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Review Article

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Information Technology Structure for Urine Drug Testing Reports

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Abstract

Urine drug testing for compliance in the management of patients on chronic opioid therapy otherwise termed pain management requires the laboratory to provide concise interpreted information. The report must integrate patient medications, drug metabolism, and positive quantitative drug findings. The history of the patient's previous tests, conversion to a hydrated standard, specimen validity data and drug-drug interactions. This requires many levels of information integration including drug information tables, conversion of analytical test data into specific quantitative drug observations, formatting all the information into a concise report, integration into drug-drug interaction reports and storage into cloud servers, and visual retrievable software for review of patient trends. We describe here how the data is collected, processed, and integrated into a urine drug test report and stored to be retrieved for additional analyses and most importantly for billing.

Keywords: *Urine drug testing; Drug-drug interaction; Analytical Data Examining and Formatting Software (ASCENT)*

Background

Urine drug testing is used to monitor patient compliance with their drug regimen and to detect the use of other medications and illicit drugs. Clinical urine drug testing should therefore be embarked upon only with a sound basic knowledge of the capabilities and limitations of each specific test. Unexpected results should be subjected to appropriate confirmatory testing. Consultative support from a laboratory director, toxicologist, or certified medical review officer is essential [1-3]. The testing laboratory is challenged with the task of testing for the requested drugs and formulating a report that is comprehensive, complete, heuristic, and concise. The resulting accumulated drug test information can also be used to monitor trends in drug usage [4-8]. Proper interpretation of a drug test requires the provider to be knowledgeable in drug metabolism. If possible, the report should highlight the patient's metabolism of the drugs.

Our drug test monitors 80 drugs or metabolites using LC-MS/MS [9]. Each specimen generates around 5 MB (megabytes) of analytical data which must be analytically correct by comparison to chemical standards, quantified, and reformatted for the final report. If possible previous positive test results should be part of the report to help the provider verify and monitor the patient. To accomplish this extensive use is made of several software systems including preformatted lookup tables, a laboratory information system, (STARLIMS) [10] analytical data examining and formatting software (ASCENT) [11], patient result formatting software (STARLIMS), data storage in the cloud in a retrievable format (MICROSOFT AZURE) [12], and software that allows retrievable visual data and exportable to be suitable for correlation with other databases (MICROSOFT PowerBI) [13].

The drug tests are ordered for several purposes. One is to ensure compliance with the drug regimen and the second is to detect the use of other drugs or agents. The list of drugs/agents is often set by the patient's provider.

Providers are often not proficient in their interpretation of urine drug tests [1-3]. Therefore, the final drug test report must enable the provider to accurately assess the results. The report must include the comparison of the patients' medications with those observed, the relationship of the metabolites observed to the prescribed medications, the history of the patient's compliance and if requested possible drug-drug interactions (Figure 1).

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Patient		Specimen		Provider	
Last Name: COMPREHENSIVE	First Name: SAMPLE	Specimen ID: ABC1234	Collection Date: 10/08/2019	Clinic Name: ABC CLINIC ONE	
Gender: Female	Date of Birth: 01/15/1985	Accession #: 98765432	Received Date: 10/09/2019	Clinic Address: 123 USA BLVD SAN DIEGO, CA 92109	
Patient ID#: PDX12345		Specimen Type: Urine	Report Date: 10/10/2019	Physician Name: JANE DOE	

Medication Prescribed: Cyclobenzaprine, Dilaudid

PATIENT TEST RESULTS SUMMARY[1]

Test Outcome: POSITIVE
ORIGINAL REPORT

CONSISTENT RESULTS - REPORTED MEDICATION DETECTED

Reported Prescription	Anticipated Positives	Amount Detected	Typical Detection Window	Comments
FLEXERIL	CYCLOBENZAPRINE	22 ng/ml	1 to 4 days after last dose	Expected Positive: Test result is consistent and expected with the prescribed medication.

INCONSISTENT RESULTS - REPORTED MEDICATION NOT DETECTED

Reported Prescription	Anticipated Positives	Amount Detected	Typical Detection Window	Comments
DILAUDID	HYDROMORPHONE	Negative	1 to 4 days after last dose	Unexpected Negative: Test result indicates the patient may not be taking prescribed medication.

INCONSISTENT RESULTS - DETECTED DRUG/MEDICATION NOT REPORTED

Analyte Detected	Potential Brand Name Drugs	Amount Detected	Typical Detection Window	Comments
OXYMORPHONE	Numorphan, Opana	100 ng/ml	1 to 4 days after last dose	Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.
TEMAZEPAM	Restoril, Valium	111 ng/ml	1 to 5 days after last dose	Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.
SERTRALINE	Zoloft	55 ng/ml	1 to 5 days after last dose	Unexpected Positive: Test result indicates the patient is taking a non-prescribed medication.

SPECIMEN VALIDITY RESULTS

Test	Reference Range	Result	Outcome
Creatinine	>20	79.11	In Range
Oxidant	<1000	0	In Range
pH	4.7 - 9.0	6.3	In Range
Specific Gravity	1.003 - 1.036	1.004	In Range

POINT OF CARE RESULTS

Test	Positive	Negative	Not Tested
AMP		•	
BAR		•	
BUP		•	
BZO		•	
COC		•	
mAMP		•	
MDMA		•	
MTD		•	
OPI		•	
OXY		•	
PCP		•	
TCA		•	
THC		•	

Transcription of POC results only; testing performed at provider location shown.

