

# MosaiQ® COVID-19 Antibody Magazine



MosaiQ COVID-19 Antibody Magazine

REF 128002

## Instructions for Use



For *in vitro* diagnostic and Laboratory Professional use only

For use under Emergency Use Authorization (EUA) Only

Prescription Use Only

### INTENDED USE

The **MosaiQ COVID-19 Antibody Magazine** is a solid-phase photometric immunoassay performed on single use microarrays for use on the automated **MosaiQ 125** instrument for the qualitative detection of total (IgM and IgG) antibodies to SARS-CoV-2 in human serum and dipotassium (K2) and tripotassium (K3) EDTA plasma. The MosaiQ COVID-19 Antibody Magazine is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The MosaiQ COVID-19 Antibody Assay should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform high complexity tests.

Results are for the detection of SARS-CoV-2 IgM and IgG antibodies. Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The sensitivity of the MosaiQ COVID-19 Antibody assay early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results with the MosaiQ COVID-19 Antibody assay may occur due to cross reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second, different IgG and/or IgM assay.

The MosaiQ COVID-19 Antibody assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

### SUMMARY AND EXPLANATION

At the end of December 2019, Chinese public health authorities reported several cases of acute respiratory syndrome in Wuhan City, Hubei province, China. Chinese scientists soon identified a novel coronavirus as the main causative agent. The disease is now referred to as coronavirus disease 2019 (COVID-19), and the causative virus is called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). It is a new strain of coronavirus that has not been previously identified in humans.<sup>1</sup>

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) is a beta coronavirus that causes the Coronavirus Disease 2019 (COVID-19) and pandemic. SARS-CoV-2 is mainly transmitted through droplets and contact routes, and the virus infects human cells via binding to angiotensin converting enzyme 2 (ACE2).<sup>2,3</sup> Infection with SARS-CoV-2 can cause mild symptoms including a runny nose, sore throat, cough and fever. However, it can be more severe for some people and can lead to pneumonia or breathing difficulties. The elderly and people with pre-existing medical conditions (such as, diabetes and heart disease) appear to be more vulnerable to becoming severely ill with the virus. Based on previous studies on SARS, an incubation period from three to fourteen days after onset of symptoms may be expected.<sup>4</sup>

Specific antibodies to SARS-CoV-2 may be detectable in COVID-19 patients during the symptomatic phase of the disease after RNA is no longer detectable.<sup>5,6</sup> The persistence of IgG antibodies allows identification of people who have been infected in the past, and likely have recovered from the illness.<sup>7</sup> It is unknown if IgG antibodies to SARS-CoV-2 confer immunity to infection. IgG detection and other serological assays will likely play an important role in research and surveillance.<sup>8</sup>

## PRINCIPLE OF THE PROCEDURE

The **MosaiQ COVID-19 Antibody Magazine** is used in combination with the MosaiQ System for the automated determination of the presence of antibodies against SARV-CoV-2 antigens in serum and EDTA plasma specimens, which are produced as part of an immune response against the virus<sup>9</sup>. The use of this magazine in association with the MosaiQ 125 instrument and associated MosaiQ reagents supports the high throughput screening of blood products for professional use within a clinical laboratory setting. The **MosaiQ COVID-19 Antibody Magazine** contains preprinted single use microarrays containing probes of antigens for the presence of antibodies against SARS-CoV-2 within serum and EDTA plasma specimens. MosaiQ microarray technology utilizes miniaturized serological techniques and permits a resource efficient means of performing testing of blood specimens.

The MosaiQ COVID-19 Antibody Magazine test combines antigen-antibody interactions with automated image capture and analysis of the reaction.

Each microarray contained in a magazine is composed of the following panels:

- COVID-19 panel for the qualitative determination of human antibodies against SARS-CoV-2.
- Empty panel without any printed probes.

The patient or control specimen and **MosaiQ Sample Diluent 2** are dispensed together by the MosaiQ 125 instrument into the COVID-19 panel containing the printed antigens and controls. An incubation step allows antibodies to bind the printed antigens. The removal of unbound antibodies using **MosaiQ Wash Buffer 1** precedes addition of **MosaiQ Detection Reagent 1**, a solution containing gold-conjugated secondary antibody that will bind to the human antibodies (IgG and IgM).

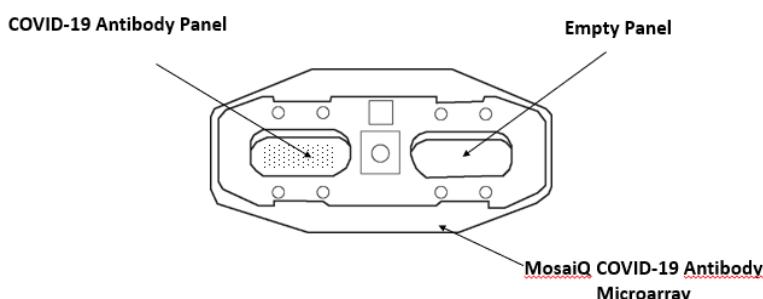
A second wash with **MosaiQ Wash Buffer 1** removes excess detection reagent, while an additional wash with **MosaiQ Wash Buffer 2** prepares the panel for the next stages of the assay. Finally, the addition of the **MosaiQ Enhancement Reagents 1** and **2** allows silver to nucleate around bound gold nanoparticles of the secondary antibody conjugate and subsequent washing with purified water reveals an optically detectable probe ready for imaging and analysis by the MosaiQ instrument.

## REAGENTS

	<b>MosaiQ COVID-19 Antibody Magazine</b>
<b>Catalogue number</b>	128002
<b>Quantity</b>	1 <b>MosaiQ COVID-19 Antibody Magazine</b> per cardboard box
<b>Sufficient for</b>	(1 x 250) 250 assays

Each microarray consists of two panels; one panel intended for SARS-CoV-2 testing and one empty panel.

The magazine has a RFID (Radio Frequency Identification) tag which contains information necessary for the traceability and on-board management such as: catalog number, lot number, expiry date, quantity and on-board stability.



- The **MosaiQ COVID-19 Antibody Magazine** is provided as a ready to use product intended to be loaded for testing onto the MosaiQ 125 instrument. Each magazine (250 microarrays) is packed in a blister with an inert atmosphere.
- This product does not contain natural rubber or latex.
- This product contains bovine serum albumin (BSA) from animals declared free from Transmissible Spongiform Encephalopathies (TSE) / Bovine Spongiform Encephalopathies (BSE) disease in its clinical forms.

## COVID-19 panel

The COVID-19 panel of the microarray contains 1 testing probe in duplicate positions on the array, and 10 control probes.

Testing and positive control probes are diluted in a buffer solution containing glycerol, phosphate-buffered saline (PBS) and sucrose. The negative control probes are made of glycerol, PBS and sucrose solution.

All the probes are printed on functionalized glass and covered with a preservative coating.

N° of probe	Reagent	Reactive ingredient
2	SARS-CoV-2 Antigen	Solution containing SARS-CoV-2 spike protein antigens in a buffered solution
6	Positive control (system processing controls)	Bovine serum albumin conjugated with gold nanoparticles to confirm proper addition of the enhancement reagents during processing. Also aids in the software image detection/analysis
2	Positive control (system processing controls)	Monoclonal anti-E antibodies (mouse monoclonal IgM antibodies from DEM1 cell line) to confirm proper addition of the detection reagent during processing
2	Negative control	Not applicable

## Empty panel

This panel does not contain any printed material and does not support any testing.

## WARNINGS AND PRECAUTIONS

- For use under Emergency Use Authorization only.
- This test has not been FDA-cleared or -approved; this test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform high complexity tests.
- This test has been authorized only for detecting total antibodies (IgM and IgG) against SARS-CoV-2, not for any other viruses or pathogens.
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- For professional use only.
- For *in vitro* diagnostic use only.
- Rx only.
- Use of recommended equipment/material and strict adherence to the procedures are mandatory.
- Do not use if blister or magazine is damaged.
- All specimens from human origin should be considered as potentially infectious. Strict adherence to Good Laboratory Practice (GLP) regulations can ensure personal safety.
- This product contains human and animal blood derivatives. Human blood materials from which this product is derived was found non-reactive for HBsAg, Anti-HCV, Anti-HIV-1 and Anti-HIV-2. No known test method can offer complete assurance that products derived from human and animal blood will not transmit infectious agents. Therefore, all blood derivatives should be considered potentially infectious. It is recommended that these reagents be handled using established good laboratory working practices.
- Refer to the Safety Data Sheet for specific safety information.
- Waste material containing blood specimen or biological products should be considered biohazardous and disposed in compliance with all local and national regulations.

## STORAGE AND HANDLING

- Store at ambient temperature (15-25°C) until the expiration date.
- Do not use microarrays beyond the labeled expiration date (year, month, day: YYYY-MM-DD).
- Do not freeze or expose to excessive heat.
- Store in the original unopened blister package.

## SPECIMEN COLLECTION AND PREPARATION

- Fresh specimens must be stored at 2-8 °C if not tested immediately.
- Specimens must be at ambient temperature prior to use.
- Centrifuge specimen at 2000 to 3000 g for 2 minutes.
- Minimum fill volume in standard sample tubes must be ≥500 µL, the assay uses 5 µL for the test.
- Do not use hemolyzed specimens.
- De-cap specimen tubes before loading on the MosaiQ 125 instrument.

- Load the specimen tubes into MosaiQ 125 instrument via sample rack.

## REAGENTS PREPARATION

- Refer to instructions of the MosaiQ 125 instrument for detailed procedure to load ***MosaiQ COVID-19 Antibody Magazine***.

## PROCEDURE

This product has been designed for use only with the MosaiQ System.

### Material provided

MosaiQ COVID-19 Antibody Magazine.

### Material required but not provided

The assay is performed on the MosaiQ 125 instrument using the following products:

Product name	REF
<b>MosaiQ 125 Instrument</b>	126001
<b>MosaiQ Sample Diluent 1</b>	155001
<b>MosaiQ Sample Diluent 2</b>	155002
<b>MosaiQ Wash Buffer 1</b>	155003
<b>MosaiQ Wash Buffer 2</b>	155004
<b>MosaiQ Detection Reagent 1</b>	155005
<b>MosaiQ Enhancement Reagent 1</b>	155007
<b>MosaiQ Enhancement Reagent 2</b>	155008

For other specific materials needed for the test procedure, please refer to the MosaiQ 125 instrument user manual.

### Test procedure

Testing must be performed using the Disease Screening (DS) test order.

Loading:

1. Open the magazine blister immediately prior to use.
2. Open the magazine station door.
3. Carry out a visual check of the alignment of microarrays. Do not use if misaligned, contact Quotient support.
4. Load the magazine.
5. Close the magazine station door.
6. Wait until the system initializes the loading drum and scans the magazine.

Removing:

1. Open the magazine station door.
2. Pull the upper part of the empty magazine from the drum and lift the magazine out.
3. Close the magazine station door.
4. Dispose the empty magazine.

Please refer to MosaiQ 125 instrument user manual for detailed information.

## QUALITY CONTROL

Quality Control material should be prepared as follows:

**For Negative control material:** Select routine serum or plasma samples that have been collected prior to September 2019 and confirm non-reactive status by testing as a routine sample. Pool all confirmed non-reactive serum or plasma samples and mix thoroughly while avoiding formation of any foam.

Aliquot the pooled serum or plasma samples into aliquots of 1 mL and store at -20 °C ( $\pm 5^{\circ}\text{C}$ ). Prior to use thaw and invert gently to mix the aliquot. Transfer to an appropriately sized sample tube and use to perform routine quality control testing.

**Positive control:** Select routine serum or plasma samples from individuals that have been previously diagnosed with a positive PCR result from an Oral or Nasopharyngeal sample and at least 14 days have passed since the onset of symptoms. Confirm reactive status by testing as a routine sample. Pool all confirmed reactive samples and mix thoroughly avoiding formation of any foam and re-confirm the reactive status by testing as a routine sample.

Aliquot the pooled serum or plasma samples into aliquots of 1 mL and store at -20 °C ( $\pm 5^{\circ}\text{C}$ ). Prior to use thaw and invert gently to mix the aliquot. Transfer to an appropriately sized sample tube and use to perform routine quality control testing.

Unused aliquots can be stored and reused up to 2 days if sealed tightly and stored at 2-8°C.

Do not mix serum and plasma samples together to obtain the pooled sample.

Should clots be present or occur in the individual samples, or the pooled sample after thawing, centrifuge the individual samples or aliquots prior to further use.

The negative control material should result in a non-reactive (NR) result determination as described in "Interpretation of Results" below.

The positive control material should result in a reactive (R) result determination as described in "interpretation of Results" below.

If the quality control material does not perform as expected, thaw and test a second aliquot. If the performance does not return to the expected level, contact Technical Support.

The control intervals should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Control material should be run at a minimum with each day of use, and following a change in magazine lot number. This is in addition to any local, state and/or federal regulations, accrediting groups or laboratory standard quality control procedures or internal requirements for quality control testing that may be established in your facility.

## INTERPRETATION OF RESULTS

Upon completion of the testing procedure, the panel's reactive pattern is analyzed by the instrument software.

The instrument will perform a logical interpretation of probe reactivity to support a qualitative result determination for SARS-CoV-2 antibodies.

The reported result displayed by the MosaiQ 125 instrument is available under the Report tab:

Test results status displayed below C19 (NR: Non-Reactive / R: Reactive)	
SARS-CoV-2 Antibody test results are Non-Reactive	SARS-CoV-2 Antibody test results are Reactive
 (box containing 'NR' in green)	 (box containing 'R' in red)

Images of the reported results (R or NR) displayed in the Report tab are shown below:

Reported Result		C19 -	NR
C19	P1  NR	P2  NR	
-		P1 NR	P2 NR

Reported Result		C19 -	R	NR
C19	P1  R	P2  R		
-		P1 NR	P2 NR	

An image of the result overview displayed in the Finished tab is shown below:

S000563363	2020-08-26	13:14	✓ Finished
			C19 -  R NR
S000560231	2020-08-26	13:14	✓ Finished
			C19 -  NR

Note: Two probes not used for the COVID-19 antibody test, as well as the associated reported result, are currently displayed as “-” with the status reported as NR (in black). This information is not linked to the SARS-CoV-2 Antibody test results and should therefore not be considered.

For information only, the MosaiQ 125 instrument displays the detailed results for each testing probes (P1 and P2 next to C19) in the Disease Screen Profile tab (refer to MosaiQ 125 instrument user manual).

The MosaiQ 125 instrument generates flags in response to different circumstances that are explained here:

#	Name	Reason	Action to be taken
1	Data Reduction Error (DRE)	There is no data returned.	If a data reduction error occurs no results are generated. Retesting is required. Subsequent data reduction errors should be investigated as per laboratory standard operating procedure.
2	Processing Error (PE)	Issue during sample aspiration and/or dispensing	If a processing error occurs no results are generated. Retesting is required. Subsequent processing errors should be investigated as per laboratory standard operating procedure.

## LIMITATIONS

- For use under Emergency Use Authorization only.
- For *in vitro* diagnostic use.
- For professional use only.
- Endogenous interferences have not been demonstrated.
- Do not use grossly hemolyzed or lipemic samples.
- The assay provides a means of investigation of adaptive immune response to infection with SARS-CoV-2 but does not provide information on an active or current infection. Adaptive immune responses may be detected weeks or months post-infection.
- The test has not been authorized for semi-quantitative detections of total SARS-CoV-2 antibodies.
- This device should not be used to diagnose or exclude acute SARS-CoV-2 infection. Direct testing for SARS-CoV-2 with a molecular assay should be performed to evaluate acute infection in symptomatic individuals.
- Results obtained with this assay may not be used interchangeably with values obtained with different manufacturers' test methods.
- A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for a second, but different serology test to confirm an immune response.
- SARS-CoV-2 antibodies may be below detectable levels in patients who have been exhibiting symptoms for less than 15 days. SARS-CoV-2 antibodies may be below detectable levels in patients who are less than 8 days from taking a PCR test.
- A negative result for an individual subject indicates the absence of detectable anti-SARS-CoV-2 antibodies. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies that are detected and are not present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
- Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.
- Results are not intended to be used as the sole basis for patient management decisions. Test results should be interpreted in conjunction with clinical observations, patient history, epidemiological information, and other laboratory findings.
- Specimens with direct evidence of antibodies to non SARS-CoV-2 coronavirus strains (common cold) such as HKU1, NL63, OC43 or 229E have not been evaluated with this assay.
- It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.
- Not to be used to determine SARS-CoV-2 infection in donated blood units. This test should not be used for blood donor screening.

## CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The MosaiQ COVID-19 Antibody Magazine Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-eus>, or at <https://quotientbd.com/covid-19>.

However, to assist clinical laboratories using the MosaiQ COVID-19 Antibody Magazine, the relevant Conditions for Authorization are listed below.

- Authorized laboratories\* using the MosaiQ COVID-19 Antibody Magazine will include the test result reports and all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using the MosaiQ COVID-19 Antibody Magazine will use the product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use the MosaiQ COVID-19 Antibody Magazine are not permitted.

- Authorized laboratories that receive the MosaiQ COVID-19 Antibody Magazine will notify the relevant public health authorities of their intent to run the MosaiQ COVID-19 Antibody Magazine prior to initiating testing.
- Authorized laboratories using the MosaiQ COVID-19 Antibody Magazine will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of the MosaiQ COVID-19 Antibody Magazine and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Quotient Suisse SA at MosaiQfeedback@quotientbdc.com any suspected occurrence of false reactive or false non-reactive results and significant deviations from the established performance characteristics of the MosaiQ COVID-19 Antibody Magazine of which they become aware.
- All laboratory personnel using the MosaiQ COVID-19 Antibody Magazine must be appropriately trained in automated immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the MosaiQ COVID-19 Antibody Magazine.
- Quotient Suisse SA, authorized distributors, and authorized laboratories using the MosaiQ COVID-19 Antibody Magazine will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.
- The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests" as "authorized laboratories."

## SPECIFIC PERFORMANCE CHARACTERISTICS

### Cross-Reactivity

The MosaiQ COVID-19 Antibody Magazine assay was evaluated for potential cross-reactivity with other medical conditions using 181 SARS-CoV-2 seronegative samples (collected before September 2019). No false positive results were observed with the potential cross-reactants summarized in table below:

Sample type/ Clinical category	Number of samples (tested in replicates of three)	Non-reactive	Reactive
ANA Positive plasma	5	5	0
Lupus	7	7	0
Rheumatoid Factor Antibody Positive plasma	10	10	0
HSV-2 IgG Positive plasma	8	8	0
HSV-1 IgG Positive plasma	8	8	0
Rubella IgG Positive plasma	7	7	0
EBV IgG Positive Plasma	10	10	0
Varicella zoster IgG or IgM Positive plasma or serum	7	7	0
Toxoplasma IgG Positive Plasma	9	9	0
Drug Abuser serum Barbiturates	3	3	0
Drug Abuser serum Oxycodone	2	2	0
Drug Abuser serum Benzodiazepines	2	2	0
Lyme IgG Positive plasma	10	10	0
ALT Positive serum	5	5	0
HTLV-I Antibody positive plasma	1	1	0
HTLV-II Antibody positive plasma	9	9	0
HBsAg Positive plasma	6	6	0
Cardiolipin IgA Positive APS plasma	7	7	0
HCV RNA Plasma	7	7	0
HIV 1/2 Antibody Positive plasma	6	6	0
Leptospira IgG positive	3	3	0
Yeast / Candida Albicans	6	6	0
Influenza B Virus Antibody IgA positive	8	8	0
Influenza A IgM & IgG and Influenza B IgM & IgG Antibody positive	4	4	0
Influenza A IgM & IgG Antibody positive	1	1	0
Influenza A IgG Antibody positive	3	3	0

Sample type/ Clinical category	Number of samples (tested in replicates of three)	Non-reactive	Reactive
Influenza A IgG and Influenza B IgG Antibody positive	4	4	0
Influenza A IgM & IgG and Influenza B IgG Antibody positive	3	3	0
Adenovirus Antibody positive	5	5	0
Polio virus Antibody positive	4	4	0
Echovirus Antibody positive	5	5	0
Coxsackie B Antibody positive	6	6	0

## Clinical Agreement

Clinical agreement studies were performed to establish the performance characteristics in terms of Positive Percentage Agreement (PPA) and the Negative Percentage Agreement (NPA).

Positive samples used to demonstrate sensitivity/PPA were taken from patients diagnosed as positive by PCR at least 7 days prior to the collection of the blood sample that was tested in this study.

	True Negative (TN)	True Positive (TP)	False Negative (FN)	False Positive (FP)	Total number of samples
Number of samples	400	30	0	1	431
NPA			99.8% (95% CI: 98.6 - 99.9%)		

Specificity/NPA (TN+FP): 99.8% clinical agreement across samples 401 samples presumed negative.

Sensitivity/PPA (TP+FN) was correlated with days post PCR specimen collection. The results are summarized in the table below:

MosaiQ COVID-19 Antibody Magazine Test Results				
Days Post PCR Specimen Collection*	Number of Samples Tested	Total Antibody Positive Results	Total Antibody PPA	95% CI
0 -7 days	0	0	N/A	N/A
8 -14 days	15	15	100%	78.2 – 100%
≥ 15 days	15	15	100%	78.2 – 100%

\*SARS-CoV-2 positive PCR result confirms presence of virus. Immune response in patient is expected to be latent following initial viral infection.  
N/A = Not Applicable

## External Clinical Agreement

An additional clinical agreement study was conducted at a site external to the manufacturer to establish the performance characteristics in terms of Positive Percentage Agreement (PPA) and the Negative Percentage Agreement (NPA).

Positive samples used to demonstrate sensitivity/PPA were taken from patients diagnosed as positive by PCR at least 7 days prior to the collection of the blood sample that was tested in this study.

	True Negative (TN)	True Positive (TP)	False Negative (FN)	False Positive (FP)	Total number of samples
Number of samples	407	94	6	1	508
NPA	99.8% (95% CI: 98.6 - 100%)				

Specificity/NPA (TN+FP): 99.8% clinical agreement across samples 408 samples presumed negative.

Sensitivity/PPA (TP+FN) was correlated with days post PCR specimen collection. The results are summarized in the table below:

MosaiQ COVID-19 Antibody Magazine Test Results				
Days Post PCR Specimen Collection*	Number of Samples Tested	Total Antibody Positive Results	Total Antibody PPA	95% CI
0-7 days	5	5	100%	47.8 – 100%
8-14 days	9	9	100%	66.4 – 100%
≥ 15 days	86	80	93%	85.4 – 97.4%

\*SARS-CoV-2 positive PCR result confirms presence of virus. Immune response in patient is expected to be latent following initial viral infection.

## Matrix Equivalency

Matrix studies were conducted using matched non-reactive and reactive EDTA plasma and serum specimens from the same donors as well as contrived positive samples representing moderate positive and low positive states of reactivity (1:2 and 1:4, respectively). The contrived positive samples were generated by spiking neat reactive serum into negative serum and neat reactive plasma into negative plasma at the respective dilutions. PPA was 100% across all dilution levels and NPA was 97.2%. Overall agreement between EDTA plasma and serum specimens was 98.6%. The results of the study show consistent performance across claimed specimen matrices, EDTA plasma and serum.

## BIBLIOGRAPHY

1. European Centre for Disease Prevention and Control (2020) COVID-19 Available from: <https://www.ecdc.europa.eu/en/covid-19-pandemic>
2. World Health Organization. Q&A on coronaviruses (COVID-19) (last page update 17 April 2020) Available from: <https://www.who.int/news-room/q-a-detail/q-a-coronaviruses>
3. IFCC Information Guide on COVID-19 (<http://www.ifcc.org/ifcc-news/2020-03-26-ifcc-information-guide-on-covid-19/>)
4. Wang G, Jin X. The progress of 2019 Novel Coronavirus (2019-nCoV) event in China. *J Med Virol.* Doi: 10.1002/jmv.25705
5. Zhao J, Yuan Q, Wang H, et al. Antibody responses to SARS-CoV-2 in patients of novel coronavirus disease 2019. *Clin Inf Dis* Accepted manuscript. Published online 28 March 2020. doi:10.1093/cid/ ciaa344
6. Xiao AT, Gao C, Zhang S. Profile of specific antibodies to SARSCoV-2: the first report. *J Infect* 2020. doi:10.1016/j.jinf.2020.03.012
7. Shen C, Wang Z, Zhao F, et al. Treatment of 5 critically ill patients with COVID-19 with convalescent plasma. *JAMA* Published online March 27, 2020. doi:10.1001/jama.2020.4783
8. World Health Organization. Laboratory testing strategy recommendations for COVID-19: interim guidance, 21 March 2020. World Health Organization
9. European Centre for Disease Prevention and Control (2020). An overview of the rapid test situation for COVID-19 diagnosis in the EU/EEA.

## SYMBOLS

Caution	Consult instructions for use	Catalogue number	Batch code	In-vitro diagnostics medical device	Use- by date	Temperature limit
Contains sufficient for <n> tests	Do not use if package is damaged	Manufacturer	Keep dry	This way up	COVID-19 Antibody Magazine	Rx Only



QUOTIENT SUISSE SA  
Business Park Terre Bonne  
Route de Crassier 13  
1262 Eysins, Switzerland

For customer service information please refer to:  
<https://quotientbd.com/page/contact>



© QUOTIENT SUISSE SA 2020 – ALL RIGHTS RESERVED

# MosaiQ 125

## USER MANUAL

*For use under Emergency Use Authorization (EUA) only.*

*For in vitro diagnostic and Laboratory Professional use only.*

*Prescription Use Only.*



Page intentionally left blank

# TABLE OF CONTENT

<b>1. ABOUT THIS MANUAL</b>	<b>4</b>	<b>13. TROUBLESHOOTING AND ERROR OVERVIEW</b>	<b>145</b>
<b>2. INTENDED USE</b>	<b>12</b>	<b>14. CYBERSECURITY</b>	<b>155</b>
<b>3. PRIOR TO USE</b>	<b>16</b>	<b>15. INSTALLATION AND REMOVAL OF THE MOSAIQ 125</b>	<b>161</b>
<b>4. SAFETY INSTRUCTIONS</b>	<b>22</b>	<b>16. WARRANTY</b>	<b>162</b>
<b>5. MOSAIQ 125 PARTS DESCRIPTION AND LOCATION</b>	<b>29</b>	<b>17. CONTACT QUOTIENT</b>	<b>163</b>
<b>6. GRAPHICAL USER INTERFACE</b>	<b>47</b>	<b>18. TECHNICAL DATA</b>	<b>164</b>
<b>7. OPERATING INSTRUCTIONS</b>	<b>54</b>	<b>19. INDEX</b>	<b>169</b>
<b>8. SAMPLE LOADING AND TESTING</b>	<b>85</b>	<b>20. APPENDIX</b>	<b>170</b>
<b>9. QUALITY CONTROL</b>	<b>110</b>		
<b>10. MOSAIQ 125 SHUTDOWN</b>	<b>115</b>		
<b>11. ADVANCED FUNCTIONS</b>	<b>117</b>		
<b>12. MAINTENANCE</b>	<b>127</b>		

# 1. ABOUT THIS MANUAL

<b>1.1 PURPOSE</b>	<b>5</b>	<b>1.7 TYPOGRAPHICAL CONVENTIONS AND TERMINOLOGY</b>	<b>6</b>
<b>1.2 AUDIENCE</b>	<b>5</b>	1.7.1 SPECIAL TYPES	6
<b>1.3 DISCLAIMER</b>	<b>5</b>	1.7.2 TERMINOLOGY	7
<b>1.4 HOW TO USE THE USER MANUAL</b>	<b>5</b>	1.7.3 CONVENTIONS	7
<b>1.5 GENERAL INFORMATION</b>	<b>5</b>	1.7.4 LIST OF ACRONYMS	7
<b>1.6 VERSION</b>	<b>6</b>	1.7.5 DISPLAY OF WARNINGS AND NOTES	9
1.6.1 EDITION	6	1.7.6 SYMBOLS	9
1.6.2 SOFTWARE	6	<b>1.8 FIGURES</b>	<b>11</b>
		<b>1.9 METRIC SYSTEM</b>	<b>11</b>

### 1.1 PURPOSE

This User Manual provides key information and recommendations on how to use the **MosaiQ 125** safely and effectively. Users must fully understand the **MosaiQ 125** and its functions before performing testing.

The User Manual is accessible on the **MosaiQ 125** software and it can be consulted during the operation of the **MosaiQ 125**. Users can consult the User Manual table of contents as a reference to identify the location of the information they need quickly and easily. For best results, please be sure to read the manual carefully.

This User Manual has been designed to assist users in running assays on the **MosaiQ 125**. It describes both the **MosaiQ 125** and the Graphical User Interface (GUI) of the software. There are step-by-step guides and procedures to illustrate how to use the **MosaiQ 125**.

### 1.2 AUDIENCE

The intended audience for this User Manual is laboratory personnel. **MosaiQ 125** allows any trained person to perform assays.

### 1.3 DISCLAIMER

Quotient Suisse SA reserves the right to make any necessary changes to this information during the course of technical development without prior notice.

Copyright © 2020, Quotient Suisse SA. All rights reserved.

### 1.4 HOW TO USE THE USER MANUAL

This User Manual includes both informational and procedural information about the **MosaiQ 125**. The User Manual contains both general information and also specific procedures regarding **MosaiQ 125**.

- Read all instructions.
- The User Manual is accessible via the GUI of the **MosaiQ 125**.

### 1.5 GENERAL INFORMATION

The **MosaiQ 125** is designed and manufactured in accordance with the safety requirements for electronic equipment and medical devices. It is the user's responsibility to comply with local and national laws, regulations, and laboratory procedures for operation of the **MosaiQ 125**.

The manufacturer guarantees that the equipment functions safely, both electrically and mechanically. The **MosaiQ 125** is tested and supplied by the manufacturer in a condition that enables a safe and a reliable operation.

Under no circumstances can Quotient, its employees, suppliers, or third parties referred to in this manual be held liable, in respect of any proceedings of any kind whatsoever, for the safety and effectiveness of the system or for any loss or harm whatsoever, be it direct or indirect, tangible or intangible, incidental or consequential, or of any kind whatsoever, or for any damage whatsoever, including but not limited to in the cases listed hereunder:

- If the recommendations are not followed or if procedures not described by Quotient are used.
- If reagents (wash buffers, sample diluents, detection reagents, enhancement reagents) other than those manufactured by Quotient are used.
- If sample tubes other than those specifically described in this manual are used, please see the description in [chapter 8.9](#) of this manual.
- If necessary, consumables (SDS Magazines with 50 or 250 microarrays) other than those manufactured by Quotient and sold by Quotient and/or by its official distributors are used.
- If the standard, regular maintenance and control procedures described in this manual, required to ensure the constant proper working order and safety of the system, are not carried out.
- If the system has not been decontaminated in accordance with the decontamination procedures described in this manual.

### 1.6 VERSION

This section details the User Manual version and hence the **MosaiQ 125** system for which this User Manual is prepared. The document version is used to manage multiple versions of a document. Please read the information below to ensure you are using the correct version for your specific **MosaiQ 125** system set-up.

#### 1.6.1 EDITION

**Date:** September 2020

**Reference no.:** MMSURM.0012.01

**Rev.** 1 - 2020-09

#### 1.6.2 SOFTWARE

MosaiQ Software Version 2.0

### 1.7 TYPOGRAPHICAL CONVENTIONS AND TERMINOLOGY

This section details the typographical conventions and terminology conventions used in this **MosaiQ 125** User Manual. To aid readability, the following conventions are used throughout the manual.

#### 1.7.1 SPECIAL TYPES

Certain system components of the GUI such as lights, menu items, fields, buttons, keys and files are indicated in a different typeface or font. Please read the information below for more special types used in the User Manual.

