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DRUGS AND DRIVING: "ZERO TOLERANCE" SYNLAB SALIVARY REPORT METHODOLOGY AND NATIONAL ACCREDITATION BODY APPROVAL CRITERIA

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DRUGS AND DRIVING: "ZERO TOLERANCE" SYNLAB SALIVARY REPORT METHODOLOGY AND NATIONAL ACCREDITATION BODY APPROVAL CRITERIA

Abstract: Legislation on the control of alcohol and drug consumption has a great impact on society, not always without controversy, depending on how this information is conveyed to public opinion. A clear example is the criteria used to establish the legal limit of alcohol consumption compatible with driving. Although society accepts the zero tolerance criterion for drug consumption, it is essential to standardise the methods used to detect and quantify the presence of drugs that influence driving and, consequently, affect road safety. In this context, establishing and determining the quantity of the minimum concentrations, in the event of a positive drug test, is essential and especially important in the case of repeat offenders or road offenders. However, this qualitative and quantitative determination must be properly audited. This article reviews the history that has led to the determination of the detectable quantities of drugs, but, above all, the traceability criteria that are typical of accredited systems in the field of Road Safety.

Resumen: La legislación sobre el control del consumo de alcohol y drogas tiene una gran repercusión en la sociedad, no siempre exenta de polémica, dependiendo de cómo se traslade esta información a la opinión pública. Un claro ejemplo, lo tenemos con los criterios que se utilizan para establecer el límite legal de consumo de alcohol compatible con la conducción. Si bien es aceptado por la sociedad el criterio de tolerancia cero en cuanto al consumo de drogas, es fundamental la estandarización de los métodos por los que se detecta y cuantifica la presencia de drogas que influye en la conducción y, consecuentemente, afecta a la Seguridad Vial. En este contexto, establecer y determinar la cantidad de las concentraciones mínimas, en caso de detectarse un positivo en drogas, es imprescindible y especialmente importante en conductores reincidentes o en los delincuentes viales. Sin embargo, esta determinación cualitativa y cuantitativa debe estar debidamente auditada. En este artículo, se hace una revisión del histórico que ha llevado a la determinación de las cantidades detectables de drogas, pero, sobre todo, a los criterios de trazabilidad que son propios de sistemas acreditados en el ámbito de la Seguridad Vial.

Palabras clave: Seguridad Vial, tolerancia cero, conducción, drogas, detección, concentración mínima, estandarización, acreditación.

Keywords: Road safety, zero tolerance, driving, drugs, detection, minimum concentration, standardisation, accreditation.

ABBREVIATIONS

Art.: Article.

PC: Penal Code.

DED: Electronic Detection Device (portable drug).

DGT: Dirección General de Tráfico.

ENAC: Entidad Nacional de Acreditación (National Accreditation Entity)

FSCSV: Prosecutor for Road Safety Coordination Chamber

FGE: Fiscalía General del Estado.

ISO: International Stantarization Organization (internationally recognised standard).

LOQ: Limit Of Quantification.

LSV: Road Safety Law.

Ng: Nanogram (1ng = 1.0E-9 g).

SV: Road Safety.

WHO: World Health Organisation.

ONSV: National Road Safety Observatory.

UN: United Nations.

SV: Road Safety.

TC: Constitutional Court.

UNE: A Spanish Standard.

EU: European Union.

1. INTRODUCTION.

In the "Global Plan - Decade of Action for Road Safety[1] 2021-2030" of the World Health Organization (WHO-UN) it has been determined that one of the main behaviours contributing to fatalities and casualties in road crashes is drink-driving. Therefore, the WHO urges governments to: design the operation of a safe road transport system through the creation of Road Safety (RS) laws, to enforce these laws and to promote road safety education. In addition, the UN body not only urges official bodies, but also private companies to address and mitigate actions that negatively affect road safety and to spread the message that high consumption of alcohol and other substances, such as drugs, contributes to "dangerous driving". The WHO also sets two targets for 2030: to halve the number of deaths and casualties from road crashes caused by alcohol-impaired drivers and to achieve a reduction in crashes caused by the use of psychoactive substances.

In relation to the above, in Spain, the National Road Safety Observatory (ONSV)[2] as a body under the Ministry of the Interior and managed through the Directorate General of Traffic (DGT), has published the so-called "Systematic review on drugs and driving (2021)". This document refers to the "Ley sobre Tráfico, Circulación de Vehículos a Motor y Seguridad Vial" (LSV)[3] , and specifically to Art. 14, which prohibits driving with the presence[4] of drugs in the body (excluding those substances used under medical prescription and for therapeutic purposes). However, in this section of the LSV the legislator warns that "(...) provided that (the driver) is able to use the vehicle in accordance with the obligation of diligence, caution and non-distraction[5] established in Art.10".

