CANADIAN FERTILITY AND ANDROLOGY SOCIETY
ART LAB SPECIAL INTEREST GROUP

CERTIFICATION PROGRAMME FOR ASSISTED REPRODUCTIVE TECHNOLOGY LABORATORY PROFESSIONALS IN CANADA

Prepared by the Committee on Professional Standards of the CFAS ART Lab Special Interest Group

Approved by the membership of the CFAS ART Lab Special Interest Group on September 21, 2011 and CFAS Board of Directors on August 28, 2012

Executive Summary

This document describes the Certification programme for Laboratory Professionals working in Assisted Reproductive Technology (ART) Laboratories in Canada. It was developed by the ART Laboratory Special Interest Group (ART Lab SIG) of the Canadian Fertility and Andrology Society (CFAS).

The term ART Laboratory Professionals, as used in this document, encompasses those referred to as Embryologists and Andrologists, and includes all professionals who provide service in ART laboratories.

History

The concept of Special Interest Groups with the CFAS was raised in 1998. In 2002, with the approval of the CFAS Board, an ART Laboratory scientists' meeting as an adjunct to the CFAS Annual Conference was held immediately after the CFAS conference at Charlevoix, Quebec. It was resolved at that meeting that a SIG should be formed, and an interim Steering Group was appointed to develop its Terms of Reference.

Following approval of the draft Terms of Reference by the CFAS Board, all ART scientists were again invited to meet at the 2003 CFAS meeting in Victoria. This meeting was attended by representatives from 19 ART clinics across Canada, who voted unanimously to form the ART Laboratory Special Interest Group (ART Lab SIG). The principle of the SIG developing job descriptions for scientists working in ART Labs in Canada was discussed and agreed unanimously. It was also agreed unanimously that the SIG should develop a set of minimum standards for Canadian ART laboratories.

At the 2004 ART Lab SIG meeting it was recommended that the SIG draft a model for credentialing lab personnel (including grandfathering clauses) to set a benchmark for professionals entering the field of ART laboratory medicine, and develop a set of minimum standards for training in ART. The SIG concluded that defining roles and responsibilities for ART laboratory professionals should be a priority.

At the October 2005 meeting in Montréal, it was decided that the SIG's Professional Standards Sub-Committee would be expanded, to support the development of a position paper on Professional Standards. It was envisaged that this paper would include competency, as well as educational expectations, and lead to the development of a series of documents.

At the 2006 ART Lab SIG meeting in Ottawa, it was reported that the Professional Standards Sub-committee was meeting to draft competency and qualification profiles for ART laboratory staff.

In 2007 the ART SIG published Competency Profiles for Assisted Reproductive Technology Laboratory Professionals in Canada. This initiative was in response to the increasing regulation of the ART field and the need to create a vision of an ART Laboratory Professional who can not only apply basic principles but also communicate, evaluate, and extend learned principles

through research, critical thinking, and continuous learning in their interaction with patients, clients, and other health care professionals to meet the needs of this ever-changing profession.

Following the publication of these competencies further guidelines on qualifications and responsibilities, guidelines for an applied training program and guidelines for the evaluation and development of competencies were published through the CFAS. These documents are referenced by various Canadian bodies including the Federal government at Assisted Human Reproduction Canada as well as Accreditation Canada who apply them in their ART clinic accreditation program.

Current status of ART Laboratory Professionals

Currently, ART Laboratory Professionals in Canada come from a wide variety of backgrounds with different levels of academic and technical training. There is currently no recognized program in Canada that provides specific academic learning in the laboratory aspects of ART. Various international programs exist such as the Masters in Clinical Embryology from Leeds University UK, the Masters of Clinical Embryology from the University of Oxford UK, the Masters in Clinical Embryology and Andrology from the Eastern Virginia Medical School USA, and the Master of Clinical Embryology at Monash University Australia.

At the time of writing this document, several Canadian Universities are in the process of considering the development of courses more specifically aimed at providing the academic background necessary to work as an ART Laboratory Professional. These Universities have started working towards the creation of a post-graduate course in clinical embryology that would provide a resource for trainee ART Laboratory Professionals to obtain the academic learning necessary to fill the current knowledge-gap in reproductive physiology, reproductive biology and reproductive endocrinology that exists in Canada.

