Re-Print – Special Report

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Western Diagnostic PATHOLOGY

Overview of the changes to Australian Standard AS4308:2008

The AS4308:2008 Standard has changes that impact on both clients and laboratories.

GENERAL POINTS

The New AS4308:2008 standard has made some fundamental changes to the way collections are done and given tighter guidelines on reporting.

Collectors

The standard requires collectors to have completed a nationally accredited course in drug screen collection and/or on-site testing. What is evident is that clients performing their own collections will need to have their staff signed off if they wish to collect samples and/or do on-site tests in accordance with Section 2 of the new standard. The standard and NATA (National Accreditation body) also requires laboratories to state unequivocally on the report the status of collections and their compliance to Section 2.

Where a collection is not performed by a registered WDP collector the following will appear on the WDP report.

'This sample has not been collected by a registered WDP Collector. Hence we cannot verify compliance to AS4308:2008 Section 2'.

The New Collection Procedure

The changes to collection are to do with the mandatory splitting of samples into 2 (thus we get a referee sample) and the requirement for an on-site creatinine test (check if the sample is dilute).

The referee sample is available in the case of dispute. At the moment, if we receive a request for a sample to be analysed again or to be sent to another laboratory we invoke a new chain of custody and send the original sample to the other laboratory for secondary testing. This has not produced any issues for us so far. The split sample makes that process easier since we can just send the 'referee" sample.

The creatinine test is a check of the dilute nature of the urine before it is sent off for testing. This can be done by a dipstick creatinine method.

Note that both of these changes have no bearing on the chain of custody. If these two items were not completed by a client then it does not invalidate the immunoassay or GCMS results. If the donor has signed that the sample is indeed theirs, and the other parts of the collection are fulfilled then action can certainly be taken on the final results even if these two items are absent.

The only concern may be the referee sample if it has been used. Although we have not been challenged on a re-invoking of a chain of custody, it's difficult to know what may become an issue later. This is important in areas where the volume delivered by the donor is not enough to safely split the sample, especially given the volume required for GCMS analysis.

The change in acceptable ID criteria may be an issue. The standard now states that a collection should not be done at all if the ID cannot be established unequivocally. This lack of ID is not necessarily a problem for some clients, however it means that the collection cannot be stated as being collected according to the new standard. We have always considered a lack of ID to constitute an incomplete chain of custody and the reports did not reference AS/NZS 4308, so this will continue to be the case.

GCMS Confirmatory Changes

There have been some changes to the GCMS cut-offs, most notably the amphetamines and some of the benzodiazepines. This was an interesting change.

The benzodiazepines were changed because each benzodiazepine reacts differently in the immunoassay and some can cause a positive immunoassay in combination but be below the GCMS cut-off for each metabolite. The change means that the chance of not confirming a benzodiazepine immunoassay screen are now less.

The amphetamine change was due, we were told by the committee, to the rise in methamphetamine use in the community. This was interesting because to improve the detection rate for abuse of these substances would have required a drop in the immunoassay cut-off not the GCMS! The drop in the GCMS cut-offs for the amphetamines will not lead to a large increase in detection, since most abusers have urine levels far in excess of the old 300 cut-offs.

For the client these changes make little difference. The main points are that if their drug policy contains these cut-offs then they will need to be amended. We have always suggested not quoting the cut-offs but referencing the AS4308:2008 standard instead (it simply avoids a lot of work if levels change)

Dilute Urines

The laboratory will confirm dilute urines with creatinines <=0.4 mmol/L using freeze point depression (Urine Osmolality). A new code will appear on those reports stating that the sample is not consistent with human urine. We are obliged to do this under the Standard.

Reports

There are a few changes to our reports related to the change from AS/NZS 4308:2001 to AS/NZS 4308:2008. These changes were not immediately applied, they will take effect in 2011.

We will be printing to an A4 report format.

The Immunoassay Results will quote *Section 4 of AS/NZS 4308:2008*.

The GCMS Confirmation Results will quote *Section 5 of AS/NZS 4308:2008.*

The issue however will be the collection itself.

If the collection was performed by an "accredited " collector and all the criteria are met (including a split sample and the creatinine) then the report will say the chain of custody was complete and we will reference *Section 2 of AS/NZS 4308:2008.*

If however we can't verify the collector as accredited and/or we don't get a split sample or a creatinine result but all the other criteria are met then we will still report the chain of custody as complete.

