Validating VIDAS as a Cascade for Low-level Positive Hepatitis B Surface Antigen Results in Dried Blood Spots

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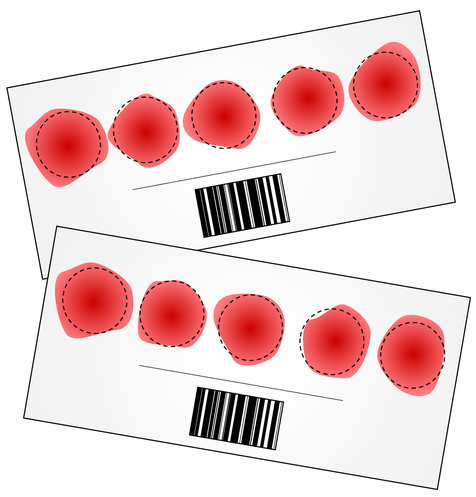
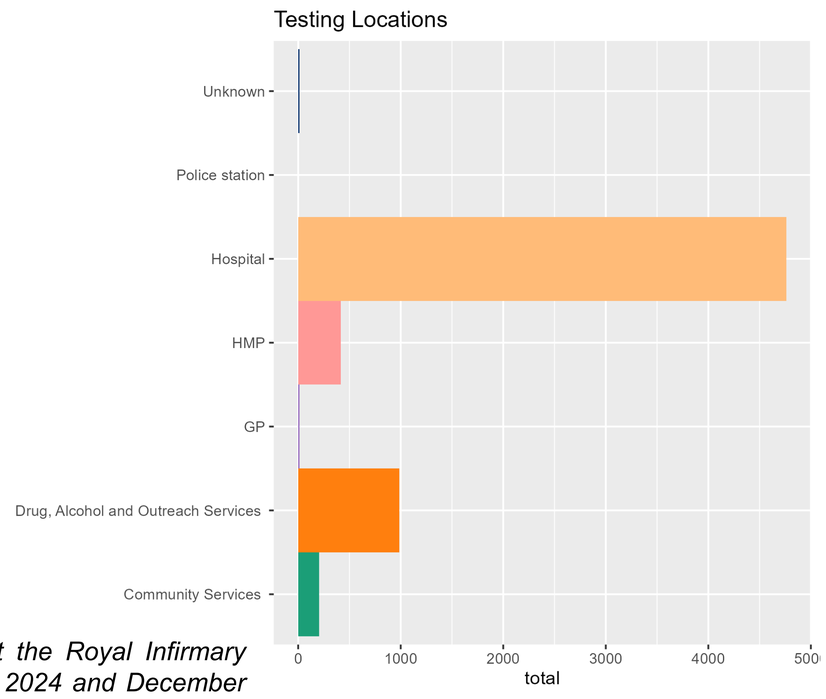
Blood Borne Virus Testing on Dried Blood Spots



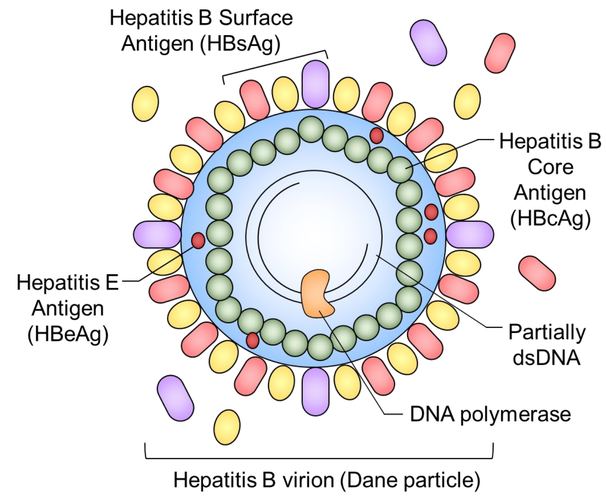
- Dried blood spots (DBS) are useful specimens for blood borne virus (BBV) testing in outreach settings, including prisons, alcohol and drug recovery services, and other settings where phlebotomy is not available. They are also useful for individuals with poor venous access or needle phobia.
- Capillary blood, usually obtained from a finger prick, is collected onto filter paper, air-dried and transported to a laboratory.
- However, compared to serum, plasma, and venous whole blood, DBS have reduced analytical sensitivity for serological testing due the limited sample volume available and the effects of sample drying and elution.

