Forensic Science Regulator

Lessons Learnt Review: Quality Failure in s5A Drugs Driving Analysis

FSR-REP-0001

This document is issued by the Forensic Science Regulator in line with Section 9(1) of the Forensic Science Regulator Act 2021.

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Foreword

This is the first lessons learnt review produced by the statutory Forensic Science Regulator (the 'Regulator'). It is published under the provision of s.9.1 of the Forensic Science Regulator Act 2021 that allows the Regulator to prepare and publish guidance or reports on any matter relating to forensic science activities carried on in England and Wales.

Lessons learnt reviews must provide not only an understanding of the basis for any quality failure or error but most importantly the lessons and actions that need to be taken to reduce or eliminate the possibility of reoccurrence. The quality failure in this review was significant in scale and merited a broader review into organisational factors and the effectiveness of regulation.

The focus of this lessons learnt review is the provision of s5A drug driving analysis as a whole and the issues that led to the quality failure rather than the actions of Synlab. The Regulator acknowledges the openness and transparency of the senior leadership at Synlab and the organisations who contributed to this review in supporting learning and improvement to avoid reoccurrence. The Regulator has identified learning points and actions taken will be reported through the Forensic Science Regulator annual report.

Forensic Science Regulator **May 2024**

1. Introduction

1.1.1 In December 2022 the Regulator produced a position statement (Annex A) on the quality failure in drugs driving analysis conducted by Synlab Laboratory Services (‘Synlab’). On 30th January 2023, the National Police Chiefs Council (NPCC) issued a press release setting out that they had concluded their review into Synlab’s analysis of drug driving samples, specifically Section 5A Road Traffic Act 1988 (Drug Driving) toxicology testing for controlled drugs (s5A analysis). The NPCC reported that 1,778 samples had drug levels reported by Synlab as above the prescribed limit, and these results had been rescinded.

1.1.2 The Regulator’s statement referred to a wider ‘Lessons Learnt’ review that would look at the quality failure from an organisational and regulatory perspective. To do this, the Regulator has considered the views and information provided by the key actors involved, as well as correspondence, processes, regulation, and guidance from the timeframe concerned. The Regulator followed up on this by holding discussions with the key actors.

1.1.3 This lessons learnt review looks at the events, decisions and organisational responses that resulted in this quality failure and outlines lessons learnt where actions should be taken to reduce the risk of a similar failure in the future. The Regulator will follow up on the learning points identified in this report through making amendments to the Forensic Science Regulator’s (FSR) Code of Practice (the Code), engagement with stakeholders and reporting on progress and outcomes through the FSR Annual Report.

1.1.4 A review was commissioned and conducted by an independent adviser to the Regulator into the scientific aspects of the quality failure in drugs driving analysis conducted by Synlab, the executive summary and recommendations of this report are set out in Annex B.

1.1.5 The work undertaken in this review was conducted over a period that covered both the non-statutory and statutory regulation forensic science. While the Regulator started fact finding in 2022 following the scientific

review, detailed consideration of the lessons learnt and actions to be taken were delayed to take into account the statutory Code coming into force on the 2nd October 2023 along with the commencement of all of the provisions of the FSR Act 2021. This was done to ensure the actions taken would utilise the provisions and powers given to the Regulator under the Act.

1.1.6 The Regulator thanks those who contributed their views and accounts to inform this review and to the independent adviser for their detailed review into the scientific basis of the quality failure.

2. Summary of events that led to the discovery of the quality failure by Synlab Laboratory Services

2.1.1 Synlab began to undertake s5A analysis on live casework in April 2019 as a sub-contractor to Key Forensic Services (‘Key’).

2.1.2 In November 2020, an independent expert acting for the defence highlighted issues in the analysis of a batch of samples carried out by Synlab and referred this to the Regulator. Following a series of discussions with Key, Synlab raised a non-conformance, engaged with United Kingdom Accreditation Service (UKAS) and informed the Regulator. Key suspended submission of samples to Synlab on 10th December 2020.

2.1.3 NPCC convened a meeting of key stakeholders on 17th December and a NPCC-led Gold Group was established in January 2021 to consider the impact of the quality issue and oversee the operational policing response.

2.1.4 Action was taken by UKAS and Key to establish the extent and nature of the quality failure and whether the situation was recoverable but further issues with the Synlab s5A analysis method were discovered over the period January to October 2021.

2.1.5 The Regulator commissioned an independent adviser to review Synlab’s scientific methods in December 2021. The review reported in March 2022 and found major weaknesses in the analytical test method, a lack of effectiveness in the quality management system and low overall confidence

in the reliability of the results reported by Synlab. In the Regulator's view the combination of these deficiencies was such that, in general, the results produced by Synlab in drugs driving cases could not be considered accurate and reliable. To attempt to recover this situation and provide robust evidence in s5A analysis the Regulator identified two options: re-analysis of any remaining blood specimens or an independent review of the raw data generated by Synlab. However, not all original samples were available for retesting as a number had already been destroyed after being tested, following standard operating practice. The remaining samples were old samples and degradation would have been a major issue and there were concerns about continuity for a number of these. A review of the raw data was carried out for all cases, and a small number were able to be retested by Key.

2.1.6 The Regulator considered the findings of the independent scientific review and the review of the raw data and concluded in a final position statement issued in December 2022 that all the analysis of blood specimens undertaken by Synlab for the purpose of Section 5A Road Traffic Act 1988 cannot be considered accurate and reliable. No credible mechanism had been identified by which this situation could be recovered save for a small number of samples that could be re-analysed by an accredited provider and a statement of evidence produced that could be used to support the reliability of the original conviction. The NPCC Gold Group reported that over the period April 2019 to December 2020 when Synlab were undertaking s5A analysis, 4,255 samples were analysed. Of these samples 2,181 had no drugs present or a level of drug that was reported as below the prescribed limit; 296 samples were from cases that were discontinued for a number of reasons including a decision by the police to take no further action or there was no conviction at court; the remaining 1,778 samples had drug levels reported by Synlab as above the prescribed limit and these results were rescinded. Key retested 97 of these, where there were still suitable samples, of which 15 were able to be proved to be above the legal limit. This did not mean the remaining 82 were incorrectly reported initially, rather that the

sample is likely to have degraded to an extent where the drug concentration is significantly lower than at the original point of testing. The results produced by Key met the required quality standards and were continued through the CJS.

3. Regulator's consideration and lessons learnt

3.1 Overview and operating context

3.1.1 The s5A offence, which set legal limits for controlled drugs, was introduced via an amendment to the Road Traffic Act 1988 in March 2015. At this time there were a small number of providers with experience of this type of analysis, a few additional suppliers entered the market over the coming years.

3.1.2 By 2017, the s5A analysis market was under significant pressure. In 2017, a severe quality failure had been detected at one provider of s5A analysis resulting in their accreditation being withdrawn and they ultimately withdrew from the s5A analysis market for the provision of this analysis. In 2018, a provider went into administration, exacerbating backlogs and resulting in submission caps being implemented at national level which in turn caused backlogs within police forces. In June 2019, there was a cyber-attack at a third provider causing s5A analysis to be suspended for several weeks.

3.1.3 The Regulator has no role in market or commercial regulation of forensic science, however this report acknowledges that the operating context for the s5A analysis market at the time was under significant pressure and notes that this may have contributed to a greater appetite for risk in commercial decision making.

3.1.4 This report considers the quality failure across the following themes: (1) root cause; (2) wider organisational risk management, (3) accreditation and regulatory processes; and (4) effectiveness of the regulatory requirements of the analysis of blood specimens under s5A.

3.2 Root Cause

3.2.1 The Regulator has relied on the report produced by the independent adviser and information from Synlab, Key and UKAS as the basis to understand the underlying scientific issues that were the root cause of the quality failure in drugs driving analysis conducted by Synlab.

3.2.2 The scientific review set out recommendations, some of which relate to the scientific approach and others which touch on wider organisational and regulatory issues. These recommendations have been considered as part of this lessons learnt review.

3.2.3 Following the scientific review, Key were commissioned to review the raw data for each individual s5A blood specimen analysed by Synlab to assess the reliability of the results generated. Through this process, which Synlab supported with a full review and constant dialogue between both parties, Key raised 75 formal queries and concluded that it was not possible to reliably determine if the results met the analytical acceptability criteria for reporting into the CJS. The assurance review commissioned by the Regulator agreed with Key's findings and findings identified by UKAS, that whilst the protocols had been implemented and followed, there was a need to revisit the uncertainty of measurement (UoM) for tetrahydrocannabinol which was the drug of interest in the majority of the reviewed cases. It also identified the need to establish that the UoM, for all quality controls across the full concentration range for all s5A specified analytes, met regulatory requirements.

3.2.4 On the basis of all of the above work the Regulator reported to the Gold Group that all analysis of blood specimens undertaken by Synlab could not be considered accurate and reliable, except for a small number of samples which could be re-analysed and confirmation of the original result provided.

3.2.5 In conclusion, the root cause of the quality failure was the lack of the correct application of a robust scientific method and ineffective quality control processes such that the results reported to the CJS could not reliably

determine that the level of drug or drugs found in a person's blood exceed the specified limit.

3.3 Wider organisational risk management processes

3.3.1 This section considers the risk management within the organisations involved, whether there were inherent risks and if these risks were recognised and managed.

3.3.2 In February 2019, the West and South Coast Forensic Procurement Consortium (the "Consortium") of police forces led by Avon and Somerset Constabulary, engaged with the Home Office's Forensic Marketplace Management team and the Eastern 'E7' Region and identified Synlab as a potential provider of drugs driving analysis to the CJS. They approached Key asking them to act as prime contractor and set up arrangements such that Synlab would be a subcontractor to Key. The subcontract arrangement came into effect in April 2019.

3.3.3 Key and Synlab entered into a commercial arrangement with a supporting operational protocol that required accreditation to ISO/IEC 17025 and the requirements of the Regulator's Codes of Practice and Conduct.

3.3.4 The Regulator approached the Consortium to establish how Synlab was identified as a suitable provider and the level of due diligence that was carried out as a new provider. Since the original contract and sub-contracting arrangements were put in place new contracts have been established, staff have since retired and the leadership of the Consortium has moved to Dyfed Powys Constabulary. The Regulator has not been able to access records of the decision-making process and of consideration given to risk management during this period. Assurances have been provided to the Regulator that the Consortium and the Forensic Marketplace Management Team undertook appropriate due diligence, including ensuring that Synlab had the appropriate accreditation and visited Synlab's premises.

3.3.5 Key conducted a non-technical audit and commissioned a technical audit by an independent consultant following commencement of the sub-contract

agreement. Key raised a number of concerns about Synlab's methods through the course of their sub-contract agreement and took various steps to check for issues such as submitting blind samples spiked with drug which revealed differences in ion ratio acceptance criteria. Synlab subsequently undertook an internal investigation and provided assurances that this was a localised issue, relating to a member of staff, rather than systemic and updated its standard operating procedures.

3.3.6 The nature of drugs driving analysis as a complex quantitative analysis requires rigorous quality control for accurate and reliable results to be provided to the CJS and to demonstrate that an individual exceeds the legal specified limit. A conviction under s5A is based on the scientific analysis that the level of the specified drug is above the legal limit. Organisations who undertake such work should have a significant breadth and depth of knowledge and experience in scientific and toxicology analysis, and experience of dealing with this type of analysis in a CJS environment. New providers of s5A analysis that lack experience of provision of this type of toxicology analysis to the CJS, could therefore introduce risk to the CJS.

3.3.7 The regulatory requirement to achieve accreditation through the establishment of an effective quality management system provides a vehicle to understand and manage those risks. There needs to be particular emphasis on demonstrating that analysis results are accurate and reliable and that the ongoing quality control systems are working effectively.

3.3.8 The Home Office consider that they mitigated the risk of a new provider by seeking advice from the Regulator and the Forensic Science Regulation Unit (FSRU, now the Office of the Forensic Science Regulator (OFSR)) and implementing measures such as the requirement that new entrants undergo an external audit. Due to the lack of available documentation from the time however, there is no clear record of the decision-making process around this.

3.3.9 Synlab acknowledge that in undertaking drugs driving analysis it had not appreciated the scientific rigour and scrutiny that results would be subject to within the CJS. Synlab did employ the expertise of an independent toxicology

consultant when establishing its methods. This took place before casework was being analysed, so methods may have been considered fit for purpose then but the issues encountered in this type of forensic casework require specialist expertise to troubleshoot and ensure that the analytical method remains robust.

3.3.10 There is only a small number of providers in the market for s5A analysis, which hold the expertise in the field of s5A analysis and there is not a readily available source of expertise for new entrants to access, which contributes to the challenges of entering this market. Further, at the time of this quality failure, s5A was still relatively a new legislation with providers having limited experience of the scientific challenges. Industry bodies and professional networks such as the Association of Forensic Science Providers (AFSP) and United Kingdom and Ireland Association of Forensic Toxicologists (UKIAFT) comprise members from forensic service providers who are performing s5A casework and are a potential mechanism for sharing expertise.