Feature	Typographical Conventions
<i>LEDs and signal lamps</i>	LEDs (Light-Emitting Diode) and signal lamps are printed in bold type. Example: <b>Power LED</b> , <b>Error LED</b>
<i>Menu items and fields</i>	Menu items and fields are printed in bold. Example: <b>File Menu</b>
<i>Buttons</i>	Buttons are printed in bold. Example: <b>Open</b> button
<i>Keys</i>	Keys are printed in bold. Example: Tap on <b>Enter</b>
<i>File examples</i>	File examples are printed in typewriter font. Example: DRIVER=C:\SERVICE\DRIVERS

### 1.7.2 TERMINOLOGY

This section provides information about the meaning of certain words and acronyms used in the user manual.

### 1.7.3 CONVENTIONS

The terms in the tables below are used consistently throughout the manual with a very specific meaning.

#### List of verbs

The table below gives the meaning of frequently used verbs.

Modal verb	Definition
May	This term is understood to grant permission. The user can do the action that is mentioned.
Shall	This term is understood to be mandatory.
Must	Users must do what is required.
Should	This term is understood to be advisory. It would be a good idea for the user to do what is described and compliance is recommended.

#### List of Terms

The table below defines frequently used terms.

Term	Definition
User	The term "User" refers to any person who uses the <b>MosaiQ 125</b> for its intended use.
Service personnel	The term "Service personnel" refers to service personnel authorized by Quotient Suisse SA.

### 1.7.4 LIST OF ACRONYMS

The table below defines frequently used acronyms, abbreviations and units of measure.

Acronyms	Definition
A	Ampere
ABD	Antibody detection or also described as AbID on the GUI
ABO	A, B, O and AB blood groups
AH	Ampere Hour - unit of electric charge
ANSI	American National Standards Institute
ASCII	American Standard Code for Information Interchange
AT	Antigen Typing
C19	Corona Virus Disease 2019
CE / EC	Conformité Européenne (European Community)
CLSI	Clinical And Laboratory Standards Institute
cm	Centimeter
CMV	Cytomegalovirus
Covid19	Corona Virus Disease 2019
dBA	Decibel
DC	Docking Cap
DDC	Disposable Dispense Cartridge
DS	Disease Screening
EMC	Electromagnetic Compatibility
EN	European Standards
EU	European Union
EULA	End-User License Agreement
ft	Feet
GB	Gigabyte

## ABOUT THIS MANUAL / TYPOGRAPHICAL CONVENTIONS AND TERMINOLOGY

Acronyms	Definition
GS1 128	General Specifications Standard, code 128
GUI	Graphical User Interface
Hz	Hertz (frequency unit)
in	Inch
IEC	International Electrotechnical Commission
IFU	Instructions For Use
IH	Immunohematology
IPA	Isopropyl alcohol
IQ	Installation Qualification
ISBT	International Society of Blood Transfusion
ISO	International Organization for Standardization
IVD	In Vitro Diagnostic
kg	Kilogram
L	Liter
lb	Pound
LAN	Local Area Network
LED	Light-Emitting Diode
LIS	Laboratory Information System
Ltd	Limited Liability Company
m	Meter
min	Minute
mL	Milliliter
mW	Microwave radiation

Acronyms	Definition
NaOH	Sodium hydroxide
nm	Nanometer
OQ	Operational qualification
OS	Operating System
PC	Personal Computer
QC	Quality Control
RAM	Random Access Memory
RBC	Red Blood Cell
RFID	Radio Frequency Identification
RS232	Recommended Standard 232
SDS	Serological Disease Screening
SRS	Software Requirement Specification
SSR	Signal to Standard Deviation Ratio
STAT	Short Turnaround Time
Syph	Syphilis
T - AH	Fuse type T: high-breaking capacity
USB	Universal Serial Bus
VAC	Volt
W	Watt
WEEE	Waste Electrical & Electronic Equipment
µL	Microliter
µs	Microsecond
°C	Temperature unit in Celcius
°F	Temperature unit in Fahrenheit

### 1.7.5 DISPLAY OF WARNINGS AND NOTES

This section provides information about the various symbols used in the user manual. In this user manual, safety messages and warnings have specific meanings. The symbol and the associated definition for each term is provided below.

Symbol	Definition
	<b>DANGER</b> Indicates a hazardous situation that, if not avoided, will result in serious injury or death.
	<b>WARNING</b> Indicates a hazardous situation that, if not avoided, could result in serious injury or death.
	<b>CAUTION</b> Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.
<b>NOTICE</b>	<b>NOTICE</b> Indicates information considered important, but not hazard-related (e.g. messages related to property damage). Not following a safety instruction can result in damage to the <b>MosaiQ 125</b> or an adverse effect on operation.
<b>INFO</b>	<b>INFO</b> Complementary information on <b>MosaiQ 125</b> description and/or operation.

### 1.7.6 SYMBOLS

This section provides information about warning symbols used on the **MosaiQ 125**.

#### Warning Symbols

Symbol	Definition
	Caution, risk of danger to person or damage to equipment. Consult User Manual.
	Biohazard
	Hot surface
LASER 2	Laser hazard radiation / do not stare into the beam / class 2 laser product
	Disconnect mains power connector before servicing.

## ABOUT THIS MANUAL / TYPOGRAPHICAL CONVENTIONS AND TERMINOLOGY

### Other Symbols

This section provides information about the informative symbols used on the **MosaiQ 125** and its documentation. On the **MosaiQ 125** type label:

Symbol	Meaning
	Catalogue number
	Serial number
	Caution, consult accompanying documents
	Consult instructions for use
	Manufacturer
	Date of manufacture (YYYY-MM-DD)
	Restriction of certain Hazardous Substances (RoHS) in electronic equipment
	Nemko certification mark for North American market access
	Disposal of electrical and electronic equipment
	Fuse

On the **MosaiQ 125** components:

Symbol	Meaning
	Temperature limit
	Humidity limitations
	Protective earth
	No heavy load
	Waste
	Purified water

## **1.8 FIGURES**

The equipment may vary slightly from the figures shown in this User Manual. However, unless otherwise noted, the procedures are the same.

## **1.9 METRIC SYSTEM**

The **MosaiQ 125**, its equipment and accessories have been developed and built using the metric system. Units of measurement are given using the metric system. All fasteners such as screws and nuts used in the **MosaiQ 125** have metric dimensions. Users must be sure to have the appropriate tools, such as metric wrenches and screwdrivers. Do not use screws and nuts from a non-metric system.

## **2. INTENDED USE**

<b>2.1</b>	<b>INTENDED USE</b>	<b>13</b>
<b>2.2</b>	<b>MOSAIQ SYSTEM COMPOSITION</b>	<b>13</b>
<b>2.3</b>	<b>PRINCIPLES OF OPERATION</b>	<b>13</b>
2.3.1	MOSAIQ 125 PROCESS WORKFLOWS	13
<b>2.4</b>	<b>RESULTING PRINCIPLES</b>	<b>15</b>
2.4.1	IMAGING	15
2.4.2	IMAGE ANALYSIS	15
2.4.3	INTERPRETATION	15

### 2.1 INTENDED USE

The **MosaiQ 125** is an automated instrument intended for the qualitative immunohematology testing and infectious disease screening of human blood using MosaiQ magazines and MosaiQ system reagents.

It is intended for professional use within a blood donor or clinical laboratory environment.

For use under Emergency Use Authorization only.

- This test has not been FDA-cleared or -approved; this test has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform high complexity tests.
- This test has been authorized only for detecting total antibodies (IgM and IgG) against SARS-CoV-2, not for any other viruses or pathogens.
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

#### NOTICE

- Immunohematology testing (IH) is defined by antigen typing and antibody detection. Currently the **MosaiQ 125** cannot perform antigen typing (AT) and antibody detection (ABD). For this reason, please ignore any reference to IH (AT and ABD) in the GUI.
- Please, consider that SDS (Serological Disease Screening) is limited to Covid19 assay only.

### 2.2 MOSAIQ SYSTEM COMPOSITION

The MosaiQ System is made up of the following key components:

- The **MosaiQ 125** consisting of:
  - Various hardware modules, some of them controlled by firmware running on various micro-controllers.
  - MosaiQ Software driving the Graphical User Interface (GUI).
- The **MosaiQ COVID-19 Antibody Magazine**.
- The associated MosaiQ system reagents (sample diluents, wash buffers, detection reagents and enhancement reagents) needed to run the assay.
- System liquid (purified water).

### 2.3 PRINCIPLES OF OPERATION

This section describes the principles of operation governing the **MosaiQ 125** test orders process.

#### 2.3.1 MOSAIQ 125 PROCESS WORKFLOWS

Centrifuged and decapped blood sample tubes are loaded into the **MosaiQ 125**.

The **MosaiQ 125** is designed for the fully-automated testing of blood donor samples. It consists of an analyzer which performs serological disease screening assays based on a qualitative *in vitro* detection method.

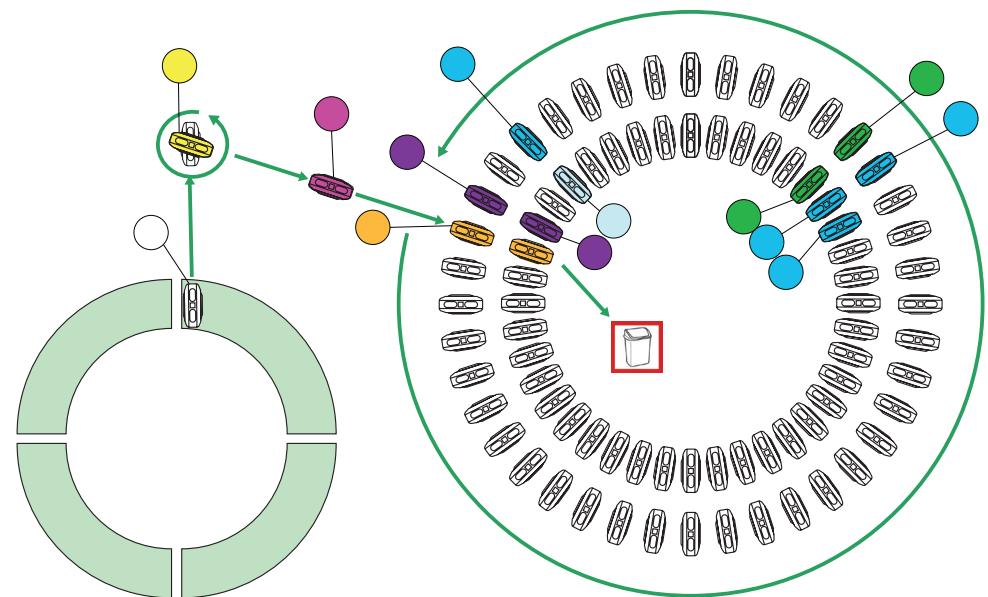
The analytical process is entirely automated. It is composed of several steps and is assay dependent. The different steps (sample dilution, shaking, incubation, washing, reagent dispensing) are performed by hardware or fluidic modules controlled by software.

## INTENDED USE / PRINCIPLES OF OPERATION

The detail of the microarray processing is described in the following figure and table.  
The microarray processing is entirely automated.

Process Step	Description
 <b>Microarray transport</b>	The microarray is extracted from the magazine and transported to the microarray turntable module.
 <b>Pipetting</b>	The pipettor module dispenses sample containing the targeted analyte into the microarray wells. The appropriate sample diluent is dispensed in accordance with the type of assay. The diluents are used to dilute the sample and enhance the binding during the incubation. The diluents also initiate the dissolving process of the microarray's preservative coating to expose the printed probes to the analyte.
 <b>Shaking</b>	The microarray is shaken by the piezoelectric shaking module to reach the required homogeneity.
 <b>Incubation</b>	The incubator module keeps the microarrays at the required temperature as it moves the microarrays through the different process modules. The targeted analyte binds the printed probes depending on the specificity.
 <b>Washing</b>	Washing 1: The appropriate wash buffer is used to remove the excess of sample and diluent. Washing 2: The appropriate wash buffers are used to remove the excess of the detection reagents needed for the assay (if applicable).
 <b>Dispensing</b>	The dispensing steps, if applicable, are used for the addition of the associated detection and enhancement reagents resulting in a detectable reaction.
 <b>Rinsing</b>	The system liquid is used to remove the excess of the enhancement reagents needed for the assay (if applicable), to reveal a clean panel ready for imaging.
 <b>Imaging</b>	The camera module takes an image of the processed microarray. The MosaiQ Software analyzes and interprets this image to provide the assay result.
 <b>Disposal</b>	The single use microarray is finally disposed of into the solid waste container.

As shown in the following illustration, the microarray is transported from the magazine to dedicated positions on the incubation ring corresponding to the different analytical processing steps until imaging and final disposal.



(microarray positions during processing)

### INFO

Each microarray contained inside the MosaiQ magazines is made of two plastic chassis enclosing two panels. The panels are made of functionalized glass onto which samples of various biological materials are printed. Control spots are also printed to verify that the **MosaiQ 125** has properly dispensed the MosaiQ system reagent and/or sample on the microarray during the assay.  
For more information on this topic, please refer to the **MosaiQ COVID-19 Antibody Magazine** instructions for use (IFU).

## 2.4 RESULTING PRINCIPLES

The resulting process begins at the end of the biological reaction.



It is based on three main phases which are automated on the MosaiQ Software; imaging, image analysis and interpretation, as described thereafter.

Although the structure of the resulting process is common, certain assay specific parameters may apply.

### 2.4.1 IMAGING

Upon completion of the analytical process, the microarray is ready for imaging.

A software controlled high-resolution camera captures a black and white image of the microarray under assay dependent, controlled illumination conditions. The resulting image is stored as an image file for subsequent analysis.

### 2.4.2 IMAGE ANALYSIS

Different metrics are used for image analysis. A parameter called the Signal to Standard Deviation Ratio (SSR) is used to measure the intensity of the microarray panel spots in relation to the background. The intensity of each spot is qualified into one of these three possible states:

- Reactive
- Non-reactive
- Technical Error: if for technical reasons (spot morphology, characteristics of analyzed spot) the status of the spot cannot be defined as reactive or non-reactive.

The mathematical definition of the SSR is as follows:

$$\text{SSR} = \frac{\text{Mean (Signal)} - \text{Mean (Background)}}{\text{StD (Background)}}$$

With:

- Mean (Signal): Mean value of the grey level of the spot signal calculated on the area of the spot.
- Mean (Background): Mean value of the grey level of the background surrounding the spot calculated on the area of the background.
- StD (Background): Standard deviation of the background surrounding the spot, calculated on the area of the background.

### 2.4.3 INTERPRETATION

Each spot of the panel that has been given one of the 3 possible states is interpreted by group or individually by the software to determine the reportable result.

The algorithm used for the interpretation is specific to each analyte. For detailed information about the interpretation algorithms, please refer to the instructions for use for the related assay.

### **3. PRIOR TO USE**

<b>3.1</b>	<b>USER QUALIFICATION</b>	<b>17</b>
3.1.1	USER QUALIFICATION	17
3.1.2	ADVANCED USER QUALIFICATION (LABORATORY ADMINISTRATOR)	17
3.1.3	USER TRAINING	17
<b>3.2</b>	<b>EQUIPMENT OVERVIEW</b>	<b>18</b>
3.2.1	MOSAIQ MAGAZINES	18
3.2.2	MOSAIQ SYSTEM REAGENTS	18
3.2.3	MOSAIQ WATER CANISTER	19
3.2.4	MOSAIQ QUALITY CONTROLS	20
3.2.5	SAMPLES	20
3.2.6	SAMPLE RACKS	20
3.2.7	SYSTEM WASTE	21

This section provides information that must be taken into consideration before using the **MosaiQ 125**.

## 3.1 USER QUALIFICATION

The equipment is intended for professional use within a blood establishment. Only trained laboratory personnel are authorized to use the **MosaiQ 125**.

### 3.1.1 USER QUALIFICATION

The laboratory personnel will be trained to perform tasks such as:

- Follow general laboratory procedures and techniques.
- Understand and follow all relevant safety rules and safety regulations.
- Understand and follow the chemical manufacturer's safety data sheets.
- Operate the **MosaiQ 125**.
- Perform **MosaiQ 125** maintenance.

### 3.1.2 ADVANCED USER QUALIFICATION (LABORATORY ADMINISTRATOR)

The advanced users, commonly known as laboratory administrators, will be trained to perform additionally tasks that are restricted to their function such as:

- Manage user profiles on the **MosaiQ 125**.
- Select the type of assays to run on the **MosaiQ 125**.
- Access to different sub-menus.
- Operate the **MosaiQ 125**.
- Perform **MosaiQ 125** maintenance.

For more details about roles and access rights, please refer to the [Appendix](#) of this manual.

### 3.1.3 USER TRAINING

To minimize any potential risk, prior to the use of the **MosaiQ 125**, the user must be trained to:

- Download the appropriate user manual, the instructions for use and the safety data sheets for every product required to use the **MosaiQ 125** from the customer portal.
- Use the **MosaiQ 125** properly.
- Prevent injury related to electrical hazards.
- Prevent bio contamination and biohazards.
- Prevent any injury related to sharp edges.
- Perform maintenance tasks on the **MosaiQ 125** and the accessories.

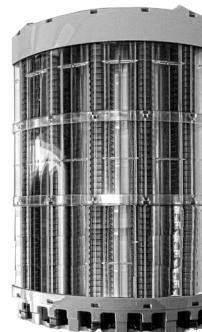
## 3.2 EQUIPMENT OVERVIEW

This section provides information on the materials that are required to operate the **MosaiQ 125**.

### 3.2.1 MOSAIQ MAGAZINES

The MosaiQ Quantum Magazine is used to hold the microarrays. Each magazine has a RFID (Radio Frequency Identification) Tag which contains information necessary for the traceability and the on-board management such as: catalog number, lot number, expiry date, volume and on-board stability.

**The MosaiQ Quantum Magazine with a capacity of 250 microarrays.**



(MosaiQ Quantum Magazine - for illustrative purposes)

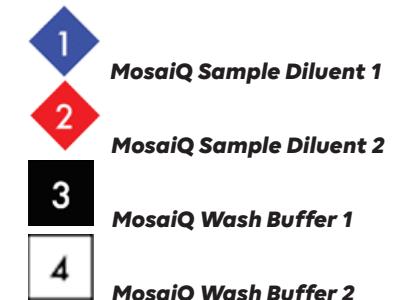
For detailed information please refer to the appropriate MosaiQ Magazine IFU.

### 3.2.2 MOSAIQ SYSTEM REAGENTS

Various reagents, including MosaiQ sample diluents, MosaiQ wash buffers, MosaiQ detection reagents and MosaiQ enhancement reagents. They are necessary to perform assays. Each bottle has a RFID (Radio Frequency Identification) Tag which contains information necessary for the traceability and the on-board management such as: catalog number, lot number, expiry date, volume.

There are two types of bottles:

- The DC (Docking Cap) bottles for MosaiQ wash buffers and MosaiQ sample diluents which are loaded in the reagent drawer. For more information please refer to [chapter 5.8](#) of this manual.



(MosaiQ wash buffers and MosaiQ sample diluents bottles)

For detailed information please refer to the appropriate IFU.

- The DDC (Disposable Dispense Cartridge) for MosaiQ detection and MosaiQ enhancement reagents which are loaded in the **MosaiQ 125** behind the reagent door. For more information please refer to [chapter 5.9.1](#) of this manual.



- 5** **MosaiQ Detection Reagent 1**
- 6** **MosaiQ Detection Reagent 2**
- 7** **MosaiQ Enhancement Reagent 1**
- 8** **MosaiQ Enhancement Reagent 2**

(MosaiQ detection and MosaiQ enhancement reagent bottles)

For detailed information please refer to the appropriate IFU.

### 3.2.3 MOSAIQ WATER CANISTER

Two water canisters.



(two water canisters)

Water canisters (reusable)	Purpose
<b>System liquid (purified water)</b>	<ul style="list-style-type: none"> <li>Used to clean the pipettor needles,</li> <li>Mixed with wash buffer according to the required concentration,</li> <li>Used to perform rinsing and cleaning operation</li> </ul>

### 3.3 MOSAIQ QUALITY CONTROLS

Quality Controls (QC) are used to ensure that disease screening is performed as intended.

**NOTICE**

Perform regular quality control of the **MosaiQ 125** at least once daily and as per laboratory and or regional specific requirement.

Laboratories must validate their own quality control method for the assays performed by MosaiQ.

Please, refer to [chapter 9](#) of this manual.

### 3.3.1 SAMPLES

**NOTICE**

For detailed information about sample preparation please follow the instructions for use for **MosaiQ COVID-19 Antibody Magazine**.

To load samples please refer to [chapter 8.3](#) of this manual.



(illustration of a filled sample tube)

#### 3.3.2 SAMPLE RACKS

Sample tubes are loaded onto the **MosaiQ 125** in MosaiQ sample racks. Twelve sample tubes can be loaded onto one rack, and in turn, ten racks can be inserted into the **MosaiQ 125**. In total 120 samples can be loaded at any one time.

During each run, the **MosaiQ 125** associates the barcode of each tube with a corresponding barcode on the rack.

To identify the sample rack, the **MosaiQ 125** needs to read the code label (near the handle) of the rack.



(sample rack with sample tubes)

1

**“% A”** stands for standard rack

Table 1

The **MosaiQ 125** accepts uncapped tubes.

Please refer to the list of appropriate sample tubes at [chapter 8.11](#). The minimum fill volume in a standard tube for routine samples shall be  $\geq 500 \mu\text{l}$ .

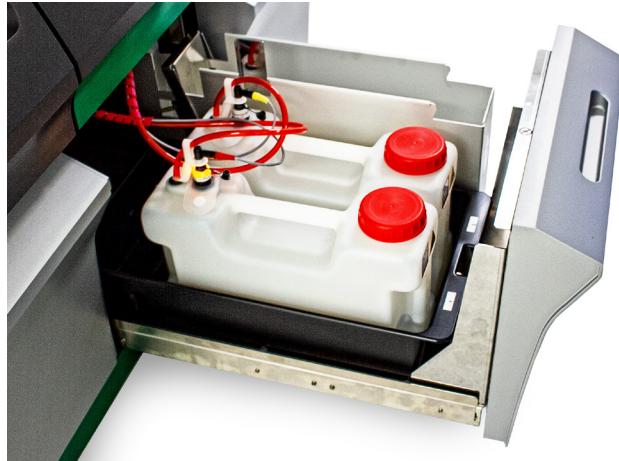
**NOTICE**

Please consult our catalog for tube size adapters and contact your local technical representative for the appropriate **MosaiQ 125** configuration.

### 3.3.3 SYSTEM WASTE

The following different container and canisters are provided with the **MosaiQ 125**:

- Solid waste container that is built into the **MosaiQ 125** (to be used with biological waste bags).
- Liquid waste canisters.



(one solid waste container and two liquid waste canisters)

# 4. SAFETY INSTRUCTIONS

<b>4.1 GENERAL SAFETY</b>	<b>23</b>
<b>4.2 ELECTRICAL SAFETY</b>	<b>24</b>
<b>4.3 BIOLOGICAL SAFETY</b>	<b>25</b>
<b>4.4 SAFETY AND TIPS ABOUT DISPOSAL AND DECONTAMINATION</b>	<b>25</b>
<b>4.5 POSITIONS OF SAFETY LABELS AND TYPE LABEL</b>	<b>26</b>
4.5.1 MISSING WARNINGS	26
4.5.2 POSITIONS OF SAFETY LABELS	27
4.5.3 POSITIONS OF ALL OTHER LABELS	27
<b>4.6 RADIO INTERFERENCE</b>	<b>28</b>
<b>4.7 LABORATORY EQUIPMENT</b>	<b>28</b>

## 4.1 GENERAL SAFETY

For the overall safety of laboratory personnel and equipment, please read the following information regarding general safety precautions before operating the **MosaiQ 125**.

### Not Following Safety Instructions

#### **WARNING**

Not following safety instructions may result in personal injury and material damage.

- Follow all safety instructions included in this manual
- Follow all warnings marked on the **MosaiQ 125**.

### Improper Use of the MosaiQ 125

#### **WARNING**

Improper use of the **MosaiQ 125** can cause personal injury, produce erroneous results and cause damage to the **MosaiQ 125**.

- The handling and maintenance of the **MosaiQ 125** shall be performed only by trained and authorized personnel.
- For more information about the maintenance of the **MosaiQ 125** please read [chapter 12](#) of this manual.
- Before operating the **MosaiQ 125**, the User Manual shall be read in full and completely understood.
- Only use the **MosaiQ 125** in accordance with the intended use as described in this manual.
- Use only the approved equipment and accessories described herein (e.g. microarrays, reagent bottles etc.)
- The manufacturer assumes no liability for any damage, including those to third parties, caused by improper use or handling of the **MosaiQ 125**.

### Missing, Improperly Opened, Damaged or Opened Protective Covers

#### **WARNING**

To avoid serious injuries with deadly consequences due to electric shock or injuries by the **MosaiQ 125** (e.g. contusion, cuts etc.), secured protective covers may only be opened or removed for certain maintenance procedures and with the highest level of caution.

- Only perform the maintenance procedures described in this manual.
- Make sure that no one is working on the **MosaiQ 125** and that all covers are attached and closed before reconnecting the **MosaiQ 125** to the mains power supply.
- Make sure that all covers are attached and intact before switching on the **MosaiQ 125**.
- Switch off the **MosaiQ 125**, disconnect it from the mains power supply and protect the **MosaiQ 125** against restarting if protective covers/gears are missing or damaged.
- Make sure that the motion of the pipettor, magazine station, or reagent carriage has stopped before opening covers and/or accessing the working area of the **MosaiQ 125**.
- Do not touch the pipettor, magazine station, or reagent carriage and other moving parts while the **MosaiQ 125** is in operation.
- Follow the safety instructions provided in this manual for all maintenance procedures.

### Overheating

#### **WARNING**

Improper positioning of the **MosaiQ 125** may cause fire or serious damage to the **MosaiQ 125** in case of overheating.

- Do not block or cover ventilation slots.
- The air must be able to circulate.



(ventilation slots)

### Sharp Edges

#### ⚠ WARNING

Sheet metal parts and circuit boards located behind protective covers may have sharp edges. Contact may lead to injuries.

- Use caution at corners and edges.

### Unauthorized Changes to the MosaiQ 125

#### ⚠ WARNING

Any changes to the **MosaiQ 125** that are not authorized by the manufacturer will lead to non-conformity with respect to the applicable regulations the manufacturer has declared. In this case, the customer is responsible for fulfilling the applicable regulations.

- Do not make unauthorized changes to the **MosaiQ 125**.

## 4.2 ELECTRICAL SAFETY

For the overall safety of laboratory personnel and equipment, please read the following information regarding electrical safety precautions before operating the **MosaiQ 125**.

**MosaiQ 125** complies with the following electrical safety standards:

- IEC 61010-1
- IEC 61010-2-010
- IEC 61010-2-101

### Not Following Rules and Regulations

#### ⚠ DANGER

Not following rules and regulations may cause serious personal injury with deadly consequences and material damage.

- National rules and legal regulations for the safe electrical operation of the **MosaiQ 125** must be observed.

### Improper Connection of Mains Power Supply

#### ⚠ DANGER

Improper connection of the **MosaiQ 125**, and peripheral devices to the mains power supply can cause serious personal injury with potential deadly consequences and material damage (e.g. fire).

- Only use grounded connectors and power cords with sufficient capacity (voltage and current) to connect the **MosaiQ 125** and PC to the mains power supply.
- Never remove ground connections.
- The use of a multi-outlet power strip is prohibited.
- Only use power cords that are provided with the **MosaiQ 125**.

### Damaged Power cords

#### ⚠ DANGER

Damaged power cords may cause serious personal injury with potentially deadly consequences and material damage (e.g. fire).

- Damaged power cords must be replaced immediately,
- No objects may be placed on the power cords,
- Power cords must be installed so that they cannot be squeezed or damaged,
- Power cords must be laid so that they do not lay in accessible areas.

### Electric Shock by Electrical Devices on Wet Surfaces

#### ⚠ DANGER

Working with electrical devices on wet surfaces (floors, worktable) may cause serious injuries with deadly consequences and material damage due to electric shock.

- Only work on dry surfaces (floors, worktable).

### Emergency Shutdown in Case of Malfunction

#### ⚠ DANGER

Malfunction of the **MosaiQ 125** may cause electrical shock, burns, cuts or contusions.

- Use the main switch to switch off the **MosaiQ 125** or the mains plug to disconnect the **MosaiQ 125** from the mains power supply.

### Obstruction of Access to Mains Power Supply

#### DANGER

Improper positioning of the **MosaiQ 125** can cause accidents, fire or serious damage to the **MosaiQ 125** because it cannot be switched off or disconnected from the mains power supply.

- Ensure that the power supply and mains switch are easily accessible.

## 4.3 BIOLOGICAL SAFETY

For the overall safety of laboratory personnel and equipment, please read the following information regarding biological safety precautions before operating the **MosaiQ 125**.

### Risk of Infection

#### DANGER

The **MosaiQ 125** must be treated as potentially infectious. Improper handling of infectious parts will cause skin irritations, illnesses and possible death.

- Strictly follow the local and national provisions, legislation and laboratory regulations.
- Strictly follow your laboratory rules regarding protective clothing.
- Avoid contact between wound /mucus membrane and samples/test reagents or parts of the **MosaiQ 125**.
- Clean, disinfect and decontaminate the **MosaiQ 125** immediately if potentially infectious material has been spilled.
- Do not use broken or chipped tubes or bottles.
- Observe the instructions for the correct use of reagents.
- Observe the legal regulations for the handling of infectious or potentially infectious material.
- The **MosaiQ 125** will be cleaned, disinfected and decontaminated before servicing. For more information please refer to [chapter 12](#) of this manual.

### Organic Solvents

#### NOTICE

Canisters and hoses can be seriously damaged by some organic solvents and become unusable. Please follow the cleaning instructions provided in this manual.

## 4.4 SAFETY AND TIPS ABOUT DISPOSAL AND DECONTAMINATION

The following information is provided to ensure the safe handling, decontamination and disposal of system fluids, electrical equipment, batteries, infectious waste, non-contaminated parts and decontamination products.

### Electrical and Electronic Equipment



The European directive about the waste of electrical and electronic equipment (WEEE) statement is applicable only to European countries. At the end of the life cycle of the **MosaiQ 125**, do not dispose of the device as unsorted municipal waste, even if it is decontaminated. Please refer to the dismantling and recycling instructions available at Quotient Suisse SA. Additionally, the **MosaiQ 125** may be shipped to Quotient for recycling in accordance with the WEEE regulations. Refer to contract terms and conditions for applicable recycling and shipping fees.

### Misuse of Battery

#### WARNING

The product contains an internal lithium battery. There is a risk of fire and explosions, which can cause burns if the battery is not handled properly.

#### INFO

The only battery used in the **MosaiQ 125** is part of the computer workstation.

- Do not attempt to recharge the battery.
- Do not expose the battery to temperatures higher than 60°C (140°F).
- Do not disassemble, crush, puncture, short external contacts, or expose the battery to fire or water.
- Spare batteries must match the values (nominal voltage, nominal current, and type) specified by the manufacturer.
- Dispose of used batteries according to the local and national provisions or legislation in force in your country.

### Chemical Waste

Chemicals must be disposed of according to the regulations in force in your country.

### Infectious Waste

#### WARNING

Potentially infectious materials and all parts that may come in contact with potentially infectious materials can cause severe contamination.

- Strictly follow the local and national provisions or legislation and laboratory regulations in force in your country.

