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External Quality Analysis – SCA®

Andrology laboratories need to produce reliable results for appropriate diagnostic and health care decisions. Since semen analysis is highly complex and procedurally difficult to standardize, quality control (QC) is essential to detect and correct systematic errors and high variability of results. The large discrepancies between assessments of sperm concentration and morphology underline the need for improved QC and standardization. Thus, Microptic S.L. has created an External Quality Control to certify that users from the SCA[®] and SCA SCOPE are using the system appropriately and that results obtained are accurate and consistent.

Important: EQA 2025 is only compatible with version 6.5 (or higher) of the software.

- If you are an SCA[®] evolution user, please go to page 2.
- If you are an SCA SCOPE user, please go to page 9.



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Steps to perform the EQA with SCA®

Get access to the EQA

- To have access to EQA, system needs to be under maintenance. In case the system is not, please request your maintenance offer from the following link: <u>https://www.micropticsl.com/company/maintenance-information-request/</u>
- 2. Go to <u>https://mysca.micropticsl.com/</u> or click on *mySCA* button from SCA[®] main menu.



3. Sign in with your SCA[®] ID and your password and go to Quality Control tab.

In case user accesses mySCA from inside SCA[®] program, it is not required to enter the credentials.

Log in Use your mySCA account to log in.
SCA⊕ ID
Password
Remember me?
Log in
Find the SCA® ID in the Hasp protection key or inside the SCA® program. If you cannot find it, click here or contact Microptic S.L.

Download required files

1. Go to *Quality Control* tab in the main menu.

System Information Personal Data Maintenance Contract Installation Control Quality Control myFiles



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2. User can download all the EQA files by clicking on the file (it is required to unzip it after downloading). It is also possible to download the files individually by clicking on each of the links below.



Motility and concentration

Opening sessions

- 1. Open SCA and log in (user and password might be required).
- 2. Go to the unzipped EQA folder and <u>Double click</u> on the session that you want to analyze (each session corresponds to one captured field)¹.
- 3. System will automatically open each EQA session.
- 4. Open the captured field and add/delete sperms manually to have a good analysis, as usually



IMPORTANT: This section has the aim of evaluating the user's ability to detect problems with the system conditions for capturing images. Among all the motility and concentration sessions there are several videos analyzed under non-optimal conditions. In them, you must identify, describe the problem and

¹ Sessions can be also opened by through the "Open" option within the MOT module. **IN NO CASE users should** analyse the EQA sessions by using their own system configuration.



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find out whether the analysis can be carried out. Only the results from the optimal videos should be transferred into the table of results" Results EQA2025.xlsx"



- 5. Press the results button **results**, go to Comparison tab and answer the questions of the **resultsEQA2025.xlsx**.
- 6. Save the session modified by the user by clicking Export Session.

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MOI	7.mot	17/03/2020 16:23	Microptic SCA MO	13,837 KB	
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We recommend saving the modified analysis sessions in case results were not close to the reference values and thus they needed to be checked.

7. Perform the same steps with the post-treated sample analysis.



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Morphology

Opening sessions

- 1. Open SCA and log in (user and password might be required).
- 2. Go to the unzipped EQA folder and <u>Double click²</u> on the session to be analyzed.
- 3. System will automatically open each EQA session.
- 4. Open the captured fields and add/delete sperms manually. To have a good analysis check each field following this criterion:
 - a. Add sperms clicking on its head (shift + left click).
 - b. Delete captured cells that are not sperm cells or sperms that are not well analyzed (right click).

It is possible to use "SpermEdit" tool to perform manual modifications faster (change classification and delete sperm). From here, the complete list of sperm cells that have been analysed is available, and it is possible to order it by Abnormality Index to have the most normal sperm cells first and the most abnormal ones at the end of the list:



² Sessions can be also opened by through the "Open" tab within MRF module. **IN NO CASE users should analyse the EQA sessions by using their own system configuration**.



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- ${\color{black}{\leftarrow}}$
- 5. Press the results button **Results** and answer the questions from the **resultsEQA2025.xlsx** file.
- 6. Save the session modified by the user by clicking Export Session.



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Save As	Analyze Reports • Home Configuration	Field Sort Report	Export View	Help	x
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We recommend saving the modified analysis session in case results were not close to the reference values and thus they needed to be checked.

"What's wrong with the image?"

This section aims the evaluation of the user's ability to detect problems with the sample preparation as well as with the system conditions for capturing images. Thus, six different sperm preparations were captured in different conditions in order to check if:

- Captured images are good
- System is detecting sperms properly
- Results are reliable



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- There is something user can do for improving the image

For doing this qualitative evaluation, images can be directly opened, similarly than with the previous morphology sessions, and checked WITHOUT INTRODUCING MANUAL CORRECTIONS. This information has to be also included in *resultsEQA2025.xlsx* the Excel file.

Upload results

Go back to mySCA \rightarrow *Quality Control* tab and upload the *resultsEQA2025.xlsx* without zipping it using the section provided for that. It is not required to upload the sessions modified by the user, just the Excel file with the results.

Please select the result's file filled (resultsEQ/	42020):					
Please, click here to upload your EQA results file (xlsx):						
Choose file No file chosen	Upload EQA results					

Otherwise, it is possible to send the Excel file to <u>nmedarde@hamiltonthorne.com</u>

In case some result is considered out of the accepted range according to the reference values, analysis sessions could be requested.

Get the certification report

Once **resultsEQA2025.xlsx** are uploaded, Microptic will analyze them comparing with the ones obtained from our reference laboratory. If results are accepted, an EQA Certificate will be sent to you and posted in mySCA.



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Steps to perform the EQA with SCA SCOPE

Get access to the EQA

- To have access to EQA, system needs to be under maintenance. In case the system is not, please request your maintenance offer from the following link: <u>https://www.micropticsl.com/company/maintenance-information-request/</u>
- 2. Inside SCA SCOPE first window, choose a user and log in (password may be required).
- 3. Go to "OPEN SCA".



4. Click on *mySCA* button from SCA[®] main menu.



If SCA SCOPE does not have Internet connection, EQA files need to be downloaded from another computer. To do this, access mySCA web (<u>https://mysca.micropticsl.com</u>/) <u>from the computer with</u> <u>Internet connection (SCA® ID and password are required)</u>, download the files as explained below and <u>save them in a USB. Then, connect this USB to the SCA SCOPE</u>.

5. MySCA web will be opened.



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	SCA ID 1503347611			
	Acquisition date 2020-04-06	End of maintenance 2022-01-01 More Info		
	SCA version installed 6.5.0.5	SCA edition Human		
	Active Modules	Inactive Modules		
	Motility and Concentration	Capture		
	Morphology	Production		
	Stage Controller	Karyotyping		
	DNA Fragmentation	Droplets		
	Manual Counter	MetaClass		
	DataShare			
	Vitality			

Download required files

1. Go to *Quality Control* tab in the main menu.

|--|

2. User can download all the EQA files in a selected folder of the SCA SCOPE / USB by clicking on the file (it is required to unzip it after downloading). Also, it's possible to download the files individually by clicking on each of the links below.





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Motility and concentration

Opening sessions

1. Still inside "Open SCA" window, create a new sample and patient called "EQA2025". Lastly, save the sample into the database.

ample	: EQA2020 -								
Reference	EQA2020	CHN EQA2	020	Doctor code			٩	Technician	Administrator
Patient				Sample delivered	17:23	• :	1	Comments	
Centre	Laboratory			 Analysis begun 	09/04/202	0	17:53	•	
Motility	centration	0.00	M/ml.	0.00 M/Samp	ble	_) -	
Motility	centration	0.00	M/ml.	0.00 M/Samp	ble	_) -	
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2. In the main menu, go to Sample > Import analysis.