Development of Certification programme

This certification programme for ART Laboratory Professionals was created after reviewing existing programmes in other countries. The models from the United Kingdom, the European Society for Human Reproduction and Embryology (ESHRE) for ART Laboratory Professionals as well as the certification model for Canadian Health Leaders (formally Canadian Health Executives) were included in this evaluation.

Certification Programme

Process

Certification for ART Laboratory Professionals in Canada involves two levels of assessment: a logbook documenting competent completion of a defined range of laboratory techniques, and an evaluation of academic knowledge associated with embryology and andrology assessed through a written examination.

It is possible to complete the two elements in either order. This permits candidates interested in a career as an ART Laboratory Professional to take the examination prior to obtaining a position in an ART clinic or for candidates who are already employed to complete the logbook prior to sitting the examination.

Registration

Candidates must be members of the Canadian Fertility and Andrology Society (CFAS) in good standing. In addition, a registration fee for certification will be payable upon inscription.

Candidates complete the application form (Appendix I) and submit it to the CFAS ART Lab SIG Executive. The CFAS ART Lab SIG Executive advises the CFAS Board on all matters related to the Certification programme. Certification of candidates will be conferred by the CFAS Board, based on recommendations from the CFAS ART Lab SIG.

Candidates already employed within an ART centre will nominate a supervisor, usually the centre's Laboratory Director (or Scientific Director), who has the experience and qualifications to confirm the candidate's competency in each of the required ART Laboratory techniques. The CFAS Board will have the authority to require the candidate to propose a different supervisor if it is judged that the supervisor is not suitably qualified or experienced.

Examination

The examination component of the certification is administered annually in association with the CFAS Annual Meeting. To be eligible to take the examination in a given year, a candidate must register their intent to sit the examination with the CFAS ART Lab SIG Executive. The deadline for this registration is June 1 of the year in which the examination will be taken. The examination consists of multiple choice questions. The pass mark is 70%. The questions cover clinical embryology and clinical andrology including aspects from the *Guidelines for the Evaluation and Development of Competencies* (CFAS 2009), as well as reproductive endocrinology and physiology, oogenesis, and spermatogenesis. Candidates will receive a complete curriculum from the CFAS when registered for the Certification programme.

Logbook

The Logbook (Appendix II) is a record of the number of specified procedures that the candidate has completed conforming to the competences laid out in the *Guidelines for the Evaluation and Development of Competences* (CFAS 2009).

For each of the procedures there is a minimum number that must be completed independently and competently. Procedures performed during the candidate's training period do not contribute to this number since, by definition, trainees work under supervision to acquire competency.

The procedures included in the Logbook are:

- Oocyte collection
- Sperm analysis and preparation for ART procedures
- Semen cryopreservation and thawing
- Insemination
- ICSI
- Oocyte, zygote and embryo evaluation
- Embryo transfer
- Embryo / oocyte cryopreservation and thawing / warming

For each procedure, the candidate's supervisor must sign the Logbook to indicate that the procedure was completed according to the competences.

Once the minimum number of procedures for each element has been completed, the Logbook must be submitted for review by the CFAS ART Lab SIG Executive who will advise the CFAS Board whether this component has been completed satisfactorily.

Certification

When a candidate has submitted a completed Logbook *and* passed the examination, their application for certification will be forwarded to the CFAS Board for approval. Successful candidates will receive a certificate indicating that the candidate is a certified ART Laboratory Professional.

To maintain their certification, a certified ART Laboratory Professional must:

- remain a member of the CFAS in good standing; ***and***
- provide evidence of sufficient Continued Professional Development (CPD) credits on an annual basis.

Certification as an ART Laboratory Professional–Andrologist:

Since ART Laboratory Professionals include both embryologists and andrologists, an ART Laboratory Professional who only works in andrology may complete the certification process for this element alone. For certification as an ART Laboratory Professional–Andrologist, applicants must complete the Andrology components of the Logbook, and the Andrology component of the written examination.

Continued Professional Development

A certified ART Laboratory Professional is obliged to participate in sufficient Continued Professional Development (CPD) activities each year to maintain their certified status.