### Disposal of Non-Contaminated Parts

- Strictly follow the local and national provisions or legislation and laboratory regulations in force in your country.

### Handling of Cleaning and Decontamination Solutions

#### **NOTICE**

Decontamination products may be hazardous. Please, follow the safety instructions provided on the product packaging and IFU.

- Strictly follow the local and national provisions, legislation and laboratory regulations.
- Do not mix bleach or decontamination liquid with alcohol.
- Do not use incompatible decontamination products.
- Please follow the cleaning instructions provided in this manual.

## 4.5 POSITIONS OF SAFETY LABELS AND TYPE LABEL

This section provides information on the various positions and types of safety labels used on the **MosaiQ 125**.

### 4.5.1 MISSING WARNINGS

This section provides information on the dangers and risks of missing warning labels.

#### WARNING

Missing or unreadable warning labels or type labels will result in non-identified dangers. This could result in serious personal injury and material damage.

- Check the **MosaiQ 125** for missing or unreadable warning labels and type labels.
- Missing or unreadable warning labels or type labels must be replaced.
- Please contact customer service.

#### 4.5.2 POSITIONS OF SAFETY LABELS

This section provides information on where to find safety labels on the **MosaiQ 125**.

Label	Type	Position
	<b>General Warning</b>	<ul style="list-style-type: none"> <li>On the magazine station door</li> <li>On the door of the process modules</li> </ul>
	<b>Biological Hazard</b>	<ul style="list-style-type: none"> <li>On the liquid waste canisters</li> <li>On the solid waste container</li> <li>On the pipettor wash station</li> </ul>
	<b>Hot Temperature</b>	<p>Hot surface label:</p> <ul style="list-style-type: none"> <li>On the left side of the front pump panel</li> <li>On the left side of the pipettor sledge</li> <li>On the right side of the pipettor sledge</li> </ul>
	<b>Electrical Hazard</b>	Above the power switch
	<b>Laser Radiation</b> <b>Do not stare into beam</b> <b>Class 2 laser product</b>	Next to the barcode scanner of the Sample Station
	<b>Laser Information / Technical Data</b>	

#### 4.5.3 POSITIONS OF ALL OTHER LABELS

Label	Type	Position
	<b>Fuse</b>	Above the power switch
	<b>No heavy load</b>	<ul style="list-style-type: none"> <li>On the top of the reconstitution drawer</li> <li>On the top of the waste drawer</li> <li>On the top of the water drawer</li> </ul>
	<b>Purified water (System liquid)</b>	<ul style="list-style-type: none"> <li>On the water canisters</li> </ul>
	<b>Waste</b>	<p>Waste container label:</p> <ul style="list-style-type: none"> <li>On the liquid waste canisters</li> <li>On the solid waste container</li> </ul>
	<b>Type label</b>	On the back, left-hand side of the <b>MosaiQ 125</b> .

## 4.6 RADIO INTERFERENCE

This section provides information about the risks of radio interference and the safe operation of the **MosaiQ 125**.

**MosaiQ 125** is a class A digital device in accordance with CISPR 11 and a Class 1 device according Radio Equipment Directive(2014/53/EU). **MosaiQ 125** complies with the following standards and directives for information concerning radio interference:

- EN 61326-2-6 (Class A for emissions) and EN 61326-1.
- ETSI EN 300 330 V2.1.1
- Radio Equipment Directive (2014/53/EU).

### Electromagnetic Compatibility (EMC)

#### INFO

The **MosaiQ 125** complies with the emissions and immunity requirements as described in standard IEC 61326-2-6. The **MosaiQ 125** has been developed and tested according to CISPR11 Class A. It may cause radio interference in domestic environments. If the **MosaiQ 125** causes radio interference, you may need to take measures to eliminate the interference.

The electromagnetic environment shall be evaluated before installation and operation of the **MosaiQ 125**.

Do not use the **MosaiQ 125** in the proximity of sources with excessive electromagnetic radiation (e.g. unshielded, deliberately operated high frequency sources) since they could interfere with the proper operation of the **MosaiQ 125**.

### Risk of harmful interference

#### INFO

The **MosaiQ 125** complies with Radio Equipment Directive requirements through application of ETSI EN 300 330 V2.1.1 standard.

## 4.7 LABORATORY EQUIPMENT

#### WARNING

All biological materials must be regarded as being potentially hazardous. All cuts and abrasions on hands must be covered. Gloves and safety glasses should be worn when handling samples and biological materials.

#### CAUTION

Strictly follow your laboratory rules regarding protective clothing.

#### INFO

The **MosaiQ 125** has been designed and developed as laboratory equipment in accordance to the requirements of the EC directive 98/79/EC (*in vitro* diagnostic (IVD) medical devices directive).

# 5. MOSAIQ 125 PARTS DESCRIPTION AND LOCATION

<b>5.1 EXTERNAL PARTS</b>	<b>30</b>	<b>5.10 REAGENT DRAWER</b>	<b>40</b>
<b>5.2 INTERNAL PARTS</b>	<b>31</b>	<b>5.11 PROCESS MODULES</b>	<b>41</b>
<b>5.3 POWER SWITCH AND MAINS POWER OUTLET</b>	<b>33</b>	5.11.1 REAGENT CARRIAGE	42
<b>5.4 VISUAL ALERT / ALARM</b>	<b>33</b>	5.11.2 WASHER MODULES	43
<b>5.5 TOUCH SCREEN</b>	<b>34</b>	5.11.3 INCUBATOR MODULE	43
<b>5.6 MAGAZINE STATION</b>	<b>35</b>	5.11.4 CAMERA MODULE	44
<b>5.7 SAMPLE STATION</b>	<b>36</b>	5.11.5 MICROARRAY TURNTABLE AND PUSHER	44
<b>5.8 WASTE DRAWER</b>	<b>37</b>	5.11.6 PIPETTOR MODULE	45
<b>5.9 WATER DRAWER</b>	<b>38</b>	<b>5.12 MATERIAL AND ACCESSORIES</b>	<b>46</b>
5.9.1 WATER CANISTERS	38	5.12.1 MATERIAL PROVIDED	46
5.9.2 COMPUTER WORKSTATION	39	5.12.2 ACCESSORIES	46

This section provides information about the various components (parts) of the **MosaiQ 125** and where to find them.

### 5.1 EXTERNAL PARTS

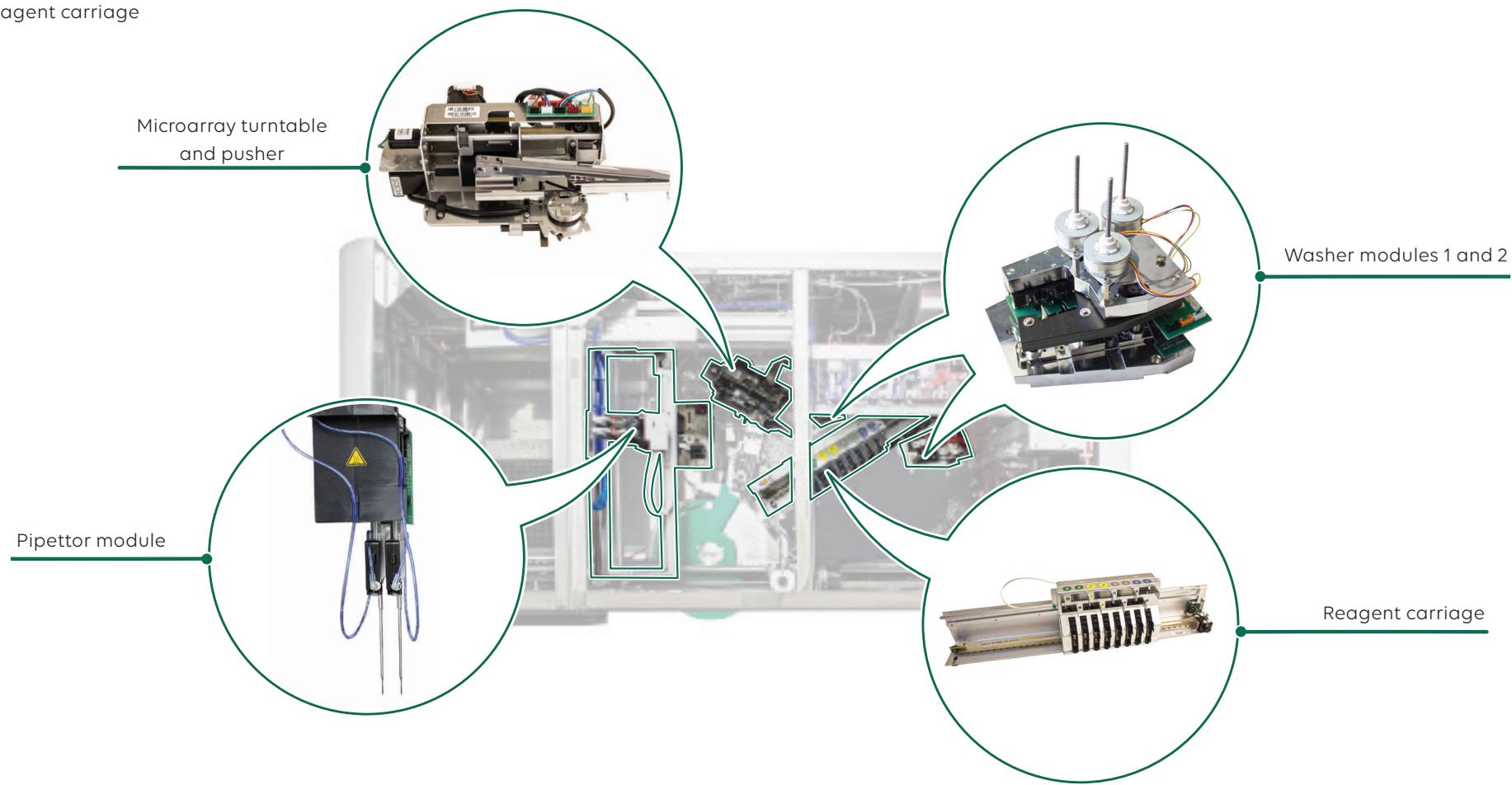
- Touch screen
- Magazine station
- Sample station
- Waste drawer
- Visual alarm/alert
- Reagent door
- Power switch
- Reagent drawer
- Water drawer



(MosaiQ 125 external parts localization)

### 5.2 INTERNAL PARTS

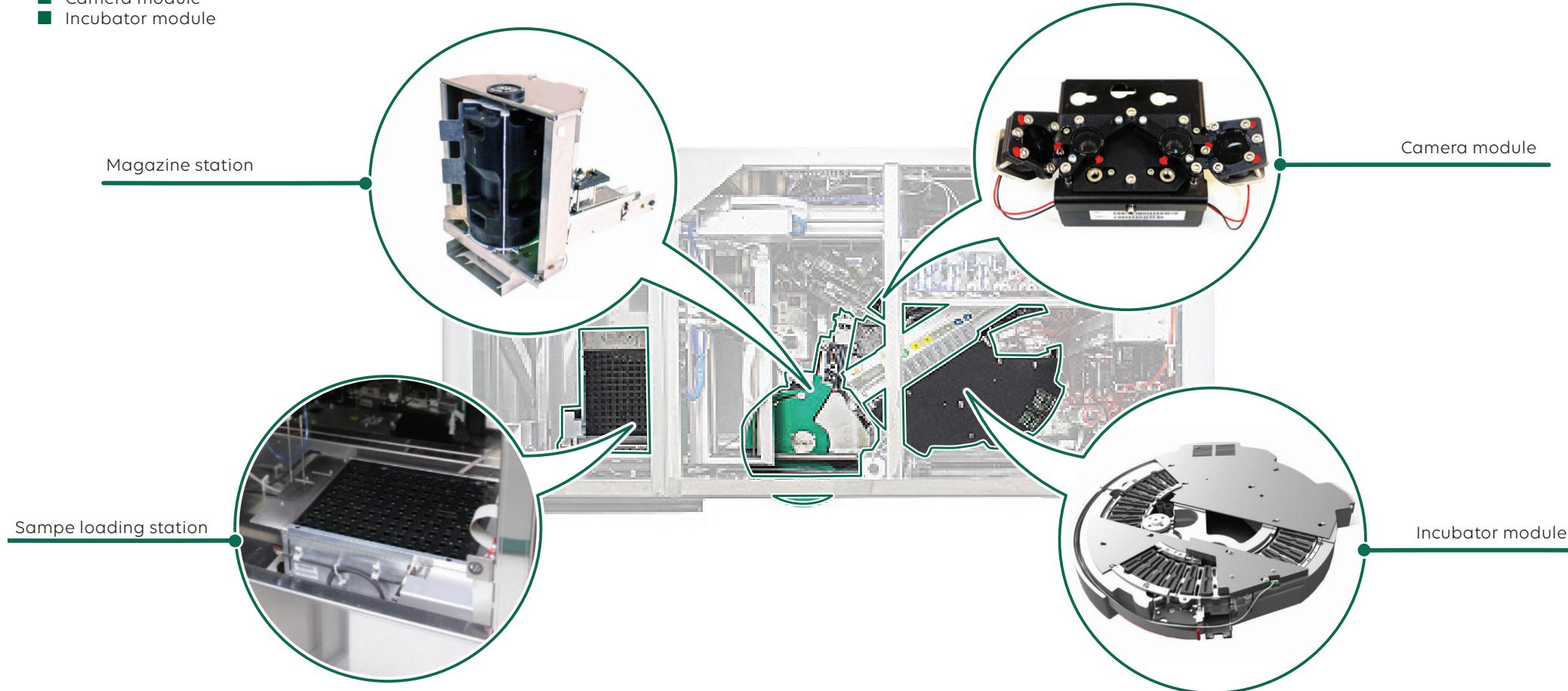
- Pipettor module
- Microarray turntable and pusher
- Washer modules 1 and 2
- Reagent carriage



(MosaiQ 125 internal parts localization - Top view / upper panel removed)

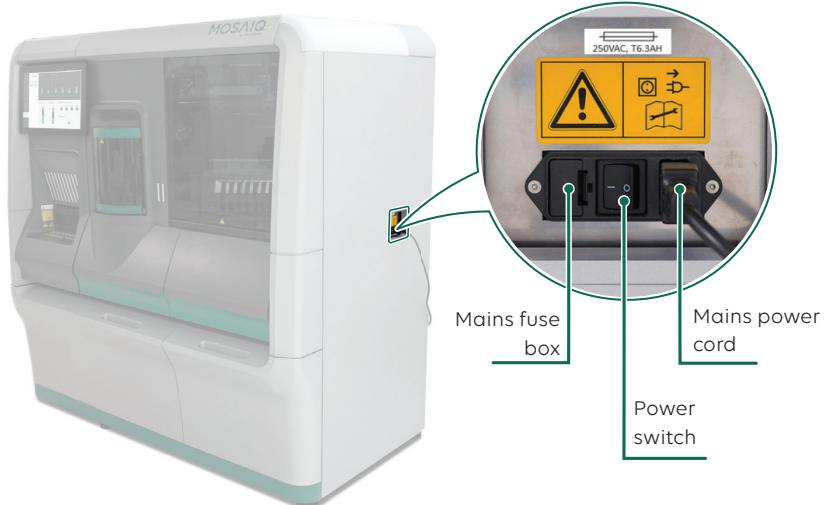
## MOSAIQ 125 PARTS DESCRIPTION AND LOCATION / INTERNAL PARTS

- Magazine station
- Sample loading station
- Camera module
- Incubator module



## 5.3 POWER SWITCH AND MAINS POWER OUTLET

The power switch is used to turn the **MosaiQ 125** on and off. The **MosaiQ 125** must be connected to the mains power supply via the mains power connector for the power switch to operate. This section shows where to find the power switch and the mains power connector on the **MosaiQ 125**.



(MosaiQ 125 power switch and mains power outlet)

## 5.4 VISUAL ALERT / ALARM

The different status of the visual alert/alarm indicate that the **MosaiQ 125** is operating properly or that the user needs to perform an action.

This section explains the meaning of the light signals sent by the **MosaiQ 125**.



(MosaiQ 125 visual alarm)

### MOSAIQ 125 VISUAL ALARM / ALERT STATUS

<b>On</b>	<b>MosaiQ 125</b> is in one of the following states: <b>Initializing</b> , <b>Maintenance</b> or <b>Processing</b> .
<b>Fast blinking</b>	<b>MosaiQ 125</b> is in <b>Error</b> state.
<b>Off</b>	<b>MosaiQ 125</b> is <b>Idle</b> or turned off.

To activate or deactivate the visual alert/alarm please refer to the general settings as described in [chapter 11.1.4](#).

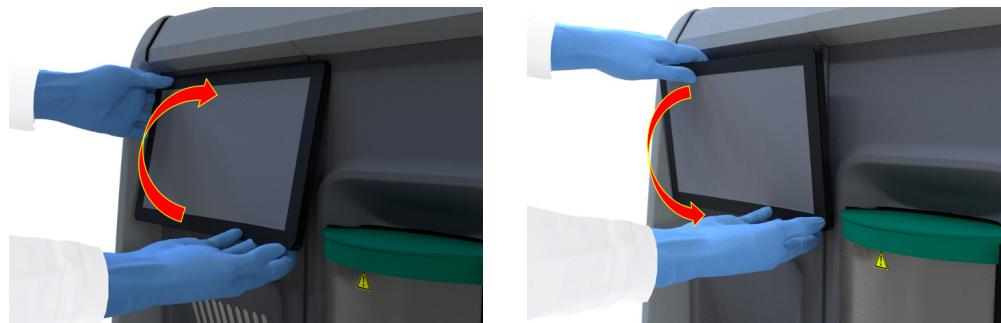
### 5.5 TOUCH SCREEN

The touch screen is the interface between the user and the **MosaiQ 125**. Users control and operate the **MosaiQ 125** via the MosaiQ Software, using the touch screen.



(MosaiQ 125 touch screen)

The touch screen can be adjusted by tilting the screen (20° upward and 10° downward).



(MosaiQ 125 touch screen adjustment)

## 5.6 MAGAZINE STATION

The magazine station is the place to load the magazines in the **MosaiQ 125**. There are two MosaiQ magazine sizes offering more operational flexibility.

The locking and unlocking of the magazine station door is software controlled.

The magazine station can hold up to four MosaiQ magazines.



(magazine station front view)

### Capacity:

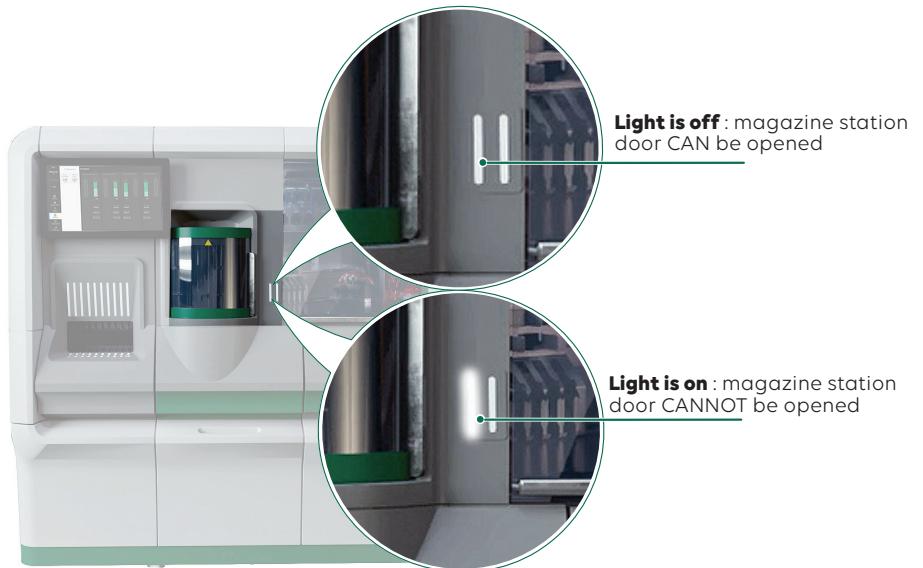
It holds upto 4 of the MosaiQ magazine x50 (MosaiQ Standard Magazine) or 4 of the MosaiQ magazines x250 (MosaiQ Quantum Magazine).

The maximum capacity is 1000 microarrays.

### Function:

The magazine station holds the MosaiQ magazines and also supplies the **MosaiQ 125** with microarrays to process.

Magazine station light status:



(magaziine station light status)

### Technology:

The magazine loading module features an RFID reader to read/write the RFID tags present on each magazine label.

### Operational mode:

Magazines cannot be loaded or removed during processing of the **MosaiQ 125**.

- To see how to load MosaiQ magazines in the **MosaiQ 125** please refer to [chapter 7.3.2](#) of this manual.
- To see which type of MosaiQ magazines that can be used please refer to the [chapter 3.2.1](#) of this manual.

## 5.7 SAMPLE STATION

The sample station is the area where sample racks are loaded into the **MosaiQ 125**.

The sample station holds up to 10 racks. Each rack has a capacity of 12 sample tubes, allowing a total of 120 samples to be loaded.

The sample station module features a barcode scanner to read the sample barcode present on each tube label for sample tube identification.

The barcode scanner also reads the rack barcodes present on each rack, for identification of each tube position in the rack.



(sample station)

### Function:

To load the sample racks and to read the rack and sample labels using a barcode scanner.

White lights located above the loading area of the sample station are used to give a permanent status on each of the 10 lanes as described below.

Light status	Lane status	Note
<b>Off</b>	<ul style="list-style-type: none"> <li>• Lane empty</li> <li>• Sample rack (samples) is finished</li> </ul>	
<b>On</b>	<ul style="list-style-type: none"> <li>• Lane is in use for scanning and pipetting</li> <li>• Sample rack (samples) will be scheduled</li> <li>• Sample rack (samples) is processing</li> </ul>	Do not attempt to remove sample rack!
<b>Blinking slow</b>	<ul style="list-style-type: none"> <li>• Available</li> </ul>	Sample rack can be loaded
<b>Blinking fast</b>	<ul style="list-style-type: none"> <li>• Error</li> </ul>	See notifications on the touch screen

### Capacity:

- 10 lanes
- 10 MosaiQ racks with a capacity of 12 tubes per rack
- Maximum capacity: 120 samples

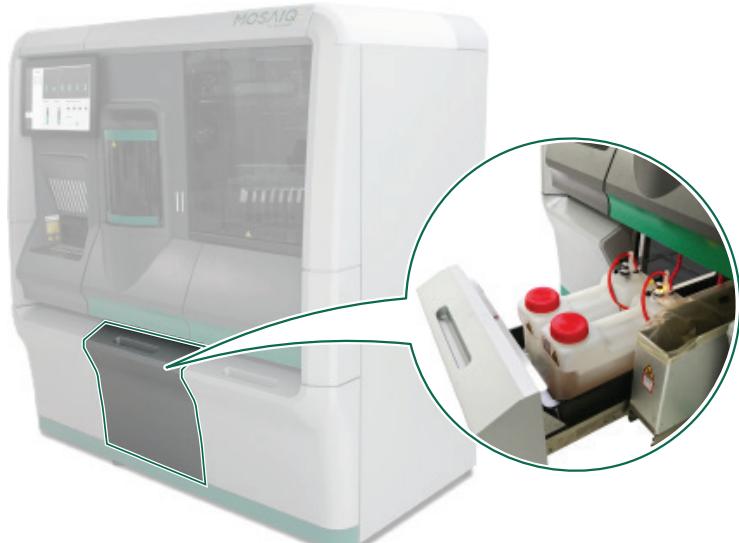
### Operational mode:

The sample rack can be loaded and removed during processing without interruption to the **MosaiQ 125** provided the **MosaiQ 125** has finished pipetting the samples.

- To load the samples in the **MosaiQ 125** please refer to [chapter 8.5](#) of this manual.
- To see the types of tubes that can be used please refer to the [chapter 8.11](#) of this manual.

## 5.8 WASTE DRAWER

The waste system has two components located in the waste drawer. One area for liquid waste with two canister and one for solid waste (used microarrays) with one drawer.



(waste drawer localization and opening)

The liquid waste canisters have yellow LEDs to indicate their status:



(waste canister LEDs)

Liquid waste LED status	
LED on	In use
LED off	Not in use

### Function:

The waste drawer collects the liquid and the solid waste.

### Capacity:

Two compartments.

- One compartment with two liquid waste canisters (red caps) with a capacity of 10 liters each, which collect all liquid waste (from MosaiQ system reagents, processed samples and system liquid) on the left-hand side (provided with your **MosaiQ 125**).
- One compartment with the solid waste container (to be used with a biological waste bag with a capacity of 50 liters) which collects all used microarrays on the right side of the waste drawer. Based on the amount of processed microarrays, the **MosaiQ 125** informs the user when the solid waste container needs to be emptied.

### Drawers

#### NOTICE

The pulled-out drawer can support the weight of waste filled canisters and no additional weight.



- Do not lean on the drawers.
- Waste drawer supports up to two filled canisters only.

- To remove and load the liquid waste canister, please refer to [chapter 7.3.9](#) and [chapter 7.3.10](#) and for the solid waste container refer to [chapter 8.3.7](#) and [chapter 8.3.8](#) of this manual.
- To cleaning of waste canister (monthly task), refer to [chapter 12.7](#) of this manual.

### 5.9 WATER DRAWER

The water drawer is located on the bottom right side of the **MosaiQ 125** and houses a maximum of two canisters containing the system liquid required to operate the **MosaiQ 125**. Users can open and close the water drawer manually. The water drawer can be opened and closed while the **MosaiQ 125** is in operation.



(water drawer localization)

#### Functions:

- To store water canisters (blue caps).
- To access the computer workstation.

#### Drawers

##### NOTICE

The pulled-out drawer can support the weight of system liquid filled canisters and no additional weight



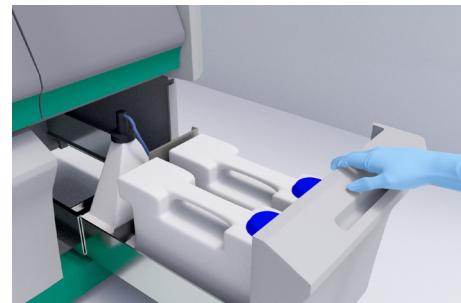
- Do not lean on the drawers,
- Place a maximum of two filled canisters in a drawer.

### 5.9.1 WATER CANISTERS

There are two canisters with a capacity of 10 L each (provided with your **MosaiQ 125**). They shall be filled with purified water (also called system liquid in this manual). Both canisters are connected to an intermediate container with a 5 L capacity.

##### NOTICE

Purified water is used in general laboratory applications such as buffers, pH solutions and microbiological culture media preparation.



(opened water drawer)

- To remove and load the water canisters, please refer to [chapter 7.3.11](#) of this manual.
- To clean the water canisters (monthly task), please refer to [chapter 12.7.5](#) and [chapter 12.7.6](#) of this manual.

#### Functions:

- The water canisters store the system liquid used to prepare the reconstituted wash buffers.

#### MosaiQ reconstituted wash buffers.

The reconstituted wash buffers are composed as follow:

- 10% **MosaiQ Wash Buffer 1** concentration in system liquid.
- 10% **MosaiQ Wash Buffer 2** concentration in system liquid.

Each MosaiQ wash buffer is diluted with system liquid in a dilution chamber as described in [chapter 5.8](#).

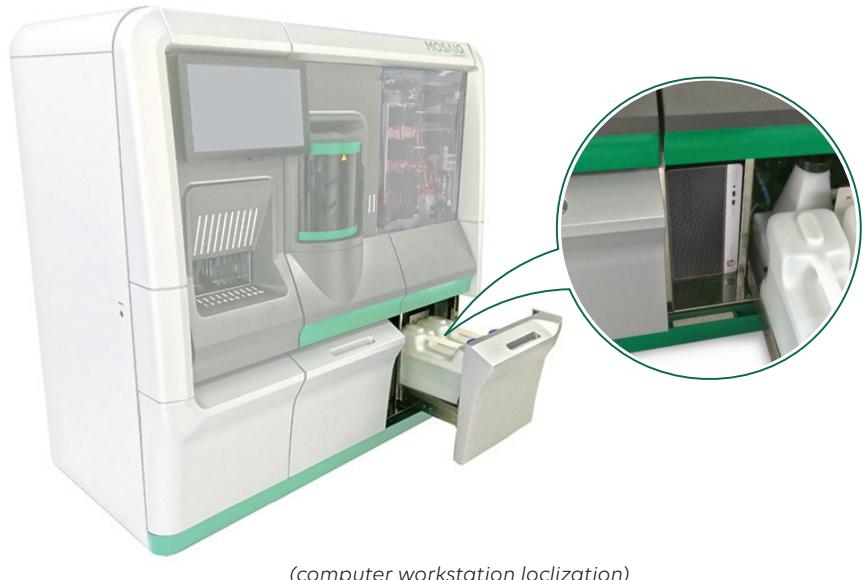
The level of concentration is monitored by a conductivity sensor.

The conductivity values are displayed each time the dilution chamber has been filled with fresh reconstituted wash buffer and the reagent drawer is closed.

##### NOTICE

### 5.9.2 COMPUTER WORKSTATION

The MosaiQ Software is installed on the computer workstation which is located on the left side of the water canisters in the water drawer.



(computer workstation localization)

#### Function:

- The computer workstation handles all data input and output for the **MosaiQ 125** and controls the assay processing.

#### NOTICE

- The computer workstation has its own mains power cord for connection to the mains power supply.
- The computer mains power cord passes through a hole on the back of the **MosaiQ 125**.
- The computer workstation has an USB port in the front panel to allow specific support operation, please refer to [chapter 14.6](#).



(computer workstation power cord)

- The computer workstation power cord is located behind the **MosaiQ 125**.
- To switch on the computer, please refer to [chapter 7.2.1](#) of this manual.
- To see the technical specifications of the computer, please refer to [chapter 18.3](#) of this manual.

### 5.10 REAGENT DRAWER

The reagent drawer holds the bottles of MosaiQ wash buffers and MosaiQ sample diluents. There are eight positions in which to place the reagent bottles. There are dilution chambers to ensure the correct ratios of wash buffer and system liquid. The reagent drawer can be opened and closed while the **MosaiQ 125** is in operation.



(reagent drawer localization and opening)

#### Function:

- To load MosaiQ wash buffer and MosaiQ sample diluent bottles.

#### Operational mode:

As the reagent drawer allows to insert two bottles of each kind of reagent, it is possible to insert a second bottle of the same reagent during processing without interrupting the **MosaiQ 125**.

- To load the MosaiQ wash buffer and MosaiQ sample diluent bottles in the **MosaiQ 125**, please refer to [chapter 8.3.6](#) of this manual.

#### Capacity:

The reagent drawer has a capacity of up to eight bottles

- Reagents: each of these reagents has a specific position on the drawer corresponding to their symbol. (2 bottles for each kind of reagent).
  - **MosaiQ Wash Buffer 1**
  - **MosaiQ Wash Buffer 2**
  - **MosaiQ Sample Diluent 1**
  - **MosaiQ Sample Diluent 2**

#### Technology:

An RFID reader embedded in the drawer is used to read and write on the RFID tags present on each reagent bottle.

In front of each bottle position there are yellow LEDs that indicate the actual reagent bottle status.



(Leds indicating the bottles position)

#### MOSAIQ WASH BUFFER AND MOSAIQ SAMPLE DILUENT BOTTLES LED STATUS

<b>Off</b>	Position available
<b>On</b>	Bottle in use
<b>Blinking slow</b>	Identifies loading position for required reagent
<b>Blinking fast</b>	Error

- To remove and load the MosaiQ wash buffer and MosaiQ sample diluent bottles, please refer to [chapter 7.3.5](#) and [chapter 7.3.6](#) of this manual.
- To clean the reagent drawer (monthly task), please refer to [chapter 12.7.1](#) of this manual.