However we have to place a comment on the report saying we cannot ascertain whether the collection was done according to Section 2. (See above)

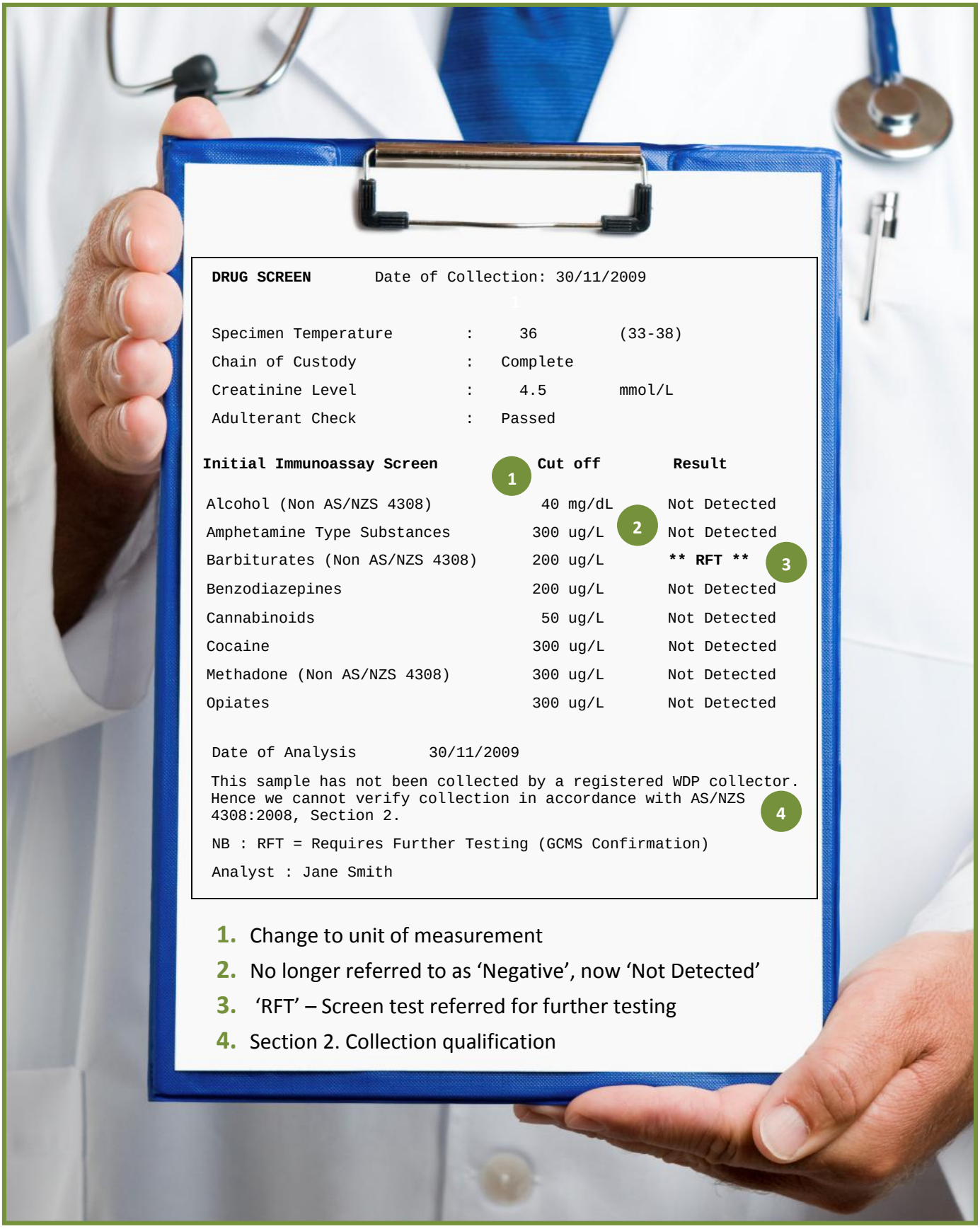
If the chain of custody is COMPLETE then we can be assured that the sample is from the donor and so all the results are valid and will stand up in court. It will contain the section 4 and section 5 (if required) comments.

If the chain of custody is not according to 4308:2008 criteria then we say the Chain of Custody is INCOMPLETE and specify what the issue was.

The standard now requires that a laboratory only advises that a non negative sample requires further testing. We cannot use the terms Detected, or Positive. This means that non-negative immunoassays will now carry a comment *****RFT****

A comment stating that ***RFT** means that the sample requires further testing (GCMS confirmation) will be added as well.