TEST RESULTS

DRUG CLASS / DRUGS	TEST METHOD	CUTOFF LEVEL	MEASURED RESULTS	CREATININE NORMALIZED RESULTS	TEST OUTCOME	Rx VERIFICATION
Natural Opiates						
MORPHINE	LCMS	50 ng/ml			Negative	Expected
HYDROCODONE	LCMS	5 ng/ml			Negative	Expected
NORHYDROCODONE	LCMS	10 ng/ml			Negative	Expected
HYDROMORPHONE	**LCMS**	**5 ng/ml**			**Negative**	**Unexpected**
CODEINE	LCMS	50 ng/ml			Negative	Expected
Semi-Synthetic Opiates						
OXYCODONE	LCMS	10 ng/ml			Negative	Expected
NOROXYCODONE	LCMS	25 ng/ml			Negative	Expected
OXYMORPHONE	**LCMS**	**10 ng/ml**	**100 ng/ml**	**126 ng/ml**	**POSITIVE**	**Unexpected**
BUPRENORPHINE	LCMS	5 ng/ml			Negative	Expected
NORBUPRENORPHINE	LCMS	5 ng/ml			Negative	Expected
Synthetic Opiates						
FENTANYL	LCMS	1 ng/ml			Negative	Expected
NORFENTANYL	LCMS	2 ng/ml			Negative	Expected
METHADONE	LCMS	50 ng/ml			Negative	Expected
EDDP	LCMS	100 ng/ml			Negative	Expected
MEPERIDINE	LCMS	2 ng/ml			Negative	Expected
PROPOXYPHENE	LCMS	10 ng/ml			Negative	Expected
TRAMADOL	LCMS	25 ng/ml			Negative	Expected
O-DESMETHYLTRAMADOL	LCMS	100 ng/ml			Negative	Expected
TAPENTADOL	LCMS	2 ng/ml			Negative	Expected
N-DESMETHYLTAPENTADOL	LCMS	25 ng/ml			Negative	Expected
Benzodiazepines						
7-AMINOCLONAZEPAM	LCMS	5 ng/ml			Negative	Expected
ALPHA-HYDROXYALPRAZOLAM	LCMS	5 ng/ml			Negative	Expected
ALPRAZOLAM	LCMS	5 ng/ml			Negative	Expected
CLONAZEPAM	LCMS	5 ng/ml			Negative	Expected
LORAZEPAM	LCMS	10 ng/ml			Negative	Expected
NORDIAZEPAM	LCMS	5 ng/ml			Negative	Expected
DIAZEPAM	LCMS	5 ng/ml			Negative	Expected
OXAZEPAM	LCMS	10 ng/ml			Negative	Expected
TEMAZEPAM	**LCMS**	**10 ng/ml**	**111 ng/ml**	**140 ng/ml**	**POSITIVE**	**Unexpected**
Barbiturates						
BUTALBITAL	LCMS	500 ng/ml			Negative	Expected
PHENOBARBITAL	LCMS	500 ng/ml			Negative	Expected
Muscle Relaxants						
CARISOPRODOL	LCMS	10 ng/ml			Negative	Expected
MEPROBAMATE	LCMS	100 ng/ml			Negative	Expected
CYCLOBENZAPRINE	**LCMS**	**5 ng/ml**	**22 ng/ml**	**27 ng/ml**	**POSITIVE**	**Expected**
Neuropathic Pain						
GABAPENTIN	LCMS	1000 ng/ml			Negative	Expected
PREGABALIN	LCMS	500 ng/ml			Negative	Expected
Antidepressants						
AMITRIPTYLINE	LCMS	10 ng/ml			Negative	Expected
DESIPRAMINE	LCMS	5 ng/ml			Negative	Expected
IMIPRAMINE	LCMS	5 ng/ml			Negative	Expected
NORTRIPTYLINE	LCMS	10 ng/ml			Negative	Expected
BUPROPION METABOLITE	LCMS	10 ng/ml			Negative	Expected
TRAZODONE METABOLITE	LCMS	20 ng/ml			Negative	Expected
VENLAFAXINE	LCMS	2 ng/ml			Negative	Expected
Stimulants						
AMPHETAMINE	LCMS	25 ng/ml			Negative	Expected
METHYLPHENIDATE	LCMS	50 ng/ml			Negative	Expected
PHENTERMINE	LCMS	25 ng/ml			Negative	Expected

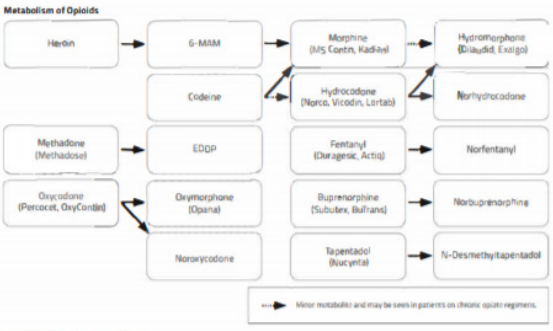
TEST RESULTS

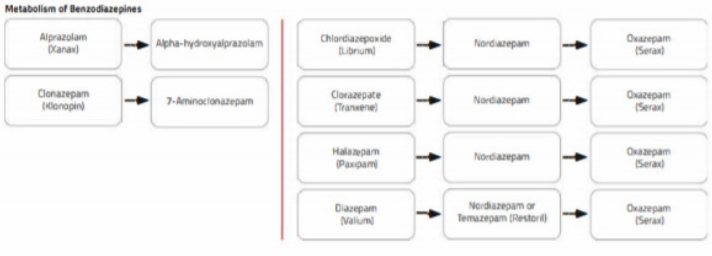
DRUG CLASS / DRUGS	TEST METHOD	CUTOFF LEVEL	MEASURED RESULTS	CREATININE NORMALIZED RESULTS	TEST OUTCOME	Rx VERIFICATION
Sedatives						
ZOLPIDEM	LCMS	1 ng/ml			Negative	Expected
SNRI/SSRI						
CITALOPRAM METABOLITE	LCMS	10 ng/ml			Negative	Expected
DULOXETINE	LCMS	10 ng/ml			Negative	Expected
FLUOXETINE	LCMS	10 ng/ml			Negative	Expected
NORFLUOXETINE	LCMS	10 ng/ml			Negative	Expected
PAROXETINE	LCMS	5 ng/ml			Negative	Expected
SERTRALINE	**LCMS**	**10 ng/ml**	**55 ng/ml**	**69 ng/ml**	**POSITIVE**	**Unexpected**
Illicit Drugs						
HEROIN METABOLITE	LCMS	5 ng/ml			Negative	Expected
COCAINE METABOLITE	LCMS	20 ng/ml			Negative	Expected
MDMA	LCMS	10 ng/ml			Negative	Expected
METHAMPHETAMINE	LCMS	50 ng/ml			Negative	Expected
PHENCYCLIDINE	LCMS	5 ng/ml			Negative	Expected
THCA	LCMS	25 ng/ml			Negative	Expected
MITRAGYNINE	LCMS	5 ng/ml			Negative	Expected
MDA	LCMS	10 ng/ml			Negative	Expected
MDEA	LCMS	5 ng/ml			Negative	Expected
Cathinones (Bath Salts)						
METHYLONE	LCMS	10 ng/ml			Negative	Expected
MDPV	LCMS	5 ng/ml			Negative	Expected
Alcohol						
ETHYL GLUCURONIDE	LCMS	500 ng/ml			Negative	Expected
ETHYL SULFATE	LCMS	200 ng/ml			Negative	Expected
Anesthetic						
DEXTROMETHORPHAN	LCMS	5 ng/ml			Negative	Expected
DEXTRORPHAN	LCMS	5 ng/ml			Negative	Expected
Dissociative Anesthetic						
KETAMINE	LCMS	2 ng/ml			Negative	Expected
NORKETAMINE	LCMS	2 ng/ml			Negative	Expected
Opioid Inverse Agonist						
NALOXONE	LCMS	10 ng/ml			Negative	Expected
6-BETA-NALTREXOL	LCMS	10 ng/ml			Negative	Expected
Nicotinic Agonist						
COTININE	LCMS	5 ng/ml			Negative	Expected
Antipsychotic						
9-HYDROXYRISPERIDONE	LCMS	5 ng/ml			Negative	Expected
QUETIAPINE	LCMS	5 ng/ml			Negative	Expected
NORQUETIAPINE	LCMS	25 ng/ml			Negative	Expected
ARIPIPRAZOLE METABOLITE	LCMS	20 ng/ml			Negative	Expected
HALOPERIDOL	LCMS	5 ng/ml			Negative	Expected
Illicit Fentanyl Analogs						
ACETYLFENTANYL	LCMS	2 ng/ml			Negative	Expected
ACETYLNORFENTANYL	LCMS	5 ng/ml			Negative	Expected
ACRYLFENTANYL	LCMS	2 ng/ml			Negative	Expected
BUTYRYFENTANYL	LCMS	10 ng/ml			Negative	Expected
BUTYRYNORFENTANYL	LCMS	10 ng/ml			Negative	Expected
CARFENTANIL	LCMS	5 ng/ml			Negative	Expected
CIS-3-METHYLFENTANYL	LCMS	10 ng/ml			Negative	Expected
CIS-3-METHYLNORFENTANYL	LCMS	10 ng/ml			Negative	Expected
FURANYLFENTANYL	LCMS	2 ng/ml			Negative	Expected
N-DESMETHYL-U-47700	LCMS	5 ng/ml			Negative	Expected
NORCARFENTANIL	LCMS	5 ng/ml			Negative	Expected

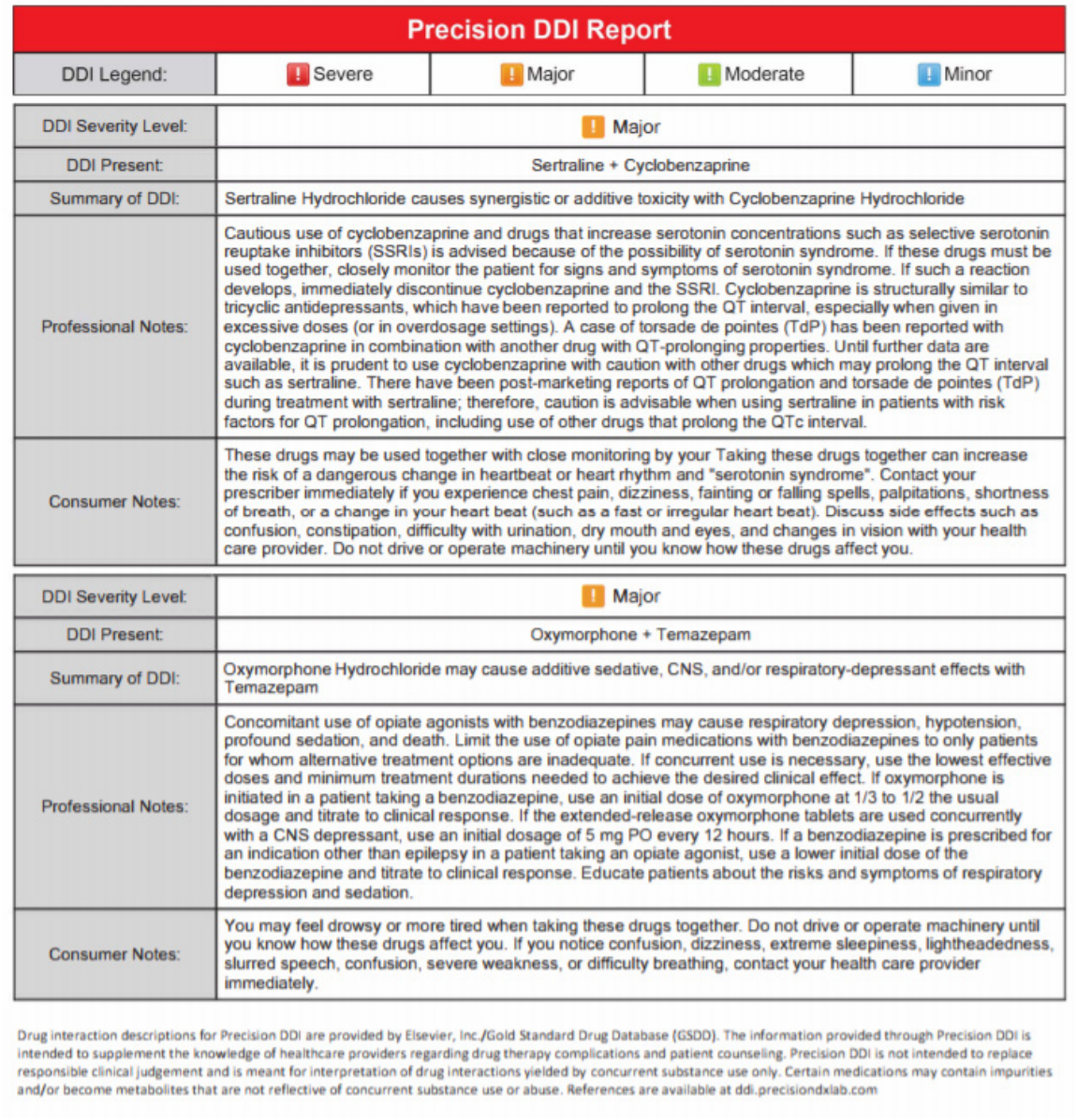
CUMULATIVE RESULTS

SPECIMEN ID			DDI3217E[3]	DDI3217D[3]	DDI3217C[3]	DDI3217B[3]	DDI3217A[3]
COLLECTION DATE			05/06/19	04/30/19	04/23/19	04/16/19	04/14/19
TYPE			Urine	Urine	Urine	Urine	Urine
DRUG	**METHOD**	**UNITS**					
HYDROMORPHONE	LCMS	ng/ml	Negative	Negative	**24**	Negative	Negative
OXYMORPHONE	LCMS	ng/ml	**126**	Negative	**457**	Negative	**2883**
FENTANYL	LCMS	ng/ml	Negative	Negative	Negative	**10**	Negative
NORFENTANYL	LCMS	ng/ml	Negative	Negative	Negative	**103**	Negative
TEMAZEPAM	LCMS	ng/ml	**140**	**518**	**179**	Negative	Negative
CYCLOBENZAPRINE	LCMS	ng/ml	**27**	Negative	**301**	Negative	**901**
SERTRALINE	LCMS	ng/ml	**69**	**407**	**68**	Negative	Negative
ETHYL GLUCURONIDE	LCMS	ng/ml	Negative	Negative	Negative	**813**	**26866**
ETHYL SULFATE	LCMS	ng/ml	Negative	Negative	Negative	**283**	**15735**

N/A indicates drug not tested.
[3] indicates creatinine normalized results







Precision DDI Report

DDI Legend:	Severe	Major	Moderate	Minor

DDI Severity Level:	Major
DDI Present:	Sertraline + Cyclobenzaprine
Summary of DDI:	Sertraline Hydrochloride causes synergistic or additive toxicity with Cyclobenzaprine Hydrochloride
Professional Notes:	Cautious use of cyclobenzaprine and drugs that increase serotonin concentrations such as selective serotonin reuptake inhibitors (SSRIs) is advised because of the possibility of serotonin syndrome. If these drugs must be used together, closely monitor the patient for signs and symptoms of serotonin syndrome. If such a reaction develops, immediately discontinue cyclobenzaprine and the SSRI. Cyclobenzaprine is structurally similar to tricyclic antidepressants, which have been reported to prolong the QT interval, especially when given in excessive doses (or in overdosage settings). A case of torsade de pointes (TdP) has been reported with cyclobenzaprine in combination with another drug with QT-prolonging properties. Until further data are available, it is prudent to use cyclobenzaprine with caution with other drugs which may prolong the QT interval such as sertraline. There have been post-marketing reports of QT prolongation and torsade de pointes (TdP) during treatment with sertraline; therefore, caution is advisable when using sertraline in patients with risk factors for QT prolongation, including use of other drugs that prolong the QTc interval.
Consumer Notes:	These drugs may be used together with close monitoring by your Taking these drugs together can increase the risk of a dangerous change in heartbeat or heart rhythm and "serotonin syndrome". Contact your prescriber immediately if you experience chest pain, dizziness, fainting or falling spells, palpitations, shortness of breath, or a change in your heart beat (such as a fast or irregular heart beat). Discuss side effects such as confusion, constipation, difficulty with urination, dry mouth and eyes, and changes in vision with your health care provider. Do not drive or operate machinery until you know how these drugs affect you.

DDI Severity Level:	Major
DDI Present:	Oxymorphone + Temazepam
Summary of DDI:	Oxymorphone Hydrochloride may cause additive sedative, CNS, and/or respiratory-depressant effects with Temazepam
Professional Notes:	Concomitant use of opiate agonists with benzodiazepines may cause respiratory depression, hypotension, profound sedation, and death. Limit the use of opiate pain medications with benzodiazepines to only patients for whom alternative treatment options are inadequate. If concurrent use is necessary, use the lowest effective doses and minimum treatment durations needed to achieve the desired clinical effect. If oxymorphone is initiated in a patient taking a benzodiazepine, use an initial dose of oxymorphone at 1/3 to 1/2 the usual dosage and titrate to clinical response. If the extended-release oxymorphone tablets are used concurrently with a CNS depressant, use an initial dosage of 5 mg PO every 12 hours. If a benzodiazepine is prescribed for an indication other than epilepsy in a patient taking an opiate agonist, use a lower initial dose of the benzodiazepine and titrate to clinical response. Educate patients about the risks and symptoms of respiratory depression and sedation.
Consumer Notes:	You may feel drowsy or more tired when taking these drugs together. Do not drive or operate machinery until you know how these drugs affect you. If you notice confusion, dizziness, extreme sleepiness, lightheadedness, slurred speech, confusion, severe weakness, or difficulty breathing, contact your health care provider immediately.

Drug interaction descriptions for Precision DDI are provided by Elsevier, Inc./Gold Standard Drug Database (GSDD). The information provided through Precision DDI is intended to supplement the knowledge of healthcare providers regarding drug therapy complications and patient counseling. Precision DDI is not intended to replace responsible clinical judgement and is meant for interpretation of drug interactions yielded by concurrent substance use only. Certain medications may contain impurities and/or become metabolites that are not reflective of concurrent substance use or abuse. References are available at ddi.precisiondxlab.com

Figure 1: Summary of information provided on each page of the urine drug test report (Pages 1-5).

Page 1: The first page is a summary of the patient's test results compared to his/her prescription regimen. On the top line the medications prescribed are identified; the analytical findings are summarized as to whether they were expected or unexpected. The first section identifies the consistent results – this is where the patient tested positive as expected for the drug or drugs prescribed. The next section identifies any unexpected negatives – drugs that are prescribed but tested negative. The third section identifies any unexpected positives – drugs that were not prescribed but were found in the patient's specimen. Below this section are the specimen validity results, which can help identify whether a patient has adulterated his/her urine sample, and if point-of-care testing (POC) is performed in office, those results are entered which allows comparison of the POC results with the laboratory test results.

Pages 2, 3: Every drug that was ordered/tested is displayed here. All unexpected results are displayed in bold red while all expected positives are in bold black. Both measured and creatinine normalized results are included in the report. Creatinine normalized results reduce concentration fluctuations caused by the patient's hydration status.

Page 4: The cumulative report provides a snapshot of the patient's last six test reports. Any drugs detected in the patient's last 6 specimens are displayed as a creatinine corrected value allowing comparison of test results over time.

Below the cumulative report are the metabolism pathways for opioids and benzodiazepines. These pathways only populate on the report if one more opioids or benzodiazepines are positive.

Page 5: The drug-drug interaction (DDI) section of the report identifies major and severe drug combinations present based on the tested drugs that are positive on the report. The Precision DDI Report displays the following: 1) Severity level, 2) Specific combination(s) promoting a DDI, 3) DDI summary.

Methods

In our system, data entry is a manual process. The accession person looks up the patient's history and if there is a previous test request gives the patient that unique identifier. It is important to include information about the time of collection and time of arrival into the laboratory. Data entry uses the STARLIMS system.

To generate the report, the STARLIMS software compares the positive and negative results observed by the INDIGO software to the patient's prescription profile. The expected drugs if positive, are scored as consistent, those that are negative are scored as inconsistent. Further, any positive drugs observed are also scored as inconsistent.

For the final report, all positive drugs observed for the immediate drug test and the 5 previous drug tests are retrieved and added to the final report using the STARLIMS software.

We use ASCENT from Indigo bioautomation (Carmel IN) to analyse our LC-MS/MS data enabling our staff to process 200 to 400 LC analytical runs of 80 drugs/metabolites per day. That is more than 16,000 chromatographic drug analyses per day per Clinical Laboratory Scientist analyst.

Our data is stored in the cloud using Microsoft AZURE and this enables us to process it using Microsoft's PowerBI visual analytics. Within a minute, the analyst can obtain a report of percent positives for any of our analytes or a combination of two analytes. We also use the Elsevier drug-drug interaction database to alert physicians of this possibility (however, most do not care).

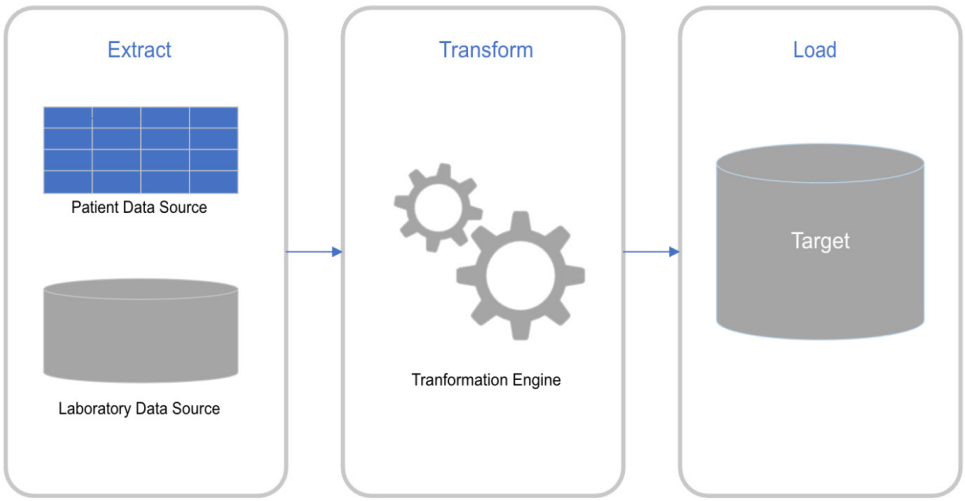


Figure 2: This diagram describes the overall data flow. In our case the patient data source can be electronically entered or manually entered from paper requisitions. The laboratory data source is from the analytical instruments.

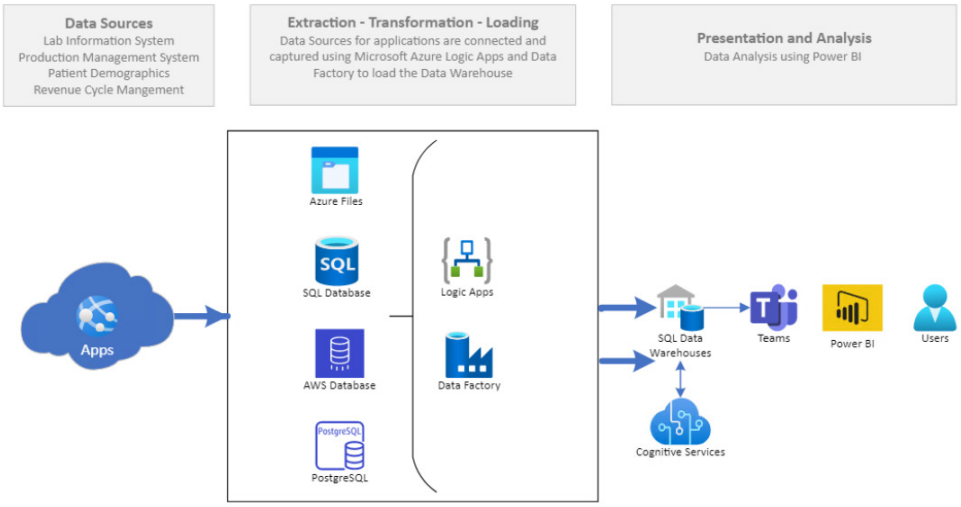


Figure 3: This flow chart shows the next steps in the data flow. The apps include the Indigo application which are loaded into AZURE files, then into the SQL database then into the cloud or AWS database (warehouse). In this group of data software and files logic application software can be applied to this data factory. The information or data stored in the SQL data warehouses can be accessed by programs such as Microsoft Teams and then into visual software such as Microsoft PowerBI for the final user to report.

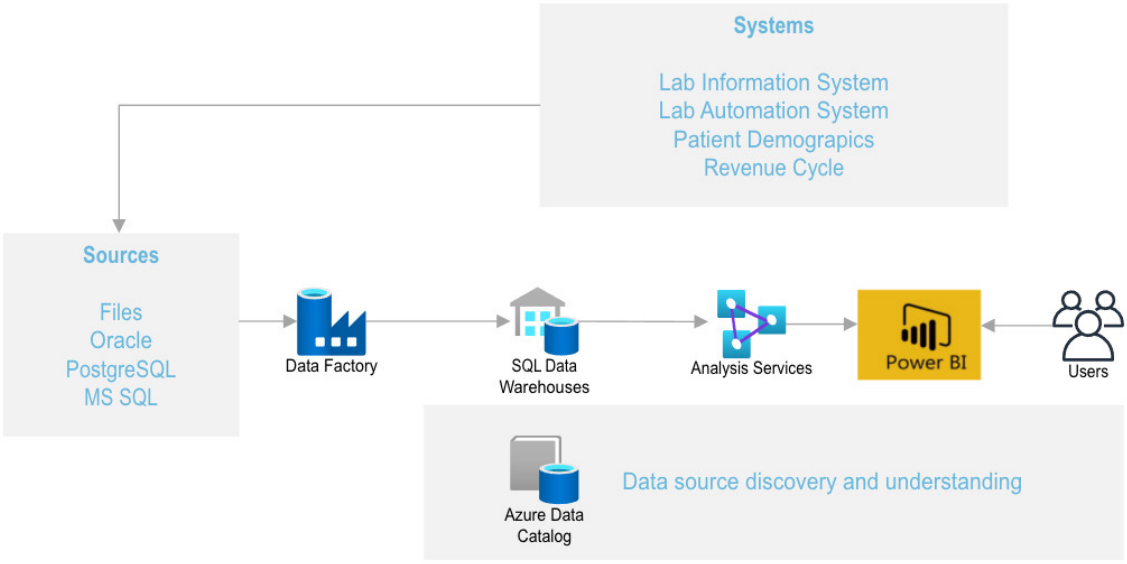


Figure 4: Another way to view the information system is that the files from the Laboratory Information System, the Laboratory information system (which tracks the specimen as it passes through the analytical system) and merges the patient demographics files (which includes patient insurance information that can be downloaded into billing software). The data in the AZURE data catalogue can be accessed and reformatted to yield discovery and understanding of patient behavior.