The CFAS ART Laboratory SIG Executive is responsible for providing certain CPD events during the course of the year, in addition attendance at recognized meetings as well as local and in clinic events such as journal clubs contribute to CPD. A complete list of recognized CPD activities with the respective CPD credits is available from the CFAS ART Lab SIG. Examples of activities that may attract CPD credits are:

- Journal Clubs – attending or presenting
- Conferences/workshops/symposia – attending or presenting
- Webinars
- Rounds
- Serving on professional committees, such as ethics committees, or expert working groups
- Manuscript reviewing/serving on editorial boards
- Completion of WHMIS certification
- Creating or revising SOPs
- Preceptorship

Loss of Certified status

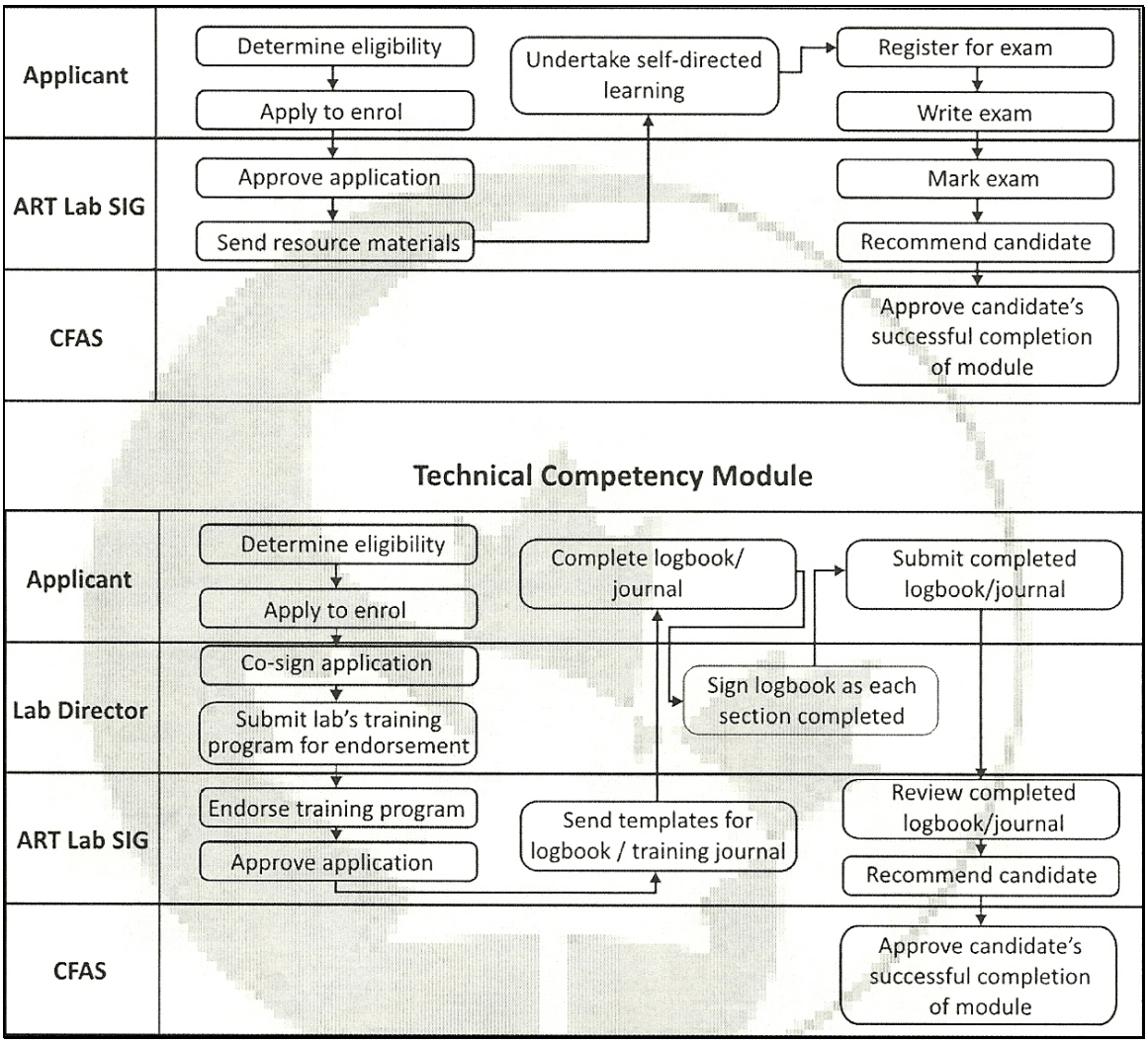
The CPD reporting period runs from January to December of the following year. Any certified ART Laboratory Professional who fails to comply with the CPD requirements for maintaining their certified status over the two (2) year reporting period will lose their certified status. Since participation in the certification programme through CPD can only be accessed by CFAS members in good standing, failure to pay membership subscription for one (1) year will also result in cancellation of certified status without further notice.

Re-Certification

Any certified ART Laboratory Professional whose certified status has been lost due to failure to comply with CPD requirements may apply for re-certification to the CFAS Board. These applications will be reviewed on a case by case basis and the CFAS Board may require the candidate to re-sit the examination and/or complete another logbook to achieve certification.

Overview of Processes for Completion of Competency Modules

Academic Competency Module



Technical Competency Module

Framework for Grandfathering of Canadian ART Laboratory Professionals

Embryologists and Andrologists Application

Whilst it would be preferable that all Canadian ART Laboratory Professionals take the examination and complete the logbook it is at this time, not feasible to function in this matter. Therefore any Canadian ART Laboratory Professional who has at least three (3) years of clinical ART laboratory experience will be eligible to be grandfathered for certification. The candidate will need to submit a record of their clinical ART experience along with an indication of the number of procedures that they have completed in each category as laid out in the certification logbook. In addition, the Laboratory Director/Scientific Director will need to attest to their competencies to practice as an ART Laboratory Professional, with special reference to the core competencies as outlined in the Guidelines for the Evaluation and Development of Competencies (CFAS 2009). The letter must be signed by both the Laboratory Director/Scientific Director and the candidate. The ART Lab SIG Executive will review each application and forward their recommendations to the CFAS Board who is responsible for issuing the certification.

Laboratory Director or Scientific Director Application

A Scientific or Laboratory Director will demonstrate their own qualifications and their capacity to grandfather their employees, by submitting the followings:

- Copy of up-to-date CV
- One page justification of their own competencies, i.e. where they work, supervision of how many employees, volume of activities, including a description of their own activities with reference to the core competencies as outlined in the Guidelines for the Evaluation and Development of Competencies (CFAS 2009). In addition, a brief description (1 or 2 paragraphs) on the policies and procedures of their training programs and how the candidate establishes that the embryologists /andrologists are competent.
- The Medical Director will submit a signed standard reference letter that will support and state that they acknowledge that the Scientific or Laboratory Director is competent to perform their duties, and that the clinic follows all the CFAS Guidelines. The Medical Director's signature will signify that the Scientific or Laboratory Director is responsible for the education, training, and competency evaluation of the ART Laboratory Professionals.

Review process for grandfathering Scientific and Laboratory Directors

A committee composed of the ART Lab SIG Executive and two (2) external senior CFAS members will review all applications from the Scientific and Laboratory Directors. All applications will be pre-scored by each member of the committee prior to the meeting (grading scheme to be developed). The only cases that would be discussed are those where the scores show a wide variation. The Scientific and Laboratory Directors in the committee will go through the same evaluation process and will not be present when their applications are being evaluated. The committee would forward all their recommendations for approval of each Scientific and Laboratory Directors to the CFAS Board of directors for final approval. The final

letter, stating acceptation or rejection of certification, will be issued by the CFAS Board of Directors.

Appendix I

Sample Application Form

Family Name:	**First Name:**	**CFAS membership number:**

Academic Qualifications:

Degree	**Subject**	**Institution**	**Year obtained**

Correspondence Address:

Street and Number:	**City:**	**Province:**

Postal Code:	**Email address:**

Clinic information:

Name:	**Street and Number:**	
City:	**Province:**	**Postal code:**

Proposed Supervisor:

Name:	**Position in Clinic**

Academic Qualifications: (list all degrees)

Years of experience in human ART	

SUPERVISOR AGREEMENT

I confirm that I agree to be the supervisor for the named candidate on this application for certification as an ART Laboratory Professional. Furthermore I understand that I must ensure that the techniques that the candidate completes for their logbook comply with the competencies outlined in the CFAS ART Laboratory Competency Standards.

Name: _____ Signature: _____ Date: _____

NB: A current copy of your laboratory training manual must be submitted with the application to ensure that the training programme conforms to the competencies as outlined in the *Guidelines for the Evaluation and Development of Competencies* (CFAS 2009).