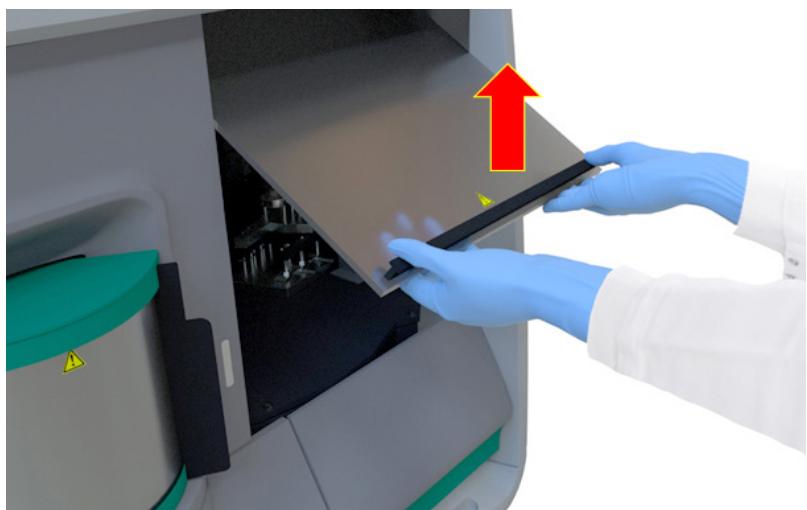
### 5.11 PROCESS MODULES

The process modules are housed within the **MosaiQ 125** body on the upper right side of the **MosaiQ 125** and include the reagent carriage, wash module, incubator module, camera module and pipettor module.

To access the process modules compartment, the reagent door must be opened.

The process modules are used at specific steps in the assay procedure, such as washing, dispensing of reagents and imaging.

- To open the reagent door, lift the door until it is locked.
- Some of the process modules are visible from the opened reagent door.

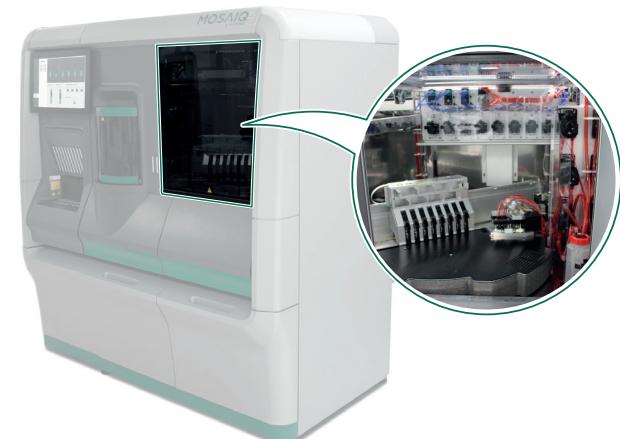


The reagent door can be opened and closed manually only when the **MosaiQ 125** is not in operation. Locking and unlocking of the reagent door is software controlled.

The reagent door light status.



When the reagent door is opened.



### 5.11.1 REAGENT CARRIAGE

The reagent carriage in the process modules compartment houses up to eight reagent bottles. The symbols of the MosaiQ system reagents indicate the position where each reagent bottle shall be inserted.



(reagent carriage localization - reagent door opened)

#### Function:

- To house MosaiQ detection and Enhancement reagent bottles.

#### Capacity:

The reagent carriage can carry up to eight reagent bottles (2 bottles of each kind of reagent). The MosaiQ system reagent are:

- **MosaiQ Detection Reagent 1**
- **MosaiQ Detection Reagent 2**
- **MosaiQ Enhancement Reagent 1**
- **MosaiQ Enhancement Reagent 2**

#### Technology:

An RFID reader is used to read and write on the RFID tags present on each reagent bottle. One yellow LED is located on the top right side of each slot on the reagent carriage. LEDs indicate the actual reagent bottle status.



(LEDs indicating the bottles status)

#### MOSAIQ DETECTION AND ENHANCEMENT REAGENT BOTTLES LED STATUS

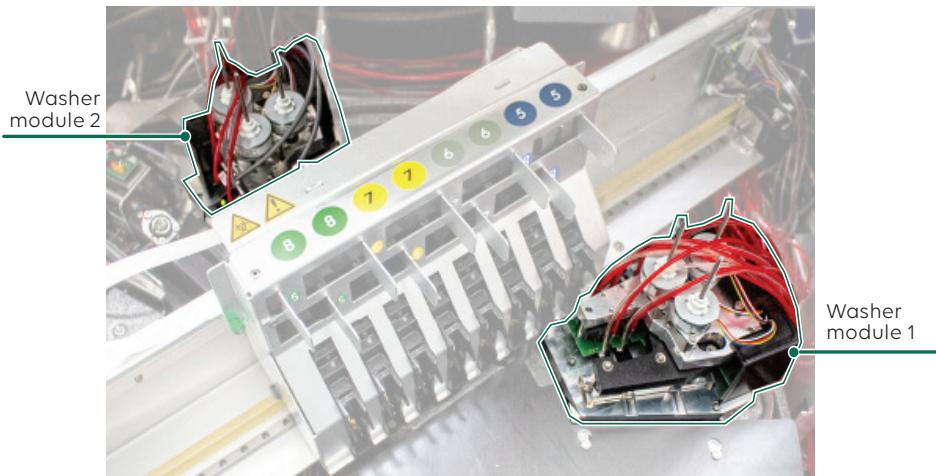
<b>Off</b>	Position available
<b>On</b>	Bottle in use
<b>Blinking slow</b>	Identifies loading position for required reagent when necessary
<b>Blinking fast</b>	Error

- To remove and load the MosaiQ detection and MosaiQ enhancement reagent bottles, please refer to [chapter 7.3.3](#) and [chapter 7.3.4](#) of this manual.
- To clean the reagent carriage (weekly task), please refer to [chapter 12.6.1](#) of this manual.

### 5.11.2 WASHER MODULES

The **MosaiQ 125** has two independent washer modules to rinse microarrays at various stages of the process.

Both **MosaiQ Wash Buffer 1** and **MosaiQ Wash Buffer 2** are loaded in the reagent drawer.



#### Function:

- Both Washer modules are used to wash the microarray at a precise stage of the assay (depending on the test performed).

#### Capacity:

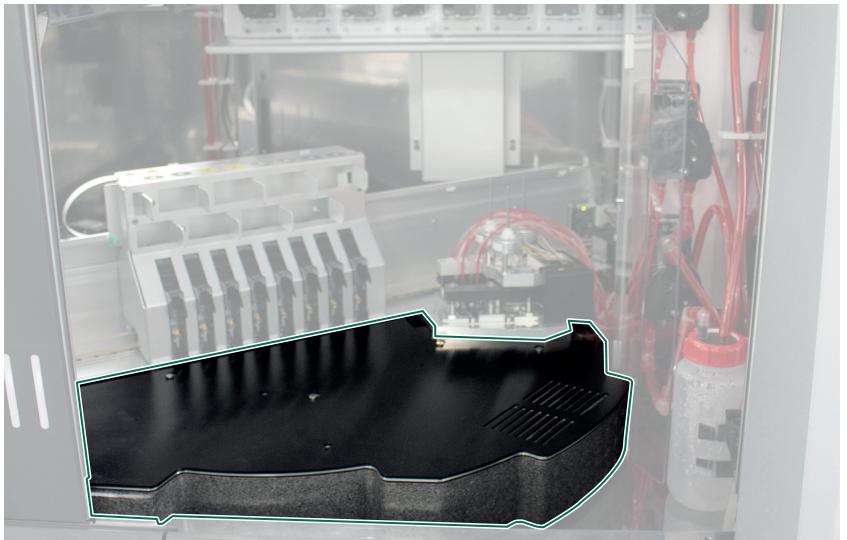
There are two independent Washer modules:

- Wash module 1 is connected to the **MosaiQ Wash Buffer 1** and **MosaiQ Wash Buffer 2**.
- Wash module 2 is connected to the **MosaiQ Wash Buffer 1** and the system liquid.

### 5.11.3 INCUBATOR MODULE

The incubator module is located on the lower part of the process modules compartment of the **MosaiQ 125**.

The incubator module is responsible for moving the microarrays to the different process modules while maintaining the assay at the required temperature of  $35^{\circ}\text{C} \pm 2^{\circ}\text{C}$ .



#### Function:

The incubator module keeps the assay at the required temperature and moves microarrays to different process modules. Each position on the incubator module is dedicated to a specific step of the assay procedure:

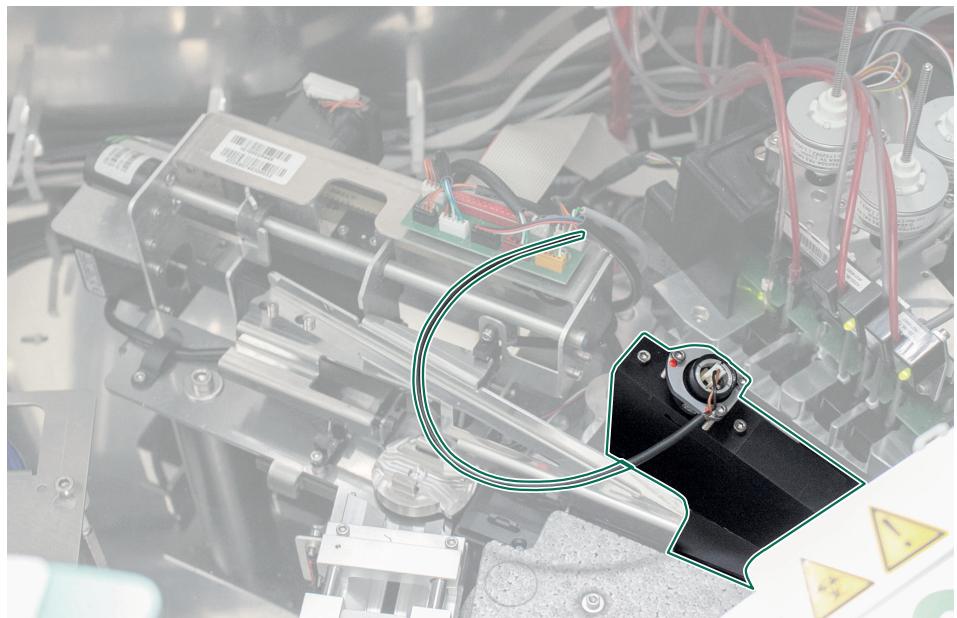
- Washing
- Dispensing of reagents
- Imaging

#### Capacity:

There is one incubation ring (with inner and outer positions) offering 80 positions for microarrays.

### 5.11.4 CAMERA MODULE

The camera module is located on the left-hand side of the process modules compartment of the **MosaiQ 125**. It generates images that are automatically transmitted to the MosaiQ Software for analysis.



(camera module)

#### Function:

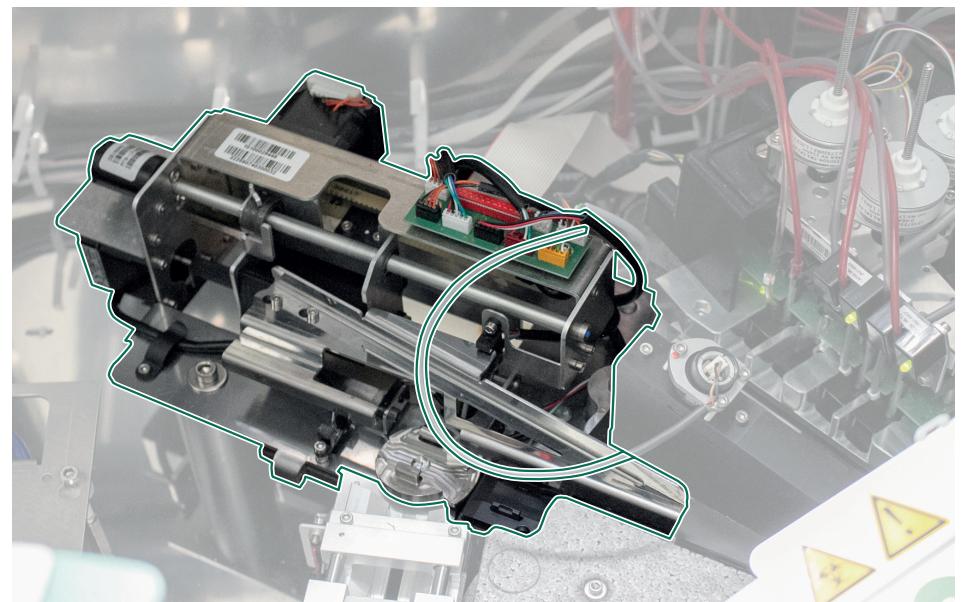
- The camera module takes a digital photo of the microarrays that have reached the end of the incubator module processing stage. The images are stored within the MosaiQ Software and are not accessible to the user.

#### NOTICE

The images taken are not accessible to the user. They can only be analyzed by the MosaiQ Software.

### 5.11.5 MICROARRAY TURNTABLE AND PUSHER

The microarray turntable is located behind the magazine station inside the **MosaiQ 125**. The turntable is a mechanical part that individually rotates the microarrays coming from the magazine towards the incubator. The pusher moves the microarray from the turntable to the shaker and finally to the incubation ring.



(microarray turntable and pusher)

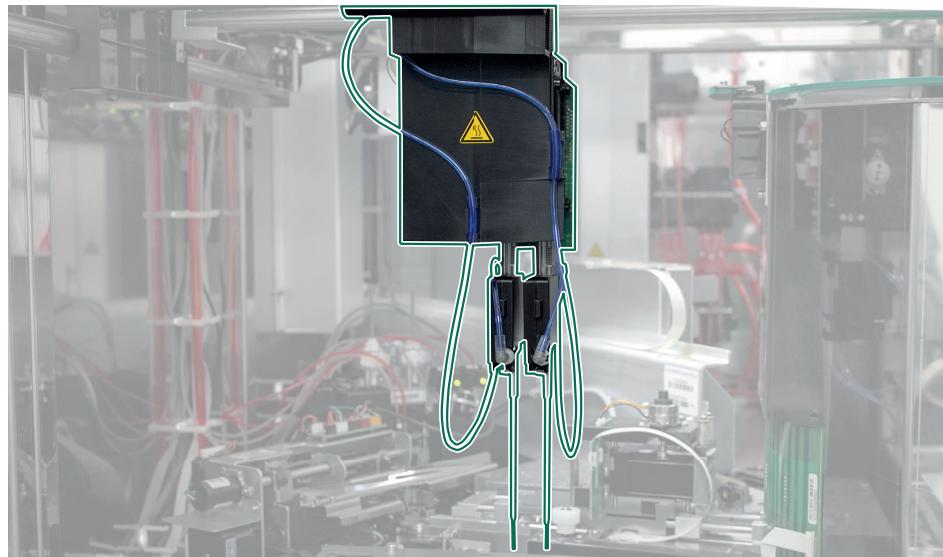
#### Function:

- The microarray turntable rotates the incoming microarrays towards the incubator module.
- The microarray turntable holds the microarray during pipetting operation.
- The pusher moves forward the microarray from the turntable to the incubator.

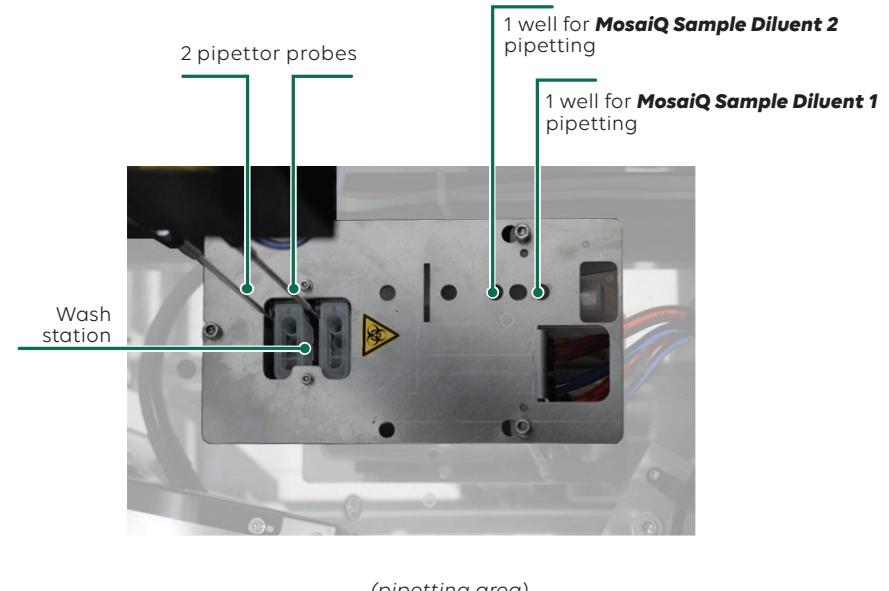
### 5.11.6 PIPETTOR MODULE

The pipettor module comprises two probes (needles):

- One probe is dedicated to AT assays using a sample of red blood cells and **MosaiQ Sample Diluent 1**.
- The second probe is dedicated to the Covid19 and ABD assays using sample of plasma or serum and **MosaiQ Sample Diluent 2**.



(pipettor module)



(pipetting area)

#### Function:

- 1 - First, the dedicated probe aspirates the appropriate diluent (depending on the test performed). It can access the sample diluents via two wells (one for **MosaiQ Sample Diluent 1** and one for **MosaiQ Sample Diluent 2**).
- 2 - The dedicated probe aspirates the sample liquid from the sample tubes.
- 3 - Finally, the probe moves above the microarray for dispensing the liquid (diluted or not) on the microarray panel.

Between each step described above, the pipettor moves to the wash station to clean itself the probes with system liquid.

#### NOTICE

For Covid 19 assay, samples can be plasma or serum of blood specimens.

#### INFO

To clean pipettor module (weekly task), please refer to [chapter 12.6.2](#) of this manual.

## 5.12 MATERIAL AND ACCESSORIES

The **MosaiQ 125** is provided with detachable components and accessories, as described below.

### 5.12.1 MATERIAL PROVIDED

Quantity	Description	Crate
1	<b>MosaiQ 125</b>	1/2
1	Computer Workstation	1/2
1	Display + display holder	1/2
10	Sample rack	1/2
2	Waste canister	1/2
2	Water canister	1/2
2	Power cord (country specific)	1/2
1	Set of covers	2/2

### 5.12.2 ACCESSORIES

Description
Sample rack
Waste canister
Water canister

# 6. GRAPHICAL USER INTERFACE

<b>6.1 GUI OVERVIEW</b>	<b>48</b>
6.1.1 MAIN SCREEN	48
6.1.2 NAVIGATION BAR	49
<b>6.2 MOSAIQ MENU</b>	<b>50</b>
6.2.1 BASIC FUNCTIONS	50
6.2.2 LABORATORY ADMINISTRATIVE FUNCTIONS	51
6.2.3 NOTIFICATIONS MENU	51
<b>6.3 LOCK SCREEN</b>	<b>53</b>

# GRAPHICAL USER INTERFACE / GUI OVERVIEW

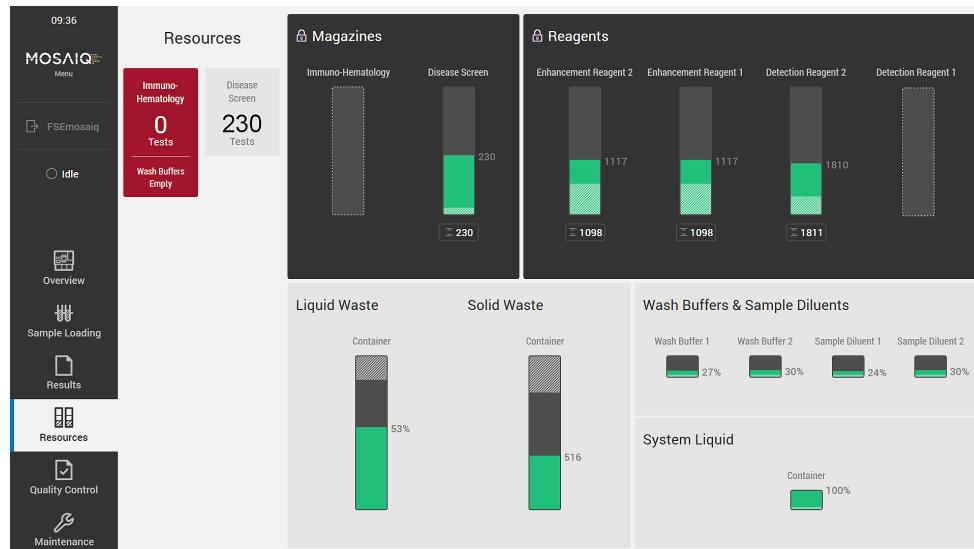
The Graphical User Interface (GUI) is displayed on the touch screen.

## 6.1 GUI OVERVIEW

This section provides an overview of the main screens, menus, functions, icons, notifications and color codes users will encounter in the GUI. It allows users to follow assay progress, resource levels and assay results.

### 6.1.1 MAIN SCREEN

The following section explains how to use the main screen.



(resources screen)

The possible actions on the touch screen are:

- Tap once on the screen with your finger to single click.
- Tap twice on the screen with your finger to double click.
- Swipe up and down to scroll lists (for example the results screen).

### INFO

The touch screen can also be used while wearing gloves.

Use the touch screen keyboard to type alphanumeric inputs, e.g. A - Z, 0 - 9, etc.).

The touch screen keyboard automatically appears each time the user taps inside an editable field on the screen.



(virtual keyboard)

### NOTICE

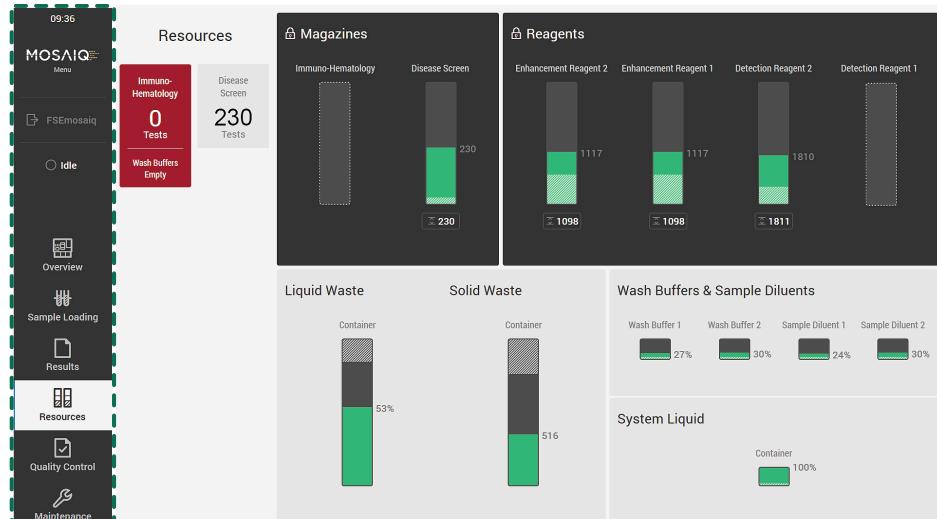
Damage to touch screen while operating.

Improper use could damage the touch screen surface.

- Do not use sharp-edged to clean the surface.
- To keep the surface clean please refer to [chapter 12.6.11](#).
- Operate with your finger without applying excessive pressure.

## 6.1.2 NAVIGATION BAR

The following section describes all functions available from the navigation bar.



(navigation bar)

	Tap to access additional functions (e.g. notifications, help, shutdown) and administrative functions (e.g. user administration, configuration). Refer to <a href="#">chapter 6.21</a> and <a href="#">chapter 6.22</a> .
	To consult the name of the user who is logged in. Tap to log off or to change users. Refer to <a href="#">chapter 6.3</a> .

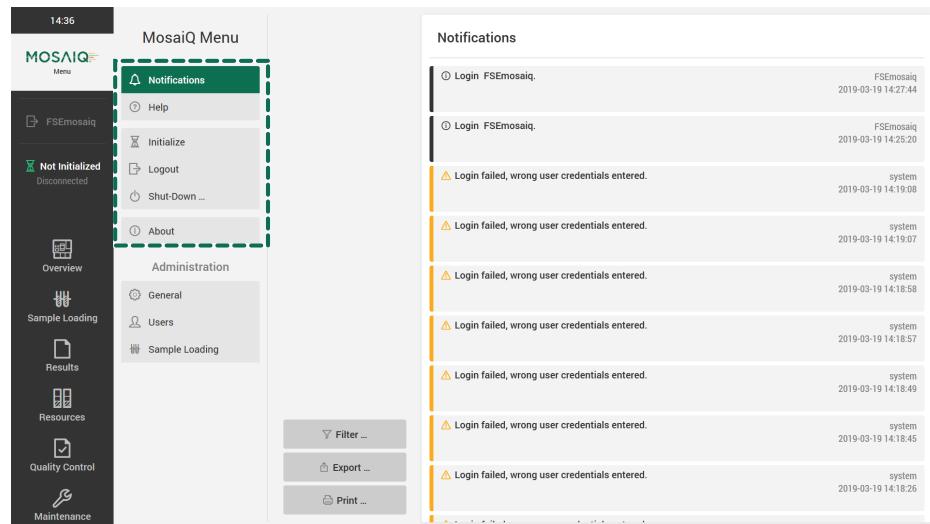
	It shows the system to status (e.g. <b>Idle</b> , <b>Initializing</b> , <b>Processing</b> , <b>Finishing</b> , <b>Maintenance</b> , <b>Error</b> ).
	Disconnected
	To consult the current process and any upcoming tasks. Refer to <a href="#">chapter 6.1</a> .
	Tap to display information about sample loading. Refer to <a href="#">chapter 8</a> .
	Tap to display all results of the process. Refer to <a href="#">chapter 8.13</a> and <a href="#">chapter 8.14</a> .
	Tap to display the available resources (e.g. MosaiQ magazines, MosaiQ system reagents and water) and the capacity of the waste system (e.g. load or remove resources). Refer to <a href="#">chapter 7.22</a> .
	Tap to display all quality controls. Refer to <a href="#">chapter 9</a> .
	Tap to display any upcoming maintenance tasks. Refer to <a href="#">chapter 12</a> .

### 6.2 MOSAIQ MENU

The following section provides information about the various menus available in the GUI.

#### 6.2.1 BASIC FUNCTIONS

The following section provides an overview of the basic functions available from the navigation bar.

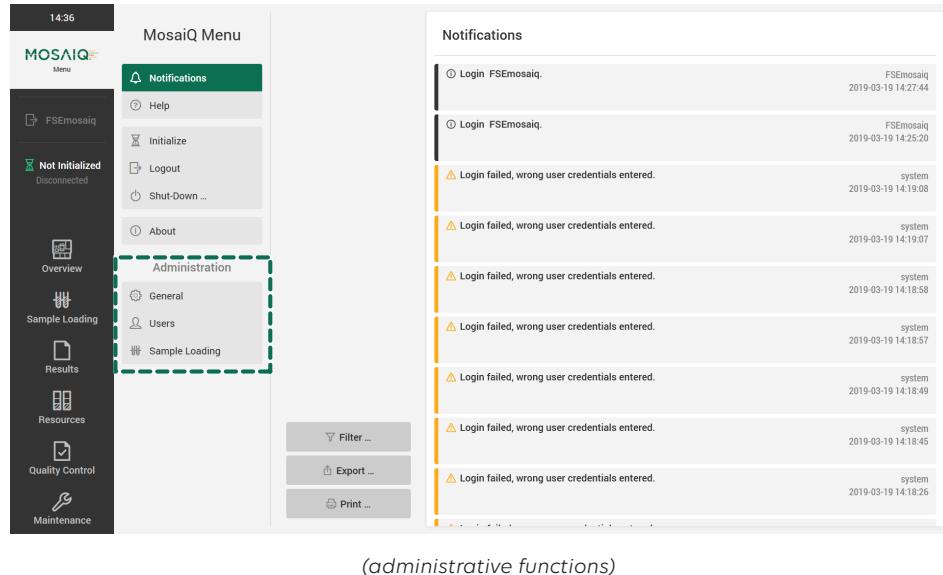


(basic functions)

Notifications	Tap to display the notifications menu and the messages. Refer to <a href="#">chapter 6.2.3</a> .
Help	Tap to access the User Manual.
Initialize	Tap to initialize the <b>MosaiQ 125</b> .
Logout	Tap to display the lock screen. Refer to <a href="#">chapter 6.3</a> .
Shut-Down ...	Tap to display the shutdown dialogue to shut down the MosaiQ Software and switch off the <b>MosaiQ 125</b> , as described in <a href="#">chapter 10</a> .
About	Tap to display information about the system software. <ul style="list-style-type: none"> <li>• MosaiQ Software version</li> <li>• Device serial number</li> <li>• Manufacturer</li> </ul>

### 6.2.2 LABORATORY ADMINISTRATIVE FUNCTIONS

The administrative functions are available for users with laboratory administrator access rights.



(administrative functions)

**INFO**

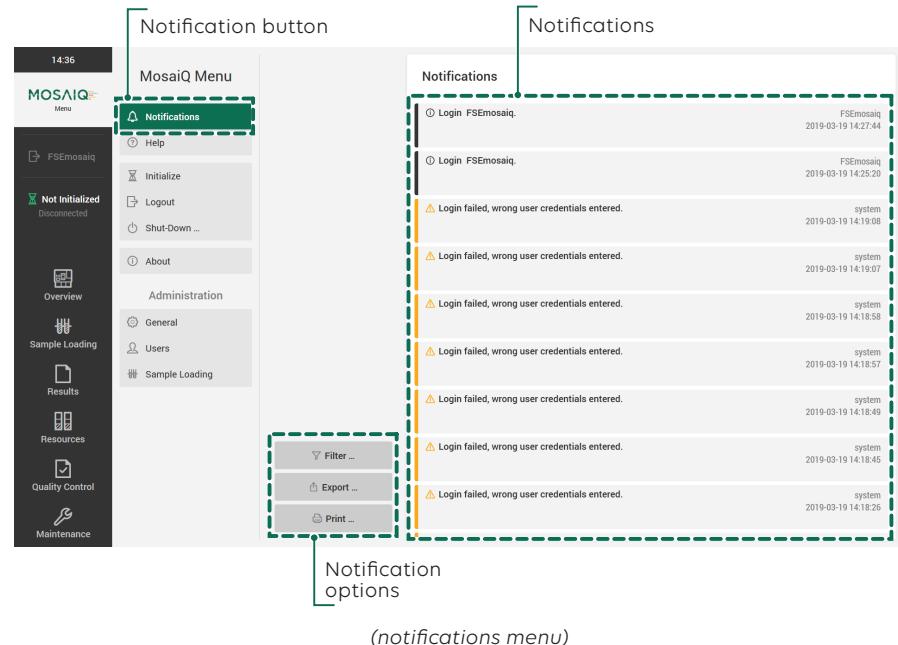
**Laboratory administrator access rights**

This menu is not displayed when the user is logged in as User.

	Tap to display the general settings.
	Tap to display a list of all users role to add, edit and delete users. Refer to <a href="#">chapter 11.3</a> .
	Tap to configure sample loading. Refer to <a href="#">chapter 8</a> .

### 6.2.3 NOTIFICATIONS MENU

The following section shows how notifications are displayed.



(notifications menu)

- Tap on the **Notification** button to access the notification list. The newest message appears at the top of the list.
- Tap on a message to display details.
- Select one option in the notifications options list (if required).

	Tap to search for a specific message and display the result on the right side.
	Tap to export and save all messages into a file.
	Tap to print out selected messages.

### Color Code

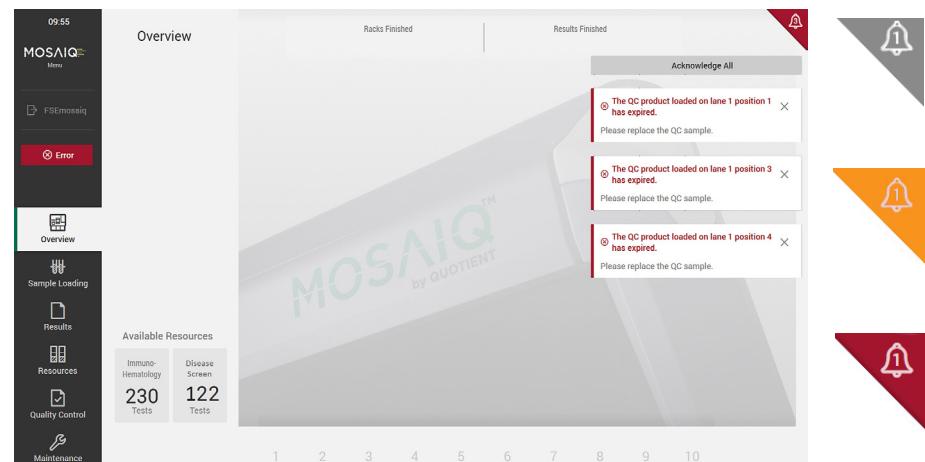
All messages appear in chronological order (the newest on the top):

Icon	Description	Type of Messages	Meaning
	<b>Information messages</b>	Indicate information	<ul style="list-style-type: none"> <li>The <b>MosaiQ 125</b> is fully functional.</li> <li>User intervention is not necessary.</li> </ul>
	<b>Warning messages</b>	Indicate a Warning message	<ul style="list-style-type: none"> <li>The <b>MosaiQ 125</b> has an issue that requires attention. The <b>MosaiQ 125</b> continues to function.</li> <li>The <b>MosaiQ 125</b> requires user intervention (e.g. a resource will be empty soon).</li> </ul>
	<b>Error messages</b>	Indicate an Error message	<p>The user must intervene in all cases of an error message.</p> <ul style="list-style-type: none"> <li>Failure or malfunction of the <b>MosaiQ 125</b> that requires user intervention.</li> <li>The <b>MosaiQ 125</b> stops because of missing resources.</li> </ul>

### Notification Reminder

A notification symbol in the top right corner reminds the user about currently active and unresolved messages. The symbol has the same color as the message severity color.

The number inside the symbol indicates the number of messages.



(notifications symbols and messages)

### Show or hide the messages:

- 1 - Tap on the **Notifications** button to show all active and unresolved messages.
- 2 - Details of a message:
  - a - Tap a message to show details.
  - b - Solve the problem and confirm that the necessary action has been taken.
- 3 - Close/confirm a message (only messages not requiring user intervention):
  - Tap on the small "X" symbol on the right side of a message.
  - Tap on the **Acknowledge All** button to close all messages.
- 4 - Tap on the **Notification** symbol again to hide all active and unresolved messages.

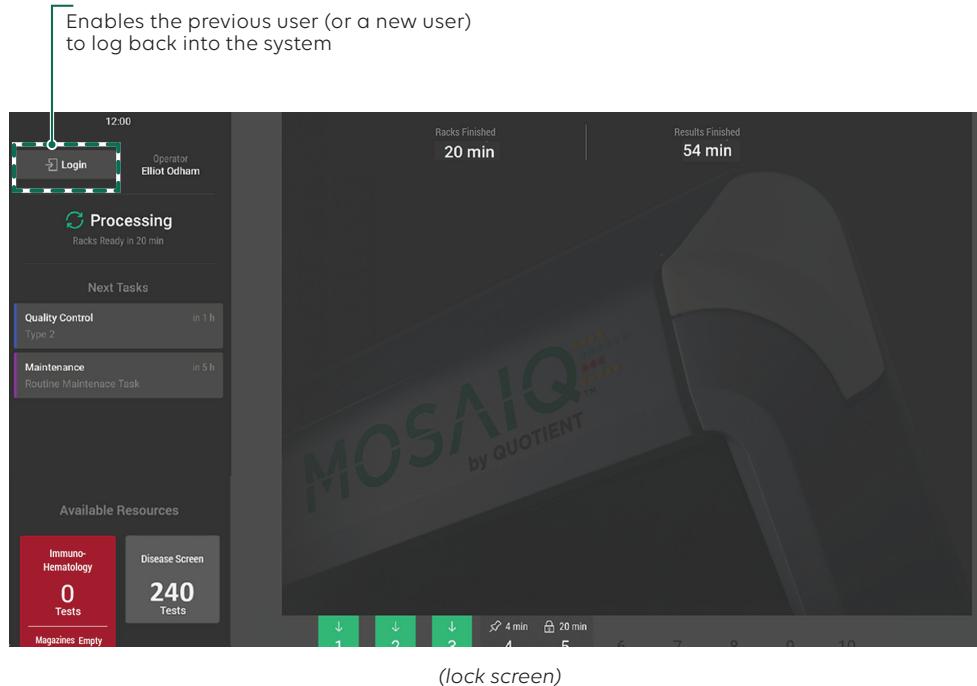
### Mute the audible warning signal:

- 1 - Tap on the **Notifications** button to show the **Speaker** symbol.
- 2 - Tap on the **Speaker** symbol.  
The audible warning signal stops and a "X" on the **Speaker** symbol appears.
- 3 - Respect the shown warning or error message (see above).

### 6.3 LOCK SCREEN

During the test run, the screen is automatically locked after a configurable time (installation settings). The lock screen shows all information about the status of the system.

■ **Login to access any functions.**



# 7. OPERATING INSTRUCTIONS

<b>7.1</b>	<b>BEFORE STARTING TO TEST SAMPLES</b>	<b>55</b>	
7.1.1	SAFETY AND TIPS	55	
7.1.2	PROCESSING SEQUENCE OVERVIEW	56	
7.1.3	PRERUN CHECKS	58	
<b>7.2</b>	<b>GETTING STARTED</b>	<b>58</b>	
7.2.1	SWITCH ON	58	
7.2.2	CHECK AVAILABLE RESOURCES	60	
7.2.3	RESOURCES OVERVIEW	60	
7.2.4	CHECKING INDIVIDUAL RESOURCES	61	
<b>7.3</b>	<b>HOW TO REMOVE AND LOAD EACH RESOURCE</b>	<b>66</b>	
7.3.1	REMOVING MAGAZINES	66	
7.3.2	LOADING MAGAZINES	67	
7.3.3	REMOVING MOSAIQ DETECTION AND MOSAIQ ENHANCEMENT REAGENT BOTTLES	69	
7.3.4	LOADING DETECTION AND ENHANCEMENT REAGENT BOTTLES	71	
7.3.5	REMOVING THE MOSAIQ WASH BUFFER AND MOSAIQ SAMPLE DILUENT BOTTLES	74	
7.3.6	LOADING THE MOSAIQ WASH BUFFER AND MOSAIQ SAMPLE DILUENT BOTTLES	76	
7.3.7	REMOVING THE SOLID WASTE BAG	77	
7.3.8	LOADING THE SOLID WASTE BAG	78	
7.3.9	REMOVING LIQUID WASTE CANISTER	79	
7.3.10	LOADING LIQUID WASTE CANISTER	81	
7.3.11	REMOVING THE WATER CANISTER	82	
7.3.12	LOADING THE WATER CANISTER	84	

This section explains how to operate the **MosaiQ 125** safely and effectively.

### 7.1 BEFORE STARTING TO TEST SAMPLES

#### 7.1.1 SAFETY AND TIPS

##### **Emergency Shutdown in case of malfunction**

Malfunction of the **MosaiQ 125** may cause electrical shock, burns, cuts or bruises.



In case of malfunction:

- Switch off the **MosaiQ 125**
- Disconnect the **MosaiQ 125** from the mains power supply.

##### **Improper operation of the MosaiQ 125 or the software**

Malfunctions can cause serious injuries with deadly consequences or damage to the **MosaiQ 125**.



- Follow the steps in the individual instructions closely.
- Check correct data input.
- Check correct application of the loading process.
- In case of improper operation on a regular basis, contact your local technical representative.

##### **Liquid in the MosaiQ 125**



Biological samples and reagents used to run the **MosaiQ 125** can cause illnesses in case of contact.



The **MosaiQ 125** can be damaged by leak of liquids.

- Switch off the **MosaiQ 125**.
- Disconnect the **MosaiQ 125** from the mains power supply.
- Wear suitable protective clothing.
- Clean, disinfect or decontaminate and dry the **MosaiQ 125** according to the applicable local and national provisions, legislation and laboratory procedures.

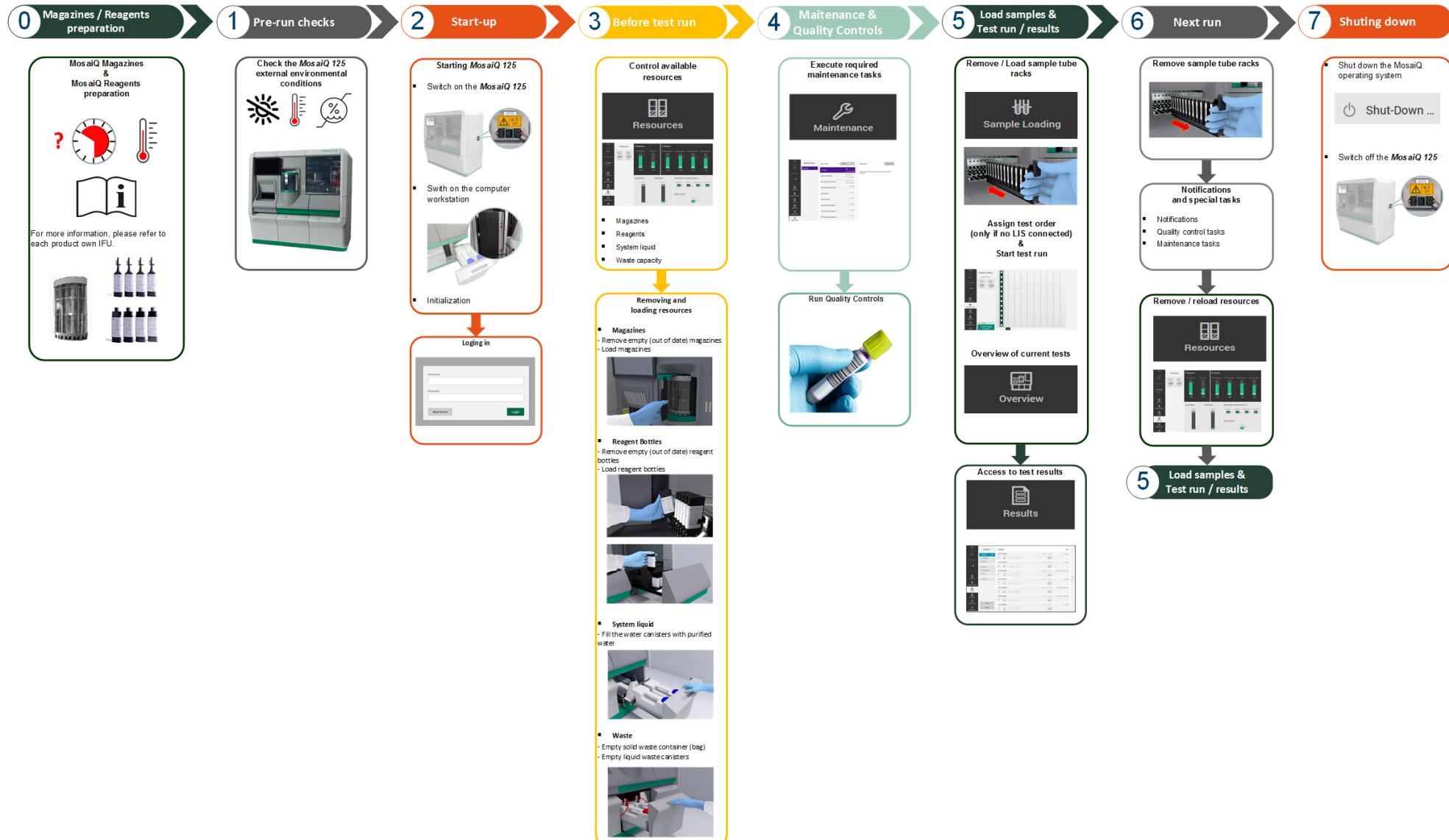
## 7.1.2 PROCESSING SEQUENCE OVERVIEW

The table and diagram below provide an overview of the operation sequence from start to finish.

Steps	Description
<b>Prerun checks</b>	<ul style="list-style-type: none"> <li>Check the <b>MosaiQ 125</b> external environmental conditions (please refer to <a href="#">chapter 18.6</a> of this manual)</li> </ul>
<b>Start-up</b>	<ul style="list-style-type: none"> <li>Switch on the <b>MosaiQ 125</b></li> <li>Switch on the computer workstation</li> <li>Initialization</li> <li>Log in</li> <li>Maintenance</li> </ul>
<b>Before test run</b>	<p>Check available resources:</p> <ul style="list-style-type: none"> <li>Magazines</li> <li>Reagents</li> <li>System liquid</li> <li>Waste capacity</li> </ul>
<b>Removing and loading resources</b>	<ul style="list-style-type: none"> <li>Magazines <ul style="list-style-type: none"> <li>Remove empty (or expired) magazines</li> </ul> </li> <li>Reagent bottles <ul style="list-style-type: none"> <li>Remove empty (or expired) reagent bottles</li> </ul> </li> <li>Load reagent bottles</li> <li>Load magazines</li> <li>Waste <ul style="list-style-type: none"> <li>Empty solid waste container (waste bag)</li> <li>Empty liquid waste canisters</li> </ul> </li> <li>System liquid <ul style="list-style-type: none"> <li>Fill the water canister with purified water</li> </ul> </li> </ul>
<b>Maintenance</b>	<ul style="list-style-type: none"> <li>Execute required maintenance tasks</li> </ul>
<b>Quality control</b>	<ul style="list-style-type: none"> <li>Run quality controls.</li> <li>Please refer to the appropriate IFU.</li> </ul>

Steps	Description
<b>Load samples and start test run</b>	<ul style="list-style-type: none"> <li>Load sample tube racks</li> <li>Assign test order (only if no LIS connected)</li> <li>Start test run</li> </ul>
<b>Overview</b>	<ul style="list-style-type: none"> <li>Switch to the <b>Overview</b> screen</li> </ul>
<b>Results</b>	<ul style="list-style-type: none"> <li>View results</li> </ul>
<b>Remove and reload samples</b>	<ul style="list-style-type: none"> <li>Remove finished sample tube racks</li> <li>Reload sample tube racks</li> </ul>
<b>Reload resources</b>	<ul style="list-style-type: none"> <li>Reload resources</li> </ul>
<b>Notifications and special tasks</b>	<ul style="list-style-type: none"> <li>Notifications</li> <li>Quality control tasks</li> <li>Maintenance tasks</li> </ul>
<b>At the end of the shift</b>	<ul style="list-style-type: none"> <li>If <b>MosaiQ 125</b> is intended to be shut down for an extended period (over 72 hours) remove all resources with exception of water</li> </ul>
<b>Shut down</b>	<ul style="list-style-type: none"> <li>Shut down the <b>MosaiQ Software</b></li> <li>Switch off the <b>MosaiQ 125</b>.</li> </ul>

## OPERATING INSTRUCTIONS / BEFORE STARTING TO TEST SAMPLES



### 7.1.3 PRERUN CHECKS

This section provides a quick summary of the activities required prior to starting the **MosaiQ 125**:

- 1 - Ensure that all **MosaiQ 125** environmental conditions are met (refer to [chapter 18.6](#)).
- 2 - Ensure that all incubation ring insulating covers are securely in place.
- 3 - Ensure that all protective covers and doors are in place and securely closed.
- 4 - Ensure that the liquid waste canisters (red caps) are empty and the lids correctly fitted.

**NOTICE**

All waste should be disposed of in accordance with your local rules. As example: COSHH (Control of Substances Hazardous to Health).

- 5 - Ensure that the connector on the liquid waste connector is securely locked in position (refer to [chapter 7.3.10](#)).
- 6 - Ensure that the solid waste drawer is empty, firmly shut and locked into place when replacing the biological waste bag .



(opening the solid waste drawer)

- 7 - Ensure that there is water at least in one canister.
- 8 - Prepare the MosaiQ system reagents, quality controls, MosaiQ magazines according to their respective IFU.

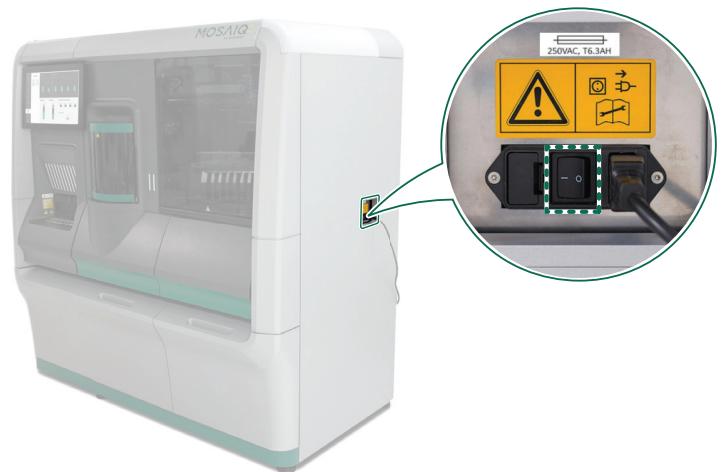
### 7.2 GETTING STARTED

This section explains the operations required for start-up of the **MosaiQ 125**.

#### 7.2.1 SWITCH ON

The following section explains how to start the **MosaiQ 125**.

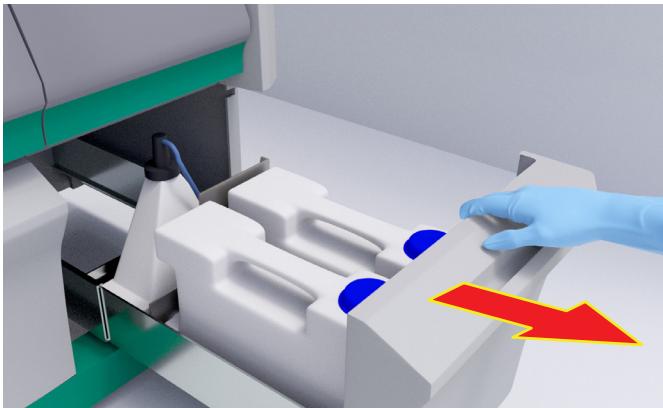
- 1 - Ensure both **MosaiQ 125** and computer workstation are connected to the mains power supply. For more information please refer to [chapter 5.7](#) of this manual.
- 2 - Switch on the **MosaiQ 125** (the switch is located on the right side of the **MosaiQ 125**).



(power switch localization)

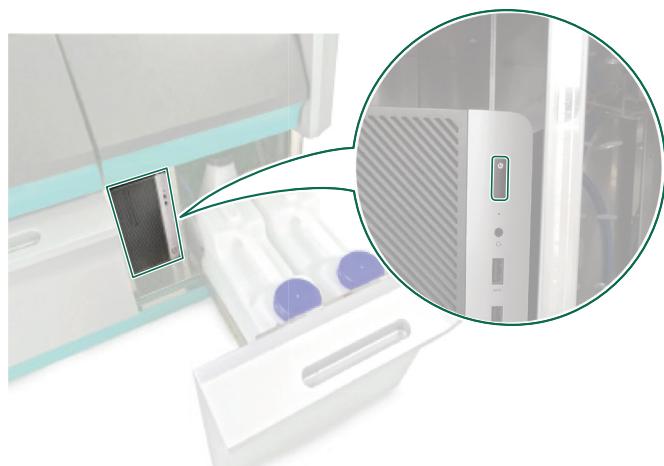
## OPERATING INSTRUCTIONS / GETTING STARTED

3 - Open the water drawer to access to the computer workstation.



(opening the water drawer)

4 - Switch on the PC.

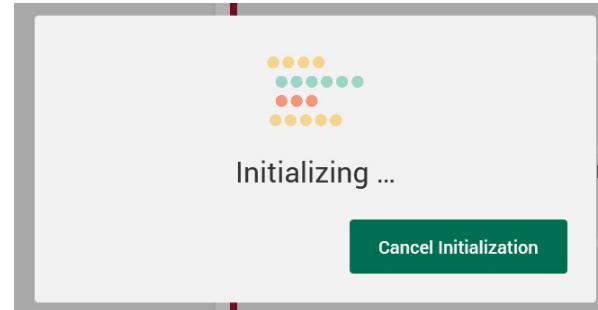


(computer workstation power button localization)

5 - Close the water drawer.

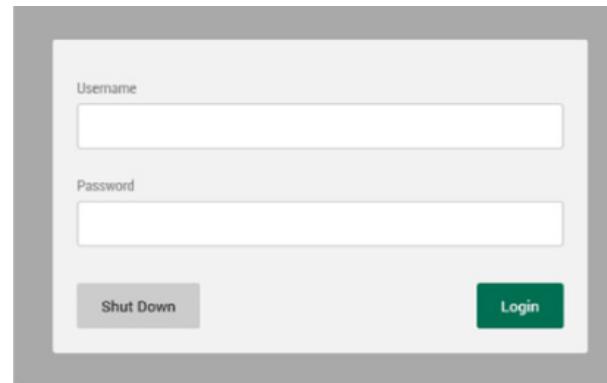
6 - Wait for the MosaiQ Software to start.

7 - Initialization starts automatically and lasts approximately 5 minutes. Initialization allows **MosaiQ 125** to check that all hardware modules are functioning as expected.



(initialization pop-up window)

8 - Once the initialization is completed, enter your user name and password then click on the **Login** button or tap on the **Shutdown** button to cancel and shut down the MosaiQ Software.



(login pop-up window)

### NOTICE

When not used during a 30 Min **MosaiQ 125** goes automatically in standby mode.

## 7.2.2 CHECK AVAILABLE RESOURCES

This section provides information about how to check the available resources on the **MosaiQ 125**.

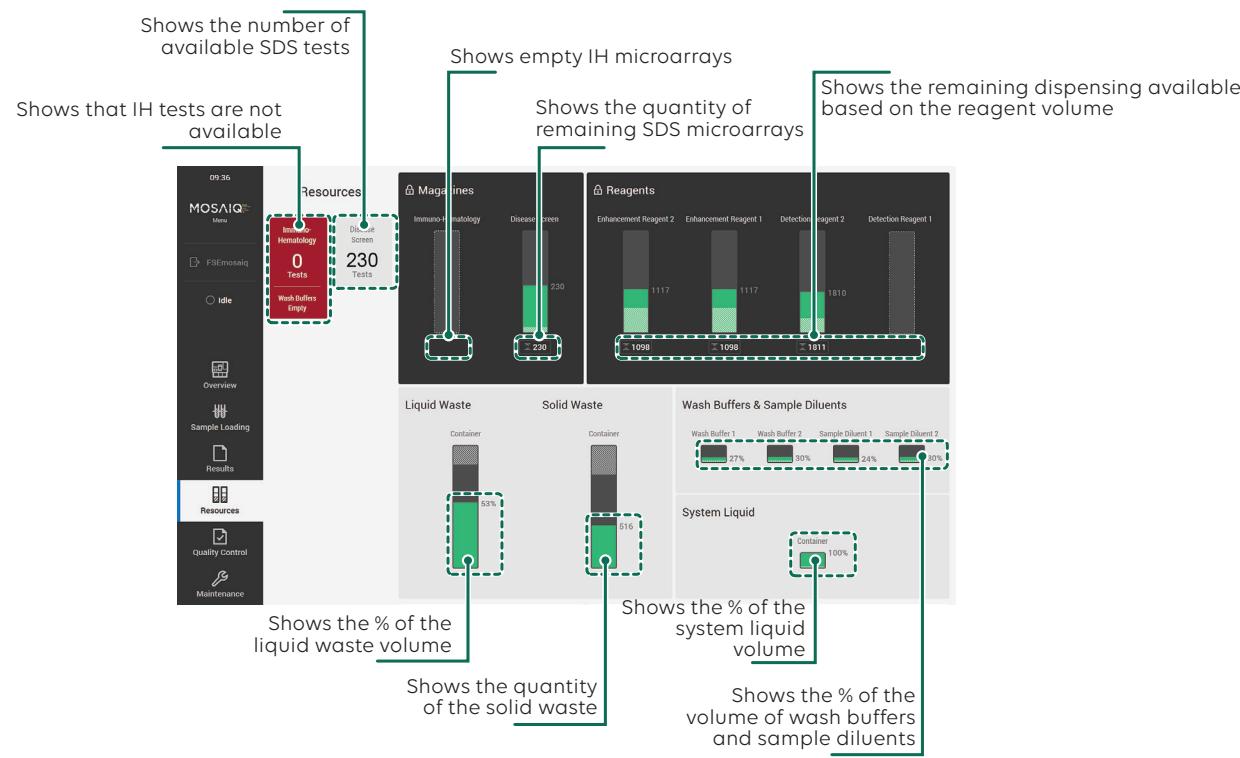
## 7.2.3 RESOURCES OVERVIEW

The following section explains how to display an overview of all the available resources. When loading samples, **MosaiQ 125** checks if conditions are met to run the tests.

If all conditions are not met, **MosaiQ 125** will display a caution message and it will prevent the execution of the run (the “**Add to Process**” button will not be available).

1 - To control available resources, tap on the **Resources** icon in the navigation bar.

2 - The **Resources** screen will display all resources conditions on the **MosaiQ 125**.



(resources screen details)

## 7.2.4 CHECKING INDIVIDUAL RESOURCES

The following section provides step-by-step instructions on how to check each resource.

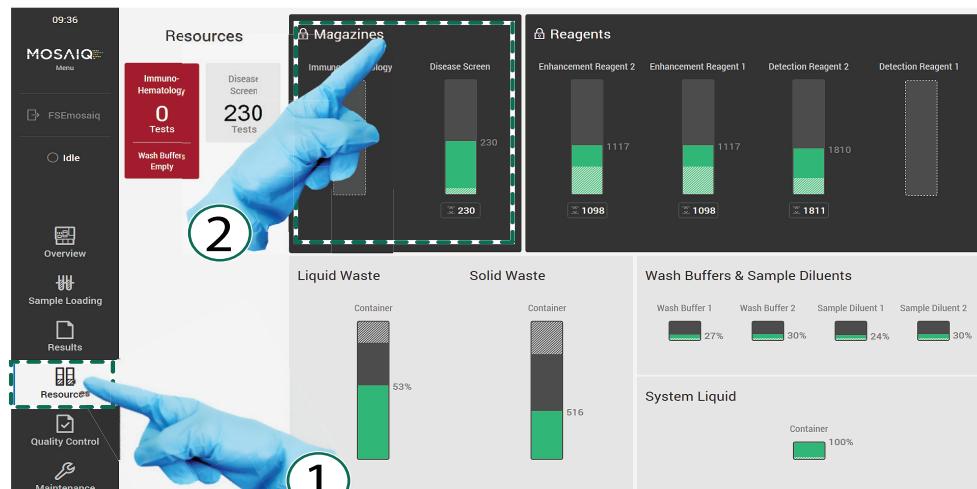
### NOTICE

Please, consider that SDS (Serological Disease Screening) is limited to Covid19 assay only.

### Magazines

To check the quantity of microarrays available in the magazines:

- ① Tap on the **Resources** icon in the navigation bar. The **Resources** screen shows the quantity of microarrays available for the Covid19 test.
- ② To see the details of each magazine, tap on the **Magazines** area of the **Resources** screen.

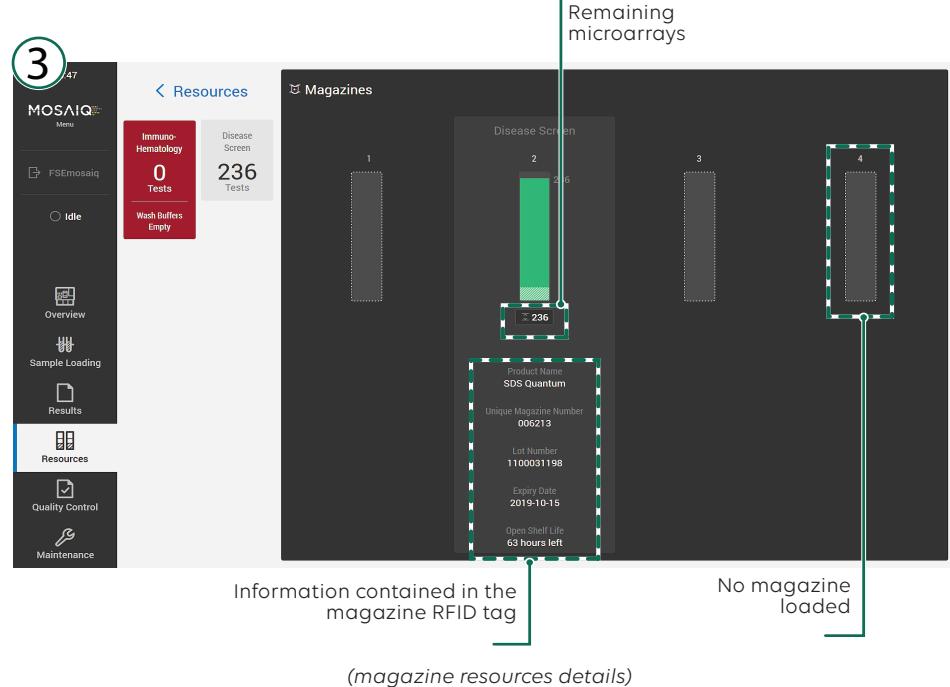


(magazine resources area)

### NOTICE

- If **MosaiQ 125** has only SDS magazines loaded, the screen will display only the SDS magazine level bar.
- **MosaiQ 125** will always use the magazine which has a shorter period of validity first.
- To return to the main **Resources** screen, tap anywhere on the resources white zone.

- ③ The **Magazines** screen shows the number of microarrays remaining in each magazine.



4 - Verify if the number of microarrays remaining in each magazine is sufficient to start the test run.

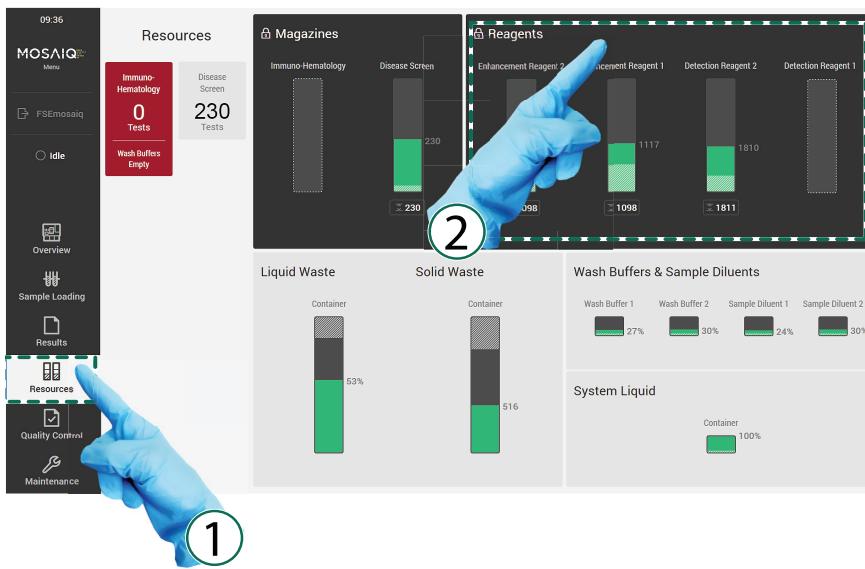
5 - The **Magazines** screen shows the detailed information about each magazine loaded in the **MosaiQ 125**, such as:

- The remaining quantity of microarrays available,
- The catalog number,
- The unique magazine number,
- The lot number,
- The expiry date,
- The remaining open shelf life.