3. Look for the EQA sessions in the unzipped EQA folder and <u>Double click</u> on the session that you want to analyze or click "Open" (each session corresponds to one captured field).



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- 4. System will automatically open the EQA session imported.
- Open the captured field and add/delete sperms manually to have a good analysis, as usually done using Play button

IMPORTANT:

This section has the aim of evaluating the user's ability to detect problems with the system conditions for capturing images. Among all the motility and concentration sessions there are several videos analyzed under non-optimal conditions. In them, you must identify, describe the problem and find out whether or not the analysis can be carried out. Only the results from the optimal videos should be transferred into the table of results "results EQA2025.xlsx"

Some of the EQA videos might be captured at different framerates than this fixed in your system configuration. In these cases, the system will display a warning message informing about it. **Users should just accept warning and review the videos as usual.**



6. Press the results button Results , go to Comparison tab and answer the questions of the *resultsEQA2025.xlsx*



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It is recommended to open the Excel file with the results in another computer instead of SCA SCOPE.

7. After performing manual modifications, save the session by clicking Export > Export session:



1	This PL > Desktop > EQA	2020 > MOT		~ 0	>> Search MOT	
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3D.C	😳 10.mot	17/03/2020 16:24	Microptic SCA MO	15,075 KB		
Deals	😳 11.mot	17/03/2020 16:25	Microptic SCA MO	13,797 KB		
Desk	💼 12.mot	17/03/2020 16:25	Microptic SCA MO	14,779 KB		
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Save as t	vpe: Motility Files (*.mot)					

We recommend saving the modified analysis sessions in case results were not close to the reference values and thus they needed to be checked.

- 8. Close the analysis
- 9. Perform the same steps with the Postreated sample analysis.



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Morphology

Opening sessions

1. Select the same sample previously created (EQA2025).



 Perform the same steps as for motility and concentration. Import Session 1 for morphology (Sample > Import analysis) double clicking on it or by selecting the session and clicking "Open".

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CC_4						
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EQA						
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- 3. System will automatically open the EQA session imported.
- 4. Open the captured fields and add/delete sperms manually. To have a good analysis check each field following this criterion:
 - a. Add sperms clicking on its head (shift + left click).
 - b. Delete if the system captured cells that are not sperm or sperm that are not well analyzed (right click).

It is possible to use "SpermEdit" tool to perform manual modifications faster (change classification and delete sperm). From here, the complete list of sperm cells that have been analysed is available, and it is possible to order it by Abnormality Index to have the most normal sperm cells first and the most abnormal ones at the end of the list:





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Edit Sperra - [2004202103 - 20042021] All * Field * 1 Field *





5. Press the results button **Results** and answer the questions from the *resultsEQA2025.xlsx* file.



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It is recommended to open the Excel file with the results in another computer instead of SCA SCOPE.

6. After performing manual modifications, save the session by clicking Export > Export session:



We recommend saving the modified analysis sessions in case results were not close to the reference values and thus they needed to be checked.

7. Close the session.



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"What's wrong with the image?"

This section aims the evaluation of the user's ability to detect problems with the sample preparation as well as with the system conditions for capturing images. Thus, six different sperm preparations were captured in different conditions in order to check if:

- Captured images are good
- System is detecting sperms properly
- Results are reliable
- There is something user can do for improving the image

For doing this qualitative evaluation, images can be directly imported into the sample, similarly than with the previous morphology sessions, and checked WITHOUT INTRODUCING MANUAL CORRECTIONS. This information must be also included in the *resultsEQA2025.xlsx* Excel file.

Upload results

Go back to mySCA \rightarrow *Quality Control* tab and upload the *resultsEQA2025.xlsx* without zipping it using the section provided for that. It is not required to upload the sessions modified by the user, just the Excel file with the results.



In case some result is considered out of the accepted range according to the reference values, analysis sessions could be requested.

Get the certification report

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