Technical Competency Module:

I am currently employed in an ART Centre and wish to complete the technical competency module (Logbook). Please indicate whether you wish to complete Full Module (embryology and andrology) or Andrology Only module.

Full Module Andrology Only

NB: For this element the clinic Laboratory Director must complete and sign the section above and a copy of the laboratory training manual must be submitted for assessment by the CFAS Certification and Evaluation sub-committee

Academic Competency Module:

I wish to register to sit the examination for certification. Please indicate whether you wish to complete the Full examination (embryology and andrology) or Andrology Only module.

Full Module Andrology Only

NB: In order to take the examination it is not necessary to be currently employed in an ART centre. In order to be eligible to take the examination at the next CFAS annual meeting this application must be received by the CFAS office by the 1st June preceding the CFAS meeting. Otherwise you will be scheduled for the examination in the following year.

APPLICANT AGREEMENT

I confirm that the information contained in this application form is correct. I agree to abide by the regulations pertaining to the certification programme for ART Laboratory Professionals. I understand that the decision of the CFAS Board regarding my application, the involvement of my proposed supervisor and any aspect of the certification process is final.

Name: _____ Signature: _____ Date: _____

Administration Use Only

Date Application Received:	
Authorized for programme by:	Date Authorized:
Candidate issued with Logbook (date):	Candidate registered for Examination(date):

Appendix II

Sample Logbook

All activities in this logbook must be completed according to the competences outlined in the *Guideline for the Evaluation and Development of Competencies* (CFAS 2009). For each activity the assigned supervisor must sign to confirm that the activity was completed.

Name:	Candidate Number: (CFAS membership #)

Supervisor Name:	Clinic name:

Certification type:

Andrology Only – Complete Andrology Module only

Full Module – Complete all sections

Note: All the procedures listed in this logbook must have been competently completed by the candidate (as laid out in *Guidelines for the Evaluation and Development of Competencies*, CFAS 2009). Procedures that form part of the training of the candidate cannot be used for demonstration of competence since by definition; an ART Laboratory Professional in training has not yet attained competency.

ANDROLOGY MODULE

Semen Analysis in the ART Laboratory involves the functional assessment of semen or sperm samples. The preparation of semen for treatment includes the assessment of a semen sample (fresh semen, frozen semen and surgically retrieved sperm sample) and selection of an appropriate washing method according to the laboratory's Standard Operating Procedures (SOP).

Semen Analysis

Competency in functional Semen Analysis includes assessment of volume, pH, concentration, motility and progression, and morphology.

Procedure Number	Date (dd/mm/yy)	Preparation method used	Candidate's Signature	Supervisor's Signature
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

Sperm Preparation – Fresh Semen

Procedure Number	Date (dd/mm/yy)	Preparation method used	Candidate's Signature	Supervisor's Signature
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

Sperm Preparation – Frozen Semen

Procedure Number	Date (dd/mm/yy)	Preparation method used	Candidate's Signature	Supervisor's Signature
1				
2				
3				
4				
5				

Sperm Preparation – Surgically retrieved sperm

Procedure Number	Date (dd/mm/yy)	Preparation method used	Candidate's Signature	Supervisor's Signature
1				
2				
3				
4				
5				

Sperm Cryopreservation

Competency in Sperm Cryopreservation includes the selection of an appropriate cryopreservation method according to the laboratory SOP, the correct labelling and identification of the samples as well as the correct indication of their location once cryopreserved. The technique of cryopreservation should be carried out according to the laboratory SOP.

Procedure Number	Date (dd/mm/yy)	Preparation method used	Candidate's Signature	Supervisor's Signature
1				
2				
3				
4				
5				

Sperm Thawing

Procedure Number	Date (dd/mm/yy)	Preparation method used	Candidate's Signature	Supervisor's Signature
1				
2				
3				
4				
5				

EMBRYOLOGY MODULE

Oocyte Collection

Competency in Oocyte Collection includes assessment of follicular fluid to retrieve oocyte-cumulus complexes (OCC) from an identified patient, washing of OCC and transfer to correctly labelled culture dishes and the replacement of those culture dishes into the correct location in an incubator. It also includes the correct entry of information regarding the oocyte collection into the patient's record (electronic or paper).

