Norman Lamb MP
Chair, Science & Technology Committee
House of Commons
London
SW1A 0AA

By e-mail via the Clerk to the Committee

Dear Chair

Randox Testing Services

I write to provide background information and the latest information in relation to the issues affecting forensic toxicology work at Randox Testing Services (RTS). Because of the ongoing criminal investigation into these matters, I have not included any sensitive information. I could provide more detailed information on an official sensitive basis, for the sight of the Committee only if that would be helpful.

Background

In January 2017, I was notified by RTS that improper manipulation of quality control data had been discovered at its Manchester laboratory. This manipulation was apparently primarily undertaken to give the impression that batches of work which had failed quality checks would instead appear as if they had passed. The consequence was that results were provided to the Criminal Justice System (CJS) when they should not have been – the analysis should have been repeated. Two members of staff apparently implicated in the manipulation were immediately suspended and have since been dismissed. Forensic toxicology work was suspended at the Manchester site.

An extensive investigation into the manipulation was initiated, involving the national accreditation body (The United Kingdom Accreditation Service, UKAS) and my office. Greater Manchester Police (GMP) was also informed and began a major criminal investigation into the matter.

Between January and April, the investigations uncovered increasingly extensive data manipulation, and in April, I advised the NPCC-led Gold Group, which is coordinating the police response to the issue, that no results from RTS from either site
(Manchester or Belfast) could be considered to be sufficiently reliable for use in the CJS. As further investigations were carried out, this advice was updated to confirm that the period in which the testing was considered to be unreliable was from November 2013 onwards, and to confirm that there was sufficient confidence in RTS alcohol testing and initial screening of drugs for these activities to be considered reliable. My office, CPS and NPCC have together ensured that CJS stakeholders including prosecutors, the judiciary and affected government departments are briefed on the issues as they develop.

The criminal investigation has expanded from RTS to include a now-defunct company, Trimega, from which RTS had bought laboratory equipment and facilities and where the suspected members of staff had previously worked. The two individuals have been arrested and interviewed under caution on several occasions; they remain on police bail. A further five individuals have been interviewed under caution, but have not been arrested. There is no indication that any of the individuals was under pressure from RTS management to decrease the number of batches that were repeated and no indication of any inappropriate incentives at RTS that may have induced the data manipulation activity.

**Impact on the CJS**

Following discussions with RTS, the company agreed to fund like-for-like retesting at an independent laboratory. Sufficient sample remains for re-testing the vast majority of affected samples.

The approximate number of cases affected is 10,000, although in a proportion is these cases, toxicology will have played a very limited part or no part in a prosecution.

Home Office policy colleagues are working with the NPCC–led Silver Group to prioritise and make practical arrangements for the retesting. Annex 1 provides a summary of progress, together with a breakdown of case types affected.

However, it is clear that the limited capacity for forensic toxicology in the commercial forensic science market means that the retesting process is likely to take 2-3 years to complete. It is anticipated that the highest priority samples (where an individual is in prison or where a court date is imminent) will be completed by mid 2018.

The instability of some of the drugs combined with the different analytical approaches between laboratories means that there is likely to be a degree of difference between the original results and those obtained on retesting. This may have an impact on some cases. A simple example is where degradation of the drug means a sample which was, at the point of the original test, in excess of the legal limit, may now be under the limit. My team is working with the Crown Prosecution Service (CPS) national lead for forensic science and with a group of toxicology experts from the forensic science providers to ensure that all potential outcomes are understood, and appropriate disclosure is made.

CPS has formally requested that courts allow adjournments in affected cases. There is, however, the possibility that adjournments to enable retesting of samples may not be granted by magistrates for all drug driving cases, and this may result in discontinuation of a number of cases.
Implications for Quality and Regulations

Although RTS held accreditation to the appropriate quality standard, the malpractice was not discovered by the usual quality checks. This raises a number of questions, including:

1. whether or not potential malpractice is more widespread than at RTS, particularly given the movement of staff between forensic service providers; and
2. whether or not the quality standards need to be strengthened.

I asked all major forensic toxicology suppliers to review their practices and safeguards against the potential for malpractice, and to conduct a detailed audit of a random selection of cases, to determine whether or not the issues could be more widespread. I have received results from all of these audits and no data manipulation was found in any. Clearly each audit was only a small sample of the overall number of samples processed, so if data manipulation is occurring in a small minority of cases, such audits would be unlikely to detect it. However, if data manipulation was occurring at a wider level, I would expect that it would have been uncovered during this exercise.

