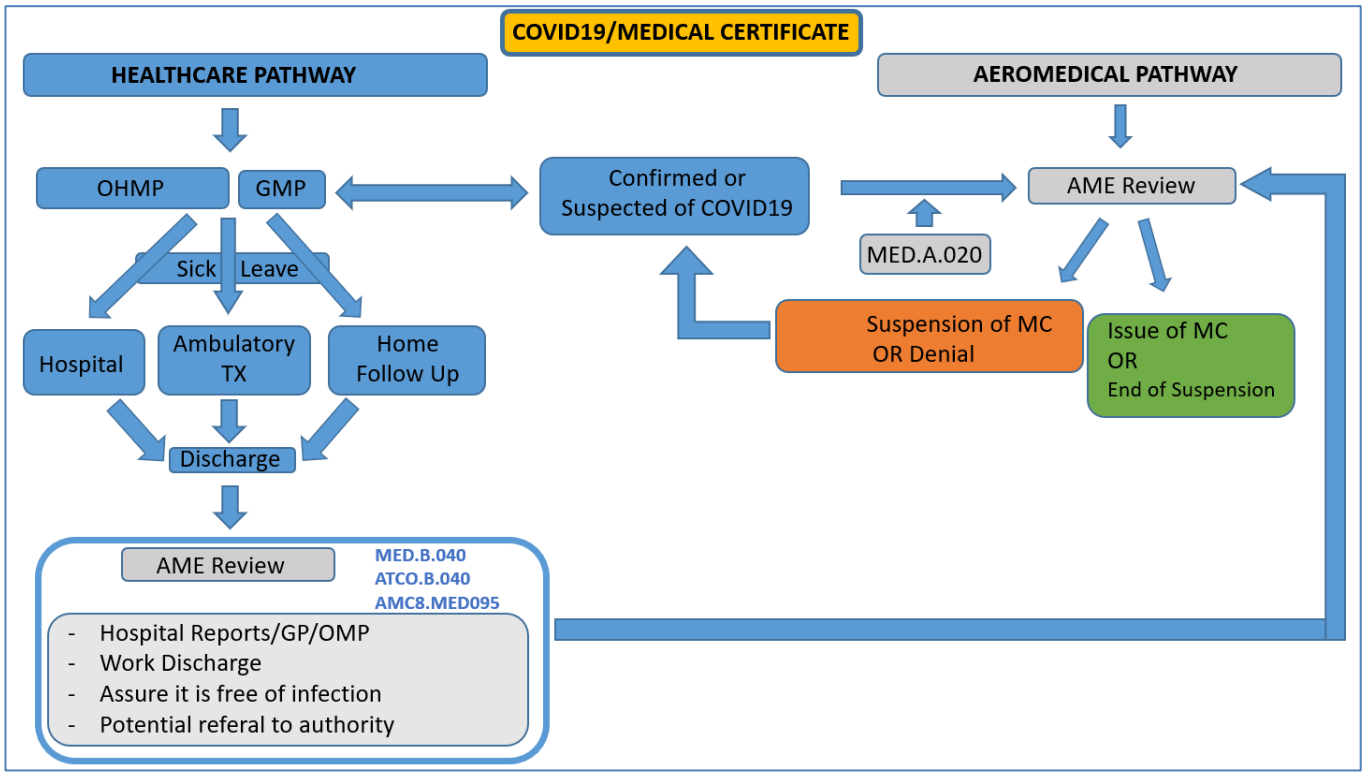
