



Government of Western Australia Department of Health

COVID-19 Point of Care serology testing

COVID-19 Point of Care serology testing is prohibited in Western Australia

Unless authorised, a person must not use a Point of Care (POC) Test as a tool to detect or diagnose COVID-19.

Point of Care (POC) serology testing (including an assay or device), as a tool to detect or diagnose acute COVID-19, is currently prohibited under the <u>Prohibition on the use of point of care serology tests directions</u>, issued on 1 April 2020 under the *Public Health Act 2016* (Western Australia).

Point of care serology test kits

Currently available point of care serology test kits have not been validated. The sensitivity and specificity of the tests is not known. While these tests are supposed to be specific for COVID-19, the amount of cross reactivity with other coronaviruses is unknown. Positive tests may not be detecting COVID-19, but an infection with another coronavirus.

There is also a risk of false negative results; antibodies to the disease are likely to take 5 to 7 days to become detectable by these basic tests. Therefore, these tests are of limited use for the diagnosis of acute infection. If used in the early stages of COVID-19, before a person has developed antibodies to the virus, there is a risk that the test will come back negative

POC testing for COVID-19 as research

For POC testing for COVID-19 to be justified as research for the purposes of contributing to public health knowledge and practice, demonstration of the following components of research need to be provided to the Chief Health Officer for review:

- a research proposal that has been endorsed by a registered research organisation
- human research ethics approval and
- evidence that the relevant POC serology test for COVID-19 has been validated, including a quality assurance protocol used for this purpose.

Unauthorised testing wastes resources required to prevent, control or abate the serious public health risk presented by COVID-19.

For further information on Testing Directions refer to WA Government website.

Last updated 2 May 2020

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