### Reagents

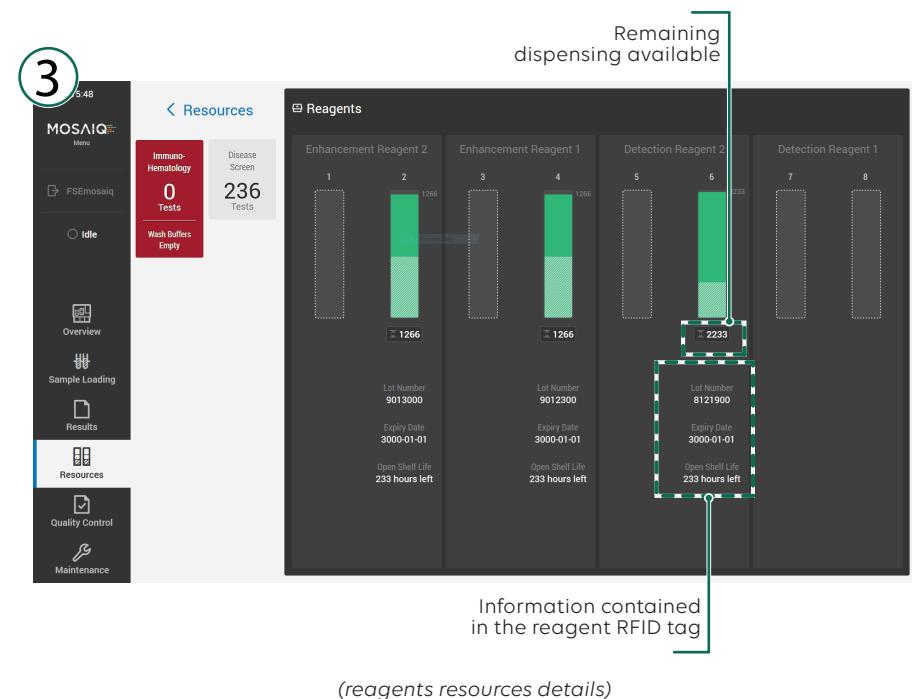
To check the quantity of reagents available:

- ① Tap on the **Resources** icon in the navigation bar. The **Resources** screen shows the remaining volume of each reagent in each bottle.
- ② Tap on the **Reagents** area to check the reagent details.



- ③ The following data are displayed for each reagent:

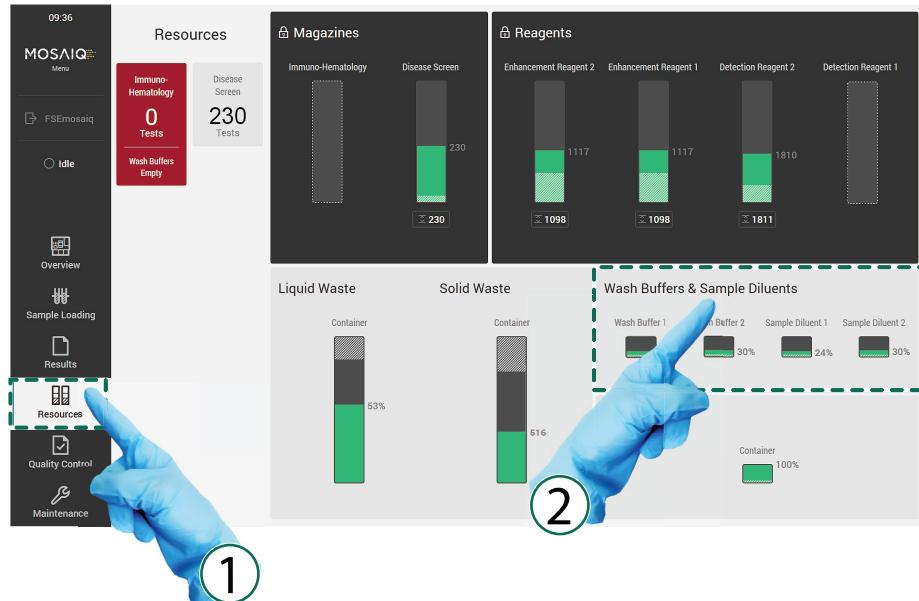
- The fill level of every bottle and the number of tests remaining,
- The lot number,
- The expiry date,
- The remaining open shelf life.



### MosaiQ wash buffers and MosaiQ sample diluents

To check the quantity of wash buffers and sample diluents available:

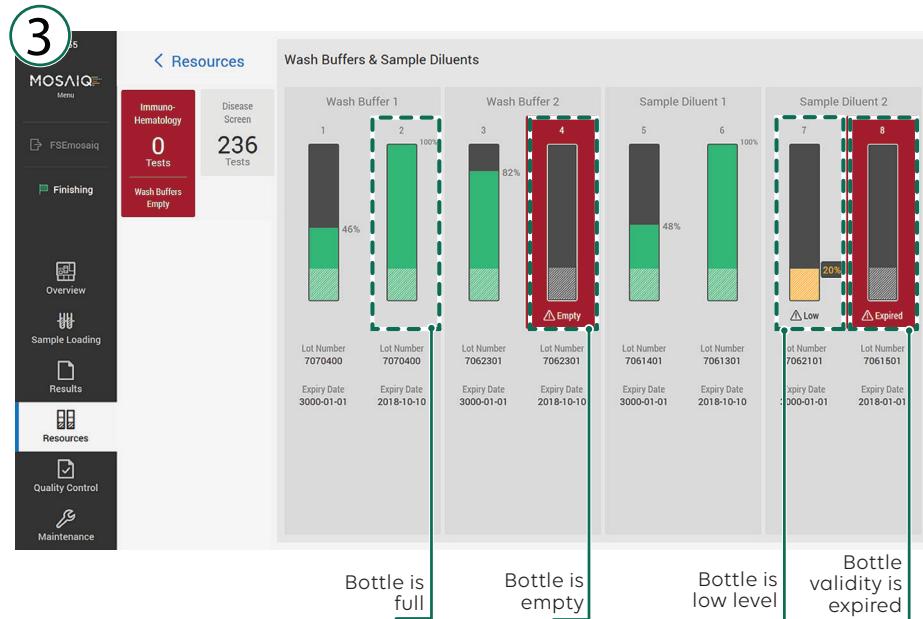
- ① Tap on the **Resources** icon in the navigation bar. The **Resources** screen shows the remaining volumes of each buffer and diluent bottle.
- ② Tap on the **Wash Buffers & Sample Diluents** area to display the details.



(buffers and diluents resources area)

- ③ The following data is displayed for each type of bottle:

- The reagent position,
- The lot number,
- The expiry date,



(buffers and diluents resources details)

If the level is too low, the diagram appears in orange with

Each MosaiQ wash buffer and MosaiQ sample diluent has a minimum set level which must be met to ensure correct processing.

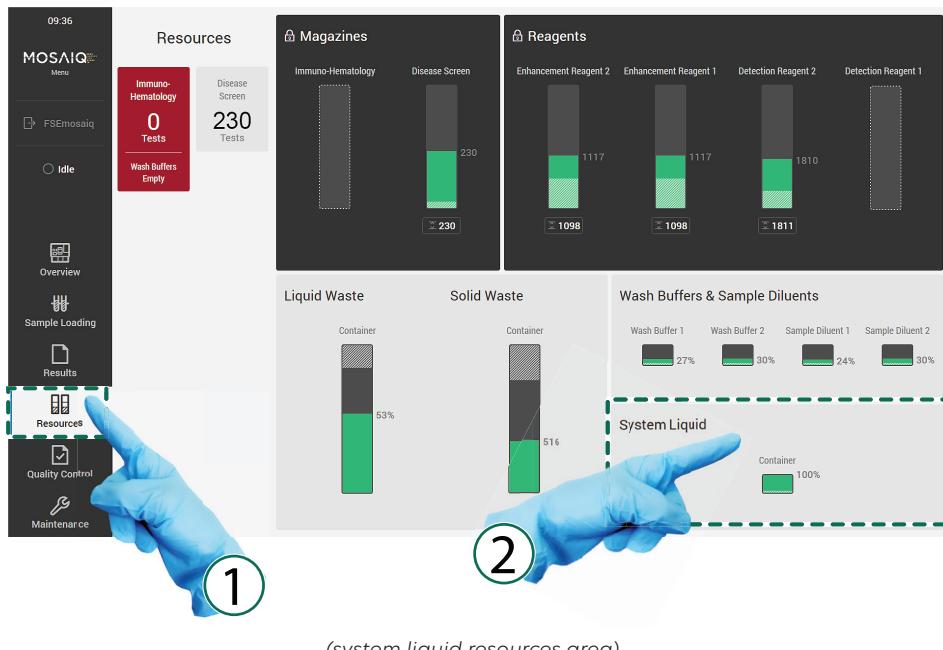
- It is possible to use one bottle or two bottles of each reagent at any one time.
- It is recommended to always load two bottles of each reagent, to allow automatic switchover when a bottle is empty without any user interaction.
- **MosaiQ 125** will always use the reagent which has a shorter period of validity first.

#### NOTICE

### Water /System Liquid

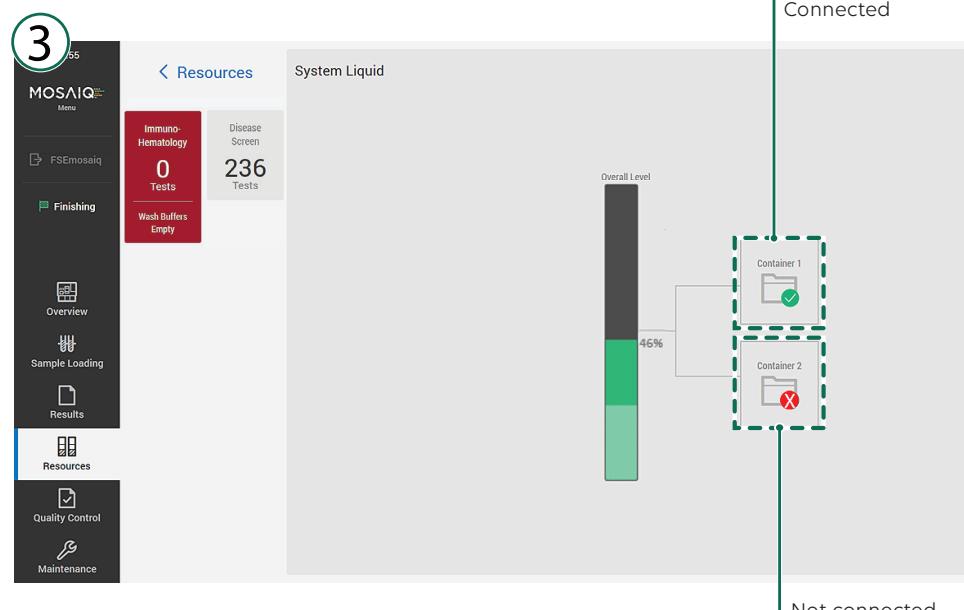
To check the quantity of water available:

- ① Tap on the **Resources** icon in the navigation bar.
- ② Tap on the **System Liquid** area to display the overall level.



(system liquid resources area)

- ③ Check the remaining volume in each canister. To refill the canister please refer to [chapter 7.3.12](#) of this manual.



- : A green dot with a check mark shows that the canister is inserted in the **MosaiQ 125**.
- : A red dot with a "X" shows that the canister is not present or not properly inserted/connected.

#### INFO

#### Re-usable canister

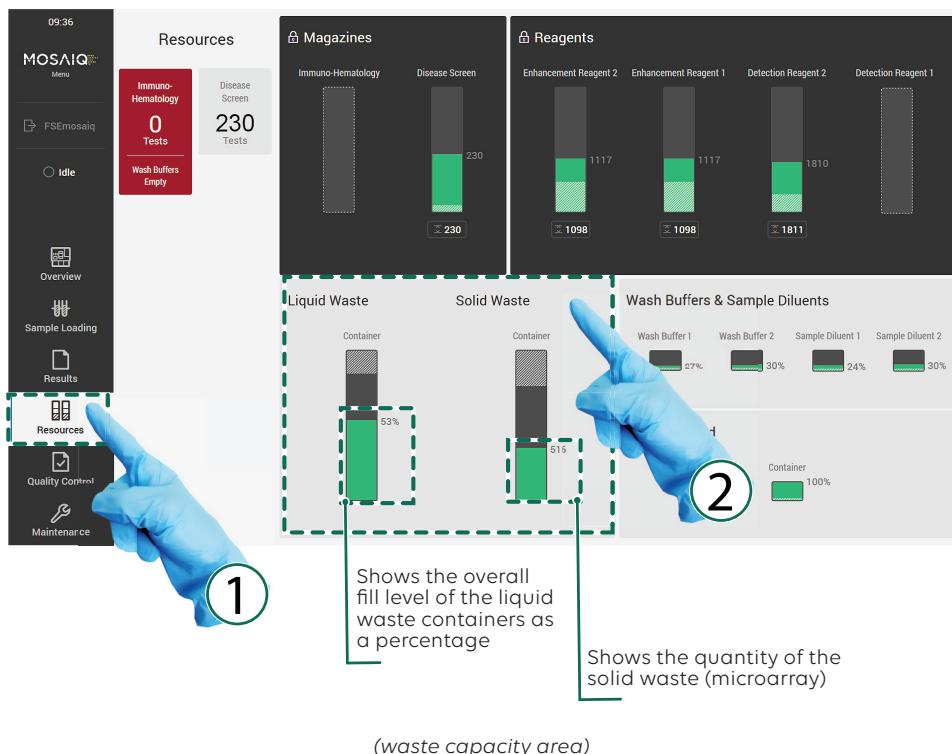
The water canister is re-usable and can contain up to 10 L purified water.

### Waste

To check the quantity of waste present in the waste container and waste canisters:

- ① Tap on the **Resources** icon in the navigation bar.
- ② Tap on the **Liquid Waste / Solid Waste** area to display the details.

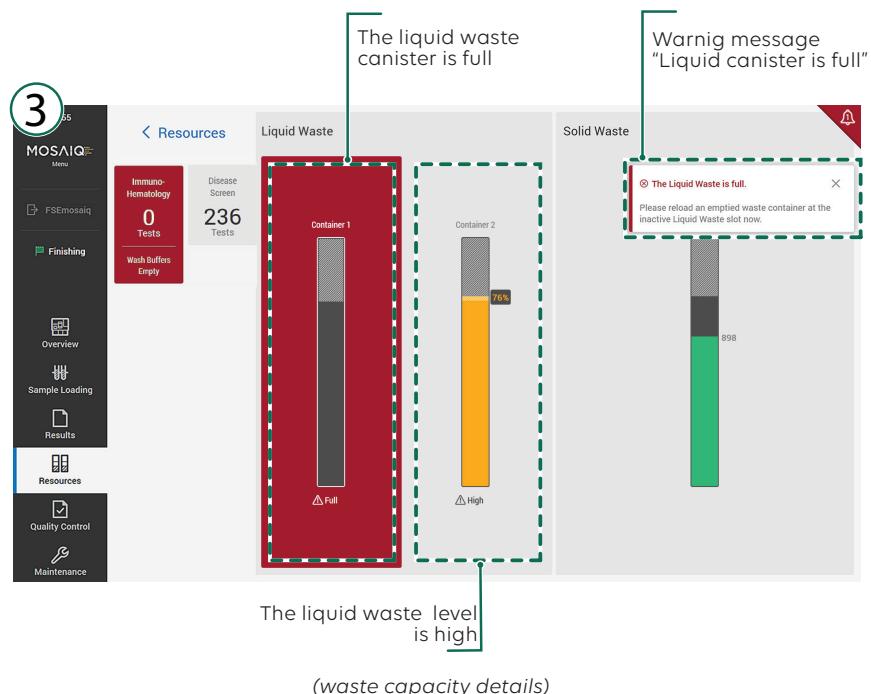
This screen shows the detailed waste volume for both liquid and solid wastes.



- ③ On the liquid and solid wastes details screen:

When both liquid waste canisters have reached their maximum capacity, a message will appear on the touch screen to inform you that both liquid waste canisters are full.

Solid waste: when the maximum calculated threshold is reached, a message will appear showing that the solid waste container is full.



#### Locked and unlocked canister

- If the system is running samples, the details screen shows a locked and an unlocked canister.
- When the instrument is running with both canisters connected, you can remove any of them if they are not full. The instrument will automatically use the one that is still connected. Only the unlocked canister may be removed. If you remove the locked canister (yellow signal LEDs are on) and no other waste canister is connected, or is full, the **MosaiQ 125** will stop.
- Remove only the unlocked canister (yellow signal LEDs are off).

#### INFO

### 7.3 HOW TO REMOVE AND LOAD EACH RESOURCE

The following section provides step-by-step instructions on how to remove and load each resource.

#### 7.3.1 REMOVING MAGAZINES

This section provides step-by-step instructions on how to remove magazines from the magazine station on the **MosaiQ 125**. The MosaiQ Software controls magazine station locking and unlocking operations.

1 - ① Open the magazine station door, and rotate the magazine carousel until the empty magazine is facing you.

2 - Remove the magazine from the magazine station

- ② Pull the upper part of the magazine toward you
- ③ Lift the magazine until it is detached



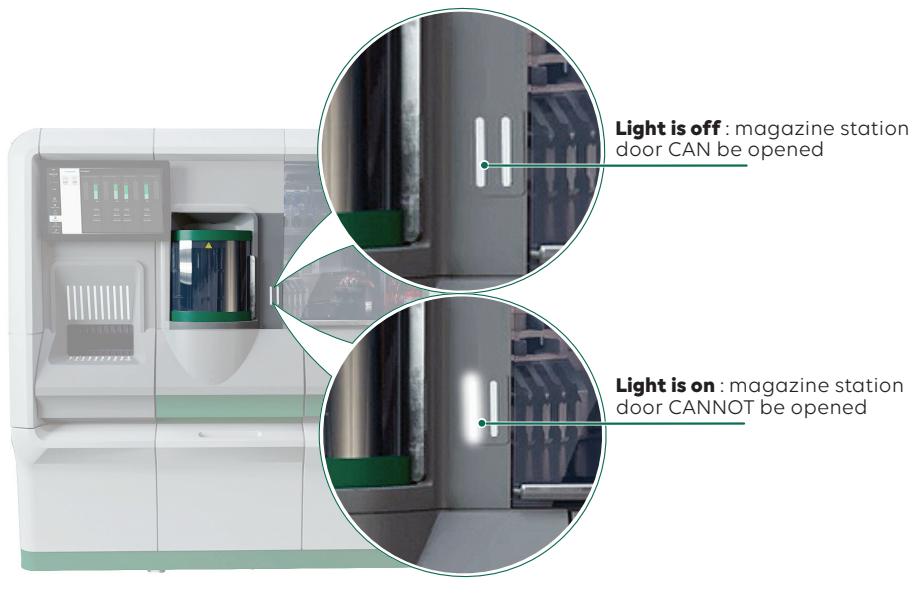
(magazine station door opening and magazine removing)

4 - Dispose of the empty magazine.

5 - If necessary, remove another magazine.

You cannot open the magazine station door when the **MosaiQ 125** is operating or performing initialization.

Wait until the light is off to open the magazine station door.



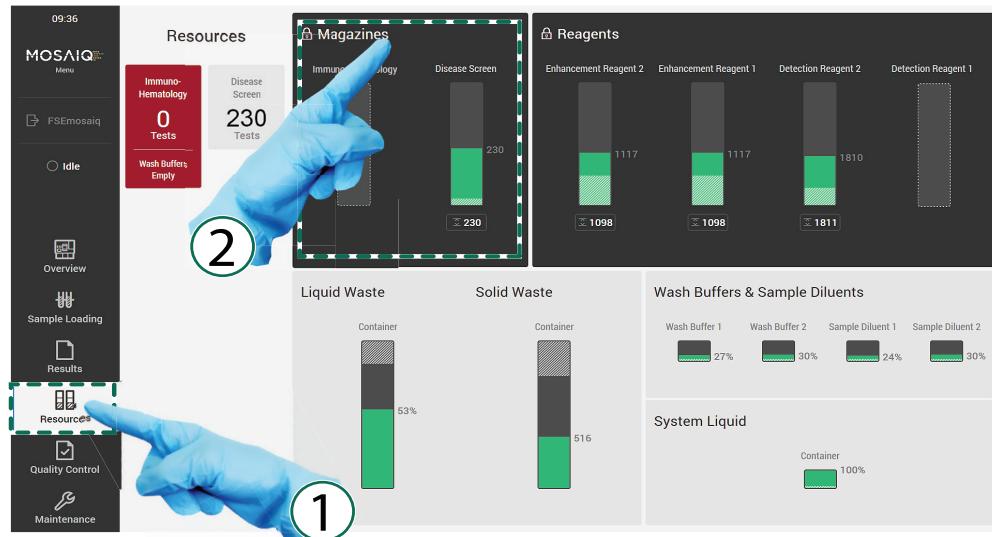
(magazine station light status)

### 7.3.2 LOADING MAGAZINES

Up to four magazines (equal or different sizes) can be loaded onto the **MosaiQ 125** at the same time.

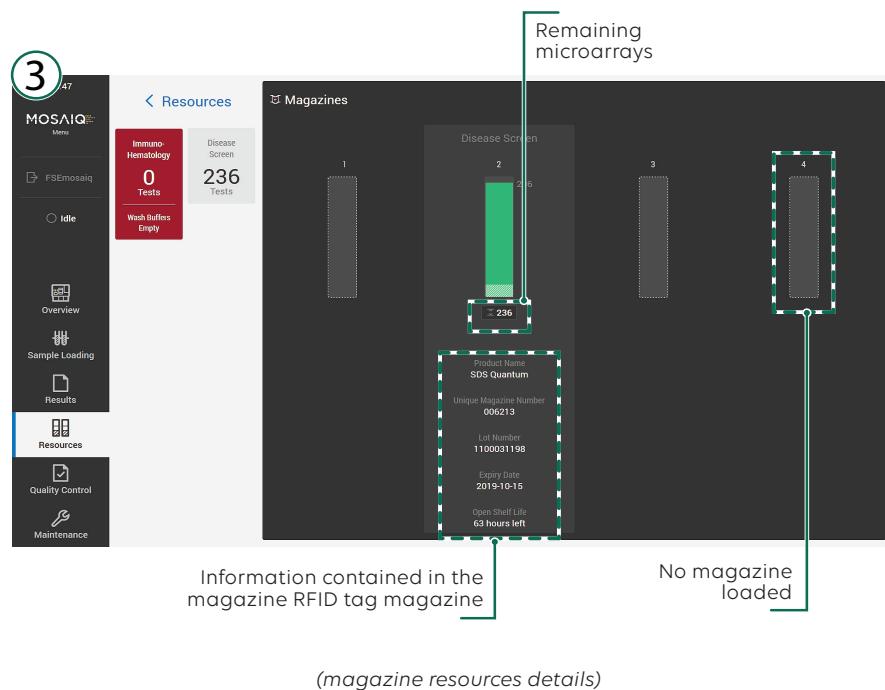
#### To load magazines:

- ① Tap on the **Resources** icon.
- ② Tap on the **Magazine** area.



(magazine resources area)

- ③ The detailed **Magazines** screen is displayed.



(magazine resources details)

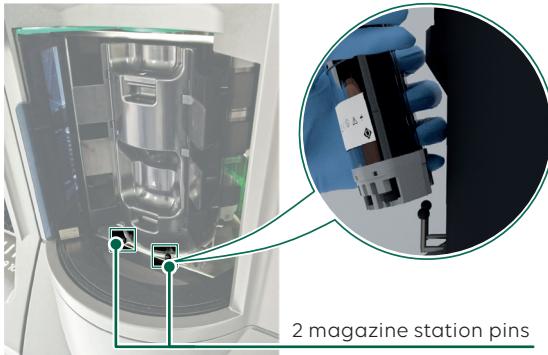
- 4 - Open the magazine station door.
- 5 - Rotate the carousel manually until you reach an available position.

#### NOTICE

The carousel is divided into 4 numbered sections.

## OPERATING INSTRUCTIONS / HOW TO REMOVE AND LOAD EACH RESOURCE

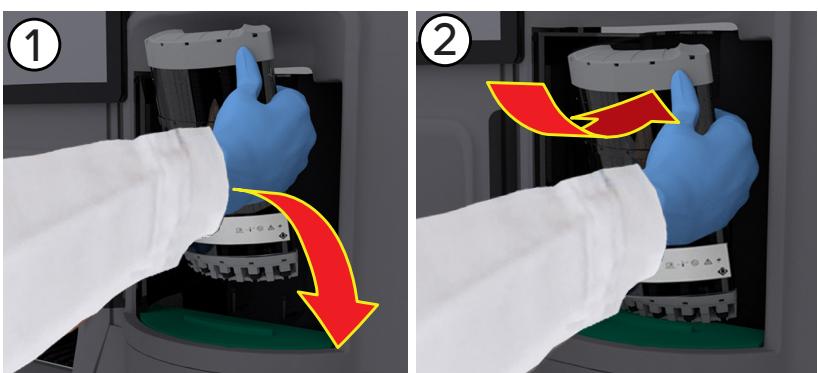
6 - Load the magazine at an angle as shown on the picture, engaging the two pins at the bottom of the microarrays carousel.



(loading the magazine in the magazine station)

7 - Slot the magazine into place, ensuring that the top bracket on the back of the magazine is securely in place.

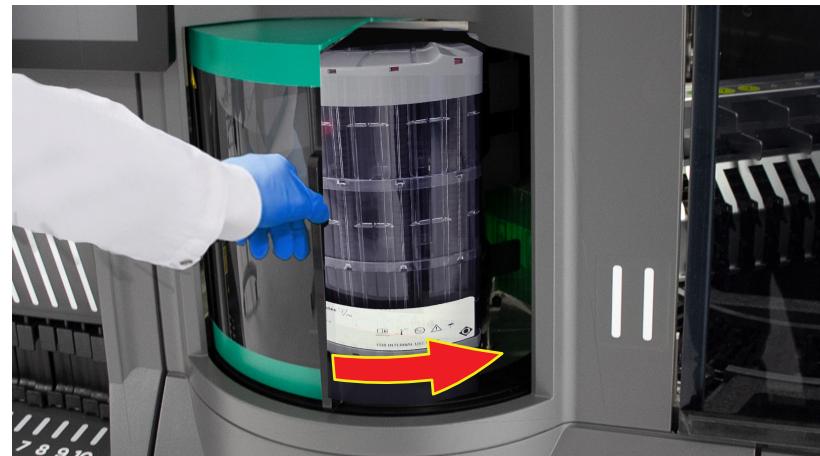
- ① Insert the bottom of the magazine first.
- ② Push the upper part of the magazine against the drum, until a click is heard.



(loading the magazine in the magazine station)

8 - To load another magazine, rotate the carousel manually until reaching an empty position and repeat the steps from point 5 to 8.

9 - Once the magazines have been loaded, close the magazine station door.



(closing the magazine station door)

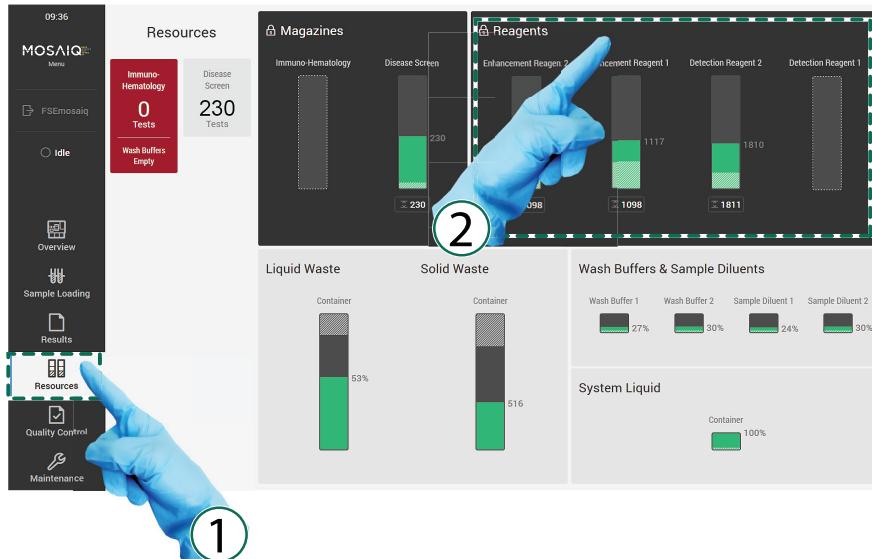
10 - The system runs a 360° rotation of the carousel to read all magazines information.

11 - Check magazine conditions (such as quantity of test available, expiry date) on the **Magazines** screen.

### 7.3.3 REMOVING MOSAIQ DETECTION AND MOSAIQ ENHANCEMENT REAGENT BOTTLES

This section provides a step-by-step instruction on how to remove reagent bottle from the reagent carriage on the **MosaiQ 125**. The system software controls the reagent door locking and unlocking.

- ① Tap on **Resources** icon in the navigation bar.
- ② Tap on the **Reagents** area to access the **Reagents** screen.



- ③ Wait until the **MosaiQ 125** status is **Idle**.



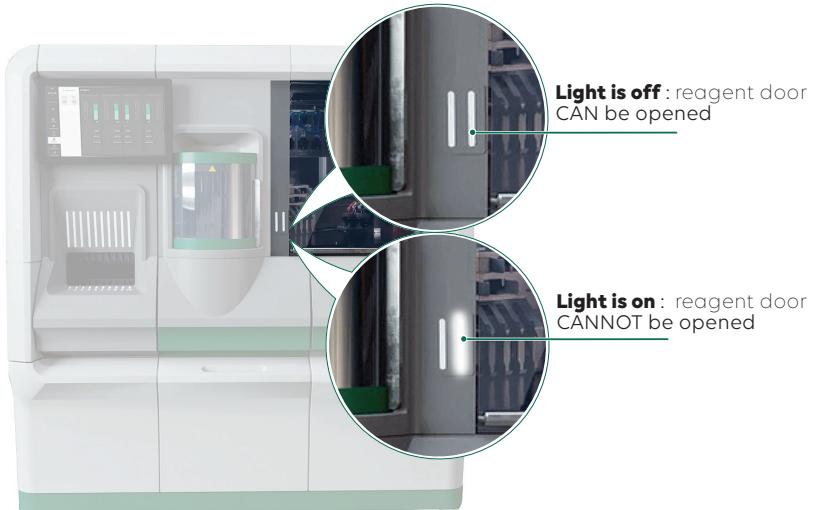
To know the remaining time before **MosaiQ 125** goes to **Idle**, go to the **Results** menu and tap on the **Processing** button.

This information is also displayed on the **Overview** screen that provides the exact time remaining until the process is finished and the status goes to **Idle**.

#### NOTICE

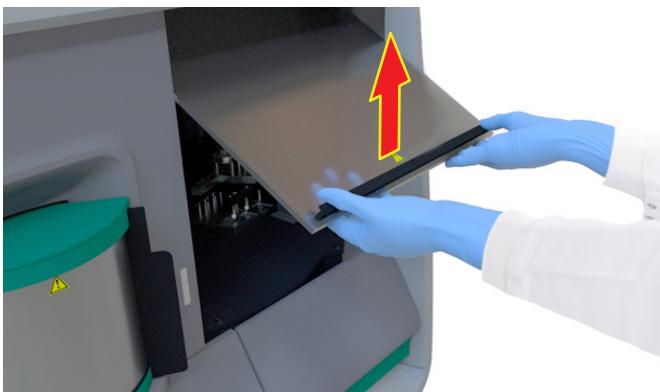
## OPERATING INSTRUCTIONS / HOW TO REMOVE AND LOAD EACH RESOURCE

**Note:** A light indicates when you can open the reagent door.



(reagent door light status)

4 - Open the reagent door by lifting the door panel up.