Data Flow diagrams (Figures 2-4) summarize the data flow.

1. Input IT info Patient demographics usually 2 or more identifiers. They are bar coded and separated into aliquots. The Software used here is SARLIMS sold by Abbott Informatics (a subsidiary of Abbott Laboratories). This is a web-based laboratory information management systems (LIMS) - used to manage the collection, processing, storage, retrieval, and analysis of information generated in the laboratory.

2. Patient drugs are recorded. These are often recorded as brand names. We developed a lookup these to the generic drugs for reporting purposes. This requires the use of a lookup table with brand names and conversion to the generic formula.

3. List of drugs to be tested. The physicians are allowed to choose any of the 80 drugs/metabolites that we test. These are incorporated into the STARLIMS database and will be reported as the results.

4. The samples are loaded into our automated test system. The samples are treated to convert them to the non-glucuronidated forms of the test drugs. The drugs are analysed using LC-MS/MS technology. The data generated by these devices is analysed by the ASCENT software from Indigo bioautomation. This converts the instrument ion detection into retention time, mass-ion plots, and detector response.

5. These observations are related to the internal standard using the INDIGO software. This identifies the drug from its mass ion and retention time.

6. The calibration curve and the INDIGO software convert the drug intensity signal to concentration.

7. The patient identifier and the analytical data are downloaded into Starlims to generate the patient report.

8. The analytical data is also exported as a CVS file into the “cloud” where it is stored as Microsoft Azure This is updated daily.

9. The stored data is then retrievable as visual data using Microsoft PowerBI. The data from the LC-MS/MS instruments was downloaded from the Indigo ASCENDTM software into an Excel file which was then visualized using Microsoft PoweBITM software.

10. The data can be exported in several predetermined formats. These include percent of any of the analytes positive, percent of any two positive analytes, and frequency and concentration of the analytes (Figures 5,6).

11. For those physicians who are interested the positive drug tests are sorted into the Elsevier drug-drug interaction database to flag those cases where harm may occur if the two drugs can cause medical interactions [14].

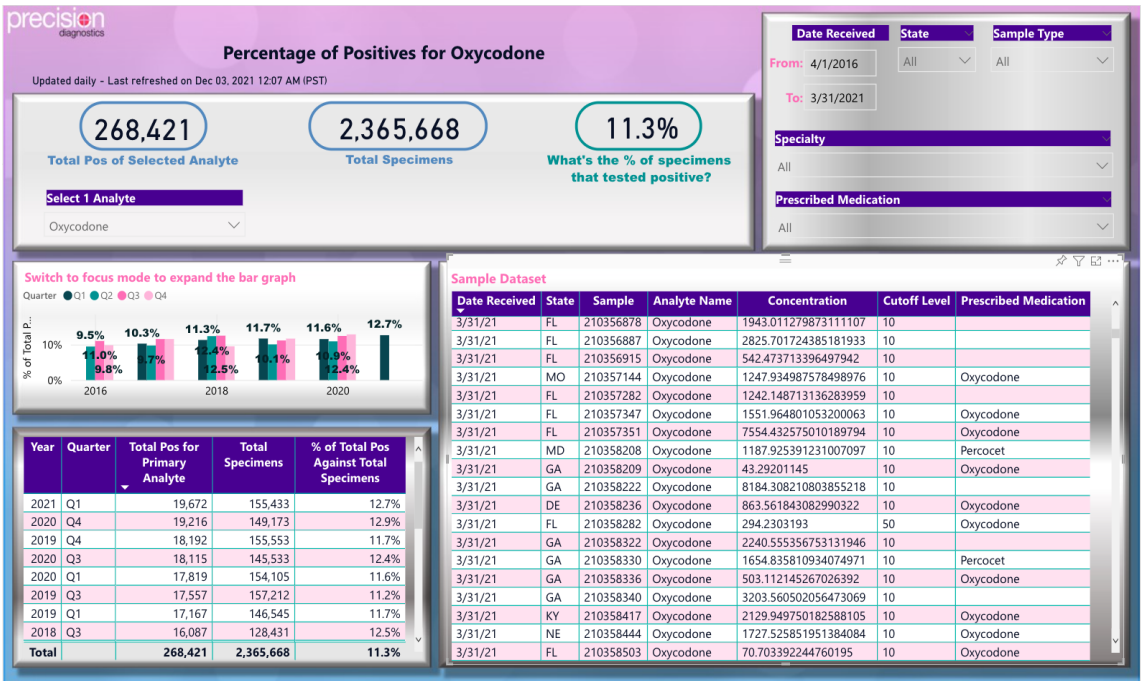


Figure 5: Power BI generated dashboard of drug test results for urine positive tests for oxycodone.

