



Generalisable lessons from the UK response to COVID-19

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Overview of UK COVID Testing

LFD tests reported*

Weekly 8.5M

Total 230M

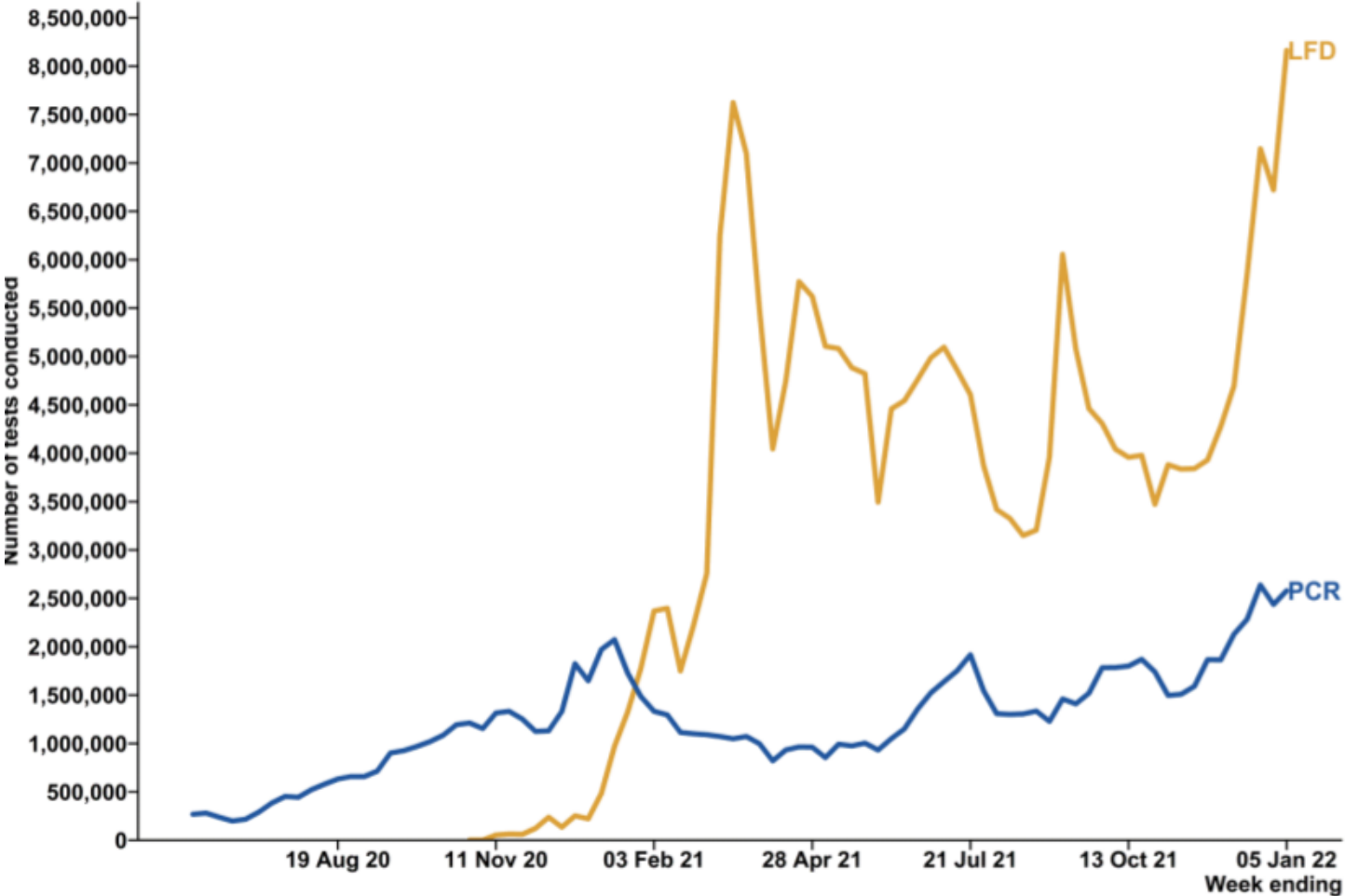
Positives 2.5M

PCR Tests reported

Weekly 2.5M

Total 471M

Figure 1. Number of LFD and PCR tests conducted, England



* Note that many self-tests are not reported

Key Lessons

IVDD regulatory framework was unfit for purpose

Regulatory capacity across all sectors must be expanded

Scientific validation of measurand-disease associations are essential for developing effective IVD strategies.

Target Product Profiles can support industry to develop technologies and evidence

Clinical Reference Standards can guide IVD performance evaluations

Early development of reference methods, materials and controls is essential

Supporting infrastructure for sample collection and platform trials is needed.

Exceptional Use Authorisations can support innovation of public benefit

Robust PMS and PMPF plans can mitigate risk of imperfect pre-market evidence

Transparency and involvement of the public in decision making ensures trust and accountability.

Global collaboration on IVDs is needed to protect citizens.

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