I have asked the Forensic Science Advisory Council (FSAC) to consider a number of measures to strengthen provisions to reduce the risk of malpractice and/or increase the probability of rapid detection. However, no reasonable set of quality standards could guarantee to prevent determined (and potentially criminal) malpractice by skilled but corrupt personnel if this were to occur. The inevitable cost of adding additional safeguards should be balanced against risk. From October this year, there has been a pre-planned additional requirement on forensic science providers (whether public sector, private sector or within policing) to demonstrate compliance with my Codes of Practice and Conduct, through a formal accreditation process carried out by UKAS. These Codes contain requirements in relation to data security that are additional to those specified in the international standard (BS EN ISO 17025:2005) against which providers have been accredited for some years.

The accreditation system is predicated on organisations being accountable for the quality of their work, and demonstrating through regular audit and through evidence of staff competence and method validity that they are sustainably competent to produce reliable results. In certain situations, it may still be possible for improper data manipulation to be concealed. UKAS has itself been conducting an internal review into accreditation of toxicology providers (more widely than in the CJS) and whether any changes to the assessment process could make discovering deliberately concealed manipulation of data more likely. I am being kept informed by UKAS of their findings. One immediate change UKAS has introduced is to increase the emphasis on “vertical audit”, where information on specific cases is followed from beginning to end. Vertical audit is more likely to uncover evidence of inappropriate data manipulation than is witnessing of a range of laboratory activities.

Potential Causes

As discussed earlier, there is no indication that any of the individuals was under pressure from RTS management to decrease the number of batches that were repeated and no indication of any inappropriate incentives that may have induced the data manipulation activity.

The committee asked Professor Aston, Chief Scientific Advisor to the Home Office whether having the Forensic Science Service (FSS) as it was would have avoided the situation. It is incontrovertible that much forensic toxicology expertise was lost from practice when the FSS closed. This loss of skills increased risk to forensic
toxicology quality and is still having an impact; the re-testing process will be lengthy because the number of skilled experts is limited. It is also the case that RTS gained contracts for forensic toxicology work as a result of FSS closure. However, it is not possible to conclude that there is a direct causal link between closure of the FSS and the current situation. It is always possible that FSS could have lost toxicology contracts to RTS or another company, even if it had remained open. It is further possible that the suspects in this case may have been employed by any forensic toxicology provider; it would be speculation to say whether or not a similar situation may have arisen.

Implications beyond the CJS

It is believed that the manipulation may have begun when the arrested individuals worked for Trimega, a company that provided toxicology services to the family courts. This company no longer operates, so the retrospective review of affected cases will be more complex and lengthy. I have briefed (a) the President of the Family Division of the High Court, (b) the Lord Chief Justice and (c) the Ministry of Justice (MoJ). There is now a second Gold Group, led by the MoJ, to oversee the response to this issue in the family and civil jurisdictions.

There is no regulatory system for scientific advice provided to the family or civil courts. This gap was discussed by the new Science and the Justice System Forum, which was convened by the Home Office and chaired by Julie Maxton of the Royal Society. The general view of that group was that the regulatory system should be expanded to cover family and civil jurisdictions. However, the Forum has no mandate to make policy and the practicalities of such an expansion of regulation would need to be considered in some detail.

I would be happy to provide any further briefing that you and the committee would find helpful.

Yours sincerely

Dr Gillian Tully

CC Nick Hurd MP, Minister of State for Police and the Fire Service
John Aston, Home Office Chief Scientific Advisor
Alan Pratt, Chief Security, Science & Innovation Officer, Home Office
Anisha Worbs/ Jessica Bonnington, Head of Police Information Policy, Home Office
Annex 1: Re-Testing Programme Summary

Total number of cases affected (Approx) – 10,000 of which:
- Road Traffic (drug driving) – around 7500
- Sexual Offences – 1000 about 90 per cent are rape offences
- Violence against the person -700 including around 275 homicide cases and 150 road deaths
- Sudden Death – 500
- Small numbers (under 25 cases) of drugs offences, theft, burglary or robbery, arson and criminal damage.

Of the 10,000:
Approximately 1500 cases have been re-tested or are undergoing re-testing
The vast majority of cases involve offences contrary to the Road Traffic Act, specifically drug/driving. These are referred to as “Road Traffic” cases. Anything else is referred to as “Casework” cases.

Prioritisation Categories:
- **Priority One Cases** - Live cases that are near or in trial including those in custody; Crown, Magistrate’s and Coroner’s Court; those convicted but not sentenced; those bailed in advance of trial or sentence; convictions where the person is in prison.
- **Priority Two Cases** - Live police investigations such as pre-charge advice cases awaiting decision, live investigations into allegations likely to be dealt with at Crown or Magistrates court.
- **Priority Three Cases** - Finalised court cases with sanctions such as release on licence, driving disqualification, community sentence and fines including spent sanctions
- **Priority Four Cases** - Those cases resulting in acquittals or where no further action.

Total number of Priority One and Priority Two Cases - approximately 900
- 550 casework approximately 300 of these have been re-tested
- 350 road traffic, all of which have been re-tested

Total number of Priority Three to Four Cases - approx 9000
- 7000 road traffic and 2000 casework