- In NHS Lothian, DBS for BBV testing are tested by immunoassay for:
  - Hepatitis C Antibody
  - **Hepatitis B Surface Antigen**
  - Hepatitis B Core Antibody
  - HIV antigen and antibody in combination
- DBS samples are tested at the Royal Infirmary of Edinburgh from a wide range of locations within NHS Lothian.

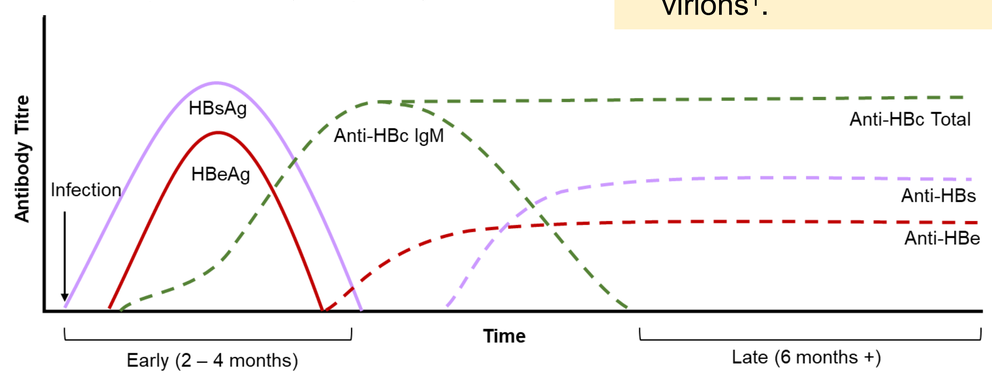


The locations of DBS samples received at the Royal Infirmary Edinburgh for HBsAg testing between April 2024 and December 2025.

Hepatitis B Virus



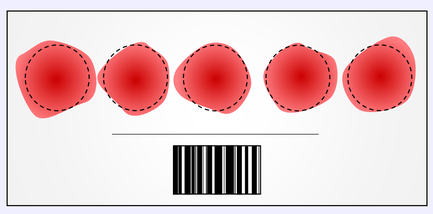
- Belongs to the Hepadnaviridae family.
- Enveloped, partially double stranded DNA virus.
- Hepatotropic virus.
- Transmitted via bodily fluids including blood, semen and vaginal secretions.
- The HBsAg subviral particles are produced in large numbers and outnumber the infectious virions[1].



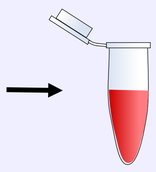
- In Scotland, 5,206 individuals are living with chronic Hepatitis B virus (HBV) infection, defined as the persistence of HBsAg for >6 months.
- Approximately 60% of individuals with a current chronic HBV infection live in the Greater Glasgow and Clyde and Lothian NHS Board areas[2].
- Chronic HBV infection can lead to progressive liver disease, including cirrhosis and hepatocellular carcinoma.
- Early and accurate diagnosis is essential, as many individuals are asymptomatic and may unknowingly transmit the virus others.
- Appropriate treatment and long-term monitoring can reduce morbidity and mortality[3].

Validation of HBsAg cascade

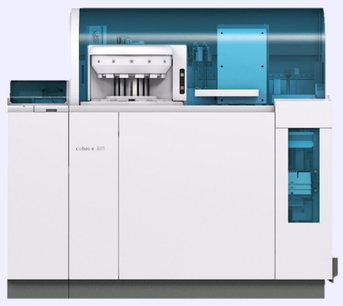
Current Workflow:



Dried blood spot card (Whatmann 903) from patient



2 x spots eluted



Roche Elecsys E801

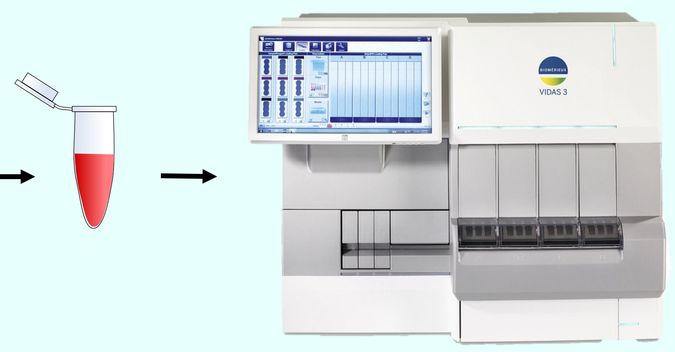
< 0.9 = Non-reactive

0.9 - <1.00 = Borderline
>1.00 = Reactive

- Borderline and low-level positive HBsAg results are reported to healthcare providers with the recommendation that “a clotted blood sample is sent for further investigation” to confirm results. However, as these patients are often tested through outreach services, obtaining follow-up blood samples can be challenging.

We aim to validate the VIDAS assay as an additional diagnostic test for use with DBS to determine whether borderline and low-level positive HBsAg results represent true-positive infections, enabling appropriate follow-up and treatment.

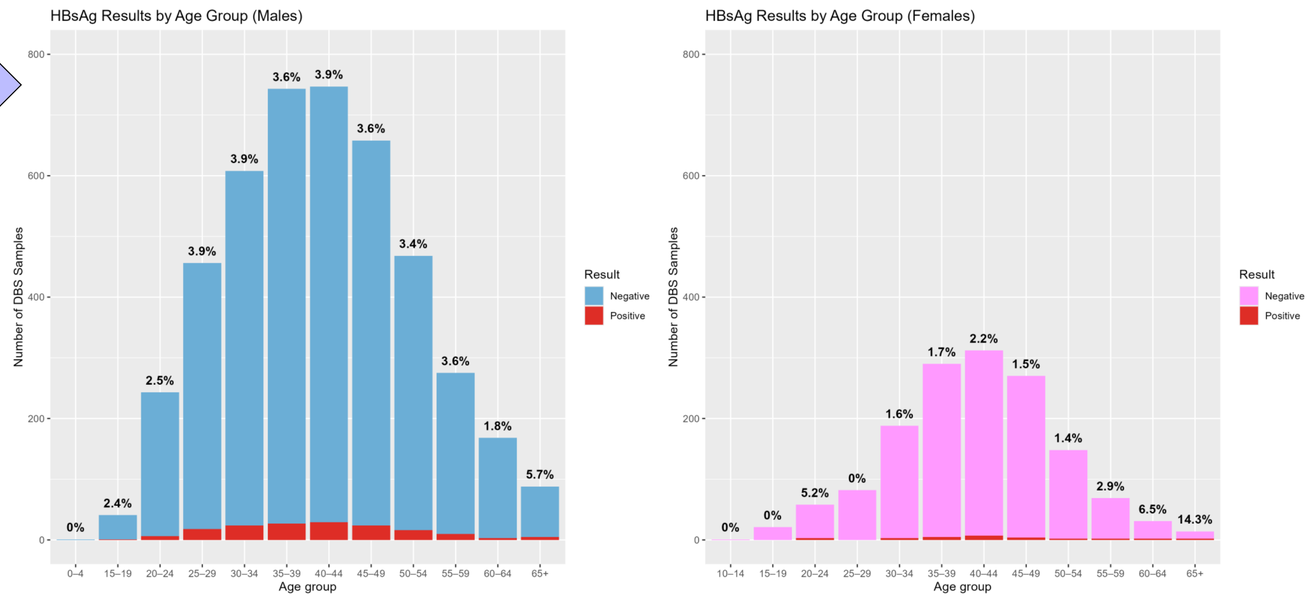
Workflow being validated:



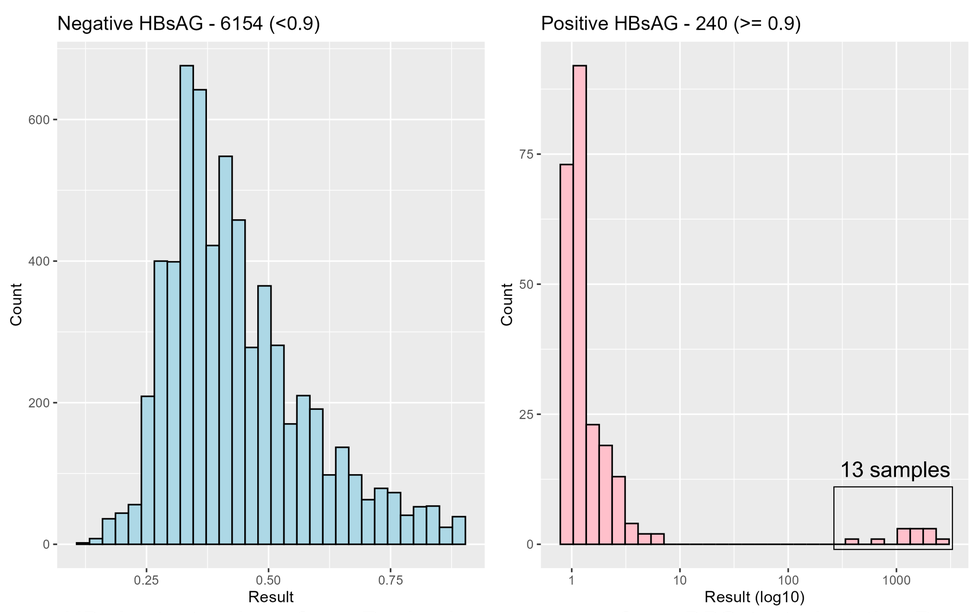
VIDAS 3. The HBsAg test is an enzyme linked fluorescent immunoassay where assay steps are performed automatically.

**this assay is currently used for clotted blood samples*

Results



HBsAg results from DBS tested at the Royal Infirmary of Edinburgh between April 2024 and December 2025 grouped by sex and age group.



HBsAg test values from Roche immunoassay from DBS tested at the Royal Infirmary of Edinburgh between April 2024 and December 2025.

Validation design

A **validation** study is being performed to determine whether HBsAg testing of DBS eluate using the VIDAS assay provides accurate, sensitive, specific, reliable and reproducible results. Currently, DBS eluate is not designated by the VIDAS as a sample type.

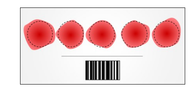
We will test:

20 ‘mock’ **positive** DBS samples prepared using EDTA blood that has been sent for Hepatitis B virus PCR

20 DBS samples that previously tested **negative** for HBsAg

DBS samples that previously tested **positive** for HBsAg

EQA samples



References
(1) Tripathi N, Mousa OY. Hepatitis B. [Updated 2023 Jul 9]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK555945/, (2) Public Health Scotland. (2025) Surveillance of hepatitis B in Scotland: Update to 31 December 2023. Published 17 June 2025. Available at: Public Health Scotland (Accessed: 17 July 2026). (3) European Association for the Study of the Liver. EASL 2017 Clinical Practice Guidelines on the management of hepatitis B virus infection. J Hepatol. 2017 Aug;67(2):370-398. doi: 10.1016/j.jhep.2017.03.021. Epub 2017 Apr 18. PMID: 28427875.