Suggestion to identify people for laboratory testing for novel coronavirus (nCoV)

The aim of this document is to provide EU/EEA Member States with a quick guidance for the testing of individuals for the novel coronavirus (nCoV). Prompt case confirmation is necessary to ensure rapid and effective contact tracing, implementation of infection prevention and control measures according to national recommendations, and collection of relevant epidemiological and clinical information.

The following guidance is subject to change as more information becomes available from ongoing epidemiological investigations in China.

Criteria to initiate testing for novel coronavirus (nCoV)

Any person fulfilling the **epidemiological AND clinical** criteria should be tested for nCoV. The laboratory method is provided below. The laboratory test should be initiated immediately when the below criteria are fulfilled.

Epidemiological criteria

- Any person with travel-history to Wuhan City in the 14 days 1 before the onset of illness \mathbf{OR}
 - Any person being in close contact² with a laboratory-confirmed case infected with nCoV

Clinical criteria

 Any person with clinical symptoms compatible with severe acute respiratory infection seeking healthcare or admitted to hospital with clinical or radiological evidence of viral pneumonia

OR

 Any person with fever or recent history of fever (>=38°C) and acute respiratory infection (sudden onset of respiratory infection with one or more of the following symptoms: shortness of breath, cough or sore throat)

Types of specimens

According to WHO interim guidance on laboratory testing of human suspected cases of nCoV infection, rapid collection of the following specimens should be considered:

- respiratory material (nasopharyngeal and oropharyngeal swab in ambulatory patients and sputum (if produced) and/or endotracheal aspirate in patients with more severe respiratory disease);
- serum for serological testing, acute sample and convalescent sample (this is additional to respiratory materials and can support the identification of the true agent, once serologic assay is available)
- other specimens to consider in unresolved cases: blood for culture, urine for *Legionella* and pneumococcal antigen detection.

Respiratory specimen collection from upper and in particular lower respiratory tract, which might be preferable, should be performed under heightened infection prevention and control measures

¹ Limited information is available, an incubation period for nCoV up to 14 days is assumed, which is based on the knowledge of MERS-CoV and SARS-CoV epidemiology data.

² Close contact: family members or people living in the same household; close (2m distance) or direct contact with the person e.g. health care or laboratory worker, direct exposure to body fluids or specimens including aerosol;

(airborne precautions) according to WHO interim guidance or national guidelines and recommendations.

Currently there is limited information about the best point in time for specimen collection. In analogy with other viral respiratory infections, it is likely that respiratory specimens collected early during the course of infection yield higher virus concentration. Subsequent specimens should also be collected during the course of infection.

Testing methodology

The specific tests currently recommended by WHO for the diagnosis and confirmation of nCoV are described in a dedicated WHO webpage, where the laboratory diagnostic protocol for real-time RT-PCR developed by Charité, Berlin Germany can also be found. Additional confirmation of positive results should be performed in specialised laboratories for coronavirus e.g. as indicated below. When possible, sequence information should be generated from positive specimens and shared, to allow comparison with available sequence data. Sequencing of viral isolates should be performed by national reference laboratories or specialised laboratories experienced in handling coronavirus analysis.

Rapid sharing of information with local, national and international public health authorities is advised for early implementation of response measures.

Laboratory support (for primary/and or confirmatory testing) by Coronavirus specialised laboratories in the EU

Any positive test can be sent for confirmation to one of the two European expert laboratories for coronaviruses: