

NATIONAL PATHOLOGY ACCREDITATION ADVISORY COUNCIL

REQUIREMENTS FOR SEMEN ANALYSIS

(First Edition 2017)

NPAAC Tier 4 Document

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Contents

Scope.....	v
Abbreviations	vi
Definitions.....	vii
Introduction.....	1
1. Personnel	3
2. Facilities and equipment	4
3. Pre-analytical	5
Specimen Collection.....	5
4. Analytical.....	7
5. Post-analytical.....	9
6. Quality Assurance and Quality Control.....	10
Appendix A Sample Reports for Semen Analysis (Informative)	11
References	13
Acknowledgements	14
Further Information	15

The National Pathology Accreditation Advisory Council (NPAAC) was established in 1979 to advise the Australian, state and territory governments on matters relating to the accreditation of pathology laboratories. A key role of NPAAC is to develop and maintain pathology quality standards for accreditation. NPAAC also advises on pathology accreditation policy initiatives and initiates and promotes education programs about quality in the provision of pathology services.

Publications produced by NPAAC are issued as accreditation materials to provide guidance to medical pathology laboratories and accrediting agencies about minimum standards considered acceptable for good laboratory practice.

Failure to meet these minimum standards may pose a potential risk to public health and patient safety.

Scope

The *Requirements for Semen Analysis (First Edition 2017)* is a Tier 4 NPAAC document and must be read in conjunction with the Tier 2 document *Requirements for Medical Pathology Services*. The latter is the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-laboratory referrals) are safely and satisfactorily met in a timely manner.

While there must be adherence to all the Requirements in the Tier 2 document, reference to specific standards in that document are provided for assistance under the headings in this document.

This document details the minimum requirements for best practice for pathology based andrology, in particular, semen analysis. It is for use in pathology laboratories providing semen analysis services. This document does not cover sperm antibody analysis.

Abbreviations

AS	Australian Standard
ISO	International Organization for Standardization
NPAAC	National Pathology Accreditation Advisory Council
NATA	National Association of Testing Authorities, Australia
WHO	World Health Organization

Definitions

Term	Definition
Azoospermia	means no spermatozoa are found in the sediment of a centrifuged specimen.
External Quality Assurance	means a program in which multiple specimens are periodically sent to laboratories in the group and reported to the participating laboratory and others. Such a program may also compare an individual's results with their peer group.
High power field	means the area of a slide which is visible under high power magnification (x400)
Laboratory	<p>means a facility for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological or other examination, including genetic testing, of materials for the purpose of providing information for the diagnosis, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of pathology investigation including the interpretation of results and advice on further appropriate investigation.</p> <p><i>This definition is adapted from AS ISO 15189 Medical laboratories – Requirements for quality and competence</i></p>
Requirements for Medical Pathology Services (RMPS)	means the overarching document broadly outlining standards for good medical pathology practice where the primary consideration is patient welfare, and where the needs and expectations of patients, laboratory staff and referrers (both for pathology requests and inter-laboratory referrals) are safely and satisfactorily met in a timely manner.
Quality Assurance	means a part of a quality management focused on providing confidence that quality requirements will be fulfilled.
Quality Management System	means those management activities involved in the direction and control of the organisation with regard to quality.
Specimen	means any tissue or fluid from a patient that is submitted to the laboratory for testing.
Specimen age	means the time elapsed between specimen collection and the commencement of analysis.

Term	Definition
Sperm vitality	means the proportion of live spermatozoa independent of their motility.

Introduction

A key role of the National Pathology Accreditation Advisory Council (NPAAC), as outlined in the *Constitution of the National Pathology Accreditation Advisory Council Order No. 1 of 1997* is to provide advice to the Australian government and States and Territories on pathology accreditation issues, including safety and quality of the provision of pathology services within Australia.