Moreover, in Spain, driving a motor vehicle "under the influence of toxic drugs, narcotics or psychotropic substances" may constitute an offence against the SV as defined in Article 379.2 of Organic Law 10/2015 of the Criminal Code (CP). For this reason, on 17 July 2019, the General State Prosecutor's Office (FGE), through the Prosecutor's Office for the Coordination of Road Safety (FSCSV), issued an Instruction for the preparation of attestations for offences of driving under the influence of toxic drugs, narcotics and psychotropic substances of Art. 379.2 of the Criminal Code. In this Instruction, the importance of the report of external signs to determine the influence of these substances is emphasised, since the Spanish legislator did not have an objective rate to determine the impairment of the subject's psychophysical faculties for safe driving, and therefore, the typical element of influence. In his own words, "the theses applied to alcohol are not transferable per se to toxic drugs, narcotics and psychotropic substances, where the scientific premises differ from alcohol for various reasons", and this is due to the fact that it has not been possible to establish the influence on the subject's

[1] See: https://www.who.int/es/publications/m/item/global-plan-for-the-decade-of-action-for-road-safety-2021-2030.

[2]See: https://www.interior.gob.es/opencms/es/el-ministerio/funciones-y-estructura/subsecretaria-del-interior/direccion-general-de-trafico/

[3] Royal Legislative Decree 6/2015, of 30 October, approving the revised text of the Law on Traffic, Circulation of Motor Vehicles and Road Safety of the Interior. BOE no. 261, of 31 October 2015 Reference: BOE-A-2015-11722.

[4] Positive for drugs: a fine will be imposed for infringement of art. 14.1. 5ª of the LSV for the presence of drugs (1000 Euros / 6 points)".

[5] The driver must use the vehicle with the necessary diligence, caution and care to avoid any damage to himself or others, taking care not to endanger himself, the other occupants of the vehicle and other road users, especially those whose characteristics make them more vulnerable".

psychophysical aptitudes that enable him to drive safely, based on a level of drug concentration detected in a saliva test.

Thus, in our country and according to data provided by the DGT[6] , "almost a third of those killed in road accidents exceeded the alcohol limit", but we can also affirm from the evidence of the observation made during more than two decades of professional practice "on the road" by the author of this research work, that the leisure and nightlife lifestyle is one of the factors that increase the probability of consuming alcohol and drugs (cannabis, cocaine and ecstasy) on the part of some drivers (Calafat, A. et al, 2000). And this consumption has become increasingly consolidated in recent years, becoming one of the most important risk factors for road accidents in Spain.

We can also state, thanks to the author's professional experience, that another risk factor is riding as a passenger in a motor vehicle whose driver has consumed alcohol or drugs, which causes every year a constant trickle of what we can call "innocent victims" (passengers, motorcyclists, pedestrians and cyclists) who die in road accidents as a result of a driver driving under the influence of alcohol or drugs, albeit after joint participation of both (driver and passenger) in night-time activities associated with leisure.

This is why, despite the DGT's SV policies, its awareness campaigns on alcohol and drug consumption prior to driving, and the surveillance and control campaigns carried out by traffic enforcement officers, there is still no real "community SV awareness" or "social road awareness" that would make us understand the dangers of this type of behaviour, but above all to prevent it and in any case, as drivers or users, to reject and report it.

Finally, we are obliged to mention those drivers who are repeat offenders or multiple offenders (classified as such according to the time elapsed between the commission of one offence and another and the number of offences committed) and who, being habitual consumers of alcohol or drugs (or both substances at the same time) could be called "addicted drivers", and who can be considered as potentially dangerous for the SV and should therefore be subject to special monitoring and treatment as patients by the health authorities[7] , in coordination with the surveillance and control work of the DGT .

2. THE STRATEGY OF THE DIRECTORATE-GENERAL FOR TRAFFIC: "ZERO TOLERANCE".

In June 2012 the DGT adopted the "zero tolerance" measure as its main line of strategy on driving and drug use, applying this "zero tolerance" to all drivers who use drugs and who get behind the wheel of a vehicle. The reasons given by the DGT[8] were that: "Spain is among the countries with the highest consumption of drugs, especially cocaine and cannabis, which results in an increased risk of road accidents and fatal or serious injuries".

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[6]See: https://revista.dgt.es/es/noticias/nacional/2022/04ABRIL/0404_Campana-alcohol-Cifal.shtml.

[7]The national regulation RD 818/2009 General Regulation for Drivers and the European regulation CD 439/1991, CD 126/2006 and CD 36/2012, state that these patients (addicts) cannot be granted or renew their driving licences as they do not have adequate aptitudes for safe driving.

[8]Document "Drugs and Driving - Zero Tolerance" (DGT).
https://www.interior.gob.es/opencms/pdf/prensa/balances-e-informes/2012/Presentacion-Tolerancia-cero-con-los-conductores-que-consuman-drogas-al-volante.pdf

Thus, according to the 2017 study by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA[9]), in the age group 15-34 years, Spain is the most affected by drug addiction in the European Union:

The sixth EU country with the highest rate of cocaine use (with a prevalence of 2.8%), after the UK (4.7%), the Netherlands (4.5%), Denmark (3.9%), France (3.2%) and Ireland (2.9%).

The fourth EU country with the highest rate of cannabis use (18.3%), behind France (21.8%), Italy (20.9%) and the Czech Republic (19.3%).

Therefore, the actions to be taken by the DGT, in line with its "zero tolerance" strategy, included the following:

Raise the awareness of society as a whole about the problem, inform drivers of the risk of drug use (without forgetting the risk posed by alcohol consumption), know the minimum consumption of alcohol and drugs that cause major driving impairment, extend drug and alcohol + drug controls on all types of roads, days and times; collaborate with other administrations in legislative, educational and training matters related to drugs and driving, and promote applied research in the field of drugs and road safety.

