FOI 22/1161 Hangzhou Fantest Biotech Ltd - Covid 19 / Influenza A & B Antigen Test Kit

MHRA RESPONSE
6 January 2023

Dear

Thank you for your information request, dated 28 November 2022, where you asked for the following information:

> "I would be grateful if you could advise me whether MHRA has approved this antigen test kit for use in the United Kingdom."

There is a process in place for the approval of COVID-19 test products, which is called the Coronavirus Test Device Approvals (CTDA) process. Information about the process and a listing of approved products can be found at the link below:

https://www.gov.uk/government/publications/covid-19-test-validation-approved-products

The product you have asked about is not included in this listing and is therefore not approved.

Please note the listing only includes products which have been approved, it does not include those which may be going through the approval process.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Service Centre
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU