Witness Name:
Cariad Evans
Statement No.
M7/Evans/01
Exhibits:
Dated:13.12.24

UK COVID-19 INQUIRY

WITNESS STATEMENT OF Cariad Evans

I, Cariad Evans, will say as follows: -

1. I have attached my CV at the end of this statement to cover the evidence of my qualifications, career history, expertise and groups I was a member of, plus major publications related to Test/Trace and Isolate during the COVID Pandemic dating Jan 2020- June 2022. *(See exhibit CE/01 [INQ000587659)*

2. In relation to my experience on the testing technologies used from the emergence of SARS-CoV-2 to the establishment of routine COVID diagnostics I would like to present this in chronological order of the first 6 months reflections, to try and highlight the experience I had of working as a clinical virologist in an NHS laboratory covering South Yorkshire and North Derbyshire. To add some context, I worked alongside 2 Consultant Virology colleagues when the pandemic started, covering a clinical virology diagnostic lab which primarily served Sheffield Teaching Hospitals (STH) Trust and regional diagnostic and clinical support to Doncaster/Bassetlaw/Rotherham/Barnsley/Chesterfield/Derby and Burton NHS Trusts.

3. On the 12th January 2020 the genetic sequence of SARS-CoV-2 was published and on the 13th the first case was identified outside of China, in Thailand. By the 15th January in our Virology department we were aware of the case definition, the

current epidemiology and on the 21st our first patient was assessed at STH (confirmed negative). As we are a member of the High Consequence Infectious Diseases (HCID) Network we were having discussions with Public Health England (PHE) on the advice issued on the 25th of January, that all travelers from Hubei were advised to self-isolate for 14 days even if asymptomatic. On the 31st of January the first 2 confirmed cases were identified an tested by colleagues in Hull Infectious Diseases Department, the cases were discussed with the HCID Network and PHE testing confirmed the case as positive. At this time no other centers were testing as the aim was for PHE to oversee all testing, no advice had yet come to NHS laboratories about testing and we started to develop our own local in house assay as part of the pandemic response, as WHO declared a PHEIC .

4. On the 5th February we set up a local workflow with our clinical Infectious Diseases colleagues to help identification of patients, testing and isolation if the case definition was met. On the 10th we ordered the plasmids, primers and probes based on a Eurosurveillance paper around developing a diagnostic PCR. PHE were updating the case definition for isolation, as further cases from South East Asian countries were identified. On the 20th of February our ID department set up a drive through for patients who didn't require admission but met the case definition, to attend for testing. On the 23rd of February we admitted our first confirmed case to our HCID Unit which provided clinical material for us to finalise the development of our assay.

5. On March the 5th our assay was performing well and passed the PHE proficiency panel, which meant we were recognized as a diagnostic laboratory by PHE. From memory at this time, we were the only NHS laboratory with testing, PHE Colindale had rolled out their assay to other PHE labs, but the current plan was to send all samples only to PHE Labs. This meant that many hospitals would have delayed results due to inherent challenges of sending samples away to designated labs, which were coming under huge and increasing demand. We had also developed a dual target assay and the PHE assay at the time had one target, therefore we observed from our patient samples an increased sensitivity and detection in our assay. By the 10th of March we were able to test all patients with viral upper respiratory tract symptoms, which aligned to the PHE guidance to test all inpatients

with influenza like illness, pneumonia or acute respiratory distress. In conjunction with PCR testing, we also set up local sequencing of the virus alongside our research colleagues and successfully sequenced the first clinical isolate. This led on to us being an early key member of the COG-UK consortium which was key to sequencing vast numbers of clinical specimens, informing us on viral dynamics, evolution of the virus and development of new strains. On the 13th of March we identified our first local case which did not meet the case definition (had no clear epidemiological risk factors) and we understood we had local transmission in our community. PHE issued guidance on self-isolation for 14 days for patients/household members and healthcare workers with fever/cough regardless of travel. We realized this would mean a large proportion of our staff workforce would be isolated, so on the 17th we set up a staff testing program, which provided results, advice and clear guidance to staff, their family and contacts, run by the clinical virology department. By this time point we were testing >400 tests a day which was a large number given the very recent launch of the assay, we were supporting testing to all our regional hospitals too. Lockdown was announced on the 23rd March and by the 29th March >1500 staff members had been tested.

6. At the start of April we achieved testing >1000 tests in a single day, which was quoted to be 10% of the overall UK testing. We were identified in Sheffield as a COVID 'hotspot' which put a lot of pressure on our regional PHE services but the reality in my opinion was that we were able to test at scale as we had had a head start by developing a local assay. The first Lighthouse laboratory at Milton Keynes was opened on April the 9th and heralded the start of scaled up testing and the government announced the aim of 100,000 tests per day as the UK target. We were then subject to PCR extraction kit shortages, as supply could not meet demand. We had to develop an extraction free technique and validate this to ensure performance for clinical testing. This is only a process that a specialist virology lab could validate so other laboratories were likely struggling due to kit supply issues with few options for resolution. In addition to kit supply issues was then the lack of swabs, different swabs were available/dry swabs/flocked versus smooth all of which needed verification and review of quality assurance.

On the 9th of April we published in Eurosurveillance *(See Exhibit CE/02 [INQ000474726])* our experience with our staff testing program to help support other organisations. Sheffield Virology Service was featured on BBC Look North as an example of a large diagnostic lab responding to the pandemic challenges. By this time point all laboratory staff were helping in the diagnostics, we had a staff test and trace service and had established a large staff testing drive through. By the end of April we were testing all non-elective admissions too to try and keep surgical pathways open for high need patients. We also participated in testing >1000 asymptomatic staff as part of a nationwide snapshot of asymptomatic incidence, which was an emerging feature of SARS-CoV-2 infection and not previously identified with other coronaviruses, previously viraemia peaked after symptom onset which meant isolation resulted in reduction of onward transmission. Our new understanding with SARS-CoV-2 was that people were infections prior to symptom onset and that some individuals may remain entirely asymptomatic *(See Exhibit CE/03 [INQ000474725]*) .

7 In May we published a couple of articles *(See Exhibit CE/04 [INQ000474727]*, the first was around the sensitivity of the dual target E and RdRp assay to help raise the importance of this diagnostically as some laboratories were still relying on one target (RdRp gene as per the original PHE assay). We also published work on the clinical impact of COVID on certain ethnicities and wrote a letter describing our clinical observations and concerns in certain protected groups *(See Exhibit CE/05 [INQ000474728]'*. Diagnostically we then were involved in the establishment of SARS-CoV-2 antibody testing for patients and staff. On the 27th the Government announced a National Track and Trace strategy, but we had already established a local staff T&T, as well as a patient outbreak management program, so we adapted local policies to reflect National advice. It was very challenging constantly making local decisions on test, trace and isolation policies which often required changes/updates from the ever-changing national advice.

8 By the end of June, we had dedicated staff running our local Test and Trace team for our trust, the staff drive through was open 7 days a week and our laboratory had evolved to provide a 24/7 regional service. The adjacent car park to the laboratory medicine building was repurposed with portacabins, to enable test

requesting, sample handling and processing. Multiple teams from Laboratory medicine were involved in the inception and running of the Drive Through Service which in addition to testing Sheffield Teaching Hospitals staff, the service provided testing to symptomatic staff household members including children, Sheffield Children's Hospital staff, Ambulance services, surrounding prisons, dental practices and community health and social care workers.

9 In June at STH we received access to the first commercial COVID platform which was the Cepheid point of care assay. For us this heralded the start of new commercial COVID diagnostics supplies and the availability of different assays and analysers. In our experience at this time point we were able to purchase COVID test kits for analysers we already had and start expanding testing across other platforms. We had control over this and experience with these platforms which helped and provided resilience. We also also published other articles which are referred to in my CV *(See exhibit CE/01 [INQ000000000]) and which can be found at CE/06 [INQ000474729], CE/07 [INQ000474730], CE/08 [INQ000474731], CE/09 [INQ000474732], CE/10 [INQ000474733])*.

10 The move away from local diagnostic purchasing and control to national allocation which subsequently happened over the coming months, resulted in the implementation of a variety of different commercial platforms. This was a real challenge as they all performed slightly differently, had to undergo local validation/verification, often had different targets, different technical specifications or methodologies which may have not been previously used in certain laboratories and turnaround times varied greatly, as well as ease of use. If we did not desire these platforms, which were being nationally 'pushed', then we had to justify our decision via a lengthy written process, which was not a good use of our time.

11 For regional laboratories the demands were different to a laboratory like ours as considerations had to made around ease of use, random access, turnaround times, ease of interpretation and the level/seniority of biomedical science staff required to run these instruments and platforms. The key priority for most laboratories was rapid resulting to help inform patient pathways and infection control measures. Another aspect of consideration was the interfacing of these solutions with IT laboratory systems and clinical systems.

12 At one point we had at least 3 different analysers in the laboratory at STH for COVID testing, plus point of care testing (POCT) for patients being admitted. We didn't implement POCT until the winter of 2020 as we awaited the ID NOW Abbott POCT which we validated as part of the national technologies validation group (TGV), as I felt strongly about the need for a molecular rapid POCT (which we had previous experience of for influenza). I know many other organisations implemented lateral flow testing for patient admissions but at the time the sensitivity was understood to be lower than molecular diagnostics. I believe many laboratories had little or no say over the instruments they were given; the variety and number of instruments was variable depending on the perceived demand and availability. It was extremely difficult to control your service and regional smaller laboratories had to rapidly learn and evolve with what they were given, rather than be able to have systems there were familiar with or desired for other reasons. Therefore, central allocation to some of these labs was a helpful process if these considerations were facilitated but it took some time for user groups and support to be available to aid sensible allocation and implementation.

13 As a clinical virologist we also found this very challenging as we were forced to use platforms with different viral targets in the genome, which made clinical interpretation difficult, and with more sensitive assays we were detecting dead non-viable virus rather than current infection. PHE did ultimately support by developing a diagnostics algorithm for clinical interpretation to assist all laboratories, but this wasn't until much later in the pandemic response.

14 Alongside my clinical virology work I was also involved in a huge number of NERVTAG meetings, the papers of which are summarised in my attached CV. *(See CE/11 [INQ000074938], CE/12 [INQ000075009], CE/13 [INQ000075015], CE/14 [INQ000120389], CE/15 [INQ000120524], CE/16 [INQ000474721], CE/17 [INQ000474722]'*.Some of the key papers focused on the viral dynamics which required interpretation of PCR results from multiple publications, confidential lighthouse laboratory datasets, and sequencing to try and understand both the duration of infectiousness but also the impact of the evolution of the virus both on diagnostics, clinical symptoms, and the potential impact of emerging variants. A summary of my attendance at these meeting is below. My contribution to

NERVTAG is in the capacity of a Clinical Virologist working within an NHS Laboratory and to give my opinion on the clinical concerns from a virological perspective, impact on hospital IPC, patient care and NHS testing/laboratory diagnostics. All contributions and comments or queries are recorded in the NERVTAG meeting minutes.