Likewise, and as an objective for the year 2030, the DGT's strategic area of surveillance and control has extended "zero tolerance" to the risk behaviours that have the greatest impact on road accidents, with the following priorities: acting on speeding, alcohol and drug consumption, use of mobile phones while driving and not using safety equipment (seat belts, helmets, child restraint systems, etc.).

2.1. RATIONALE AND PROCEDURE FOR SALIVARY DRUG TESTING.

Until relatively recently, and due to the lack of portable Electronic Detection Devices (DED) with the appropriate technology, it was not common for "on the road" tests to be carried out to detect whether the driver had consumed drugs. The reason for this is that only by carrying out a blood test could one be sure of the results, but, in addition, carrying out these blood tests and their subsequent transfer to the laboratory for analysis was relatively complex and legally difficult.

Subsequently, the importance of the issue and the DGT's commitment to detecting recent drug use and the presence of drugs in the driver's system became very relevant for both the SV and the professional driver's working environment. Gradually, drug testing was implemented with portable DED devices[10] that allow the detection and analysis of recent drug use in the driver's saliva. Through the rapid collection of oral fluid samples (as a non-invasive procedure), an "indicative positive[11] " for recent use of five drugs

[9]See: https://www.euda.europa.eu/publications_en

[10] See: https://www.toxicology.abbott/es/es/screening-devices/sotoxa-mobile-test-system.html

[11] It is called an "indicative" sample and detects the possible **presence** of illegal substances. See: https://revista.dgt.es/es/sabia-que/normas/2018/0703como-se-hace-un-control-de-drogas.shtml

(amphetamines, methamphetamines, opiates, cannabis and cocaine) can be obtained. However, a second saliva sample, called an "evidential test", is required to be collected in order to name and quantify the type of drug detected in this second sample, and thus confirm the "indicative positive" obtained; this second saliva analysis will be carried out in a reference laboratory. The transfer to the laboratory of this 'evidential test' is carried out in a sealed 'saliva collection tube' identified with a bar code, which is placed in a cooler, after being recorded in a document governed by a strict chain-of-custody protocol.

The obligatory nature of this complementary laboratory test (evidential test) after the initial control (circumstantial test) and the ratification in the reference laboratory of the type of drug detected and its quantity, will give presumption of legal veracity to the offence for the presence of drugs in the driver's organism, as well as the corresponding opening of an administrative sanctioning file by the DGT.

3. THE DOCTRINE OF THE STATE ATTORNEY GENERAL'S OFFICE FOLLOWING THE "POSITIVE" SALIVARY DRUG TEST.

According to the doctrine of the Attorney General's Office (FGE)[12] , and once a "positive result[13] " has been obtained in the salivary index test carried out in a portable DED that is capable of analysing oral fluid, the subsequent analysis of the saliva in an "approved laboratory" is mandatory, depending on the necessary control activities by the competent administration, also guaranteeing the "chain of custody[14] " of the saliva collected for analysis to ensure the legality of the procedure for obtaining saliva samples and subsequently converting them into prosecution evidence. The FGE also specifies that the agents in charge of traffic surveillance must receive specific training for their performance, as this type of test is more complex than alcohol detection tests.

Once in the laboratory, salivary samples are processed by analytical equipment consisting of a gas chromatograph[15] (capable of vaporising substances of different volatilities) and a mass spectrometer[16] (capable of generating ions from neutral molecules in the gas phase, separating them according to their mass and detecting them by recording the information appropriately), determining what type of drug and how much is in the salivary sample. These kits are capable of detecting up to forty types of drugs and quantities as small as one nanogram[17] (ng). These laboratory results are then reviewed one by one by specialised medical staff, who sign and validate the final report to be sent to the DGT.

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[12] Circular 10/2011 of 17 November (BOE FIS-C-2001-000010).

[13] The term "positive" does not indicate a certain rate in nanograms, but any result that indicates the mere presence of drugs in the body, i.e. it is not a quantitative test, but a qualifying test with a positive or negative result.

[14] Chain of custody is understood as the process by which it is accredited that the seized object is the same as the one that has finally been analysed. A possible breach of the chain of custody could lead to a violation of the right to due process.

[15]See:https://www.mncn.csic.es/docs/repositorio/es_ES/investigacion/cromatografia/espectrometria_de_masas.pdf

[16]University of La Rioja. Laboratory and Workshops Service**.** Gas Chromatography**:** Qualitative analysis by gas chromatography mass detection Without previous sample preparation operations. 75 € / hour. Mass spectrometry: Qualitative analysis by electrospray mass spectrometry/high resolution Without previous sample preparation operations. 120 € / hour.

[17] Billionth part of a gram: 1 ng = 1e-9 gr.

However, as we have already indicated, unlike alcohol tests, a "zero tolerance" SV policy has been adopted in the case of toxic drugs, since the LSV[18] expressly and tacitly prohibits the presence of narcotic substances in the driver's body. A road policy that is not exempt from criticism, as several authors reproach the discrepancy between the positive results detected in the DED and the positive laboratory results (Ramírez, J, 2024).

