

MEDSAFE (New Zealand Medicines and Medical Devices Safety Authority) is the **New Zealand Medicines and Medical Devices Safety Authority**. It is a business unit of the Ministry of Health and is the authority responsible for the regulation of therapeutic products in New Zealand.

MEDSAFE published an alert for a single typographical error Interpretation of Results section of the Instructions for Use (IFU) for the Rapid COVID-19 Antigen Self-Test, the word “position” was used instead of “positive” for the test result. The alert also states that the procedure card and the images on the outer packaging are correct.

MEDSAFE noted that the quality of the test had not been affected by the use of “position” instead of “positive” in the IFU. The single typographical error is unlikely to cause an issue with the consumer’s ability to run and read the test correctly, as the procedure card contained within the kit and the graphics on the kit box are correct.

Healgen immediately corrected the IFU, and any remaining IFU’s were destroyed. The incorrect IFU from the impacted product was removed and replaced with the updated version. Manufacturing records were updated to reflect the new part number allocated to the corrected IFU. As a result, no further product with the incorrect IFU will be shipped to the customer.

Healgen Rapid COVID-19 Antigen Self-Tests are authorized for use in New Zealand as a testing tool for people with COVID-19 symptoms or household contacts under the COVID-19 Public Health Response (Point-of-Care Tests) Order 2021. This order restricts the tests that can be used in New Zealand.

Not all batches of Healgen Rapid COVID-19 Antigen Self-Test Kits are affected by this issue; only some batches contain the incorrect IFU. We know that some batches of the 5-test and 20-test packs are affected, but other pack formats may also contain the incorrect IFU.

Should you require clarification on the subject covered by this bulletin, please contact; quality@healgen.us.