(opening the reagent door)

5- Press the lock mechanism of the empty reagent bottle together.



6 - Pull the empty reagent bottle backward at a 45° angle.



(removing the reagent bottle)

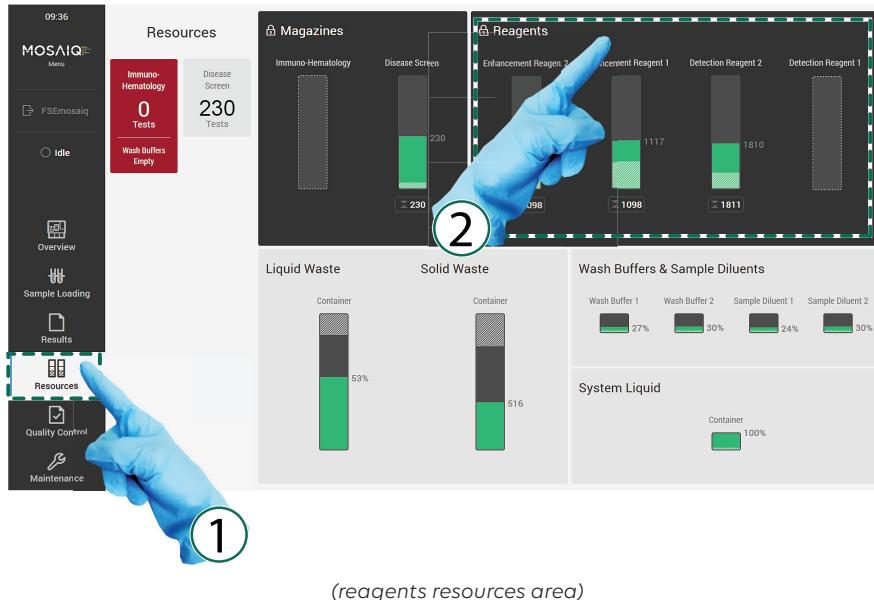
7 - Remove the empty reagent bottle.

8 - Dispose of the empty reagent bottle (follow the disposal information on the product IFU).

### 7.3.4 LOADING DETECTION AND ENHANCEMENT REAGENT BOTTLES

This section provides step-by-step instructions on how to load reagent bottles (MosaiQ detection reagents and MosaiQ enhancement reagents) into the **MosaiQ 125**. The system software controls reagent door locking and unlocking operations.

- ① Tap on the **Resources** icon in the navigation bar.
- ② Tap on the **Reagents** area to access the **Reagents** screen.



- ③ Wait until the **MosaiQ 125** status is **Idle**.



(reagents resources details screen)

#### NOTICE

To know the remaining time before **MosaiQ 125** goes to **Idle**, go to the **Results** menu and tap on the **Processing** button.

## OPERATING INSTRUCTIONS / HOW TO REMOVE AND LOAD EACH RESOURCE

4 - Open the reagent door.



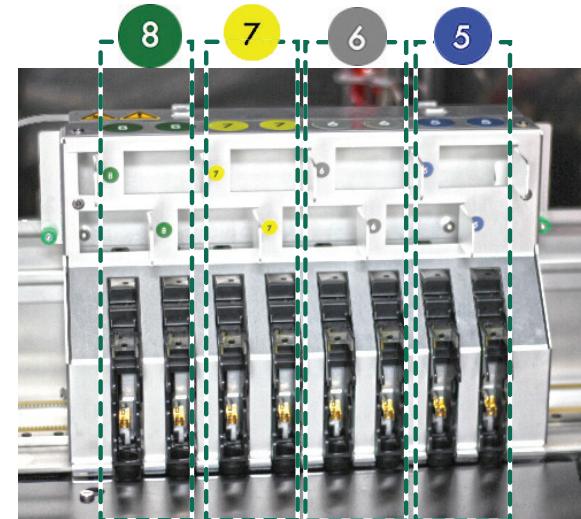
(opening the reagent door)

5 - Insert the reagent bottle at an angle into the corresponding reagent carriage position.



(insertion of the reagent bottle)

The reagent carriage can support two bottles of each reagent.



(2 slots for each MosaiQ detection and MosaiQ enhancement reagent bottles)

**NOTICE**

The correct reagents positions on the reagent carriage following the colored symbols.

6 - Press the lock mechanism of the reagent bottle cap together.



(reagent bottles lock mechanism)

7 - Release the lock and make sure that it snaps into place.

8 - If necessary, load another reagent bottle.

9 - Close the reagent door.

10 - Wait until the system initializes the reagent carriage.

11 - Check the MosaiQ system reagent conditions (volume available, expiry date) on the **Resources** screen.

**NOTICE**



The upright symbol on the reagent bottles packaging is meant for transport and storage purposes only.

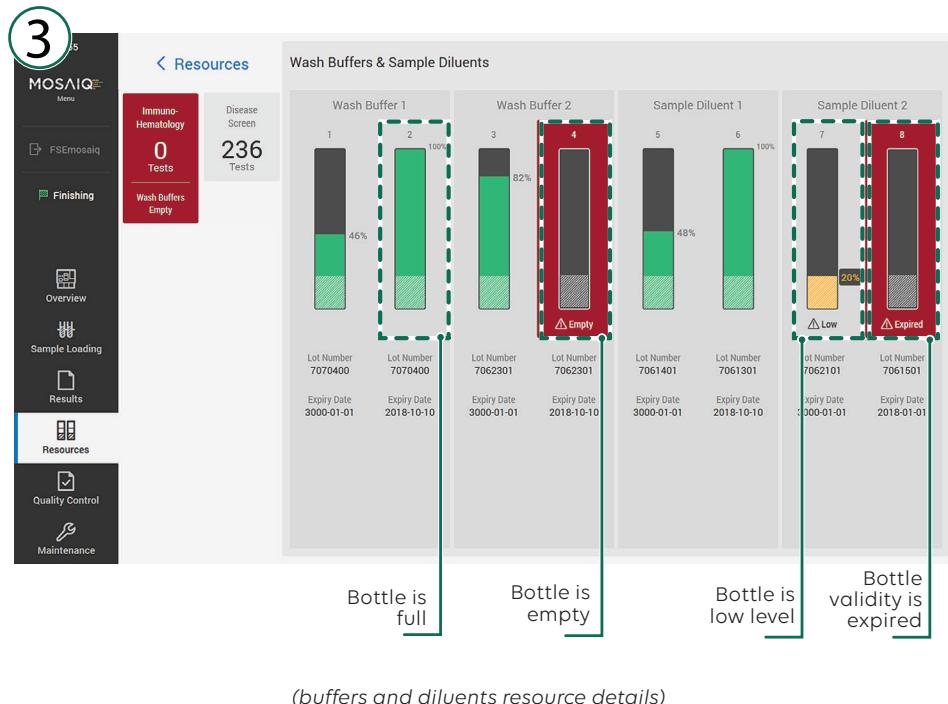
### 7.3.5 REMOVING THE MOSAIQ WASH BUFFER AND MOSAIQ SAMPLE DILUENT BOTTLES

This section explains how to remove the bottles from the **MosaiQ 125**. The bottles are located in the reagent drawer. The reagent drawer can be opened and closed manually when the **MosaiQ 125** is in operation.

- ① Tap on the **Resources** icon in the navigation bar.
- ② Tap on the **Wash Buffers & Sample Diluents** area.

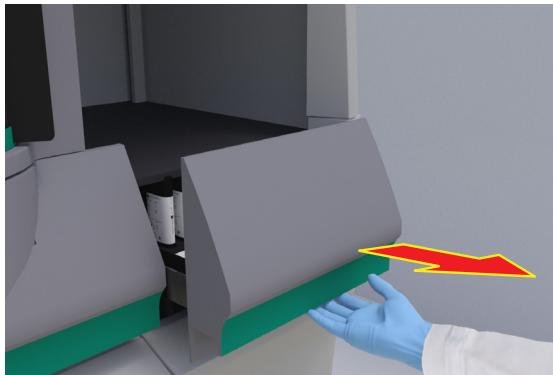


- ③ Empty and low-level bottles are displayed in red and orange on the screen respectively.



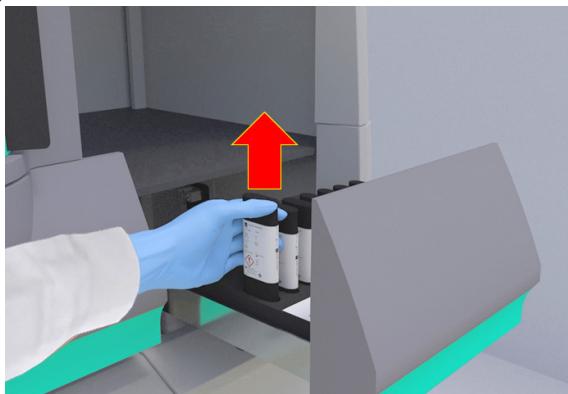
## OPERATING INSTRUCTIONS / HOW TO REMOVE AND LOAD EACH RESOURCE

4 - Open the reagent drawer.



(opening the reagent drawer)

5 - Draw the empty bottles out.



(removing of the buffer or diluent bottle)

6 - Dispose of the empty bottles (follow the disposal information on the product IFU).

### INFO

Bottles can be removed even when they are low level and not empty.



### NOTICE

The upright symbol on the reagent bottles packaging is meant for transport and storage purposes only.

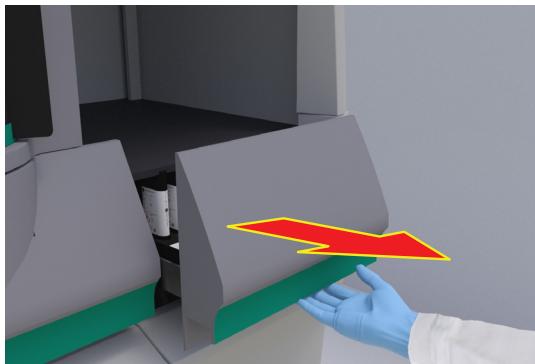
### 7.3.6 LOADING THE MOSAIQ WASH BUFFER AND MOSAIQ SAMPLE DILUENT BOTTLES

This section explains how to load the bottles into the **MosaiQ 125**.

The bottles are located in the reagent drawer.

The reagent drawer can be opened or closed when the **MosaiQ 125** is in operation.

1 - Open the drawer.



(opening the reagent drawer)

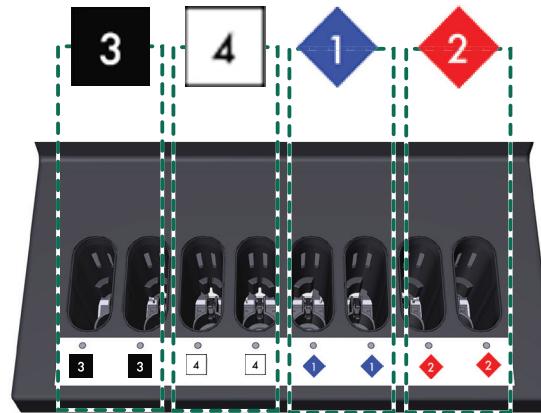
2 - Insert the MosaiQ wash buffer and MosaiQ sample diluent bottles upside down in the appropriate location.

3 - Press the bottle down slightly.



(inserting the buffer and diluent bottles)

4 - Bottles can be loaded in duplicate for higher throughput if required.



(2 slots for each MosaiQ wash buffer and MosaiQ sample diluent bottles)

### 7.3.7 REMOVING THE SOLID WASTE BAG

This section explains how to empty the solid waste container of the **MosaiQ 125**. The solid waste container is located in waste drawer. Since this waste is of a biological nature (blood samples), a biohazard waste bag is used to line the waste container. The solid waste drawer can be opened and closed manually when the **MosaiQ 125** is in operation.

**NOTICE**

Use commercially available 50 liter biohazard waste bags.

There is a waste buffer with a capacity of 30 microarrays, allowing up to 12 minutes to replace the bag during operation.

- 1 - Tap on the **Resources** icon in the navigation bar.
- 2 - Tap on the **Liquid Waste / Solid Waste** area to check the level.
- 3 - Open the waste drawer.
- 4 - Pull out the solid waste container.
- 5 - Pull the rear holding clamp and release the full bag.
- 6 - Remove the full bag.
- 7 - Dispose of the full bag according to your laboratory biohazard waste procedure.



(removing of the solid waste bag)

During the emptying and loading operation, on the **Resources** screen, an icon shows that the waste drawer door is open and the remaining quantity of microarrays in the waste buffer container.



(solid waste drawer status and back up bin capacity)

### 7.3.8 LOADING THE SOLID WASTE BAG

This section explains how to load the solid waste container in the **MosaiQ 125**. The solid waste canister is located in the waste drawer. Since this waste is of a biological nature (blood samples), a biological waste bag is used to line the solid waste container.

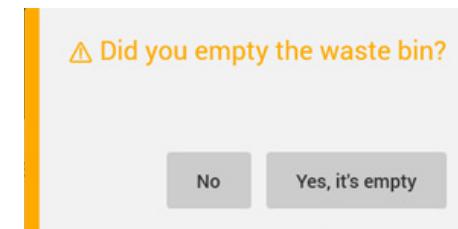
The solid waste drawer can be opened and closed manually when the **MosaiQ 125** is in operation.

- 1 - Open the waste drawer.
- 2 - Pull out the solid waste container
- 3 - Insert one side of the empty waste bag over the front edge of the waste container.
- 4 - Press the holding clamp against the back edge of the container.
- 5 - Place other side of the waste bag over the holding clamp.
- 6 - Gently release the holding clamps.



(placing of the solid waste bag)

- 7 - Close the waste drawer.
- 8 - Tap on the **Resources** icon in the navigation bar.
- 9 - Confirm the message by tapping on the **Yes, it's empty** button.



(confirmation message)

### 7.3.9 REMOVING LIQUID WASTE CANISTER

This section explains how to remove the liquid waste canister from the **MosaiQ 125**. The liquid waste canister is located in the waste drawer. Even when the **MosaiQ 125** is in operation, it is possible to remove one of the cannisters even if its not completely full. The liquid waste drawer can be opened and closed manually.

#### INFO Re-usable canister

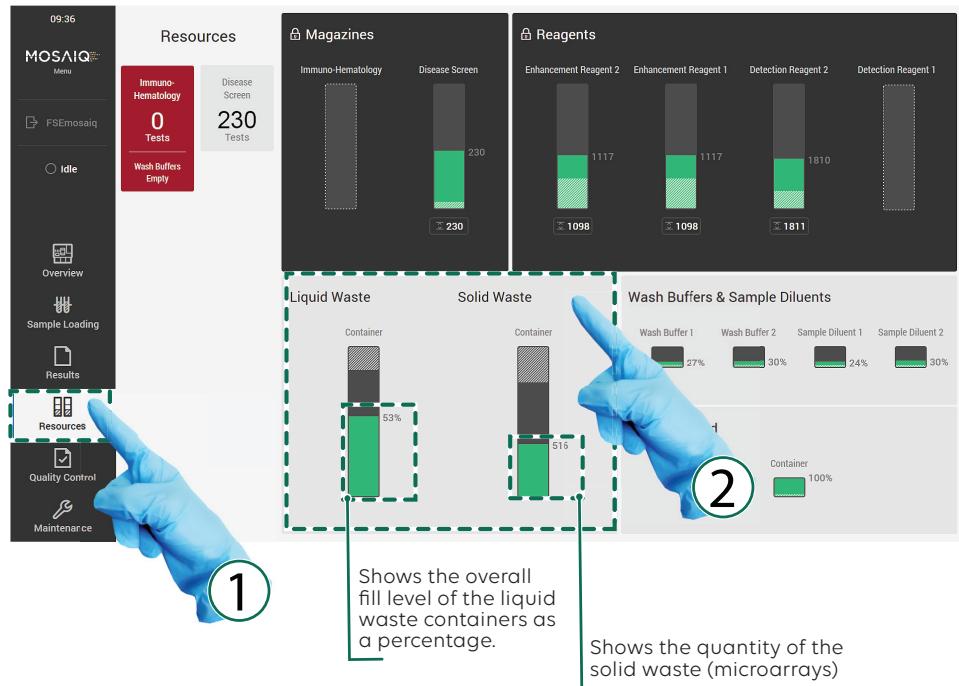
- The liquid waste canister is re-usable and can hold up to 10 L.
- The liquid waste canister must be cleaned monthly, please see: [chapter 12.7.1](#) of this manual.

#### CAUTION

The liquid waste canister should be filled in accordance with the laboratory local manual handling guidelines for maximum weight limit at work. It is recommended to make a visual mark on the canister to visualize the filling limit complying with the maximum weight as per local regulation.

When filled with 10 L of liquid waste, a canister can weight up to 11,2 kg.

- ① Tap on the **Resources** icon in the navigation bar.
- ② Tap on the **Liquid Waste / Solid Waste** area to check the level.



(waste capacity area)

## OPERATING INSTRUCTIONS / HOW TO REMOVE AND LOAD EACH RESOURCE

3 - Detailed information for each waste canister and waste container is displayed.



(solid and liquid waste capacity details)

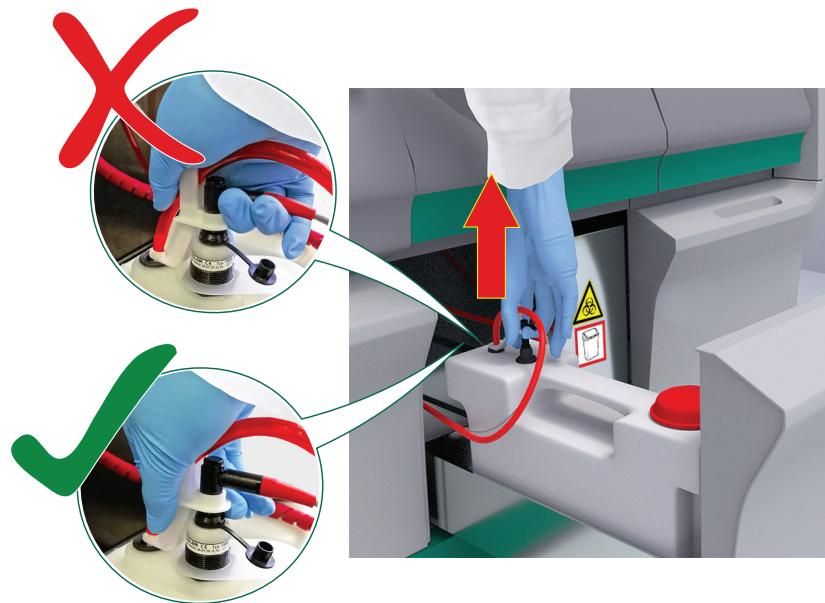
4 - Open the waste drawer.



(opening of the waste drawer)

5 - Remove the canister which is not in use (signal LED off).

6 - Pull up the level sensor connectors only by holding the white plastic support. Avoid pulling or bending the black parts and the electric wire because these are fragile, and they may be damaged.



(removing of the liquid waste level sensor)

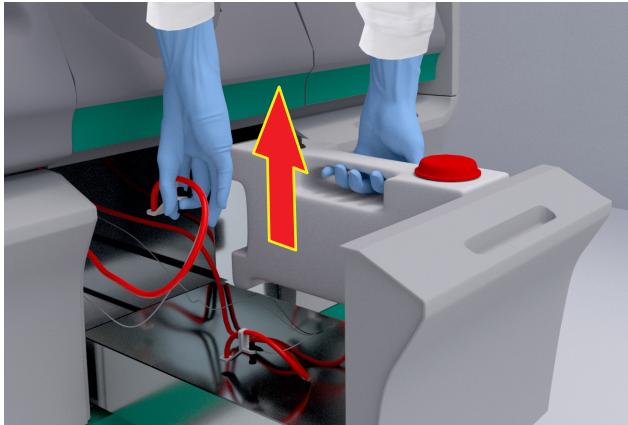
7 - Fit the stoppers onto the canister level sensor holes.



(fitting the stopper of the canister level sensor hole)

8 - Remove the canister.

9 - Leave the connectors in the canisters drawer.



(removing of the liquid waste canister)

10 - Open the canister screw caps.

11 - To empty the waste canister, tip it on its side gently.

12 - Close the screw caps.

### Risk of injury

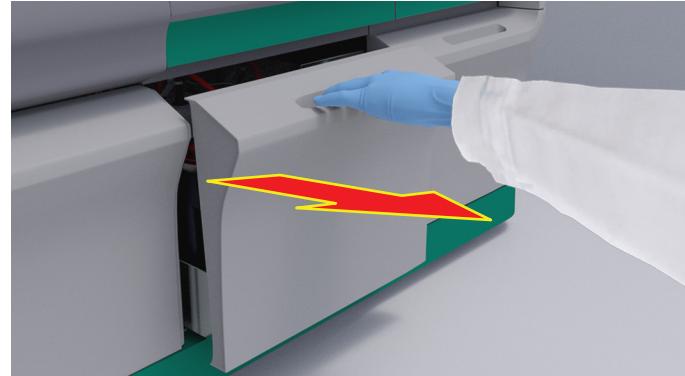


While emptying the liquid waste canister wear protective glasses and gloves.

### 7.3.10 LOADING LIQUID WASTE CANISTER

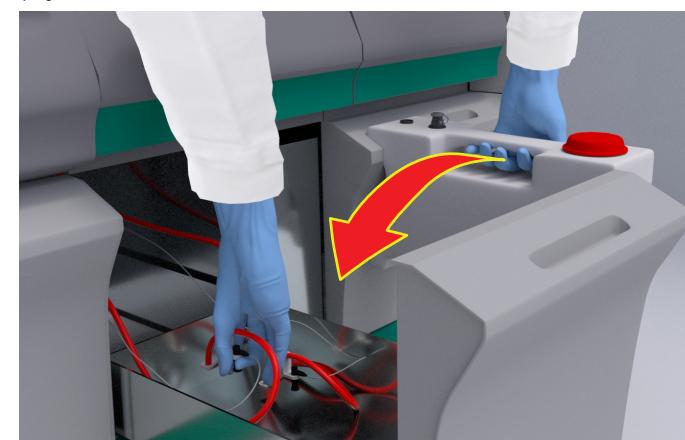
This section explains how to load the liquid waste canister into the **MosaiQ 125**. The liquid waste canister is located in the waste drawer. The liquid waste drawer can be opened and closed manually when the **MosaiQ 125** is in operation.

1 - Open the drawer.



(opening of the waste drawer)

2 - Insert the empty canister.



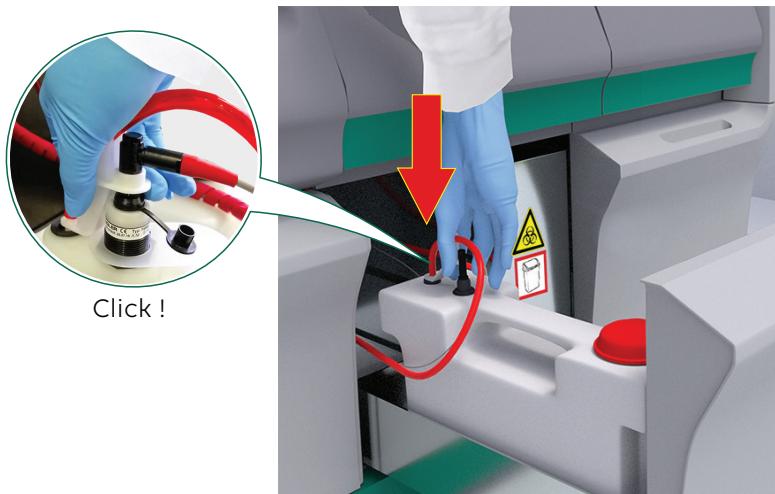
(inserting of the empty liquid waste canister)

3 - Remove the stoppers from the canister level sensor holes.



(removing the stopper of the canister level sensor hole)

4 - Plug in the level sensor connector and insert the liquid waste connector into the canister, until a click is heard.



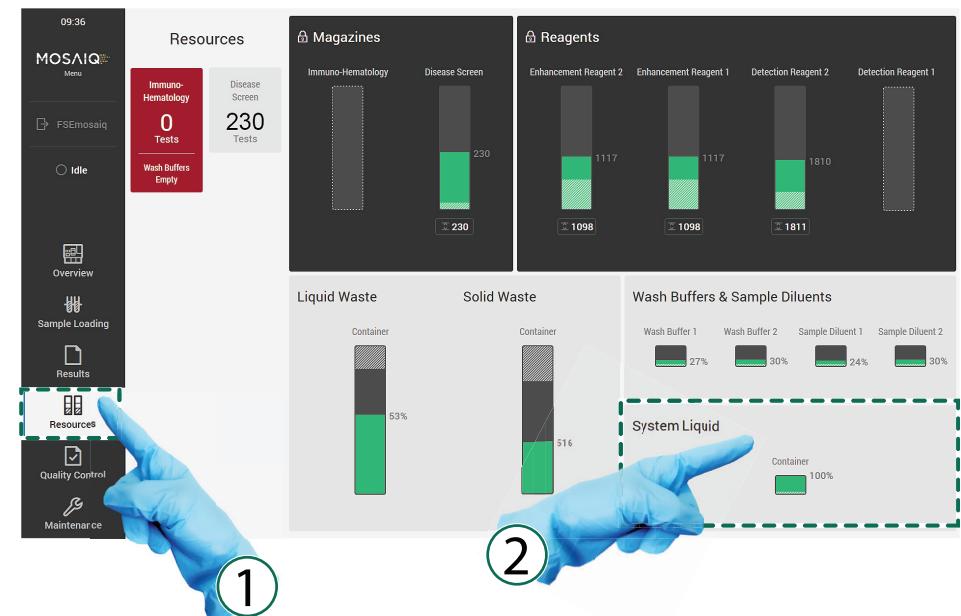
(plugging in the liquid waste level sensor)

### 7.3.11 REMOVING THE WATER CANISTER

This section explains how to remove the water canister from the **MosaiQ 125**. The water canisters are located in the water drawer. The water drawer can be opened and closed manually. The users can open and close this compartment when the **MosaiQ 125** is in operation if a canister needs to be replaced or refilled.

To remove the water canister:

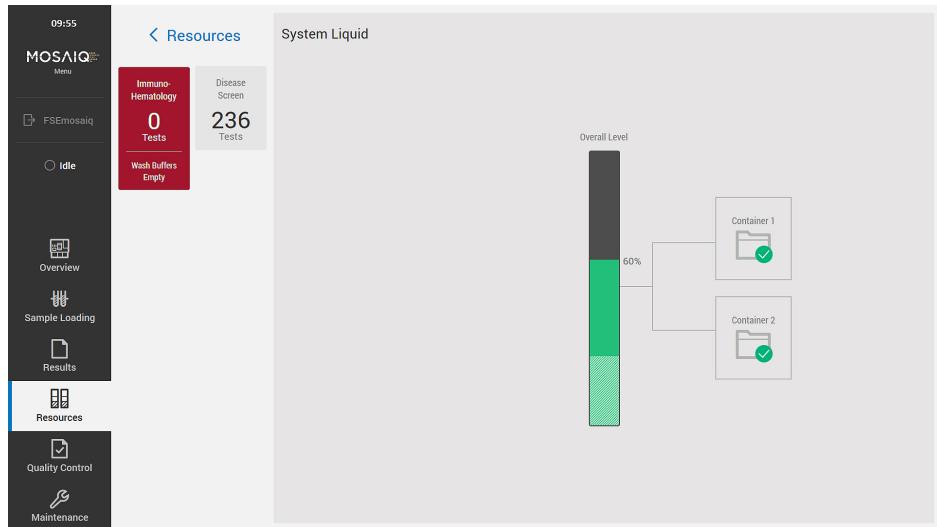
- ① Tap on the **Resources** icon in the navigation bar.
- ② Tap on the **System Liquid** area to check the percentage of remaining volume in each canister.



(system liquid resources area)

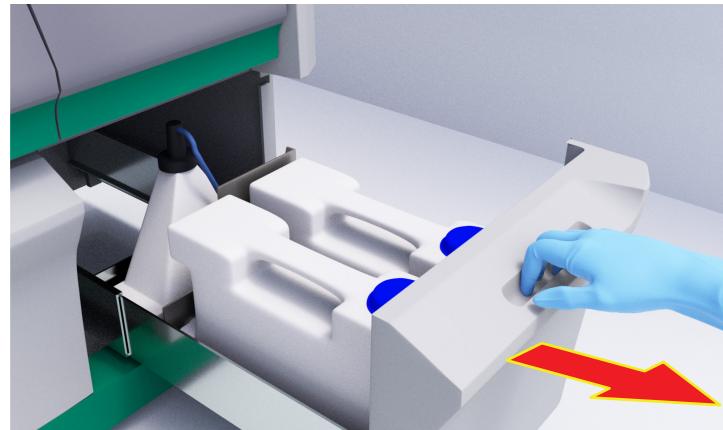
## OPERATING INSTRUCTIONS / HOW TO REMOVE AND LOAD EACH RESOURCE

Detailed information for each water canister is displayed.



(water canisters detailed information)

3 - Open the water drawer.



(opening the water drawer)

4 - Remove the canister straightforward, to prevent damaging the connection between the canister and the reservoir.



(removing of the water canister, mind the water canister / reservoir connection)

### 7.3.12 LOADING THE WATER CANISTER

This section explains how to load the water canister into the **MosaiQ 125**. The water canisters are located in the water drawer.

The water drawer can be opened and closed manually when the **MosaiQ 125** is in operation if a canister needs to be replaced or refilled.

The water canister must be filled in accordance with the laboratory local manual handling guidelines for maximum weight limit at work. It is recommended to make a visual mark on the canister to visualize the filling limit complying with the maximum weight as per local regulation.

When filled with 10 L of purified water, a canister can weigh up to 11,2 kg.

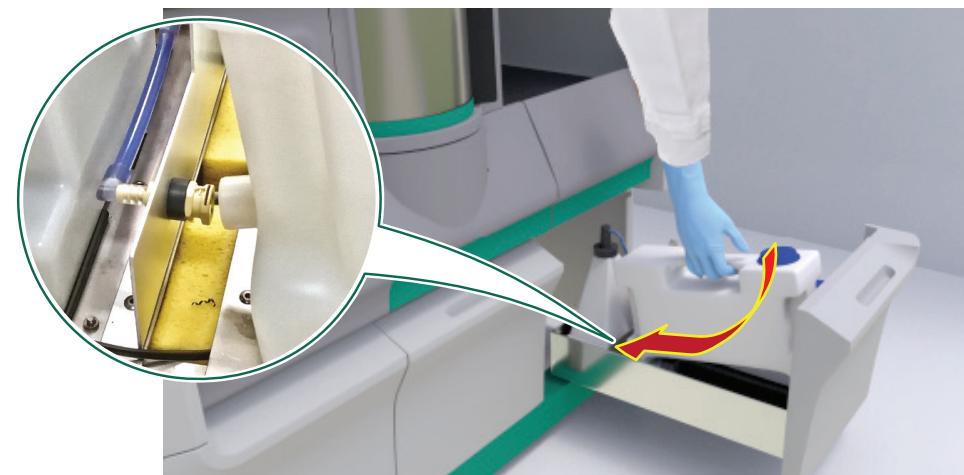
#### CAUTION

#### NOTICE

- The **MosaiQ 125** requires purified water (i.e. deionized water). For more information on the water quality required, please contact your local technical representative.
- The purified water must be used at room temperature.
- At a minimum, one 10 L canister must be present for the system to operate.
- Up to two 10 L canisters can be installed at the same time.