These authors state that the "cutoff" (analytical cut-off points determined in ng/ml)[19] , of the brands of portable DED, the laboratory-confirmed detection limits and the quantity of the psychoactive substance detected cannot be contrasted.

4. PRESENCE OF DRUGS IN THE BODY: THE ADMINISTRATIVE SANCTION AND THE DOCTRINE OF THE CONSTITUTIONAL COURT.

The LSV imposes an administrative penalty of 6 points and a fine of 1,000 euros on anyone who drives with the presence of drugs in their system. At this point we will mention the Plenary 174/2017 of the Constitutional Court[20] (TC), due to the question of unconstitutionality raised in relation to several articles of RD 339/1990 [21] , and specifically on the relevance of raising a question of unconstitutionality in relation to Art. 12 of Law 6/2015, by classifying as an administrative offence driving a vehicle "with the presence of drugs in your body", without it being necessary to prove that the presence of these drugs has influenced your ability to drive. The High Court "does not consider that the challenged precepts are unconstitutional for prohibiting drug use, through a rule that aims to protect the SV". It also clarifies that the challenged precepts "are not intended to prohibit drug use in general". Therefore, what it prohibits is: drivers driving "with the presence of drugs in the organism (...)". Thus, it is "typified as an administrative offence, so that the prohibited conduct constituting an administrative offence is not consuming drugs, but driving if this type of substance has been consumed". But what is even more interesting is that the High Court equates the consumption of toxic drugs with the consumption of drugs under medical prescription and for therapeutic purposes, since: "The risk that driving with the presence of this type of substance in the body may entail for traffic safety will be the same both in the case that the drugs consumed are under medical indication and in cases in which the consumption of these is not for therapeutic purposes".

As a result, the TC does not consider that the challenged precepts violate constitutional articles and that this invalidates the approach and the concept of what should be understood by "drugs"; moreover, it guarantees that this concept is defined as a substance that has sufficient entity to alter the psycho-physical capacities of the person who consumes it, and that "The aim of the rule, in classifying driving with the presence of drugs in the body as an administrative offence, is to prevent people from driving if they have taken substances that can alter the psycho-physical conditions for driving, given the risk that driving under such conditions can entail for traffic safety (...)".)".

[18] RD 6/2015 of 30 October, amended Law 18/20221 of 20 December BOE no. 304. A cutoff point is the concentration of a substance at which a diagnostic test is considered positive.
[19] A *cutoff* point is the concentration of a substance at which a diagnostic test is considered positive.
[20] BOE no. 15 of 17 January 2018. Sec. TC.
[21] BOE no. 63 of 14 March 1990, approving the articles of the Law on Traffic, Circulation of Motor Vehicles and Road Safety.

5. CUT-OFF POINTS AND MINIMUM PSYCHOACTIVE QUANTITIES.

Once again, the DGT warns, in the document "Systematic review on drugs in driving" (2021), that there are no international or national agreements on the cut-off points (quantified in ng/ml)[22] to be established in the procedures for controlling substance consumption in drivers and that Spain was one of the first countries to regulate testing by saliva sample. To this end, the DGT claims to have taken into account the values recommended at international level in the field of occupational safety, where a number of prestigious bodies, the Substance Abuse and Mental Health Services Administration (SAMHSA)[23] in the United States, the European Workplace Drug Testing Society (EWDTS)[24] , or the National Safety Council's Alcohol, Drugs and Impairment Division (NSC-ADID)[25] in Europe and the United Kingdom), have issued updated reports on the recommendations of the cut-off points to be established, in accordance with the requirements of the ISO[26] /IEC[27] standards in Europe.

Thus, based on the above, the Ministry of the Interior established positivity values for evidential analysis in the laboratory published in the document "Systematic review on drugs in driving" (2021). So much so that the DGT claims to adjust these values to the most recent and applicable international recommendations, and also to the evidence generated by the Spanish experience in this field.

TABLE 1.

Comparison of the analytical cut-off points for the oral fluid evidence test for the consumption of psychoactive substances in drivers of the Directorate General of Traffic and other international organisations.

ANALITO	**Cutoff saliva (ng/ml)**			
	EWDTS	SAMSHA	NSC-ADID	**DGT**
Amphetamine	15	15	15	**15**
Cocaine	8	8	8	**8**
Ketamine	10			**10**
MDA	15	15	15	**15**
MDEA	15	15		**15**
MDMA	15	15	15	**15**
Methadone	20		10	**10**
Methamphetamine	15	15	15	**15**
Morphine	15	15	5	**5**
THC	2	2	2	**2**

Source: Own elaboration according to DGT (2021).
"Systematic review on drugs and driving".

[22] Nanogram (ng): A unit of mass corresponding to one billionth of a gram.
[23] See: https://www.samhsa.gov
[24] See: http://www.ewdts.org
[25] See: https://www.nsc.org/workplace/get-involved/divisions/alcohol-drugs-impairment-division
[26] Royal Spanish Academy: International Organisation for Standardisation, the international standardisation system for the regulation of products and services.
[27] International Electrotechnical Commission, the world's leading standards commission that develops and publishes international standards for electronic technologies.

Note: EWDTS: European Workplace Drug Testing Society (UK).
SAMHSA: Substance Abuse and Mental Health Service Administration (USA).
NSSC-ADID: National Safety Council - Alcohol, Drugs and Impairment Division (USA).