Semen analysis is performed in different categories of laboratories including general pathology laboratories and specialised andrology laboratories. Furthermore, it must be noted that semen analysis is performed for several different clinical indications. The most common of these are the investigation of fertility and for confirmation of sterility following vasectomy. The *Requirements for Semen Analysis (First Edition 2017)* sets out the minimum acceptable standards for good laboratory practice in relation to the performance of pathology-based semen analysis for these varied indications.

It is recognised that certain aspects of the performance of semen analysis may differ depending upon the clinical indication for the requested service. This document defines points in the request-test-reporting cycle where requirements for semen analysis, when performed for the purpose of post vasectomy clearance, may be varied.

This document is not intended to serve as a technical manual for the performance of semen analysis. For additional technical guidance on recommended methodologies, laboratories should refer to the World Health Organisation (WHO) *Laboratory Manual for the Examination and Processing of Human Semen*.¹ The methods described in the WHO publication are regarded as best practice.

These standards have been developed with reference to current Australian legislation and other standards from the International Organization for Standardization including:

AS ISO 15189 Medical laboratories – Requirements for quality and competence.

These requirements should be read within the national pathology accreditation framework including the current versions of the following NPAAC documents:

Tier 2 Document

- *Requirements for Medical Pathology Services*

All Tier 3 Documents

In addition to these standards, laboratories must comply with the relevant state and territory legislation (including any reporting requirements).

In each section of this document, points deemed important for practice are identified as either ‘Standards’ or ‘Commentaries’.

- A standard is the minimum requirement for a procedure, method, staffing resource or facility that is required before a laboratory can attain accreditation – standards are printed in bold type and prefaced with an ‘S’ (e.g. **S2.2**). The use of the word ‘**must**’

in each standard within this document indicates a mandatory requirement for pathology practice.

- A Commentary is provided to give clarification to the standards as well as to provide examples and guidance on interpretation. Commentaries are prefaced with a 'C' (e.g. C1.2) and are placed where they add the most value. Commentaries may be normative or informative depending on both the content and the context of whether they are associated with a standard or not. Note that when comments are expanding on a standard or referring to other legislation, they assume the same status and importance as the standards to which they are attached. Where a Commentary contains the word '**must**' then that commentary is considered to be normative.

Please note that any Appendices attached to this document are informative and should be considered to be an integral part of this document.

Please note that all NPAAC documents can be accessed at -

www.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-publication.htm

While this document is for use in the accreditation process, comments from users would be appreciated and can be directed to:

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1. Personnel

(Refer to Standard 4 in *Requirements for Medical Pathology Services*)

2. Facilities and equipment

(Refer to Standard 5 in *Requirements for Medical Pathology Services*)

- S2.1 If the semen specimen is to be collected at or adjacent to the laboratory, a fit for purpose, private room must be made available.**

3. Pre-analytical

(Refer to Standard 6A in *Requirements for Medical Pathology Services*)

Maintenance of optimal specimen collection and delivery conditions is crucial for quality analysis. Semen pH, sperm motility and sperm vitality are parameters that degrade rapidly from the time of ejaculation. It is generally accepted that semen analysis should commence within one hour of specimen collection in situations where these parameters are of clinical interest. Therefore, under optimal circumstances, specimen collection should occur close to the point of testing to minimise the delay between collection and analysis.

Collection at home may also be appropriate, provided that the recommended optimum specimen collection and delivery times, as defined by clinical indication, can be reasonably met.

It is recognised however, that compliance with recommended specimen collection to analysis intervals can be difficult to meet in certain situations, particularly if collection at the laboratory is not feasible or acceptable to the patient. Nonetheless, in circumstances where any time labile analytical parameter is clinically relevant, laboratories should take reasonable steps to ensure compliance in order to maintain the quality of analysis, the reliability of reported results and to minimise the need for specimen recollection.

Specimen Collection

- S3.1 Patients must be provided with a laboratory grade specimen container which is fit for purpose.**
- S3.2 Written specimen collection advice must be made available to requesting practitioners and patients.**
- S3.3 Specimen collection advice must specify the optimal collection procedures and instructions for storage, transport and delivery of specimens, including that:**
 - (a) the patient should abstain from ejaculation for a period of no less than 2 days and no more than 7 days prior to collection**
 - (b) masturbation without the use of a lubricant is the preferred method of specimen collection**
 - (c) where a patient is unable to collect a sample by masturbation, a condom may be used to facilitate semen collection during intercourse. The patient must be advised how to obtain a condom which is non-toxic to spermatozoa (no spermicide, no lubricant, non-latex) for this purpose**
 - (d) the specimen should be maintained at a temperature between 20°C and 37°C during transportation to the laboratory**
 - (e) the specimen should be delivered to the laboratory to allow commencement of analysis within one hour of collection.**

S3.4 Upon receipt of the specimen, the laboratory must ensure that the specimen is labelled in accordance with written protocols.*

C3.4 Laboratories should accept and analyse specimens delivered outside of optimum specimen age recommendations, but in doing so **must** include relevant interpretative comments in the report where any analytical parameter, other than overall sperm count, falls outside the lower reference limits.

S3.5 The laboratory must make reasonable efforts to obtain the following information from the patient which may be relevant to the interpretation of analytical results:

- (a) time of collection**
- (b) the number of days of ejaculatory abstinence**
- (c) storage conditions between collection and receipt into the laboratory**
- (d) the use of lubricants or condoms as aids to collection**
- (e) whether any of the ejaculate was lost during collection.**

* Refer to Standard SA6.3 in the *Requirements for Medical Pathology Services (First Edition, 2013)*

4. Analytical

(Refer to Standard 6B in *Requirements for Medical Pathology Services*)

- S4.1 Laboratories must employ validated and/or verified recognised test methodologies.**
- C4.1 The analytical methods detailed in the most recent edition of the WHO laboratory manual¹ are recommended.
- S4.2 After receipt in the laboratory, the specimen must be maintained between room temperature and 37°C prior to analysis.**
- S4.3 When the specimen has been delivered within the optimum timeframe, subject to liquefaction, the time-labile parameter of sperm motility must be performed within one hour of specimen collection, or as soon as practically possible thereafter.**
- S4.4 Following receipt by the laboratory, semen analysis must not commence until liquefaction is complete.**
- C4.4(i) If liquefaction has not occurred within 60 minutes of collection, then additional treatment by means of mechanical mixing or enzymatic digestion may be necessary to induce liquefaction.
- C4.4(ii) If semen liquefaction is induced this should be recorded and a suitable comment included in the report.
- C4.4(iii) Assessment of sperm motility should occur as early as possible after liquefaction.
- S4.5 Semen specimens must be thoroughly mixed before analysis.**
- S4.6 The following parameters must be measured when semen analysis is performed for assessment of fertility:**
- (a) semen volume
 - (b) sperm number and/or concentration
 - (c) sperm motility
 - (d) sperm morphology
 - (e) presence of cells other than spermatozoa
 - (f) presence of agglutination and its nature.
- C4.6(i) If azoospermia is suspected after an examination of 50 High power fields, repeat examination following centrifugation of the specimen at 1000g or greater for 10 minutes, **must** be performed for confirmation.

- C4.6(ii) When azoospermia is present, semen pH should be measured to assist in the identification of retrograde ejaculation or abnormalities of the vas deferens such as congenital absence or blockage in Cystic Fibrosis.
- C4.6(iii) Where total sperm motility is below the lower reference limit, sperm vitality should also be assessed.
- C4.6(iv) When analysing sperm motility, assessment of the quality of forward progression of the spermatozoa may be of diagnostic and therapeutic use in some circumstances and should be reported if clinically relevant.