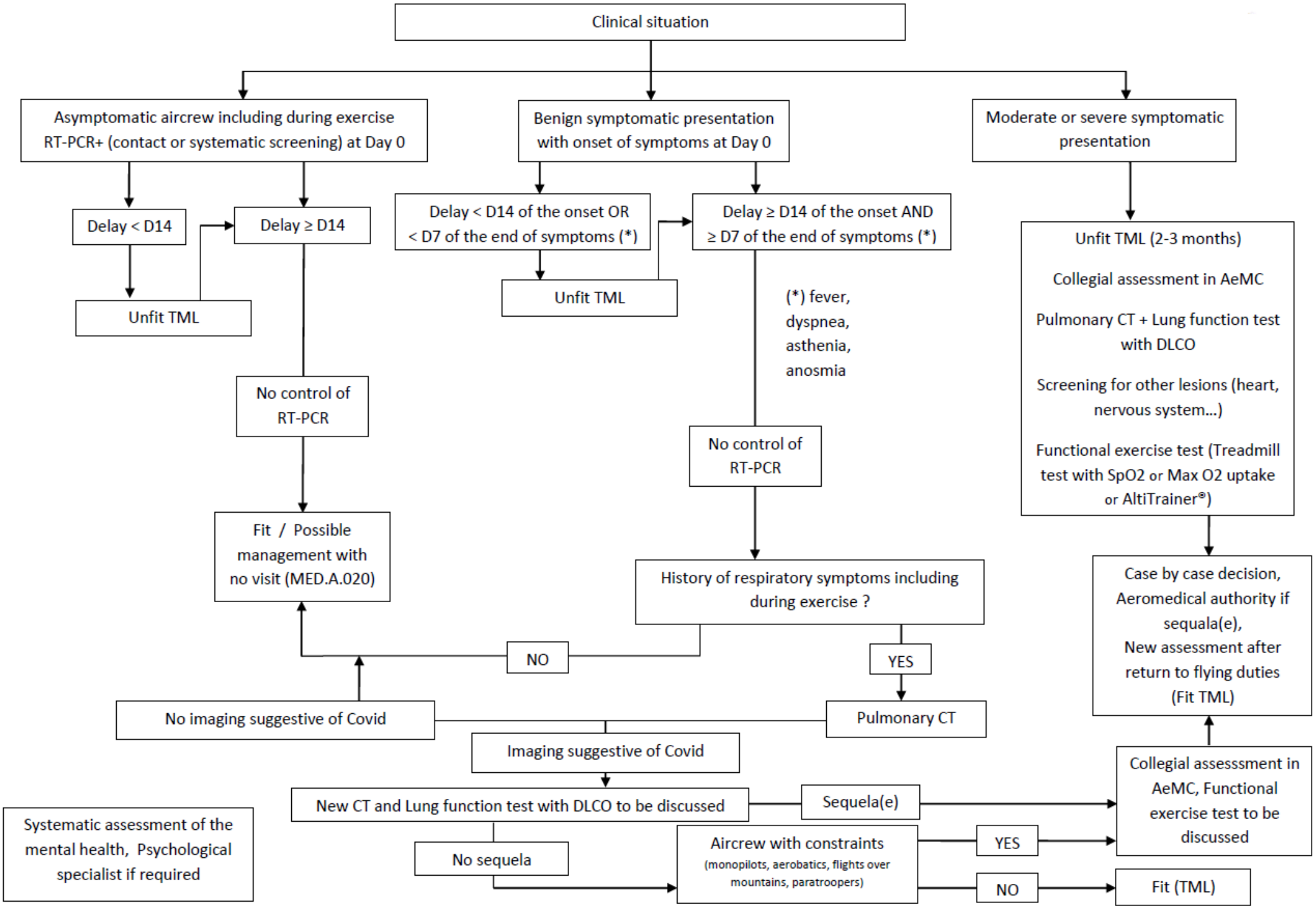