Comparative analysis of the detection limits (cutoff) of the analytes in table 1:

5.1.1 International Consensus: Analytes such as amphetamine, methamphetamine, MDMA, MDA, cocaine and THC show homogeneous values (15 ng/ml for stimulants; 8 ng/ml for cocaine and 2 ng/ml for THC, demonstrating that the standards are widely accepted for their detection.

5.1.2. Variability in specific analytes: Methadone and morphine show lower limits in NSC-ADID and DGT, indicating more sensitive criteria, possibly for forensic and road safety reasons.

5.1.3. Trend of the DGT standard: Spanish DGT regulations include all relevant analytes, but also adopt stricter limits in some cases, indicating a prioritisation of early detection for administrative and also criminal preventive purposes.

TABLE 2.

Comparison of cut-off points (positive): DED Sotoxa[28] , SynLab laboratory and those established by the DGT.

ANALITO	ABBOT SOTOXA[29] TOX400SEU	SYNLAB Laboratory SYNLAB[30]	DGT DGT[31]
6-AM (morphine) (OPI)[32]	40 ng/ml	>2.6 ng/ml	2 ng/ml
Amphetamine (AMP)	**50 ng/ml**	>18.8 ng/ml	15 ng/ml
Benzoylecgonine (BE)	30 ng/ml	>9.9 ng/ml	8 ng/ml
Cocaine metabolite (COC)	**30 ng/ml**	>10 ng/ml	8 ng/ml
Codeine (OPI)	**40 ng/ml**	>12.2 ng/ml	5 ng/ml
Ketamine		>12.6 ng/ml	10 ng/ml
MDA	50 ng/ml	>18.3 ng/ml	15 ng/ml
MDEA	50 ng/ml	>18.2 ng/ml	15 ng/ml
Methamphetamine (MDMA)	**50 ng/ml**	>18.7 ng/ml	15 ng/ml
Methadone (OPI)	**40 ng/ml**	>12.2 ng/ml	10 ng/ml
Morphine (OPI)	**40 ng/ml**	>6.2 ng/ml	5 ng/ml
Cannabis (THC)	**25 ng/ml**	>2.5 ng/ml	2 ng/ml

[28] See: ANNEX I. Explains the "composition and operating principles of the Abbot-SoToxa analyser".
[29] See: https://www.toxicology.abbott/es/es/screening-devices/sotoxa-mobile-test-system.html
[30] Extracted from the report of the confirmatory assay for drugs in saliva by LC-MS/MS of the SYNLAB laboratory.
[31] DGT (2021); "Systematic review on drug driving" (2021).
[32] OPI: Opioids.

Source: Own elaboration (2023); based on reports from the commercial SYNLAB, drug monitoring and toxicology company SYNLAB.

Key observations from table 2:

5.2.1 SOTOXA (DED). Shows the highest values and reflects more permissive positive cut-off points, not an actual concentration.

5.2.2. SYNLAB. Reports actual values above a detectable minimum and reports quantitative results above a threshold, but not normative.

5.1.3. DGT. Provides the lowest values, and are legal cut-off thresholds of toxicological confirmation, establishing the legal limits of the administrative offence and the corresponding sanction.

6. THE CLINICAL ANALYSIS COMPANY SYNLAB.

"Any test, anywhere, anytime" - that is the motto of the German company Synlab Group (SYNLAB) .[33]

SYNLAB was founded in 1998 by Dr. Bartl Wimmer in Augsburg together with a group of partners as an association of independent laboratory physicians. Since then it has grown mainly through acquisitions, offering tests for the presence of the coronavirus during the pandemic. SYNLAB has not gone unnoticed by large institutional investors worldwide, who over the years have taken equity stakes in the company. Currently, the main shareholder is the well-known British venture capital fund Cinven (also with an office in Madrid), which holds around 43% of the shares, according to the German company's estimates. This is followed by the Danes of Novo Holdings (17%); the Canadians of the Ontario Teachers' Pension Fund (OTPP) with 8%; the same percentage as the founder of SYNLAB and his close associates; and the State of Qatar through its sovereign wealth fund (5%).

In Spain, its relationship with the Ministry of the Interior (according to the Public Sector contracting platform of the Ministry of Finance), has been forged through the DGT, which has tendered the "service of determination and quantification of drugs and alcohol in oral fluid and blood samples" on the basis of a contract[34] awarded for a value of 4,999,980.00 Euros to SYNLAB DIAGNÓSTICOS GLOBALES S.A.U (A59845875). In addition to the DGT, this clinical laboratory has been contracted by other administrations: the Regional Government of Andalusia for clinical analyses for the Jaén Centre for the Prevention of Occupational Risks in Jaén, the Madrid Metro and the Generalitat de Catalunya[35] among others.

[33] See: https://valenciaplaza.com/asi-es-synlab-empresa-alemana-compra-sistemas-genomicos

[34] See:https://contrataciondelestado.es/wps/portal/!ut/p/b0/04_Sj9CPykssy0xPLMnMz0vMAfIjU1JTC3Iy87KtUlJLEnNyUuNzMpMzSxKTgQr0w_Wj9KMyU1zLcvQj_byycwN9yy2dXPLygvNDIoyrVA3Myx1tbfULcnMdAUNYE4U!/ and BOE 97 of 23 April 2019.

