

THE PATHCARE NEWS

AN UPDATE ON SARS-COV-2 ANTIBODY TESTING



In response to the many questions being asked of us as to when we would be able to offer antibody testing; this is a brief note of explanation as to the processes we have to follow before we may offer the tests.

REGULATOR

For suppliers of invitro diagnostic tests to sell test kits to us, approval and registration with SAHPRA (South African Health Products Regulatory Authority) is necessary.

This requirement is also applicable to rapid testing for SARS-CoV-2 antibody kits. One kit currently has Section 21 approval from SAHPRA, but was not made available to the private sector in South Africa. A number of lesser known laboratories (and not ISO accredited) are making claims of being able to provide these – they are not approved by SAHPRA yet and consequently their use in the private sector in South Africa would not be legal at this stage.

INDEPENDENT EVALUATIONS

As we could see the usefulness of such testing, the private laboratories that are part of the National Pathology Group (NPG) engaged with SAHPRA early in order to contribute to the necessary validations to ensure international test kits would also be useful in the South African population.

PathCare, Lancet and Ampath did independent studies in four different locations to compare the testing proficiency of at least four different manufacturers' kits and submitted these to SAHPRA. The NHLS, through the Department of Haematology and Molecular Medicine, at Wits also ran a validation study and submitted these data to SAHPRA. There is a difference between the outcome of the data from the NHLS and that of the independent laboratory submissions.

PROCESSES FOLLOWED

Many engagements have taken place over the last few weeks in order to find a way forward to allow SAHPRA to register some of these tests for use in laboratories, but to date this has unfortunately not been forthcoming. Submissions and appeals have been made to SAHPRA, the Ministerial Advisory Committee, and the National Department of Health.

Unfortunately, until such time as this registration takes place, we may not offer antibody testing in our labs.

We will keep you updated on any progress as it occurs.

Yours,
Dr John Douglass