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a) Aim of this QAP System:

The aim is to send out 2 external QAP samples / year, with the sending-reporting timeline to be approximately March/April and September/October.

The SQA automated semen analyser family (ie. SQA-V Gold or SQA-Vision) needs sperm of high motility to be used for an external QAP program (as the motility and morphology are closely aligned by an algorithm). This makes it logistically tricky to obtain enough high motility pooled-frozen semen to be used with a greater frequency than 2/year in the first instance.

The QAP system will be run and managed by an external QAP provider called "QAP-Online".

There are IVF labs and General Pathology labs operating as part of this QAP group, so to cover the range of handling techniques and sample knowledge, a standard set of information will be sent. This is in an attempt to control any motility loss during storage, handling and thawing, so the motility and morphology obtained by the analysers can be relatively consistent. For this first series of samples, this is the major "unknown" and extreme care has to be taken in the handling, storage and thawing of the samples; so the results are not unrealistically variable.

Even though the samples have been batch tested and analyzed several times, if there are any issues with thawing/handling/storage/motility of your sample, then in this interim phase, please contact Simon Cooke <u>simon.cooke@ivf.com.au</u>.

If there are any QAP system/software/logon/access/data entry issues, then Dr Jim Stanger at <u>office@fertaid.com</u> is the best contact.

As the system becomes tested and streamlined, Jim Stanger as the QAP provider will then become the primary contact point for all items.

b)Handling and Storage of the SQA sample prior to testing:

- 1. The straw of frozen semen will arrive in a metal cane captured top/bottom with plastic goblets. This is so the frozen straw does not fall out whilst you are handling/storing it.
- 2. Remove your cane which will be labelled with your company name on the top of the metal cane.
- 3. Inside is a 0.5ml CBS straw of frozen pooled human semen. It is important that this stays frozen, and is not subjected to air temperature for more than 5-10 seconds, to protect the sample from thaw-freeze-thaw-freeze cycles that will reduce the motility of the sample (and the related morphology).
- 4. Place the cane straight into Liquid nitrogen for storage.
 - If you do not have liquid nitrogen, place the metal cane into a container of Dry ice for short term storage,
 - Failing Liquid nitrogen/dry ide availability you have 2 more options:
 - i. Store for a short time in a -80degree pathology sample freezer, or,
 - ii. Have your SQA trained staff available upon receipt of the QAP sample, and thaw the sample immediately, and perform the analysis immediately for your QAP run.

c)Thawing and Testing of the sample by SQA:

- 1. Remove the straw from your storage location, and thaw the provided QC straw by placing on a warm stage (37°C) for 20 minutes. These samples have been quality tested to be reproducible when thawing on a warm stage. If you do not have a warm stage, note that in your QAP records, as a potential reason if your standard deviation of your SQA motility and morphology is a little lower.
- 2. To help some pathology labs who may not have certain types of tubes in their system, one 5ml round-bottom tube will be provided with the sample, and will be labelled as SEMEN. After thawing, carefully cut just above the bottom seal of the straw, place the straw into the tube labelled as SEMEN and cut just below the top seal of the straw, allowing the contents to enter into the tube by gravity. Swirl gently to mix (avoiding the creating of bubbles). Ensure all the sample is expelled from the straw.

- 3. Remove 300uL from the SEMEN tube, and aliquot into the sample pot (also provided) labelled as DILUTION. Add 300uL of QwikCheck Dilution media (warmed at 37°C) to the DILUTION sample pot. Mix sperm and dilution media thoroughly. Please take care to avoid creating bubbles while mixing.
- 4. Load a SQA-V capillary with the diluted QC sample, from the DILUTION sample pot.
- 5. Run this diluted QC sample through the SQA-V as a 'test patient', using the details provided below. Note that all fields are left blank except:
 - Patient ID [001],
 - volume [0.5mL],
 - leukocytes [<1M/mL]).
- 6. It is **CRITICAL** that this sample is run through the SQA-V on the '**diluted 1:1 with media**' **setting.** Instructions for SQA-V Gold are:
 - When the SQA-V prompts you "IS SAMPLE VOLUME SUFFICIENT FOR COMPLETE TESTING >.5mL"
 - Select "NO"
 - Select "DILUTE SEMEN 1:1 WITH MEDIA"

Failure to select the "diluted 1:1 with media" setting will mean your concentration is <u>double</u> that of every other respondents concentration.