S4.7 The following parameters must be measured when semen analysis is performed for post vasectomy clearance:

- (a) semen volume**
- (b) sperm number and/or concentration**
- (c) sperm motility.**

- C4.7(i) The presence of spermatozoa should be assessed by examination of 50 High power fields.
- C4.7(ii) If no spermatozoa are seen after an examination of 50 High power fields, repeat examination following centrifugation of the specimen is not usually required.
- C4.7(iii) If no spermatozoa are seen, the sperm count may be reported as “less than 1 per 50 High power field” or “0 seen in 50 high power fields”.
- C4.7(iv) If spermatozoa are present, the sperm concentration **must** be determined and motility assessed.

S4.8 Where automated semen analysers are used as the primary and/or sole technique for semen analysis, calibration of the three principal analytic parameters (number, motility and morphology) must be performed against reference material.

5. Post-analytical

(Refer to Standard 6C in *Requirements for Medical Pathology Services*)

S5.1 When known, the semen analysis report must include the following information which may be relevant to interpretation:

- (a) the number of days of ejaculatory abstinence
- (b) the time of collection and time of testing and/or the interval between specimen collection and analysis
- (c) method of collection
- (d) an indication of any loss of specimen volume at point of collection
- (e) the temperature at which motility was assessed.

C5.1 Results of semen analysis should be provided in a structured report format. Sample reports are shown in *Appendix A* of this document.

S5.2 Each of the parameters measured (as per S4.6 or S4.7) must be reported.

C5.2 Interpretive comments relating to factors that may have an impact on analytical results, such as the time elapsed between collection and analysis, should be provided when clinically relevant.

S5.3 Where automated semen analysers have been utilised, the instrument type must be noted on the report.

6. Quality Assurance and Quality Control

(Refer to Standard 7 in *Requirements for Medical Pathology Services*)

- S6.1 Laboratories performing semen analysis must comply with the quality assurance requirements specified in the NPAAC *Requirements for Medical Pathology Services*.**
- S6.2 Quality assurance specific to semen analysis must be appropriate to the technology used and assess the performance of all parameters being tested.**

Appendix A Sample Reports for Semen Analysis (Informative)

1. Semen Analysis (non post vasectomy) Report

Laboratory Details including Name, Address & Telephone
NATA Accreditation Number
Referring Doctor Name & Address

Patient Name, DOB and Address

Test Name (Semen Analysis or Semen Analysis & Sperm Antibodies)

Sample code / file number
Receipt & Test Date
Time specimen collected (a)
Time processed by scientist (b)
Age of specimen (hours, min) (a-b)
Method of Collection
Sexual Abstinence (days)
Sample Complete/Incomplete

Volume	(lower reference limit)
pH	(lower reference limit)
Appearance	
Viscosity	(normal/increased)
Liquefaction	(complete/incomplete)
Agglutination	%

Sperm Concentration	M/ml	(lower reference limit)
Sperm Total Count	M	(lower reference limit)

Total % Motile	%	(lower reference limit) State whether at room temp or 37°C
% rapid		
% non-progressive		
% immotile		

Morphology % normal forms (lower reference limit)
(differential abnormality breakup optional perform if requested)
Note on nature of any increased numbers of round cells – leucocytes and/or immature germ cells

Sperm Antibodies (If requested)
Result of test used e.g. Direct IgG Immunobead Agglutination Test:
% binding (test reference limit & source)

Comment Summarising the findings and any qualifications to the results

2. Semen Analysis (post vasectomy) Report

Laboratory Details including Name, Address & Telephone
NATA Accreditation Number
Referring Doctor Name & Address

Patient Name, DOB and Address

Test Name (Semen Analysis Post Vasectomy)

Sample code / file number
Receipt & Test Date
Time specimen collected (a)
Time processed by scientist (b)
Age of specimen (hours, min) (a-b)
Sample Complete/Incomplete

Volume (lower reference limit)

Sperm Concentration M/ml (lower reference limit)

Total % Motile %

Comment Summarising the findings and any qualifications to the results.

References

1. World Health Organization. WHO Laboratory Manual for the Examination and Processing of Human Semen, 5th ed. Geneva: World Health Organisation; 2010.

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