

12 July 2022

Dear

ATISN 16422 – HIV Virus

Thank you for your request to the Welsh Government for information under the Freedom of Information Act (2000) (FOIA) received on 21 June 2022 relating to the HIV virus. You have requested:

1. *Copy of, or hyperlink to, the peer-reviewed scientific paper confirming that the HIV virus has been isolated and purified with its viral genome sequenced.*
2. *Details of the approved diagnostic test for HIV virus, purportedly the cause of AIDS infection.*
3. *Reference is made to PrEP [pre-exposure prophylaxis], this being a medication people can take regularly to prevent them from getting HIV from sex or injection drug use. Can you please confirm when this medication was approved for use in Wales by the Medicines and Healthcare Products Regulatory Agency [MHRA].*

Our Response

1. A copy of the peer review paper is attached – *HIV-NGS-MiSeq Dudley et al 2014*.

For the genome sequencing that is carried out for resistance testing in Wales is outlined in the diagram on page 4 and resistance testing is on a sample-by-sample basis. This method is tested against known samples for Sanger sequencing as well as *National Institute for Biological Standards and Control (NIBSC)* control material.

The virus is not technically purified as only a part of the genome is amplified and sequenced, however this is the region where the drug resistance is targeted.

For further information, you may wish to contact Public Health Wales (PHW) using the following link: foi.phw@wales.nhs.uk

2. The manufacturers and platforms used in Wales are:
 - Abbott Alinity ([Alinity m HIV-1 Assay | Abbott Molecular](#))
 - Vidas 3 Biomerieux ([VIDAS HIV panel, 4th generation hiv screening | bioMérieux Clinical Diagnostics \(biomerieux-diagnostics.com\)](#))
 - Alere Determine ([Determine HIV-1/2 Ag/Ab Combo | Abbott Point of Care \(globalpointofcare.abbott\)](#))
 - Biorad Geenius ([Geenius System | Bio-Rad](#))
 - For the online the lab use Roche HIV Duo ([Elecsys® HIV Duo \(roche.com\)](#))All reactive tests have a second confirmatory sample.

3. The European Medicines Agency authorised the use of or emtricitabine/tenofovir disoproxil for pre-exposure prophylaxis (PrEP) in combination with safer sex practices to reduce the risk of sexually acquired human immunodeficiency virus type 1 (HIV-1) infection in adults at high risk in July 2016. The authorisation applied in the UK.

Next steps

If you are dissatisfied with the Welsh Government's handling of your request, you can ask for an internal review within 40 working days of the date of this response. Requests for an internal review should be addressed to the Welsh Government's Freedom of Information Officer at:

Information Rights Unit,
Welsh Government,
Cathays Park,
Cardiff,
CF10 3NQ

or Email: Freedom.ofinformation@gov.wales

Please remember to quote the ATISN reference number above.

You also have the right to complain to the Information Commissioner. The Information Commissioner can be contacted at: Information Commissioner's Office,
Wycliffe House,
Water Lane,
Wilmslow,
Cheshire,
SK9 5AF.

However, please note that the Commissioner will not normally investigate a complaint until it has been through our own internal review process.

Yours sincerely,