[35] See: https://contractaciopublica.cat/ca/detall-publicacio/200026255

7. LIMITS OF QUANTIFICATION AND UNCERTAINTY RANGES IN SYNLAB LABORATORY RESULTS.

There is additional information on the saliva samples submitted by the SYNLAB laboratory for the substances listed above in the table; it is used as a "positivity criterion" that the concentration of the substances is greater than or equal to the values of the limit of quantification (LOQ)[36] , plus the "uncertainty value" of the test, otherwise the result is negative. Furthermore, SYNLAB refers to the fact that their laboratory has "the expanded uncertainty for K=2 for the whole working range".

To clarify the concept of "uncertainty", we must say that it is the "doubt" that may exist about the result of any measurement, i.e. it tells us about the reliability of that measurement.

Therefore, all measurements that are made have some "uncertainty" and must be quantified in order to decide whether the measurement made is sufficiently reliable for the purpose that has been required. Furthermore, it should be noted that, "error" is not the same as "uncertainty", namely:

Error: The difference between the measurement value of a device and the standard or reference value[37] that is taken as accurate. When making a comparison between values, error and uncertainty are generated according to metrology. Thus, together error and uncertainty can be used to know if an instrument is within the maximum tolerated error.

Uncertainty[38] : After making several measurements during a calibration process, small differences between them are discovered. But which measurement is the correct one, the mean and its standard deviation are found, finding out what is the normal difference between the measurements, making the final measurement sufficiently reliable.

Accuracy: Measures the degree of agreement between the result obtained and the true value (or the one taken as such).

Accuracy: Shows the agreement between two or more measurements that have been taken in the same way**.**

Expanded uncertainty[39] : Before publishing the combined uncertainty component, it is necessary to multiply the result by the selected sigma value to obtain the required confidence level. After multiplication, the result is the expanded uncertainty, i.e. the uncertainty with a given confidence level included.

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[36] The term refers to the lowest concentration that can be reliably achieved, provided it is within the precision limits specified in routine laboratory operation.

[37] Standard, with the highest accuracy available at a given location or in a given organisation, and from which measurements are derived.

[38] NSGT (2012) Uncertainty of a measurement result, expressed as an experimental standard deviation. Ver: https://www.insst.es/documents/94886/326879/930w.pdf/f657c677-ebab-4f99-8474-667d73e22882

[39]INSGT (2012): A quantity that defines a range around the outcome of a measurement, and in which a significant fraction of the distribution of values that could reasonably be attributed to the measurand is expected to be found.

Evaluation of the uncertainty K=2: The calibration is performed by an authorised laboratory (external calibration) and the expanded uncertainty data are given in %, where K=2 corresponds approximately to a confidence level of 95 %.

Therefore, we can state that the salivary drug analytical results of the SYNLAB laboratory have a level of confidence or expected accuracy that is around the 95 % range/boundary.

8. THE SYNLAB LABORATORY AND ITS ACCREDITATION BY THE NATIONAL ACCREDITATION BODY THROUGH AUDITS.

The National Accreditation Body (ENAC G-78373214 - C/Serrano 240, 4ª A-B, 28016 Madrid) is the only body designated by the Government to operate in Spain as the National Accreditation Body[40] , regulating the functioning of accreditation in Europe, which is based on five fundamental principles: "Non-profit, independence, non-competition, international evaluation and mutual recognition[41] ". Furthermore, ENAC may sign collaboration agreements with the General State Administration and with the Administrations of the Autonomous Communities as may be appropriate for the better performance of its activities and functions[42] .

ENAC "accreditation" should be a guarantee of the correct execution of a certain type of activities, through a certificate issued by this entity.

By way of example, ENAC has carried out the following activities:

In 2013, it has accredited the Instituto de Salud Carlos III[43] de Investigación en enfermedades raras according to the UNE-En ISO 15189 standard for the performance of analyses.

Year 2016, "external audit of accreditation of testing and technical ocular inspection activities" of the Guardia Civil crime laboratories .[44]

Year 2018, has performed "audit services" at the University of A Coruña .[45]

Year 2022, has accredited[46] to the Scientific Police of the National Police Force for the "performance of technical-police inspections at crime scenes", in accordance with the ISO 17020 standard.

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[40] RD 1715/2010 BOE 7 de núm. 7 of 8 January 2011, "(...) in accordance with the provisions of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No.: 339/93.

[41] See: *https://www.innotec-laboratorios.es/que-es-la-acreditacion-enac/*

[42] BOE no. 7, 8 January 2011.

[43]See:https://www.isciii.es/QueHacemos/Servicios/DiagnosticoGenetico/Documents/ACREDITACION_SDG_IIER_sin_anexo_tecnico.pdf

[44]See:https://www.isciii.es/QueHacemos/Servicios/DiagnosticoGenetico/Documents/ACREDITACION_SDG_IIER_sin_anexo_tecnico.pdf

[45]See: https://www.udc.es/export/sites/udc/contratacionadministrativa/contratos-menores/publicar-Disp-adic-54.xls_2063069239.xls

[46] See: https://www.enac.es/actualidad/policia-cientifica-inspeccion-ocular

Year 2023, has carried out "accreditation activities aimed at the evaluation of laboratories" of the Complutense University of Madrid .[47]

On the other hand, in relation to the activities of a private laboratory (such as SYNLAB), they can be: testing, calibration, inspection, certification or verification entities among others, however, any activity that aims to assess whether a product, service, system, installation, etc. must conform to certain requirements and may be subject to accreditation.