Procedure Number	Date (dd/mm/yy)	Number of COC collected	Candidate's Signature	Supervisor's Signature
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

Insemination

Insemination refers to the insemination of collected OCCs with the appropriate washed sperm sample without the use of microinjection techniques. Competency in the process of Insemination includes the assessment of sperm concentration and adjustment as required to obtain optimal fertilization without polyspermic fertilization, positive confirmation that the appropriate sperm sample is mixed with the correct oocytes by use of identifiers according to the laboratory's SOP, and the insemination of oocytes with sperm with sterile technique.

Procedure Number	Date (dd/mm/yy)	Candidate's Signature	Supervisor's Signature
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Intracytoplasmic Sperm Injection (ICSI)

ICSI involves the microinjection of a correctly identified spermatozoon into a correctly identified Metaphase II oocyte. Competency in ICSI includes demonstration of the set-up of the ICSI microscope and manipulators as well as the appropriate selection of a suitable spermatozoon for injection. The injection of Metaphase II oocytes should result in a level of fertilization in accordance with the laboratory's standards and a level of degeneration post-injection that does not exceed 10%.

Competency includes at least five cases using surgically retrieved sperm.

Procedure Number	Date (dd/mm/yy)	Number of MII oocytes injected	Sperm Source	Candidate's Signature	Supervisor's Signature
1			Ejaculate		
2			Ejaculate		
3			Ejaculate		
4			Ejaculate		
5			Ejaculate		
6			Ejaculate		
7			Ejaculate		
8			Ejaculate		
9			Ejaculate		
10			Ejaculate		
11			PESA/TESE		
12			PESA/TESE		
13			PESA/TESE		
14			PESA/TESE		
15			PESA/TESE		

Oocyte, Zygote and Embryo Evaluation

Competency in Oocyte, Zygote and Embryo Evaluation includes the assessment of oocytes for maturity prior to ICSI as well as abnormalities (e.g. smooth endoplasmic reticulum, organelle grouping, cytoplasmic pitting, etc), the assessment of normal and abnormal fertilization and the assessment of embryo development (e.g blastomere quality, multinucleation, binucleation, micronucleation) according to the laboratory's SOP. One table must be completed for each type of assessment (oocyte, zygote and embryo). Assessment of all of a patient's gametes or embryos is a single Procedure.

Procedure Number	Date (dd/mm/yy)	Evaluation of Oocyte/Zygote /Embryo	Number assessed	Candidate's Signature	Supervisor's Signature
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

Embryo transfer

Competency in Embryo Transfer involves the assessment and selection of the appropriate embryo(s) for transfer, demonstration of the correct process of patient and embryo identification prior to the transfer, the appropriate loading of the embryo into the transfer catheter and handover to the physician according to the laboratory and clinical SOPs.

Procedure Number	Date (dd/mm/yy)	Candidate's Signature	Supervisor's Signature
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Embryo / Oocyte Cryopreservation and Thawing/Warming

Competency in Embryo/Oocyte Cryopreservation includes either the vitrification or "slow freezing" of oocytes and embryos according to the laboratory's SOP, as well as demonstration of the appropriate labelling of samples and identification of the location of sample storage.

Competency in Embryo/Oocyte Thawing/Warming includes selection of the appropriate protocol according to the method of cryopreservation, location and identification of the appropriate stored samples, and application of the protocol according to the laboratory SOP.

Cryopreservation method:_____

Procedure Number	Date (dd/mm/yy)	Number of embryos/oocytes cryopreserved	Candidate's Signature	Supervisor's Signature
1				
2				
3				
4				
5				

Warming/thawing method:_____

Procedure Number	Date (dd/mm/yy)	Number of embryos/oocytes warmed/thawed	Candidate's Signature	Supervisor's Signature
1				
2				
3				
4				
5				

Case Report

In addition to completing the techniques indicated in the logbook it is necessary to complete a short case report. This report should be on a case that you have seen which you found interesting. In the case report you should indicate the details of the case, the outcome and any other pertinent information. You should use a literature review to explain the outcome of the case and/or suggest alternative treatment for future cycles that may resolve any issues that were seen.

Please attach the case report to your logbook when submitting for review. Ensure that your name and CFAS membership number are clearly indicated on the case report. The case report should be a maximum of 1000 words.