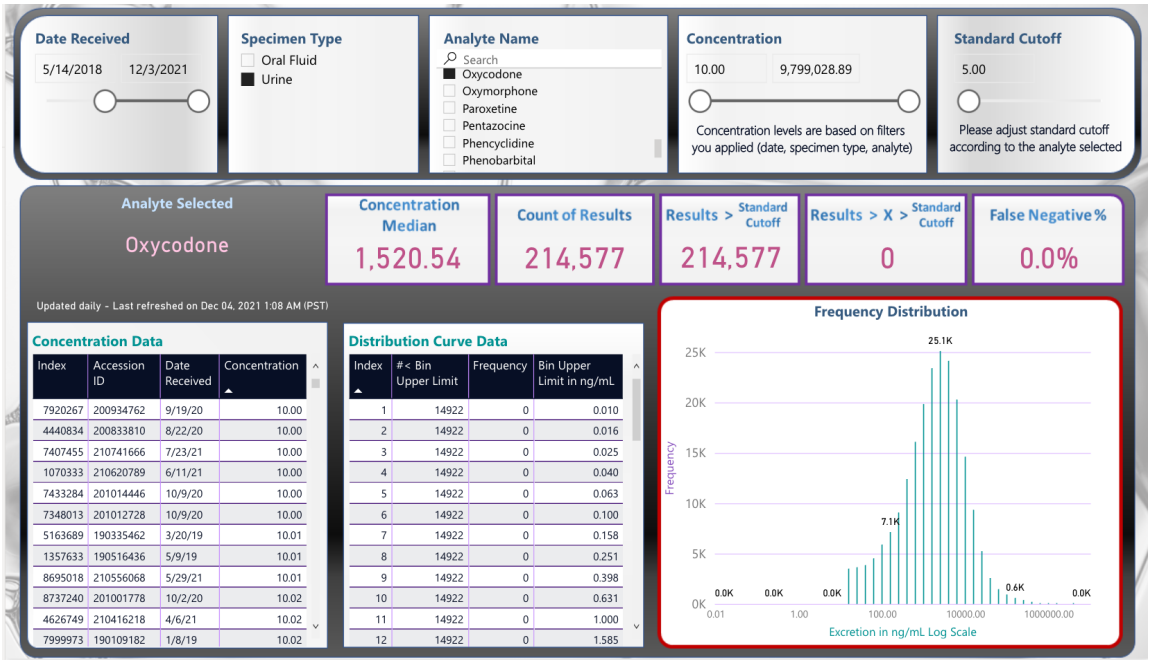


Figure 6: Power BI generated frequency distribution curve of concentration of drug test results positive for oxycodone.

Results and Discussion

As Reisfield GM et al. (2007) have pointed out, "Urine drug testing can be a valuable component in the care of the patient on chronic opioid therapy, but the interpretation is highly complex and dependent on a host of patient and laboratory variables. Available data suggest serious deficiencies in physicians' abilities to accurately interpret urine drug test results, and the consequences of misinterpretation are potentially serious".

Therefore, it is necessary for the laboratory report to be as comprehensive as possible and easily interpretable. We describe here our approach to help the patient provider with interpretation tools. We describe the drugs being tested, their metabolites, the method of testing (immunoassay or LC-MS/MS), the quantitative data on the test drug, detection times, whether the drug was expected from the provided prescription data (described as consistent results) and if unexpected drugs were observed (recorded as inconsistent results). Also included are the previously recorded drug test observations which enable the provider to determine the patient's pattern of drug use, without the necessity of reviewing

previous lab tests. As part of the report, we provide metabolism charts of the most encountered opioids and benzodiazepines. In addition, if desired we can provide the provider with information on potential severe drug-drug interactions [14,15].

The importance of having previous results on the report cannot be underestimated. As Bashir has pointed out "In the clinical care environment, the primary question that a clinician needs addressing is patient compliance: "Is my patient adhering to their treatment program? I want to know if the positive test result is from old use or new use". If the physician is following a patient's adherence, then the sequential urinary concentration of the drug and or metabolite can prove to be helpful as it allows comparison between current and previous results. Following "spikes" and "trends" in the urine concentration can often identify when "new" drug use took place. If the patient is compliant in a rehabilitation treatment program, then the drug concentration of the abused drug MUST decline, although this decline may not be linear due to hydration and/or PK characteristics of the drug" [16].

To meet these needs of the providers, designing and delivering a comprehensive concise urine drug test report requires the integration of several software systems. In our case, these are Abbott Starlims, Indigo Bioautomation, Microsoft Azure, MicrosoftBI, and laboratory designed lookup tables of drugs and metabolites. Examples of our publications using our data systems are references [17-19].

Conclusion

The panelists believe that clinicians should follow manufacturer instructions for specific POC UDM tests and direct any questions about interpreting results to an expert in toxicology or clinical pathology. Laboratories performing UDM have a responsibility to provide clear test results, answer questions, and offer support on clinical decisions. When clinicians are confronted with unexpected results, potential causes for false-positive and false-negative results (e.g., quinolone antibiotics, tolmetin; are important to investigate. A summary of communications and discussions about results with the laboratory and other experts can be included in the medical record to document the medical necessity of testing and related clinical decision-making.

Interpretation of drug screening results should be done with caution, while considering not only the presence or absence of the parent drug but also the pharmacological properties of the parent drug and its metabolites, the analyte concentration, technology used and the potential of sample tampering.

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