These requirements may be established by law and therefore have regulatory status or be legislated in standards, specifications or other voluntary documents. ENAC accreditation not only gives any laboratory or company being assessed a way of knowing whether its activity is being carried out correctly, but also guarantees the maximum efficiency of its services to the clients of those laboratories.

To assess the correct operation of the laboratory, annual follow-up audits are scheduled and every four years a reassessment audit is scheduled. Follow-up audits review whether there have been changes in procedures, new equipment purchased, etc.

In short, what ENAC can assess and certify is the correct compliance with the standard[48] UNE-EN ISO/IEC 17025 in that year. For information, in the reassessment audits, all the points of the standard during the previous four years are reviewed more exhaustively. If the laboratory fails to meet the requirements in any of these audits, the accreditation may be suspended.

For information, reassessment audits review more comprehensively all points of the standard during the previous four years. If the laboratory fails to meet the requirements in any of these audits, the accreditation may be suspended.

[47] See:[47] https://www.ucm.es/file/208-2023-enac-1-

[48] BOE 19 of 22 January 2018 - Ministry of Economy, Industry and Competitiveness publishing the "General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017)".

9. TABLE 3. SCOPE OF ACCREDITATION[49] ENAC Nº 1169/LE2347, ISSUED TO LABORATORIOS SYNLAB DIAGNÓSTICOS GLOBALES SA. ON TESTING (REVISED 23/12/2022).

NATIONAL ACCREDITATION BODY (ENAC)

PRODUCT/ MATERIAL TO BE TESTED *PRODUCTS/MATERIALS TESTED*	**ESSAY** *TYPE OF TEST*	**STANDARD / TEST PROCEDURE** *STANDARD SPECIFICATIONS/ TEST PROCEDURE*
Saliva (direct or saliva in buffer) Whole blood *Saliva (direct or saliva in buffer) Blood*	Quantitative determination of substances of abuse by ultra-fast high performance liquid chromatography with tandem mass spectrometry detection.	Internal procedure LCMS-004 Rev.15 LCMS-0010 Rev.9

SUBSTANCE	LOQ[50] ng/ml Saliva	LOQ ng/ml Blood
Morphine	**1**	**1**
Codeine	1	2
Heroin	**2**	**2**
Amphetamine	**1**	**2**
Methamphetamine	**1**	**2**
MDA	2	2
MDMA	2	2
MDEA	2	2
Cocaine	**1**	**2**
Methadone	**2**	**2**
Ketamine	2	2
LSD	2	2
Clonazepam	2	2
Alprazolam	2	2
Diazepam	1	2
Lorazepam	2	2
Oxazepam	2	2
Nordiazepam	1	2
Tramadol	1	2
Phencyclidine	2	2
Dextropropoxyphene	1	2
Zolpidem	1	2

ENAC CALIBRACIÓN ISO 17025 Nº62 / LC10.039

Source: SYNLAB (Own elaboration)

[49]See:https://synlab.es/fileadmin/user_upload/Calidad_docs/Anexo_Tecnico_ISO_17025_version_7.pdf
[50] LOQ: Limit of Quantification or lowest level.

KEY OBSERVATIONS FROM TABLE 3:

9.1. INCREASED SENSITIVITY IN SALIVA.

For fifteen of the twenty-two substances in the table, the LOQ in saliva is lower than in blood, highlighting the effectiveness of this matrix for early detection of the substance.

9.2. EQUAL SENSITIVITY IN MATRICES FOR CERTAIN COMPOUNDS.

Seven substances (e.g. LSD, ketamine, benzodiazepines) have the same LOQ in both matrices (2 ng/ml), indicating that the matrix does not significantly affect the analytical sensitivity for these compounds.

9.3. POSSIBLE CLINICAL AND FORENSIC IMPLICATIONS.

Saliva has established itself as a non-invasive and highly sensitive alternative for toxicological analysis, such that the lower LOQ in saliva favours its use in settings such as: drug checkpoints, detoxification programmes or occupational monitoring, where access to a blood test may be limited and not very operational.

9.4. SALIVARY ANALYSIS VS. BLOOD ANALYSIS.

Saliva has positioned itself as a high-value matrix in analytical toxicology, not only because of its lower invasiveness, but also because of its ability to offer higher levels of sensitivity for rapid detection of recent consumption.

Early detection is particularly relevant in prevention and real-time control situations, both at drug checkpoints and in road accidents involving a driver under the possible influence of these substances.

The use of saliva, in combination with laboratory analysis, represents an efficient analytical tool with a higher sensitivity than blood. This is in terms of limit of quantification for a broad spectrum of substances of abuse.

The recommendation to incorporate salivary analysis as a reference matrix in early detection protocols and modern toxicological diagnosis has proved to be correct.

10. CONCLUSIONS.

First. The UN urges governments and institutions (public and private), through the enforcement of SV laws, to achieve a reduction in drug-related road fatalities.