Figure 2 specific assessment of applicants post COVID-19 infection

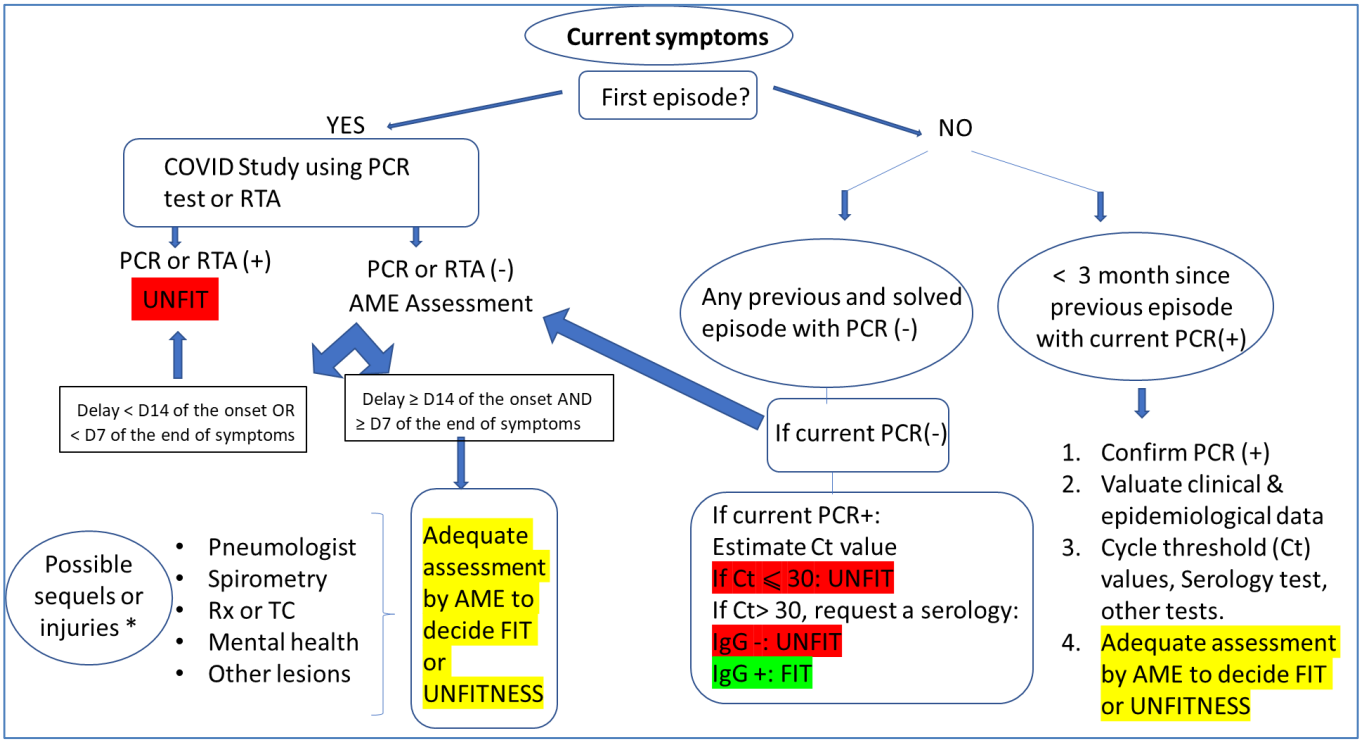
The flowchart below developed by the Percy AeMC in the coordination of the French Ministry of Armed Forces and the French DGAC, is summarizing the steps to take for the assessment of applicants the COVID-19 positive during their active infection and post infection.