An example is as follows:



DRUG SCREEN Date of Collection: 30/11/2009

Specimen Temperature	:	36	(33-38)
Chain of Custody	:	Complete	
Creatinine Level	:	4.5	mmol/L
Adulterant Check	:	Passed	

Initial Immunoassay Screen	Cut off	Result
Alcohol (Non AS/NZS 4308)	40 mg/dL	Not Detected
Amphetamine Type Substances	300 ug/L	Not Detected
Barbiturates (Non AS/NZS 4308)	200 ug/L	** RFT **
Benzodiazepines	200 ug/L	Not Detected
Cannabinoids	50 ug/L	Not Detected
Cocaine	300 ug/L	Not Detected
Methadone (Non AS/NZS 4308)	300 ug/L	Not Detected
Opiates	300 ug/L	Not Detected

Date of Analysis 30/11/2009

This sample has not been collected by a registered WDP collector. Hence we cannot verify collection in accordance with AS/NZS 4308:2008, Section 2.

NB : RFT = Requires Further Testing (GCMS Confirmation)

Analyst : Jane Smith

1. Change to unit of measurement
2. No longer referred to as 'Negative', now 'Not Detected'
3. 'RFT' – Screen test referred for further testing
4. Section 2. Collection qualification

Details of Changes

Section 1. Scope and General

Collector
The collector as defined now needs to have completed a nationally accredited course in collection and/or on-site testing.

Western Diagnostic Pathology has partnered with Registered Training Organisation Medibank Health Solutions trading as Carepoint Education and Training (51660) to deliver a Nationally recognised 'Authorised Drugs of Abuse Collector' Training Course.'

See www.saferworkplace.com.au/TrainingServices.htm

Section 2. Specimen Collection, Storage, Handling Dispatch.

General
The procedure requires the provision of a referee specimen in case the resolution of disputed results is required.

Privacy
Procedures must allow for individual privacy. Observed collections may be conducted in situations where there is an unacceptable risk to the integrity of the specimen.

Chain of Custody
The minimum requirements of a chain of custody form have been listed. The only change is the need to document the onsite creatinine result.

Precautions
A paragraph has been added to state that if ID of the donor cannot be established unequivocally then the collector shall **not proceed with the collection.**

Collection Procedure

- Donor does not flush toilet until sample has been handed over
- Integrity checks are now : colour, temperature (33-38) and on-site creatinine test
- If integrity is an issue then you take another sample and forward both to the lab.
- Preparation for Dispatch - The specimen is now split between two containers.

Section 3. General Laboratory Requirements

Specimen Reception

Storage of referee sample now required.

Specimen Integrity Testing

a) Drug testing to occur irrelevant of the creatinine result.
b) Creatinine of 0.5 – 1.8 mmol/L. Suggest a repeat and make note of the dilute nature of the sample.
c) Creatinine < = 0.4 mmol/L need for further testing (specific gravity or alternative). Lab to state that the sample is **not consistent with human urine**.

Long Term Storage

Positive samples (+referee sample) to be stored frozen for at least 3 months.

Section 4. Laboratory Screening Procedure

Method

The methods are no longer listed.

Personnel

Lab supervisor qualifications have been defined.

Test Report

Immunoassay report to quote Section 4 of AS/NZS 4308:2008.

Record Keeping

Now based on NPAAC guidelines or the requesting authorities policy.

Section 5. Laboratory Confirmatory Procedures

Personnel

Lab supervisor qualifications have been defined.

Measurement of Uncertainty

MOU must be determined and applied to the interpretation.

Changes to GCMS cut-offs area as follows:

Drug	New	Old
Amphetamine	150	(300)
Methylamphetamine	150	(300)
MDMA	150	(300)
MDA	150	(300)
Alphahydoxyalprazolam	100	(200)
7-amino-clonazepam	100	(200)
7-amino-flunitrazepam	100	(200)
7-amino-nitrazepam	100	(200)

Test Report

GCMS work to reference Section 5 of AS/NZS 4308:2008

Appendix A : On Site Screening Procedure

This is a whole new section. Major Points are :

- Cut-offs for on-site testing to be the same as Immunoassay Screen
- Device must have verification data, any modifications then it has to be done again.
- Collector must be competent in doing on-site test (assume documentation must be available)
- Device must be within expiry date (need evidence of lot number and expiry date).
- Have to run neg and pos control for each batch of device
- Run a quality control with every 25 tests, alternate pos and neg.
- On-site test must be done in presence of donor.
- Interpret according to manufacturers' guideline.
- Record the result in permanent record.
- Positives despatched to lab.
- Collectors must participate in external QA or similar system
- All QA and double check data to be keep for viewing by accrediting authority.
- If report issued then refer to Appendix A of AS/NZS 4308:2008