PATIENT DATA

ID

001 BIRTH DATE 00/00/00 ABSTINENCE DAYS

SAMPLE DATA

ACCESSION #=

00/00/00	
11=46	
00/00/00	
11=46	
` FRESH	
0.5ml	
< 1M/ml	
NORM.	
NORM.	
NORM.	
	11:46 00/00/00 11:46 FRESH 0.5ml < 1M/ml NORM. NORM.

d)Initial registration of the SQA analyser to QAP-Online:

With this module, we are using QAP a little bit differently. Whilst QAP is generally linked to an individual, in this SQA-QAP series we are testing the "SQA analyser" as the counting mechanism (not the human), so the SQA analyser will be entered as the "person".

A suggestion is to have the "lab supervisor" or "chief scientist" email as the contact point, and the password then only becomes important when entering QAP data (that any person can do).

This only needs to be done once for each machine, and each year the machine that is still used is selected to be used for the following year QAP entries.

Existing QAP online users:

1. You should have QAP access privileges already. Jump to point #3.

New QAP online users:

2. You will need to contact the QAP-Online manager (Jim Stanger) <u>office@fertaid.com</u> for details on how to register into this QAP system, and how to set up a QAP group and supervisor.

To "register" your SQA analyser/s, once you have access into QAP-Online:

- 3. Each analyser will need to be registered as an individual, so repeat this series of instructions for each analyser that you have.
- 4. Once you have a QAP group, the supervisor opens QAP-Online.



5. Now add a new "Staff Member" to your QAP group (remember, we are not adding a new staff member though, we are adding an analyser)



6. Enter the location and the serial number of your analyser (ie. Sydney SQAV-1234 in this example). When/if you have >1 analyser, this will mean the locations and machine are clearly visible when reviewing your results. When completed press SUBMIT. Review the summary and press UPDATE STATUS.

Create a registration for a New Staff Member for your Group										
Title:	*		<- Update							
First Name:	*		<- Update							
LastName:	Sydney SQAV-1234	×	<- Update							
Institution or Clinic Name:	Already populated									
Street:	Already populated									
Suburb:	Already populated									
City:	Already populated									
State:	Already populated									
Post or Zip Code:	Already populated									
Country:	**Australia** 🗸									
Email:	Already populated	<- Update	Important= please check this is correct							
Work Telephone:	Already populated									
Contact FAX Number:	Already populated		important if email incorrect							
Occupation:	Andrology V									
LanguagePreference	English V * Development information only at prese	ent								
Laboratory:	~									
Register for IVF Daily	Encouraged as an educational acitivity									
Submit	Reset									

7. The important details will also be emailed to the person nominated in the registration. The NAME, location, Logon Code and Password now relates to the ANALYSER (not an individual), so is information to locate in the documents associated with this SQA analyser (ie. It means anyone can enter the results obtained for that analyser).

8. When logged into QAPOnline as the "analyser", you now need to join the QAP module you are entering your results to. Press the JOIN link,

12 18	Home LogOut									
Nome*	QAPonline*	eLearning*	<u>My Profile*</u>	Interact	Buy Credits	Exit*				
The Process	<u>s</u> <u>Information</u>	<u>Company*</u>	Schemes*	<u>Join*</u>	Enrolments	Questions:*	Results*	<u>Audits*</u>	<u>Help*</u>	
	My QAP Group	<u>Staff</u>	My EQA Sch	hemes	<u>Laboratories</u>	<u>Ch</u>	ange Laborat	ories	Leave	

9. Select the MES module, and press the ENROLL link.

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314	MES2016- MES SQA Trial Scheme	0 Credit Units 🤇	ENROLL
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10. Ensure you select PROFESSIONAL from the pulldown link (Red arrow), and press "SUBSCRIBE NOW"

_	Professional/Discipline part of my normal working environment V involvement in Andrology	elect the level of professional
U wish to support	SIRT/Scientists in Reproduction	✓ or <u>Add your Society name</u>
Years of professional Expertise	2016 Please indicates the year you have acted independently in 0000 if you are not qualified to perform this assessment profession	thise area eg 2010. Enter ally.
	Professional Expertise is new in 2006. It has been added to provide See <u>Profile/Expertise</u> for more information.	
Analysis Method	There are no specific methods attached to this enrollment	
(Subscribe Now	
	Return to my AP Home page WITHOUT subscribing	

e) Entry of results to QAP-Online:

1. Open the webpage http://www.fertaid.com/FertAid/QAPonline.asp and Log in to QAPonline



2. Select QAPOnline, and click QUESTIONS. This should open up any outstanding module question. Select a month across the top in case the question is not visible.

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The Process	Information		QAP GR	OUP	Schem	es*	<u>Join*</u>		Enrolments	Ques	tions:*	Results*	Audits*	<u>Help*</u>	
															_

- 3. Enter the data as displayed on the SQA printout (or the v-Sperm report) for:
 - Concentration (Conc.)
 - Total Motility (PR+NP)
 - Progressive Motility (PR)
 - Morphology Normal Forms (WHO 5th)