**Notice by SITTA CC, legal and strategic advice:**

This WHO notice proofs that a positive test is not, repeat not suitable to detect an infection. A positive test only proofs presence of elements of a virus. Only if complete virus(es) which are able to multiply and actually multiply are within the body the human is infected. But that does not mean sickness as the natural immune system still is able to manage the virus(es). It also does not mean infectious in the meaning that the human can infect others. PCR tests are therefore due to lack of informative substance not suited to serve as fundament for any legislation or any kind of administrative activity in fighting a disease or a so-called pandemic. This WHO clarification destroys therefore any and every public action based on PCR testing.

Dr iuris Harald Sitta

**WHO Information Notice for IVD Users 2020/05**

**Nucleic acid testing (NAT) technologies that use polymerase chain reaction (PCR) for detection of SARS-CoV-2**

20 January 2021

Medical product alert

Geneva

Reading time: 1 min (370 words)

[**Français**](https://www.who.int/fr/news/item/20-01-2021-who-information-notice-for-ivd-users-2020-05)

[**Español**](https://www.who.int/es/news/item/20-01-2021-who-information-notice-for-ivd-users-2020-05)

**Product type:**Nucleic acid testing (NAT) technologies that use polymerase chain reaction (PCR) for detection of SARS-CoV-2

**Date:** 13 January 2021

**WHO-identifier:**2020/5, version 2

**Target audience:** laboratory professionals and users of IVDs.

**Purpose of this notice:** clarify information previously provided by WHO. This notice supersedes WHO Information Notice for In Vitro Diagnostic Medical Device (IVD) Users 2020/05 version 1, issued 14 December 2020.

**Description of the problem:** WHO requests users to follow the instructions for use (IFU) when interpreting results for specimens tested using PCR methodology.

**Users of IVDs must read and follo**w the IFU carefully to determine if manual adjustment of the PCR positivity threshold is recommended by the manufacturer.

WHO guidance [Diagnostic testing for SARS-CoV-2](https://www.who.int/publications-detail-redirect/diagnostic-testing-for-sars-cov-2) states that careful interpretation of weak positive results is needed (*1*). The cycle threshold (Ct) needed to detect virus is inversely proportional to the patient’s viral load. Where test results do not correspond with the clinical presentation, a new specimen should be taken and retested using the same or different NAT technology.

WHO reminds IVD users that disease prevalence alters the predictive value of test results; as disease prevalence decreases, the risk of false positive increases (*2*). This means that the probability that a person who has a positive result (SARS-CoV-2 detected) is truly infected with SARS-CoV-2 decreases as prevalence decreases, irrespective of the claimed specificity.

Most PCR assays are indicated as an aid for diagnosis, therefore, health care providers must consider any result in combination with timing of sampling, specimen type, assay specifics, clinical observations, patient history, confirmed status of any contacts, and epidemiological information.

**Actions to be taken by IVD users:**

1. Please read carefully the IFU in its entirety.
2. Contact your local representative if there is any aspect of the IFU that is unclear to you.
3. Check the IFU for each incoming consignment to detect any changes to the IFU.
4. Provide the Ct value in the report to the requesting health care provider.

**Contact person for further information:**

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