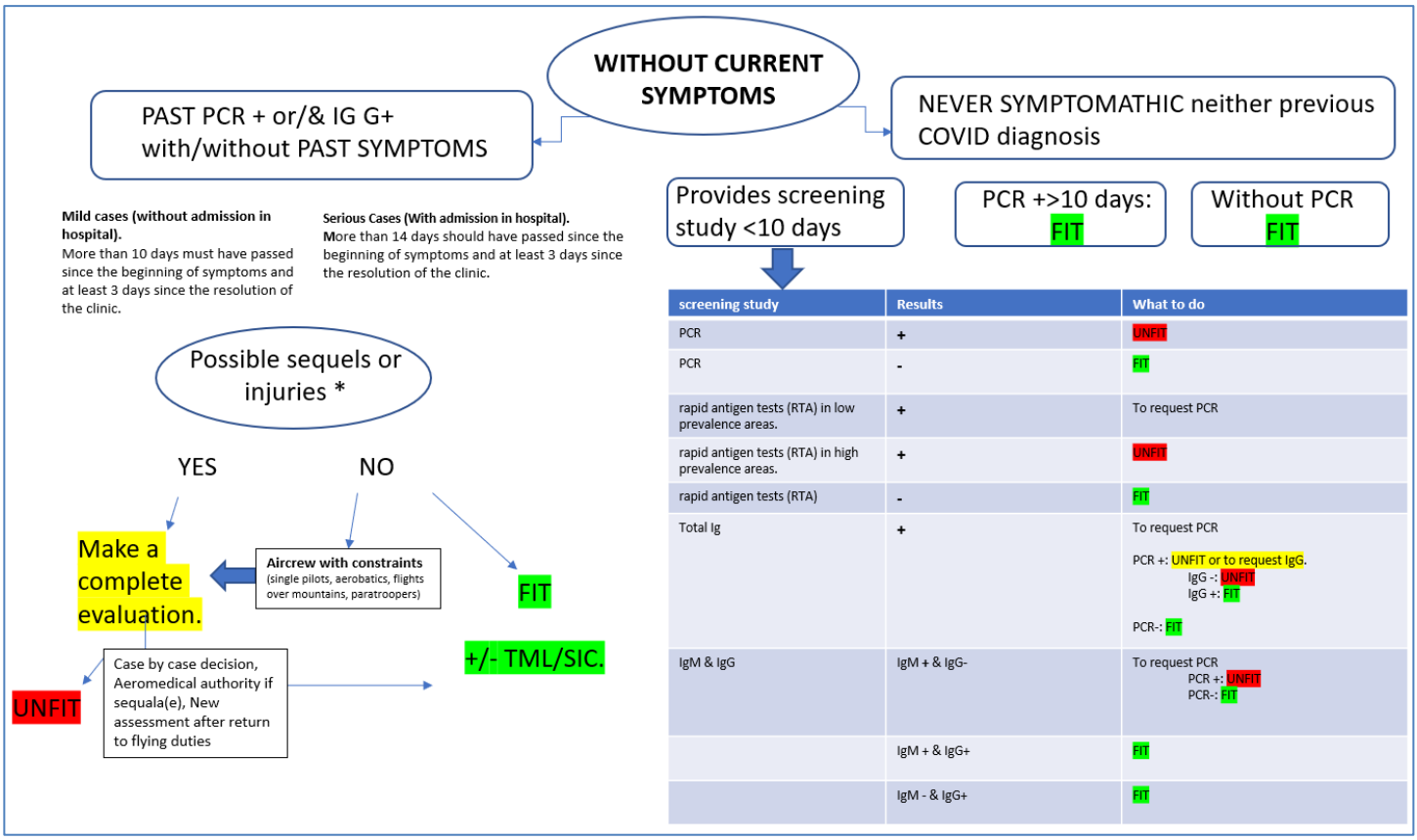

Clinical situation
Asymptomatic aircrew including during exercise RT-PCR+ (contact or systematic screening) at Day 0
Benign symptomatic presentation with onset of symptoms at Day 0
Moderate or severe symptomatic presentation
Delay < D14
Delay ≥ D14
Unfit TML
Delay < D14 of the onset OR < D7 of the end of symptoms (*)
Unfit TML
Delay ≥ D14 of the onset AND ≥ D7 of the end of symptoms (*)
(*) fever, dyspnea, asthenia, anosmia
Unfit TML (2-3 months)
Collegial assessment in AeMC
Pulmonary CT + Lung function test with DLCO
Screening for other lesions (heart, nervous system...)
Functional exercise test (Treadmill test with SpO2 or Max O2 uptake or AltiTrainer®)
No control of RT-PCR
No control of RT-PCR
Fit / Possible management with no visit (MED.A.020)
History of respiratory symptoms including during exercise ?
Case by case decision, Aeromedical authority if sequala(e), New assessment after return to flying duties (Fit TML)
NO
YES
No imaging suggestive of Covid
Pulmonary CT
Imaging suggestive of Covid
Collegial assesssment in AeMC, Functional exercise test to be discussed
New CT and Lung function test with DLCO to be discussed
Sequela(e)
Systematic assessment of the mental health, Psychological specialist if required
No sequela
Aircrew with constraints (monopilots, aerobatics, flights over mountains, paratroopers)
YES
NO
Fit (TML)

More specifically and considering all the above, the AMEs should consider performing the following actions for the assessment of COVID in aircrew/ATCO:

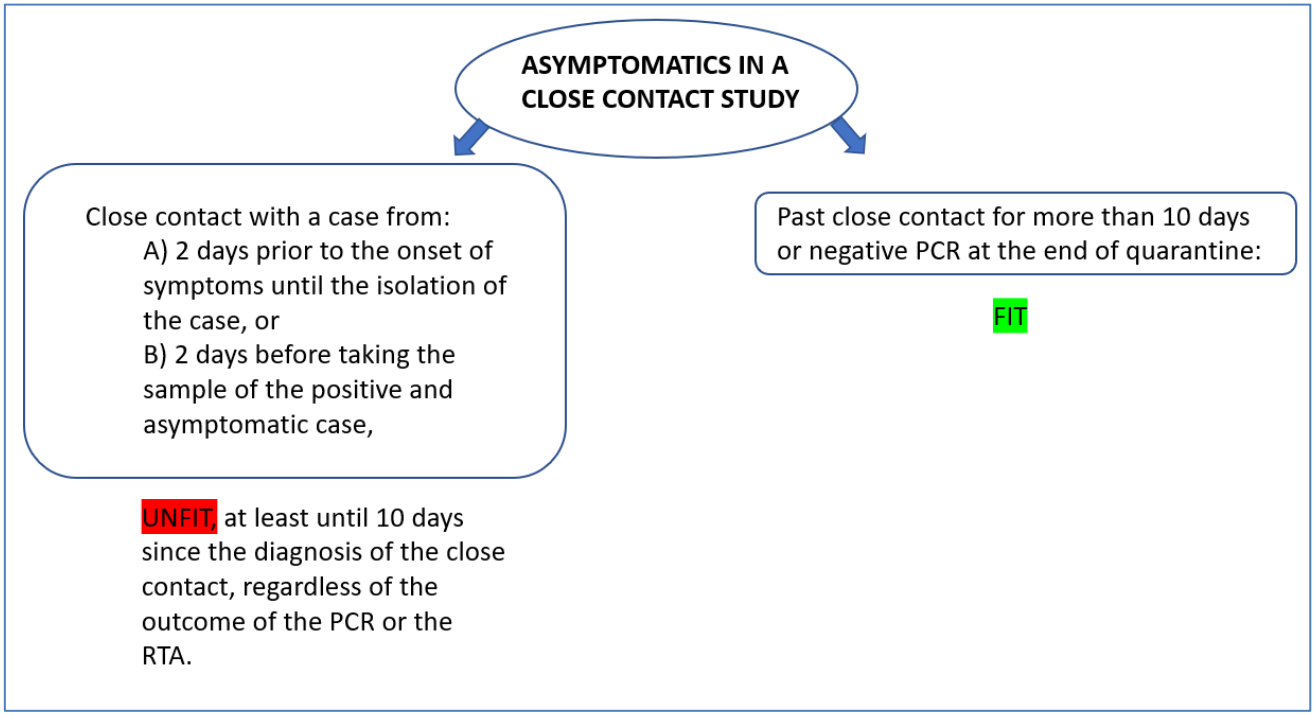
1. AMEs should ensure that medical requirements defined in Reg. (EU) 1178/2011 and 2015/340, and AMCs and GM are fully respected.
2. Aero-medical evaluation is performed taking into account the history, clinical examination, and relevant additional investigations and procedures AME consider appropriate according to the findings and their assessment.
3. The assessment should take into account both the clinical perspective and the transmissibility.
4. The circumstances of the history, the favourable progression, the absence of sequelae or injuries, a supporting report from the treating physician, and the laboratory diagnosis testing if necessary, may lead to an unfit assessment, un-restricted fit assessment or the need of a close follow up and/or to impose operational limitations.
5. The AME should inform the applicant that full and up to date clinical report must be provided in order to proceed to a new exam.

Depending on whether the applicants are symptomatic or asymptomatic the approach in the assessment may be adapted as detailed below:





screening study	Results	What to do
PCR	+	UNFIT
PCR	-	FIT
rapid antigen tests (RTA) in low prevalence areas.	+	To request PCR
rapid antigen tests (RTA) in high prevalence areas.	+	UNFIT
rapid antigen tests (RTA)	-	FIT
Total Ig	+	To request PCR PCR +: UNFIT or to request IgG. IgG -: UNFIT IgG +: FIT PCR-: FIT
IgM & IgG	IgM + & IgG-	To request PCR PCR +: UNFIT PCR-: FIT
	IgM + & IgG+	FIT
	IgM - & IgG+	FIT



In regard to the SARS-CoV-2 vaccination, as with any other drug, in the context of MED.A.020, ATCO.MED.A.020 and corresponding GM, the recipients are required to observe the precautions

stipulated by its manufacturer. Furthermore, they should consider consulting with their AME prior of receiving the vaccine and discuss regarding potential precautions needed to be observed after being administered the vaccine.

The aviation personnel should be advised to consider taking the vaccine and should be reminded of their responsibilities in relation to the provisions of MED.A.020 Decrease of medical fitness and its corresponding GM as well as the equivalent ATCO.MED.A.020 and its corresponding GM and consult their AME before performing any safety related tasks.

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