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Our Ref 11722

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Dear

FREEDOM OF INFORMATION – DRUG SCREENING

I write in response to your request for information in relation to drug screening.

Question:

- FOI request, in relation to toxicology screening tests used by NHS Lothian. I would like data statistics of the reliability rate, and false positive/ false negative rates on all type of drug screenings used by GP surgeries and drug misuse clinics across NHS Lothian.

In particular MELD (Mid and East Lothian drugs) located in Musselburgh, Ladywell way, EH21 6AB.

I wish to be provided statistics on the accuracy of all types of toxicology screenings used by the facility. In particular I would like to know the specific brand of test used, type of tests, and data accuracy of both urine screenings and mouth-swab screenings used by this facility. I would like to know which lab is used by this facility to screen these test results and the devices/ process used by the lab/ clinic during these screenings.

Furthermore, I ask to be provided any statistics on false positive/ false negative rates of both types of these tests, the overall reliability of these tests and the number of tests that are routinely sent for secondary lab confirmation. I would also like to see the official NHS clinical guidelines and protocols that should be observed when administering these screenings, alongside official protocols and guidelines of how these test results are interpreted by staff.

Answer:

Urine and Oral fluid toxicology screens are undertaken by NHS Lothian's Department of Laboratory Medicine (Blood Sciences, Clinical Biochemistry) to provide a service for local Addictions Services and Harm Reduction Teams including Mid Lothian and East Lothian Drug and Alcohol Partnership (MELD).

Toxicology screening within the Clinical Biochemistry laboratory is undertaken by LC-MS/MS (Liquid Chromatography, Tandem Mass Spectrometry) methodology using Waters Acquity HPLC systems coupled with Xevo TQD mass spectrometers. The methods are accredited by UKAS (UK Accreditation Service) to ISO 15189 standard which is an international standard that specifies quality management and competence requirements for medical laboratories to

ensure accurate and reliable diagnostic results. Toxicology screens undertaken by LC-MS/MS methodology are classed as a 'confirmation method' since these are highly sensitive and specific for the drugs and metabolites included in the panels. These methods are not prone to the same type of assay interference in traditional immunoassay based methods such as urine dipstick tests. Due to the nature of the methodology and the standard which we operate to, toxicology screens undertaken within Clinical Biochemistry are not retested by a secondary method, similar to other laboratories undertaking this type of analysis.

The Clinical Biochemistry department has a robust quality management system in place to ensure accuracy and reliability of all tests undertaken including drug screens. This includes internal and external quality control procedures. Due to the nature of the method used and the standard to which the laboratory operates, errors with toxicology screens undertaken within the department are very rare. The laboratory does not have statistics on false positive or false negatives rates.

The tests we use within the East Lothian Substance Use Service are:

Salivette Cortisol blue oral saliva swabs – there is limited detail within the leaflet

Surescreen Diagnostics Multi-Drug Rapid Test Panel (Urine) - there is a detailed leaflet in the box with these tests, it gives details of the result based on cut off concentrations for each drug the panel tests for and its accuracy for each drug result. The section on accuracy states 'A side by side comparison was conducted using the Multi-Drug Rapid Test Panel and commercially available drug rapid tests. Testing was performed on approximately 250 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS (Gas chromatography/mass spectrometry - which it states in this leaflet as the preferred confirmatory method). The accuracy is then displayed in a table for each drug type as % agreement with GC/MS.

AMP- 97.0-99.4% accurate

BZO- 96.4-98.8%

BUP- 99.0-99.3%

COC- 99.9-93.2%

MTD- 97.7-99.2%

OPI- 91.3-94.3%

Matrix Diagnostics Matrix Cup MD1 170 - there is a detailed leaflet also inside the box for these, and it uses the same format as the surescreen. The results are based on cut off concentrations for each drug it tests for and the accuracy is also established by running urine sample against GC/MS. This brand also gives a % for positive, negative and then total results.

AMP: positive 95.8%, negative 100%, total 98.1%

BZO: positive 95.3%, negative 92.9%, total 93.9%

BUP: 100% 100% 100%
COC: positive 98.2%, negative 98.2%, total 98.2%
EDDP: positive 95.8%, negative 100%, total 98.1%
OPI: positive 96.8%, negative 97.9%, total 97.3%
6MAM: positive 96.8%, negative 100%, total 98.2%

I hope the information provided helps with your request.

If you are unhappy with our response to your request, you do have the right to request us to review it. Your request should be made within 40 working days of receipt of this letter, and we will reply within 20 working days of receipt. If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal complaint to the Scottish Information Commissioner within 6 months of receipt of our review response. You can do this by using the Scottish Information Commissioner's Office online appeals service at www.itspublicknowledge.info/Appeal. If you remain dissatisfied with the Commissioner's response you then have the option to appeal to the Court of Session on a point of law.

If you require a review of our decision to be carried out, please write to the FOI Reviewer at the email address at the head of this letter. The review will be undertaken by a Reviewer who was not involved in the original decision-making process.

FOI responses (subject to redaction of personal information) may appear on NHS Lothian's Freedom of Information website at: <https://org.nhsllothian.scot/FOI/Pages/default.aspx>

Yours sincerely

ALISON MACDONALD
Executive Director, Nursing
Cc: Chief Executive