3.3.11 There is a wider commercial dimension to effective knowledge sharing in s5A analysis in that contracts are awarded in cycles with organisations bidding for tenders, which may result in them winning all, some, or none of the bid work. Organisations are thus pitting against each other on commercial terms including price and turnaround times. Methods and processes therefore represent intellectual property belonging to that organisation and it is not necessarily in their interest to share this with other companies that may become their competitor. Key consider that they provided support to Synlab throughout the course of the subcontract agreement.

3.3.12 The subcontracting arrangements, however, did not cover in detail the scientific quality, accountability to the CJS and how scientific risks should be managed. The contractual arrangements relied on Synlab achieving accreditation to carry out s5A analysis and that it was Synlab’s responsibility to demonstrate its ongoing compliance to the required standards once accreditation had been granted.

3.3.13 In October 2023 the statutory Code of Practice for forensic science came into force and the remaining provisions of the FSR Act 2021 were commenced. The statutory basis for the regulation of forensic science is a significant change both in terms of the statutory Code being admissible in criminal proceedings and giving the Regulator powers to conduct investigations and take enforcement action based on a belief there is a risk to criminal investigations or proceedings. The statutory Code also introduced the role of Senior Accountable Individual who is accountable for the strategic leadership of the forensic unit's compliance with the Code. The Senior Accountable Individual is accountable for risks related to any forensic science activity undertaken by, or under the control of, the forensic unit with a particular focus on monitoring and mitigating the risk of quality failures which could adversely affect an investigation or impede or prejudice the course of justice in any proceedings.

3.4 Lessons learnt relating to organisational risk management

3.4.1 Learning Point 1: All parties involved did undertake some diligence prior to s5A analysis for the CJS commencing: commercial teams followed process to carry out pre-contract checks, Synlab employed a consultant to establish its methods, Key conducted a non-technical audit and commissioned a technical audit. This was sufficient to assure all parties that Synlab was fit for purpose to commence s5A analysis. However, these steps did not adequately and robustly identify and mitigate the risks to the CJS in this challenging and complex scientific analysis. To address and mitigate these risks commercial and procurement processes should ensure and record steps that are taken to identify and mitigate risks to the CJS when establishing contractual agreements with s5A providers (including subcontracting agreements) and there should be a clear record of decision-making and risk assessment and mitigation action.

3.4.2 Learning Point 2: For new entrants who are seeking to undertake forensic science activities that are subject to the statutory Code the contracting

authority and the Senior Accountable Individual, as defined in the statutory Code, should consider and implement measures to manage and mitigate risk in s5A analysis, this should take into account context such as experience in the provision of forensic science services to the CJS. Measures could include a probationary period where limited volumes of live case work material are examined or analysed with clear review points following an audit or assessment of performance and risks, or a requirement for audits after a period of time or defined volume of samples analysed.

3.5 Accreditation and regulatory process

3.5.1 This section considers the effectiveness of accreditation and the regulatory processes applied to Synlab to ensure that accurate and reliable s5A analysis results are provided to the CJS. The non-statutory Regulator's Codes of Practice and Conduct were in place at the time Synlab undertook s5A analysis and set a requirement for organisation to achieve accreditation to ISO/IEC 17025. Accreditation to the international quality standard for testing laboratories ISO/IEC 17025 is awarded to organisations following assessment by UKAS, as the single national accreditation body for the UK.

3.5.2 Synlab Laboratory Services, part of Synlab Group, and predominantly a provider of medical diagnostics services, acquired Synergy Health Laboratory Services (SHLS), whose core business was workplace drug and alcohol testing services. SHLS had held accreditation for toxicology testing and in 2018 Synlab attained accreditation for the analysis of drugs driving toxicology testing for blood specimens under s5A. Synlab had not previously undertaken drugs driving analysis within the CJS, although SHLS had briefly held accreditation for two drugs for s5A analysis in 2016. In December 2018, Synlab were granted accreditation for s5A analysis for a wider range of drugs. Live casework analysis was initiated in April 2019.

3.5.3 Initially, Synlab undertook analysis of blood specimens in drugs driving cases and provided these results to Key who reported the result into the CJS. However, this approach was changed (for all customers except one) to

Synlab providing certificates of analysis for cannabis, cocaine and benzoylecgonine direct to the CJS.

3.5.4 In June 2019, UKAS undertook an assessment of Synlab and found evidence that the processes for the analysis of duplicates and management of quality control samples were not being fully implemented. At this stage there were limited quality control samples available. As a result, Synlab voluntarily suspended its accreditation for the analysis of specified drugs for s5A analysis while it dealt with the findings of the assessment and sought to clear the findings raised by UKAS.

3.5.5 In August 2019, Key instructed an independent consultant to audit Synlab's methods, due to persistent concerns Key held. While no casework was being undertaken at the time of the audit, the independent consultant found that Synlab's methods were theoretically 'fit for purpose and valid' with recommendations for a re-visit once the methods had been transferred to newer instrumentation.

3.5.6 Synlab's accreditation was reinstated in August 2019 following further UKAS assessment and s5A analysis recommenced with a reduced scope of accreditation.

3.5.7 Following the reinstatement of Synlab's accreditation, a remote surveillance assessment was conducted by UKAS in July 2020. The visit in July could not be conducted on site due to government restrictions in relation to Covid and so a remote assessment was carried out with the associated limitations and did not look at s5A work.

3.5.8 As outlined at 2.1.2 of this report concerns were raised in November 2020 by an expert acting for the defence in a case analysed by Synlab in early June 2020. As a result of investigations by Key and Synlab, Synlab voluntarily suspended their accreditation and the undertaking of live casework, the Regulator was formally notified on 16th December 2020. It is not possible to establish whether had the UKAS assessment in July 2020 been on site it would have picked up on the issues that were revealed through the defence

review. In this context, the accreditation and assessment process did not adequately detect significant quality issues. It is acknowledged that the UKAS assessment and accreditation process was not designed to specifically look at risk to the CJS.

3.5.9 Following the voluntary suspension UKAS undertook multiple visits and assessments of Synlab to try to resolve issues. Between January and August 2021 UKAS issued several assessment reports, four of these were remote assessments. UKAS recommended reinstatement of Synlab's accreditation, subject to Synlab clearing mandatory actions. During this period the NPCC Gold Group reported that there was a general feeling of optimism that the actions would be cleared and that Synlab's reinstatement of accreditation would follow. The suspension of accreditation by UKAS continued through to January 2023 when UKAS accreditation was withdrawn retroactively for the entire period that Synlab had been operational for s5A analysis.

3.5.10 There was an agreement in place between the non-statutory Regulator and UKAS to share information relating to quality issues, facilitated by organisations signing a confidentiality waiver to permit this exchange of information. There were regular meetings between the Regulator and UKAS during this period where updates were given on a range of regulatory projects and risks, UKAS highlighted the suspension of accreditation to the Regulator but did not highlight any potential risks or need for regulatory action.

3.5.11 Under the non-statutory basis for regulation of forensic science that was in place at the time, the Regulator's role was to set standards through the Codes of Practice and Conduct, and following a referral could conduct an investigation, issue a general report or a lessons learnt report. The adoption of standards, meeting the requirements set out in the Codes of Practice and Conduct, acting on any recommendations made by the Regulator and taking action on lessons learnt was voluntary.

3.5.12 The regulation of s5A analysis during this period relied on the Appendix to the non-statutory codes referred to as FSR-C-133 which set out the

regulatory requirements for s5A analysis. The role and status of the Appendix is dealt with in the effectiveness of regulatory requirements section below but it is acknowledged that it was in development during the time period Synlab was operational. The requirements had been shared with the forensic community, and it was used by UKAS in accreditation assessments.

3.5.13 During the period that Key were reviewing the analytical data from Synlab following identification of the quality failure, UKAS were developing Lab 51, a guidance document which aimed to provide consistency of approach to toxicology analysis, including s5A analysis. UKAS consider that the aim of Lab 51 was to clarify requirements that were already defined. This document was not available publicly at this time but the development of these requirements and the utilisation of them by UKAS when assessing Synlab was considered to create a perception of 'changing goalposts' which meant that Synlab, Key and UKAS were approaching the requirements for s5A analysis differently during this review period. Lab 51 was published in June 2021.

3.5.14 The scientific review by the Independent Adviser exposed the extent of the quality issues, but the trigger for the exploration into the extent of the issues at Synlab was the scrutiny by a defence scientist as opposed to through the UKAS accreditation assessment process or the initial referral to the Regulator. This argues for better and more robust mechanisms to communicate significant risks of quality failures between UKAS and the Regulator so that the Regulator can take actions appropriately.

3.5.15 The Forensic Science Regulator Act 2021 introduces a statutory basis for the Regulator to intervene where they have reason to believe that a person may be undertaking a forensic science activity to which this Code applies in a way that creates a substantial risk (that being a risk which is more than theoretical) of (a) adversely affecting any investigation; or (b) impeding or prejudicing the course of justice in any proceedings.