	2020 NERVTAG meetings 1 – 40: attendance	2021 NERVTAG meetings 41-63:attendance	2022 - NERVTAG meetings 64-65: attendance	2020 Birdtable meetings	Other Extraordinary meetings*	Non-COVID-19 meetings 2020-2022
Cariad Evans	32	20	2	7	3	4

15 Regarding lessons from the pandemic and future learning I believe there are a few key points in relation to test, trace and isolate specifically. From my observations there appeared to be little involvement from the clinical virology community into the testing strategy that evolved throughout the UK during the pandemic. I did not notice many other clinical virologists (working in large NHS trusts) in meetings, advisory groups or linked in for advice as strategies regarding testing evolved. I know much of the community were frustrated that their expertise was not being utillised and I think this is an important lesson for the future. The UK Clinical Virology Network includes some extremely experienced and knowledgeable individuals whose knowledge could have been accessed earlier and should be approached in any future pandemic, as well as providing an established communications network. The PHE Colindale Virology Cell did evolve into a helpful meeting group for the whole community for discussion around diagnostics and testing challenges which was very valuable, I think this model should be used again and implemented early on in a future pandemic. I think it was clear that the expansion of PHE in response to the pandemic, to have different groups/cells leading certain aspects, was of huge benefit overall and strengthened the pandemic response.

16 In addition, I feel that early SARS-CoV-2 diagnostics should have been available to all laboratories to develop and implement much sooner than it was, rather than a controlled PHE diagnostics strategy for many weeks/months, especially in the

advent of a respiratory viral emergence which was inevitably going to take off at pace. Rapid early sharing of the PCR development and optimization of the PHE assay with the UK virology diagnostics community could have saved a lot of time for many and taken unnecessary pressures off PHE (now UKHSA) laboratories, which were overwhelmed in March 2020. It was my experience in the 2009 swine influenza pandemic that initial testing was again overseen by PHE and its laboratories, which led to long delays in results for non-PHE laboratories, which has significant impact on case identification, and outbreak control. I appreciate early in the emergence of a new viral pathogen the importance of UKHSA overseeing case ascertainment, clinical characterisation, surveillance reporting and the need for robust outbreak information, but I think this could be achieved in conjunction with large NHS virology laboratories.

17 I would suggest another important lesson is specifically around NHS staff testing in a future pandemic plan. The NHS staff workforce is in essence a large community of the public, which inevitably not only acquire infections but if testing is not in place and isolation alone is advised, then staffing numbers are significantly compromised in these situations. Therefore, our local lesson from 2009 was to develop a staff testing initiative, was our approach in 2020 and I believe ensured many staff could remain at work, isolation was only indicated in those with true infection and therefore resources for contact tracing were more focused and effective. I appreciate we were in a unique position of offering such a staff testing strategy, but many other large NHS Trusts could do in the future and given our new understanding of self-testing, lateral flow diagnostics and rapid POCT alternatives future pandemic response strategies should include this.

18 I believe some of the successes that emerged later in the pandemic response should be identified in the future as early priorities, for example; the Virology cell meetings run by Colindale PHE, which ensured rapid accurate dissemination of information with the virology community, as well as a forum of consensus discussion for diagnostic strategy and clinical management. The commercial diagnostics user subgroups which supported each lab in the verification, implementation and running of their technologies. The technical validation group which ensured a standard validation process, which supported laboratories in

bringing in new platforms at speed and meant individual laboratories did not struggle with local validation which is challenging and time consuming.

19 Overall, I believe the COVID pandemic was unprecedented in its approach to viral testing, no previous pandemic plans described nor emphasized the role of diagnostics in the way they were used for COVID. This led to an impact on laboratories never experienced before, with staff from all different expertise and backgrounds having to adopt, adapt and oversee 24/7 diagnostic services regardless of their prior capabilities. Small laboratories with little experience had to suddenly test all patient admissions, whether symptomatic or not through every NHS pathway. All laboratories rose to this challenge and maintained testing during extremely demanding times, which is a lesson to us all and a reminder of the capabilities we have in the NHS. We need to harness this learning and have a clear strategy for a future pandemic testing approach.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief of its truth.

PD

Signed: ______

Dated: _____23rd May 2025 ____________