

PRESS RELEASE FROM BIVDA

FOR IMMEDIATE RELEASE

BIVDA Comments on COVID-19 antibody test authorisation by Public Health England

BIVDA is delighted to see that an IVD is again making headlines this morning as testing continues to underpin the fight against the Coronavirus. The Roche test, which detects antibodies to the virus and could therefore indicate which people have previously been infected, is the latest to achieve CE marking but the first to have been evaluated by Public Health England, with a number of other companies who have had CE marked kits available for a longer period still undergoing evaluation.

The IVD industry has been working flat out over the past few months to develop and manufacture tests and reagents for healthcare systems around the world. Initially this was focussed on tests to detect actively infected individuals mostly using PCR technology from swab samples. The focus has now moved to laboratory based tests for antibody in blood, while companies are also continuing to refine and improve the lateral flow technology which would allow for antibody testing from a finger prick of blood.

Commenting on the progress made so far, BIVDA Chief Executive Doris-Ann Williams said;

“The Government are in the process of revising their testing strategy to cover the next 9-12 months and the IVD industry will continue to support in any way possible but there are questions within the BIVDA membership over apparent pre-selection of laboratory antibody tests from a small number of companies when others with CE marked tests have not been selected for evaluation by Public Health England.”

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For more information please contact External Affairs Manager Jon Harrison at jonh@bivda.org.uk

About BIVDA

The British In Vitro Diagnostics Association, usually referred to as BIVDA, is the national industry association for the manufacturers and distributors of in vitro diagnostic (IVD) products in the UK. BIVDA represents over a hundred organisations ranging from British start-up companies to UK subsidiaries of multinational corporations. BIVDA members sales into the NHS were approximately £900 million in 2019 and there is IVD manufacturing for both export sales and for product to enter into corporate global stock. Information from diagnostic tests makes up about 70% of the information used for clinical decision making in patient care.