3.5.16 The statutory power to conduct an investigation under section 5 of the FSR Act was introduced through a Commencement Order in July 2022 and the

power to issue compliance notices, under section 6, were introduced in October 2023. The use of these powers through effective escalation, detailed scientific scrutiny, risk assessment and suitable compliance notices could have reduced or eliminated the risk to the CJS in s5A analysis.

3.6 Lessons learnt relating to accreditation and regulatory processes

3.6.1 Learning Point 3: The accreditation and regulatory processes did not provide an effective risk escalation mechanism to minimise the impact of the quality failure in the analysis of blood specimens for the purpose of Section 5A Road Traffic Act 1988. The initial period of suspension in 2019 should have warranted additional scrutiny even when accreditation was reinstated given the lack of experience of Synlab both in s5A analysis and providing forensic science evidence to the CJS. UKAS has conducted its own lessons learnt review and implemented a three-month review requirement for such circumstances.

3.6.2 Learning Point 4: The Regulator should establish formal arrangements with UKAS such that if there is a suspension (voluntary or otherwise) of accreditation this is notified to the Regulator so an assessment of the impact of this suspension can be made. This would allow effective application of the new statutory powers under provisions of the FSR Act. The Regulator should assess the level of risk and consider whether to use the powers under section 6 of the Act and issue a Compliance Notice to manage and mitigate any risks to the CJS.

3.7 Effectiveness of regulatory requirements

3.7.1 This section considers the regulatory requirements for s5A analysis, the challenges of ensuring quality in this analysis and the work the Regulator is conducting in consultation with stakeholders to revisit the regulatory requirements.

3.7.2 As outlined above the offence of driving with a specified drug in the body above a specified limit was introduced in England and Wales in March 2015 by an amendment to the Road Traffic Act 1988 and the relevant legal limits were introduced under the statutory instrument 'The Drug Driving (Specified Limits) (England and Wales) Regulations 2014'. To support the implementation of the legislation, a Home Office (HO) and Department for Transport (DfT) specification was produced setting out requirements for organisations who undertake drug driving analysis, requirements for the analytical method and the requirement for this work to be accredited to the ISO/IEC 17025 standard.

3.7.3 The HO and DfT specification did not address how quality standards and requirements should be applied in s5A analysis and initially there was a lack of defined published requirements that would ensure a harmonised approach.

3.7.4 Prior to the statutory Code coming into force, the non-statutory Codes of Practice and Conduct provided the basis for the regulation of forensic science including s5A analysis. There was an Appendix to the codes on 'The Analysis and Reporting of Whole Blood Specimens in Relation to s5A Road Traffic Act 1988 (Drug Driving)' which set requirements for s5A analysis and was referred to as 'FSR-C-133' This was developed by the FSRU in collaboration with the HO, DfT, UKAS, the Crown Prosecution Service and providers of toxicology analysis, to address potential disparities in approaches to s5A analysis and set out:

a. Requirements for analysis
b. Quality and environmental requirements
c. Monitoring for quality control
d. How to deal with contamination
e. Reporting of results including the Forensic Science Regulator's Expanded Uncertainty of Measurement.

3.7.5 FSR-C-133 was formally published as 'issue 5' in December 2021. Prior to its publication, FSR-C-133 was in a draft form and was made available to

providers of s5A analysis, including Synlab. UKAS utilised FSR-C-133 as part of its accreditation assessment process. FSR-C-133 has now been incorporated into the statutory Code as the 'FSA-specific requirements' to the forensic science activity of FSA – DTN 102 – Toxicology: analysis for drugs in relation to s5A of the Road Traffic Act 1988.

3.7.6 The forensic science regulatory challenge of setting requirements including accreditation for drugs driving analysis is significant. S5A analysis is a comparatively recent introduction and is unusual in that unlike other areas of forensic science where comparisons or identifications are made, this is an area of forensic science where the analysis is quantitative and the outcome is a requirement to demonstrate that the analytical result exceeds a specified legal limit. In general, the forensic science regulatory framework does not prescribe the method to be used but instead relies on organisations defining the method and undertaking robust validation and meeting the requirements of established standards such as ISO/IEC 17025.

3.7.7 This quality failure is mainly related to the incorrect or ineffective application of requirements for s5A analysis, there is an appetite from providers and stakeholders to review and refresh the statutory Code FSA-specific requirements for s5A analysis. Providers of s5A analysis are of the view that the CJS would be better served by a greater level of prescription of the method and quality control processes for s5A analysis.