Secondly. In Spain, the DGT (Ministry of the Interior) has established a policy of "zero tolerance" at the wheel, classifying driving with the presence of drugs in the body as risky behaviour. This behaviour is always punished, either as an administrative offence or as a criminal offence.

Thirdly. Despite the lack of international agreements on "cut-off points", the DGT has established the "cutoff" of the minimum psychoactive quantities. These quantities are in line with those of public and private organisations in both the EU and the USA. With

this, the DGT has determined the quantitative positivity of any drug recently consumed by a driver, which will then be analysed in the reference laboratory.

Fourth. The doctrine of the FGE supports the procedure for collecting salivary samples after the positive circumstantial test, through: the specific training of the agents in the collection of the sample, the guarantee of the chain of custody and a subsequent salivary analysis in a reference laboratory.

Fifth. The TC upholds Art. 14 of the LSV, clarifying that the Law does not prohibit the consumption of drugs; what it prohibits is driving with the presence of drugs in the body.

Sixth. The TC equates and places on the same level the risk that a driver who has consumed drugs, even those taken under medical prescription, can generate for the SV.

Seventh. The "cut-off points" of the portable DED (SoToxa Abbott) used to carry out the first "index test", double or triple the "cut-off points" of reference carried out by the SYNLAB laboratory.

Eighth. The "cut-off points" of the SYNLAB clinical laboratory are higher than those determined by the ISO standard, which the DGT applies to establish minimum psychoactive quantities in laboratory analysis equipment.

Ninth. The approval of the clinical salivary analysis of the SYNLAB laboratory is endorsed by the National Accreditation Entity (ENAC), which certifies compliance with the UNE standard of the equipment and the procedure used by the SYNLAB laboratory in obtaining salivary diagnoses, both in the type of drug detected and in its quantity.

Tenth. The evaluation of the equipment and the procedure for obtaining the analysis of saliva samples from the SYNLAB laboratory by ENAC, accredits the 95% level of confidence or precision of the final results obtained and reflected in its final report.

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ANNEX I

COMPOSITION AND PRINCIPLES OF THE ABBOT-SOTOXA ANALYSER

1.1. COMPOSITION .[51]

The Abbot SoToxa analyser consists of a portable analyser system (DED), a test cartridge or kit and an oral fluid collection device.

1.1.1. The analyser:

It is a portable digital saliva testing device, which uses algorithms to determine the intensity of contrast lines (which will appear on the test cartridge strip after the whole process) and can also display on a screen and print the qualitative and nominative results of the detected drugs.

1.1.2. The test cartridge:

Composed of an immunoassay strip [5253] a single-use, disposable, fast paper chromatographic strip containing dry reagents and a buffer solution. This kit is inserted into the analyser which heats it to the optimal temperature for the test.

1.1.3. The collection device:

It is a disposable device that collects oral fluid (saliva). It should be rubbed on the gums, tongue and inside of the cheeks until the presence indicator turns blue.

1.2. TESTING PROCESS:

The oral fluid collected in the collection device is combined with the buffer solution, then mixed and incubated before contacting the immunoassay strips installed in the test cartridge with a *'moisture-controlled membrane'*.

The mixture of the solution and the saliva obtained flows down the capillary of the cartridge strip and carries away the labelled anti-drug antibodies deposited on it. In the absence of drug in the sample, the antibody binds to the drug-protein mixture forming a line. In the presence of drug, the formation of this line is weaker.

The DED then reads the intensity of the lines on the immunoassay strip from the cartridge and compares this intensity to a predetermined threshold or cut-off point of drug

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[51] Abbott (2020); "SoToxa Portable Oral Fluid Analyser" (User Manual).
[52] A rapid chromatographic immunoassay is used for the quantitative detection of multiple drugs and drug metabolites in saliva, providing only a preliminary analytical test result.
[53] Chromatography is a technique performed in laboratories to separate components in simple or complex mixtures. There are many different types of chromatography, ranging from paper chromatography and thin layer chromatography to gas chromatography.
See:https://www.onelab.com.ar/cromatografia-que-es-y-para-que-sirve-informacion-completa

concentration, giving a qualitative (not quantitative) result. The results are then displayed on the DED screen and can be printed out.

1.3. POSITIVE RESULTS.

The Abbot SoToxa DED manual specifies that positive results obtained must be confirmed by a second method such as gas chromatography mass spectrometry (GC-MS). In addition, the DED and its results are not intended for home use, clinical, therapeutic or diagnostic settings.

1.4. COMPOSITION OF THE IMMUNOASSAY STRIP OF THE CARTRIDGE.

The chromaticity immunoassay content consists of a strip that is impregnated with a series of dried reagents containing monoclonal antibodies[54] (mAbs). These antibodies (AC) are laboratory-created proteins and are used to identify drug of abuse metabolites in biological fluids.

mAbs have a high sensitivity and bind, for example, to morphine and its metabolites, so they can be used to generate a marked result by "screening" the test strip or cartridge membrane, selectively detecting elevated levels of specific drugs in saliva.

[54] Monoclonal antibodies have a multitude of applications today, both in biomedical research and in the diagnosis and treatment of numerous pathologies. This quality of monoclonal antibodies is due to their high specificity and high affinity for the therapeutic target.