3.7.8 However, a more prescriptive approach would only be one part of an effective regulatory approach to s5A analysis. Given the central and critical role that forensic science plays in ensuring the accuracy and reliability of s5A analysis there is an important role for proficiency testing of all providers to inform and provide assurance that the requirements in the Code are being met and inform an understanding of risk to the CJS. The importance of proficiency testing is highlighted in the independent adviser's report.

3.8 Lessons learnt relating to effectiveness of regulatory requirements

3.8.1 Learning Point 5: S5A analysis is complex and requires stringent quality control and a robust analytical method to detect low levels of drugs to give confidence that the measured result is above the specified legal limit. Although regulatory requirements have been produced to address these challenges and ensure a harmonised approach, the Regulator will review and update the current statutory Code FSA-specific requirements taking a more prescriptive approach to setting these requirements.

3.8.2 Learning Point 6: The Regulator will facilitate a proficiency testing scheme across providers of s5A analysis.

4. Annex A: Final Position Statement by the Forensic Science Regulator: Drug-Driving Analysis undertaken by Synlab Laboratory Services Limited ("Synlab") (December 2022)

4.1.1 The analysis of blood specimens for prosecution under the Section 5A Road Traffic Act 1988 offence for the presence of drugs and the determination of whether the concentration of any drug(s) found exceeds a specified limit is a highly complex and challenging area of forensic science.

4.1.2 Following a referral to the Regulator regarding the drug-driving analyses carried out by Synlab, and alongside subsequent action taken by the United Kingdom Accreditation Service (UKAS) resulting in the withdrawal of accreditation for Section 5A analysis, a review was commissioned by the Regulator into the analysis undertaken by Synlab. The review identified weaknesses in the analytical test method used and a lack of effectiveness in the quality management system. The combination of these deficiencies is such that it brought into question the ability of Synlab to report Section 5A results with the required degree of confidence. Synlab conducted their own review into the analytical work they had undertaken, this led to a number of results being rescinded and reports being re-issued.

4.1.3 The Regulator reported that to recover this situation, and establish accurate and reliable test results that would provide robust evidence in Section 5A cases, would require either:

a. re-analysis of any remaining blood specimens, which had been suitably stored since the original analysis was undertaken, by an organisation that holds accreditation for Section 5A analysis and is compliant with the FSR Codes of Practice and Conduct, or
b. an independent review of the original/reprocessed data generated by Synlab for each individual blood specimen along with the supporting calibration and quality control data. Suitably competent forensic

toxicology practitioners working in an organisation that holds ISO/IEC 17025 accreditation for Section 5A analysis and is compliant with the FSR Codes of Practice and Conduct, could produce a detailed and comprehensive statement of evidence as to whether the data generated by Synlab provides a scientifically reliable basis for determining if a blood specimen contains a concentration of drug(s) that exceeds the specified limit.

4.1.4 The Regulator's position was considered by the NPCC Gold Group that was coordinating the multiagency response to the issues raised in relation to the drug-driving analyses conducted by Synlab.

4.1.5 The re-analysis referred to at 3(a) was considered but not proceeded with for the majority of blood specimens due to expected degradation of the drugs originally found.

4.1.6 On behalf of the NPCC Gold Group, Key Forensic Services (KFS) were commissioned to undertake the independent review referred to at 3(b) of the original/reprocessed data generated by Synlab for each individual blood specimen along with the supporting calibration and quality control data. As the KFS review progressed concerns were highlighted regarding the robustness of the analytical data and the quality control processes, such that it was not possible to reliably determine if the results would meet the analytical acceptability criteria for reporting to the criminal justice system.

4.1.7 The Regulator commissioned independent assurance of the review by KFS to ensure that agreed protocols had been implemented. Whilst the protocols had been implemented and followed, this evaluation agreed with the need to revisit the uncertainty of measurement (UoM) for tetrahydrocannabinol (THC), on which the majority of the reviewed cases were based. It also identified the need to establish that the UoM for all quality controls across the full concentration range for all S5A specified analytes, met the necessary regulatory requirements.

4.1.8 The reviews, assessments and evaluations that have been undertaken by KFS, UKAS and the FSR have been comprehensive and rigorous and have required significant resource to be made available by the organisations concerned.

4.1.9 As a consequence of the issues highlighted by KFS, UKAS and the FSR reviews, the overall confidence in the Synlab test methods, and their implementation of quality acceptance criteria, does not give the necessary assurance of the results produced and the subsequent reliability of the evidence that would be presented in court. Additionally, due to the nature of the issues noted there is no guarantee that further review or evaluation of the data would be able to adequately address the concerns raised. No concern was highlighted during any of the reviews that there was inappropriate manipulation of data or information by Synlab in relation to the Section 5A analysis undertaken.

4.1.10 In conclusion, and for the reasons outlined above, it is the view of the Regulator that all the analysis of blood specimens undertaken by Synlab for the purpose of Section 5A Road Traffic Act 1988 cannot be considered accurate and reliable. No credible mechanism has been identified by which this situation can be recovered save for a small number of samples that could be re-analysed by an accredited provider and a statement of evidence produced that could be used to support the reliability of the original conviction.

4.1.11 Alongside the scientific reviews commissioned by the Regulator a wider “Lessons Learnt” review has been instigated that will look at the root causes, wider organisational risk management processes and effectiveness of the regulation of the analysis of blood specimens under Section 5A Road Traffic Act 1988.

5. Annex B: Executive Summary and Recommendations from Scientific Review

5.1 Executive Summary

5.1.1 This report concerns analytical work undertaken by Synlab Laboratory Services under the provisions of Section 5A of the Road Traffic Act 1988 as introduced on the 2nd March 2015. Examination of datapacks by Experts acting on behalf of the Defence identified a number of analytical issues which were subsequently found to be significant and which ultimately led to the loss of accreditation of Synlab Laboratory Services to undertake S5A analyses. This has, and continues to have, consequences to the Criminal Justice System.

5.1.2 The main focus of the report is to ensure that all of the analytical issues have been identified, to understand the root causes and to ensure that all cases potentially affected have been identified.

5.1.3 Contributing factors to the problems include a lack of capacity at Synlab Laboratory Services to deliver S5A casework alongside their other work, little knowledge of the extent of analytical challenges to S5A casework, a lack of a “support network” to assist the laboratory when advice would have been useful, lack of detail in the laboratory’s initial operating procedures against which accreditation was granted and accreditation of a method for quantification of THC in blood which proved ultimately not to be sufficiently robust for the analytical requirements of some of the S5A analyses undertaken even though the initial validation showed the method to have been working satisfactorily.

5.1.4 Although a number of peer-reviews of the analytical data have been undertaken, with various analytical criteria being used at various times, a significant error rate between reviews has been noted. Consequently, although it is highly likely that the vast majority of cases will have been identified I am not confident that a full list of problematic cases has been

identified. There are likely to be a number of case batches which will fully meet the updated acceptance criteria and therefore which will contain case results which are scientifically acceptable. Unfortunately the results of external proficiency testing schemes analysed by Synlab Laboratory Services, which are designed to give an independent assessment of a laboratory's performance, do not provide full confidence that case results are necessarily reliable.

5.1.5 A number of recommendations have also been made to minimise the risk of a similar event happening in the future.

5.2 Recommendations

5.2.1 During the review a number of issues have been identified which should be addressed to ensure that new entrant FSPs, in particular, deliver S5A analyses which are sufficiently robust to provide reliable results to the CJS. In order to achieve this goal a number of recommendations are made.

a. The analytical requirements for S5A analyses should be significantly tightened up. This could be done via the FSR's Codes of Practice and Conduct (e.g. FSR-C-133) which will give UKAS something much more substantial and specific to accredit FSPs against.
b. Ensure that FSPs have sufficient knowledge, experience and capacity to deliver casework of sufficient quality and in a timely manner.
c. Define a probationary period for new FSPs during which extra scrutiny would be made to ensure work is being carried out according to all scientific and regulatory requirements.
d. Ensure that any subcontracted work is closely monitored by the subcontracting laboratory; use of blind trials and close examination of full analytical results, via random dip-checks, could be encouraged.
e. Cessation of S5A analyses if any analytical issues are identified at any FSPs to allow time for full investigation, with UKAS and FSR being informed the same day, should be considered. Such investigations may sometimes be very quick, but sometimes take much longer.

Outsourcing of unanalysed case samples in the interim should be considered.

f. If there is a likelihood of incorrect results having been reported, the CJS must be informed immediately.

g. Retesting of affected samples in any new investigations at any FSP should be considered at the earliest opportunity.

h. A monthly, or 3-monthly, PT scheme specifically for S5A blood drug analysis should be sourced and implemented at the earliest opportunity.

i. Implementation of a “double-blind” PT scheme, where FSPs have no knowledge that a particular sample is a PT sample, rather than a case sample, could be considered.

Published by:

The Forensic Science Regulator

23 Stephenson Street

Birmingham

B2 4BJ.

www.gov.uk/government/organisations/forensic-science-regulator