To load the water canister:

- 1 - Open the water canister screw cap and fill it with 10 L of purified water.
- 2 - Close the screw cap.
- 3 - Open the water drawer.
- 4 - Insert the canister into the **MosaiQ 125** straightforward, to prevent damaging the connection between the canister and the reservoir.



(loading of the water canister, mind the water canister / reservoir connection)

5 - Press down on the front of the canister.

6 - Ensure that the water canister is fitted correctly to the intermediate reservoir to avoid any leakage of purified water.

# 8. SAMPLE LOADING AND TESTING

<b>8.1</b>	<b>SAMPLE PROCESS FLOW OVERVIEW</b>	<b>86</b>		
<b>8.2</b>	<b>GLOBAL SAMPLE PROCESS FLOW</b>	<b>87</b>		
8.2.1	SAMPLE ORDERING- PHASE 1	87		
8.2.2	SAMPLE PROCESSING - PHASE 2	88		
8.2.3	SAMPLE CONFIRMATION - PHASE 3	88		
8.2.4	SAMPLE REVIEW - PHASE 4	89		
<b>8.3</b>	<b>PREPARING SAMPLE RACKS AND TUBES</b>	<b>90</b>		
<b>8.4</b>	<b>SELECTING LOADING LANE</b>	<b>90</b>		
<b>8.5</b>	<b>INSERTING SAMPLE RACKS</b>	<b>91</b>		
<b>8.6</b>	<b>TEST ORDERS</b>	<b>95</b>		
8.6.1	AUTOMATIC TEST ASSIGNMENT	95		
8.6.2	MANUAL TEST ASSIGNMENT	95		
<b>8.7</b>	<b>INDIVIDUAL TEST ORDER ASSIGNMENT</b>	<b>97</b>		
<b>8.8</b>	<b>BARCODE READING ERRORS</b>	<b>98</b>		
8.8.1	CHECK BARCODE LABELS	98		
8.8.2	EDIT SAMPLE ID(S)	99		
			<b>8.9</b>	<b>Barcode Specifications</b>
			8.9.1	LABEL
			8.9.2	FORMAT AND STANDARD
			8.9.3	NUMBER OF CHARACTERS SUPPORTED
			<b>8.10</b>	<b>SAMPLE TUBE REQUIREMENTS</b>
			<b>8.11</b>	<b>SAMPLE TESTING MONITORING</b>
			8.11.1	OVERVIEW
			8.11.2	END OF A RUN
			<b>8.12</b>	<b>COVID19 TEST RESULTS</b>
			<b>8.13</b>	<b>REPEATING TESTING BY "DATA REDUCTION ERROR" OR "TECHNICAL ERROR"</b>
			<b>8.14</b>	<b>TEST RESULTS FLAGS</b>
			<b>8.15</b>	<b>REVIEWING RESULTS</b>
			<b>8.16</b>	<b>FILTERING OF TEST RESULTS</b>
			<b>8.17</b>	<b>PRINTING TEST RESULTS</b>
				<b>99</b>
				<b>100</b>
				<b>100</b>
				<b>101</b>
				<b>101</b>
				<b>104</b>
				<b>105</b>
				<b>107</b>
				<b>108</b>
				<b>109</b>

## 8.1 SAMPLE PROCESS FLOW OVERVIEW

The following table shows the different possible scenarios for each test together with the associated process status. There are 7 different possible process order status.

**Standby**: The sample is loaded in a rack, the order has been placed and is waiting to be put in process.

**Processing**: The order is placed in the **Processing** status from the **Standby** status after the rack has been added to process (first execution of the order).

**Confirmation**: The order may be placed in the **Confirmation** status from the **Processing** status in the following cases:

- From the **Processing** status, if one of the confirmation criteria defined in the application is met.
- From the **Review** status, by user request and if the result of the order has not been already confirmed.

**Finished**: The order is placed in the **Finished** status from the **Processing** or **Confirmation** status when the final result is available after the processing or confirmation(s) is (are) completed.

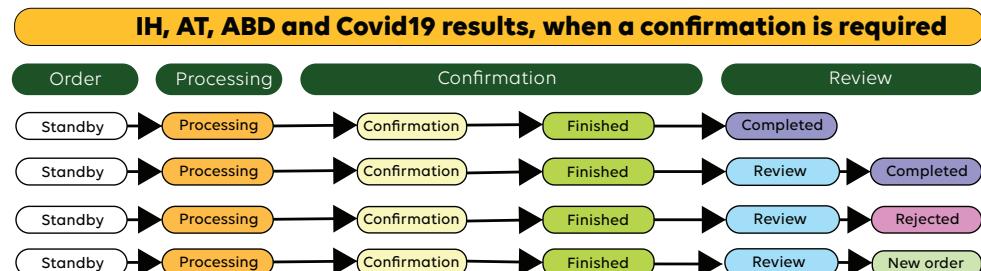
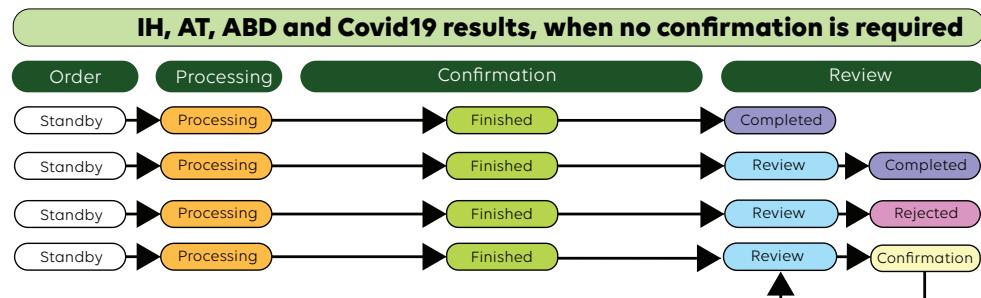
**Review**: The order may be placed in the **Review** status from the **Finished** status if one of the review criteria defined in the application is met.

**Rejected**: The order may be placed in the **Rejected** status from the **Review** status by user request. In the **Rejected** status, the result will not be transmitted to the LIS.

**Completed**: The order may be placed in the completed status in the following cases:

- From the **Finished** status if the review criteria are not met.
- From the **Review** status, by user request. (Manual Validation).

In the **Completed** status, the result is validated, displayed and transmitted to the LIS (if connected).



## 8.2 GLOBAL SAMPLE PROCESS FLOW

This section provides information on how the sample is processed from the sample loading until the results.

The sample processing workflow is composed of four key phases.

- Sample Ordering
- Sample Processing
- Sample Confirmation
- Sample Review

The description and requirement of the **MosaiQ 125** order execution and display rules are based on the definition of 7 different order logic status that define their position in the process, the corresponding behavior, user interaction capability and display method.

These status definition and properties are described in the following chapters.

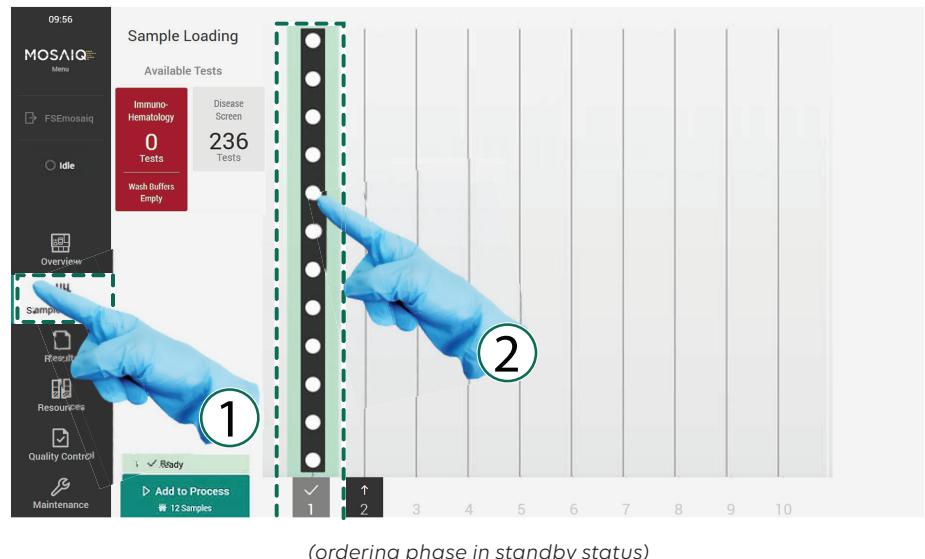
The 7 possible process order status are :

- Standby
- Processing
- Confirmation
- Finished
- Review
- Rejected
- Completed

In the following sub-chapters, each of the four key phases is described with the corresponding process order status.

### 8.2.1 SAMPLE ORDERING- PHASE 1

After the sample has been loaded into the **MosaiQ 125** test orders can be placed for each sample. After placing the orders, they are in **Standby** status and are waiting to be added to the process (see [chapter 8.5](#)).



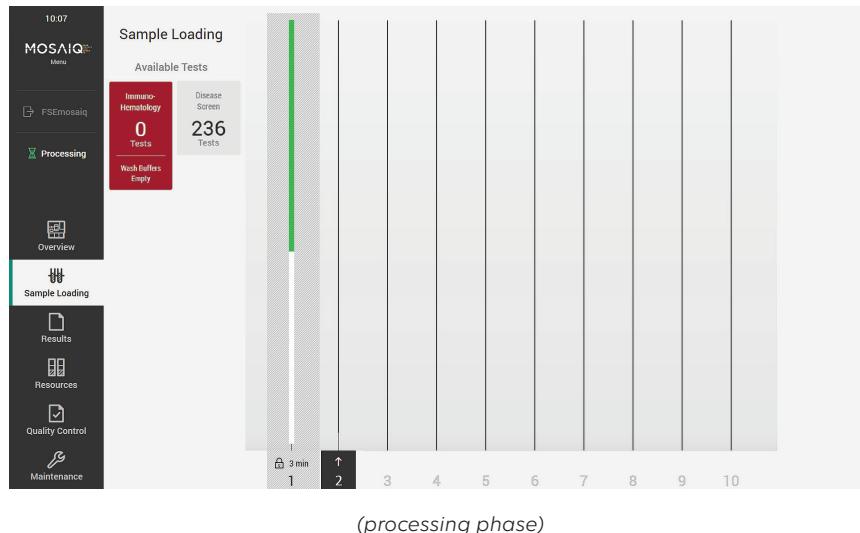
#### Order status : Standby

The sample is loaded in a rack, the order has been placed and is waiting to be put in process.

### 8.2.2 SAMPLE PROCESSING - PHASE 2

Once the rack has been added to process, all corresponding orders will be set to the **Processing** status. The orders for each sample will be frozen (no longer possible to add or cancel an order) until it has been processed.

The samples will be processed in the chronological order. The resulting phase will proceed to the analyse of the data to calculate the order results.



#### Order status : Processing

The order is placed in the **Processing** status from the **Standby** status after the rack has been added to process. (First execution of the order).

#### Order Status: Finished

The order is placed in the **Finished** status from the **Processing** or **Confirmation** status when the final result is available after the processing or confirmation(s) is completed.

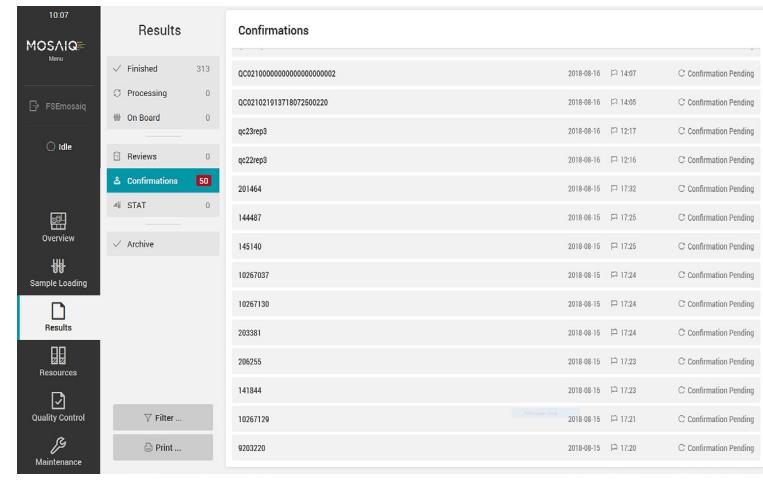
### 8.2.3 SAMPLE CONFIRMATION - PHASE 3

After the sample processing, the results will be checked against confirmation criteria. If a confirmation is needed the order will be repeated and placed in the **Confirmation** status.

If a confirmation is needed the test order will be automatically assigned and placed in the **Confirmation** status. User is required to manually add to order the confirmation.

A second confirmation will be needed if the first two results are not concordant.

The initial result and confirmation result are then used to establish the reported result. When the confirmation phase is completed the reported result will be placed in the **Finished** status.



(confirmation phase)

#### Order status : Confirmation

The order may be placed in the **Confirmation** status from the **Processing** status in the following cases:

- From the **Processing** status, if one of the confirmation criteria defined in the application is met.
- From the **Review** status, by user request and if the result of the order has not been already confirmed.

#### Order Status: Finished

The order is placed in the **Finished** status from the **Processing** or **Confirmation** status when the final result is available after the processing or confirmation(s) is (are) completed.

### 8.2.4 SAMPLE REVIEW - PHASE 4

When the order is in the **Finished** status it will be checked against the review criteria. If they are met the status will be set to **Review**.

Otherwise the order will be set to the **Completed** status.

When an order is in the **Review** status, the user has the possibility to validate, reject or repeat the order.

- If a repeat is required for an unconfirmed result, a confirmation will be performed.
- If a repeat is required for an already confirmed result a new order will be assigned to the sample.

#### Order status: Rejected:

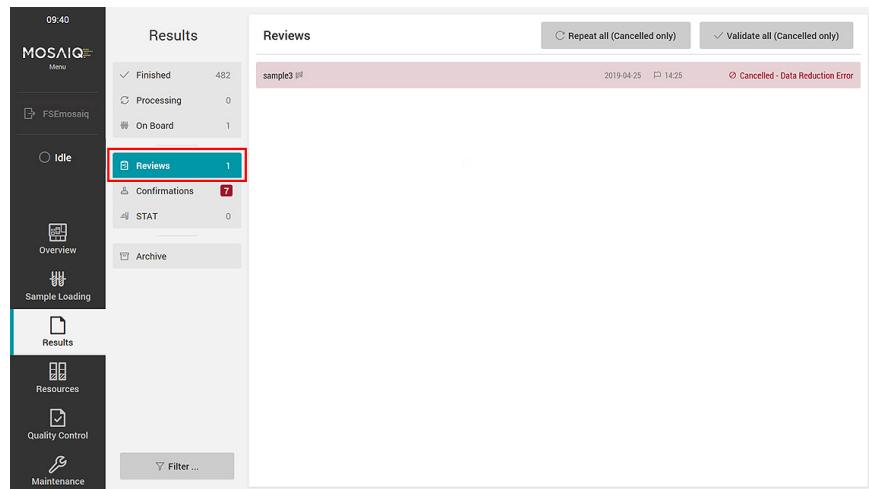
The order may be placed in the **Rejected** status from the **Review** status by user request. In the **Rejected** status, the result will not be transmitted to the LIS.

#### Order status: Completed:

The order may be placed in the **Completed** status in the following cases:

- From the **Finished** status if the review criteria are not applicable.
- From the **Review** status, by user request. (Manual Validation).

In the **Completed** status, the results are validated, displayed and transmitted to the LIS (if connected).



(completed status)

After the review step the order status will be either in the **Finished**, **Review**, **Rejected** or **Completed** status.

#### Order status : Finished:

The order is placed in the **Finished** status from the **Processing** or **Confirmation** status when the final result is available after the processing or confirmation(s) is completed.

#### Order status: Review:

The order may be placed in the **Review** status from the **Finished** status if one of the **Review** criteria defined in the application is met.

## 8.3 PREPARING SAMPLE RACKS AND TUBES

The following sections explain how to load and test samples into the **MosaiQ 125**.

### WARNING

Please consult our catalog for tube size adapters and contact your local technical representative for appropriate **MosaiQ 125** configuration.

This section explains how to prepare sample racks and sample tubes before they are loaded onto the **MosaiQ 125**. Failure to load the sample racks and tubes correctly may result in error messages.

Sample tubes hold patient or donor red blood cell samples that have been centrifuged prior to testing. Sample tubes must correspond to the references described in [chapter 8.11](#) of this manual, to be compatible with the **MosaiQ 125** sample racks.

The **MosaiQ 125** can hold up to 10 sample racks, with each sample rack accommodating 12 sample tubes for a maximum capacity of 120 sample tubes.

### NOTICE

Ensure all samples fulfill the sample preparation requirements prior to loading on **MosaiQ 125**. For detailed information about specimen preparation please follow the instructions for use for **MosaiQ COVID-19 Antibody Magazine**.

For detailed information please refer to the **MosaiQ COVID-19 Antibody Magazine** instructions for use for serological disease screening assays. Within one sample rack, only sample tubes of the same type may be used to avoid problems during the aspiration of liquids.

### NOTICE

The sample racks provided with the **MosaiQ 125** are used for standard sample tubes as referred in [chapter 8.11](#).

If you need a specific rack for sample tubes with other specifications, please contact your local technical representative.

Each sample rack includes a contact pin that is located at the top center of the rack.



(rack contact pin)

## 8.4 SELECTING LOADING LANE

Select the sample rack type corresponding to the run to be processed by **MosaiQ 125**.

Insert the tubes in the sample rack making sure that the Sample ID barcode is visible from the same side as the rack barcodes.



(visible sample tubes barcodes)

The sample loading supports loading of up to 10 sample racks on individual lanes for samples and controls. The status of each lane is indicated by its corresponding lane status indicator (white lights). The loading station uses a laser beam to read the racks and tube barcodes, please follow the related safety information.

### WARNING

### Eye injuries due to laser radiation

Laser products that are normally safe for momentary exposure due to the protection afforded eyes by aversion reactions, such as blinking, but that can be dangerous if someone deliberately looks into the beam.

Caution is required for visual impairments caused by residual images or reflection actions caused by surprise.

### NOTICE

### Handling and cleaning of optical surfaces

- Do not touch any optical surfaces.
- Only clean the optical surfaces with a soft and lint-free wipe.
- Do not use any harsh detergents or solutions (e.g. acetone).

### 8.5 INSERTING SAMPLE RACKS

This section provides step-by-step instructions on how to load sample racks into the **MosaiQ 125**.

#### Environmental conditions

##### WARNING

If the operating temperature in the laboratory is  $\leq 16^{\circ}\text{C}$  ( $60.8^{\circ}\text{F}$ ), **MosaiQ 125** must be switched on for a minimum of 2 hours before processing any assay.

#### Improper loading or removing of sample racks

##### WARNING

Improperly loaded or removed sample racks can produce erroneous results due to incorrect pipetting activities and may damage the pipettor.

#### Use of sample racks

##### WARNING

Insert the sample racks carefully to avoid tipping over and spilling the sample tubes.

#### Risk of contamination (biological hazard)

##### WARNING

Do not insert your hands inside the sample station (pipetting area) while **MosaiQ 125** is connected to the mains electrical supply.

#### INFO

Never load more than one sample rack at the same time. For proper barcode identification, the sample racks must be loaded one after the other, as indicated by the white light.

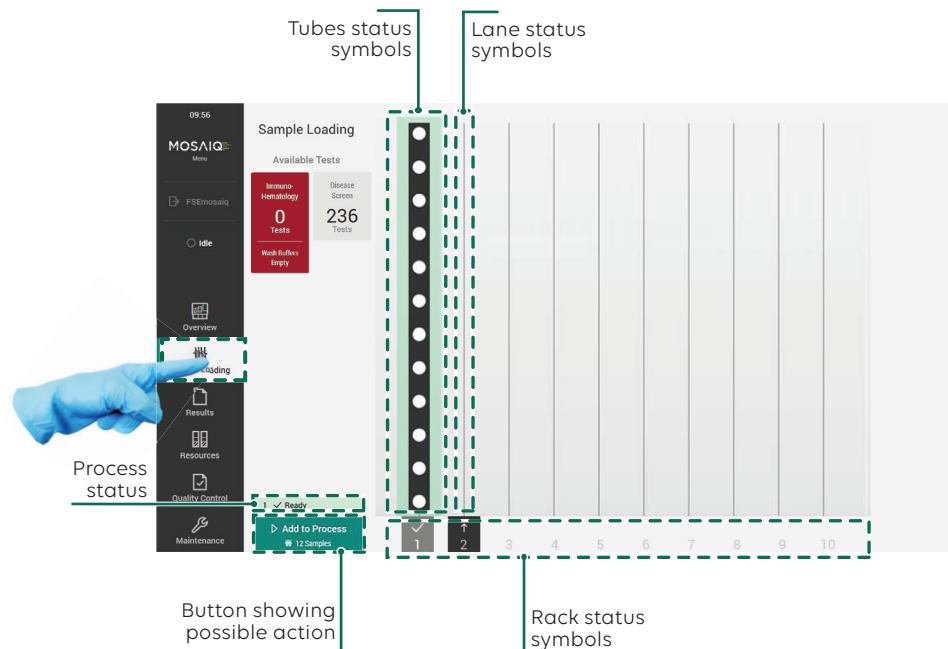
Ensure that your hand does not obscure any of the barcodes on the sample rack or sample tubes to guarantee successful reading.

- Select a lane, slide the sample rack slowly into the selected lane.
- Repeat the steps indicated to load multiple sample racks. The system will automatically focus on the leftmost empty lane so that the sample racks can be inserted in a rapid motion.
- The following window is displayed.

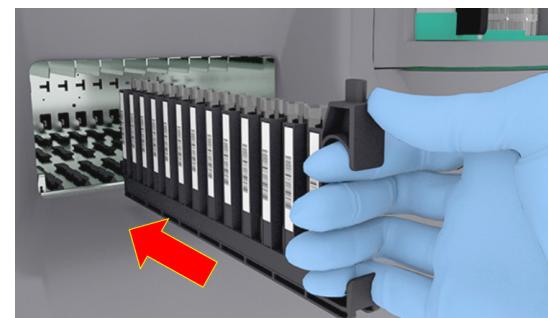
#### NOTICE

Always handle the racks by holding them on the handle.

- 1 - Tap on the **Sample Loading** icon in the navigation bar.



- 2 - To use a different lane, tap on the desired lane number, provided it is empty (e.g. lane 1).
- 3 - Wait until the white light on the chosen lane flashes slowly.
- 4 - Insert the sample rack carefully into the selected lane and slide it in.



## SAMPLE LOADING AND TESTING / INSERTING SAMPLE RACKS

- 5 - Press the sample rack briefly against the pressure of the spring, until you hear a click.
- 6 - The barcodes of the sample tubes are read automatically as the sample rack is inserted into the **MosaiQ 125**.



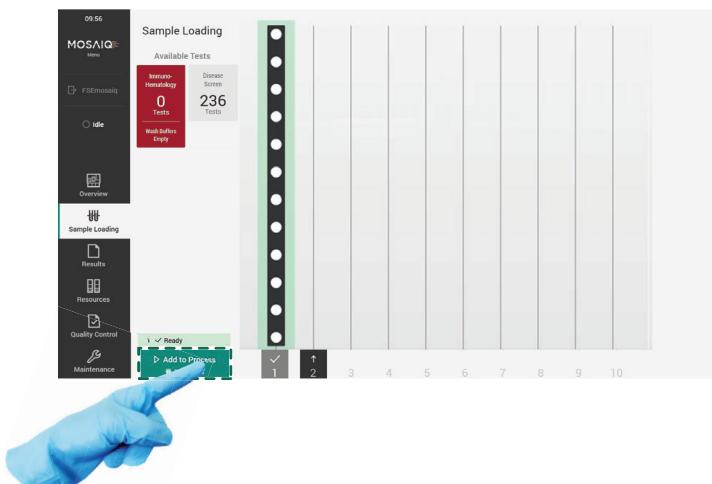
(inserted sample rack)

### INFO

#### Missing sample ID (barcode error)

If the **MosaiQ 125** cannot read a sample ID (barcode), please refer to [chapter 8.8](#) of this manual.

- 7 - Proceed to automatic or manual test assignment (refer to Automatic Test Assignment [chapter 8.6.1](#) and refer to Manual Test Assignment [chapter 8.6.2](#)) if test order needs to be specified.
- 8 - Tap on the **Add to Process** icon to run the test.



(starting of the assay process)

### Definition of the terms used to describe racks and tube appearances

Message	Explanation	Message	Explanation
Empty:	No rack loaded	Processable (collapsed)	The lane is waiting for a rack to be loaded.
Reading:	<b>MosaiQ 125</b> is adjusting the focus of the barcode reader.	Processable (expanded)	Ready to be processed as displayed in Overview mode.
Loadable	Lane is ready to be loaded with a rack.	Scheduled (collapsed)	Ready to be processed as displayed in Loading Sample mode.
Loaded	Lane has been loaded with a rack.	Scheduled (expanded)	Scheduled test order as displayed in Overview mode.
Querying Test Orders	<b>MosaiQ 125</b> is checking for test order.	In use	Scheduled test order as displayed in Loading Sample mode.
Finished (collapsed rack)	Test is finished as displayed in Overview mode.	Loaded warning (example missing resources)	Pipetting sequence is ongoing.
Finished (expanded rack)	Test is finished as displayed in Loading Sample mode.	Warning (example Sample ID)	Lane has been loaded with a rack but some sample tubes information is missing.
Error	Rack information could not be read.	Error message	Lane has been loaded with a rack but all sample tube information are missing.

## SAMPLE LOADING AND TESTING / INSERTING SAMPLE RACKS

Lanes racks and tubes appearances on the screen:

Empty	Reading	Loadable	Loaded	Querying Test Orders

Finished (collapsed rack)	Finished (expanded rack)	Loaded warning (example missing resources)	Warning (example Sample ID)	Error

Processable (collapsed)	Processable (expanded)	Scheduled (collapsed)	Scheduled (expanded)	In Use

### NOTICE

The collapsed views only show the racks status.

The expanded view show both the tubes and the racks status.

Rack status symbols

	Loading of a sample rack is possible.
	Reading the sample rack information.
	Checking for LIS test order.
	Waiting for test orders.
	All sample test tubes assigned to test order.

	Samples are pipetted into microarrays. It shows an indication of the time remaining until end of the pipetting sequence.
	Removing of the sample rack is possible
	All test on this rack are finished
	An error (e.g. missing sample ID) has occurred. The affected sample tubes on the screen are also marked.
	Error with the sample rack.

Samples tubes appearance on the screen in operation

	Loaded sample tube with test order assigned
	Empty position
	Loaded sample tube with no test order assigned
	Warning

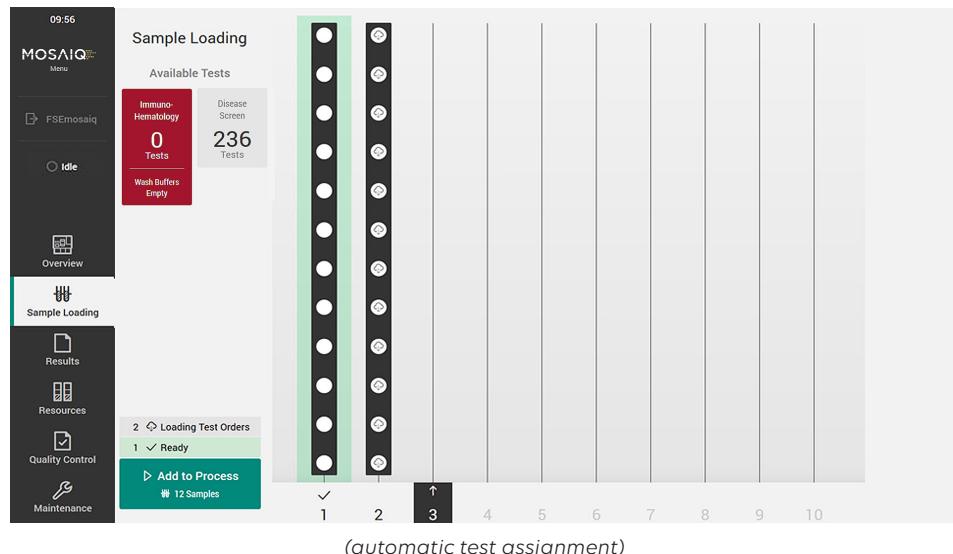
## 8.6 TEST ORDERS

Test orders can be assigned automatically by LIS or manually on the GUI.

### 8.6.1 AUTOMATIC TEST ASSIGNMENT

This section provides step-by-step instructions on how to assign test orders automatically.

- If the **MosaiQ 125** is connected to a LIS-system, the **MosaiQ 125** will automatically query the host for test orders when the sample rack is loaded.
- The following screen is displayed and shows the rack with all tube symbols as white circles.



#### INFO

##### Problems with automatic test assignment

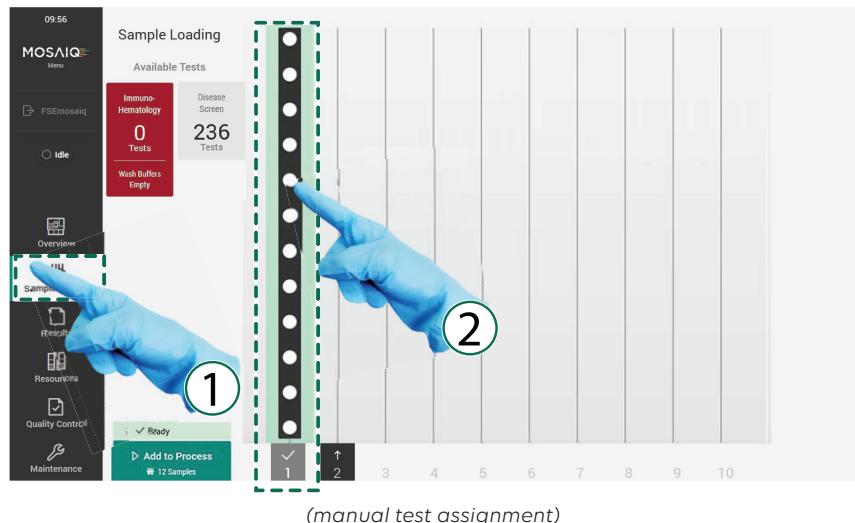
If the **MosaiQ 125** is connected to a LIS-system, but the samples could not be automatically assigned to one or more tests, then:

- Check if the test request was sent from the LIS-system to the **MosaiQ 125**.
- Check the barcodes of the sample tubes.
- Check the connection to the LIS-system.

### 8.6.2 MANUAL TEST ASSIGNMENT

This section provides step-by-step instructions on how to assign test order manually.

- ① Tap on the **Sample Loading** icon
- ② Tap one of the lanes (Lanes 1-10) to view sample tube details.



- ③ The following screen is displayed with all IDs for each sample tube.

Lane 1	Loaded	Apply Profile	AT	Set as STAT
1	ID 189			Missing Test Order
2	ID G10161624374696			Missing Test Order
3	ID 159			Missing Test Order
4	ID 167			Missing Test Order
5	ID 175			Missing Test Order
6	ID 194			Missing Test Order
7	ID 163			Missing Test Order
8	ID 156			Missing Test Order

(all sample ID on the sample rack on lane 1)

## SAMPLE LOADING AND TESTING / TEST ORDERS

To select all sample tubes, tap the tick box next to the Lane headline.

1 - All tick boxes of the sample tubes are marked with a tick mark. To select one or more sample tubes, tap the tick box next to the sample tube number and ID.

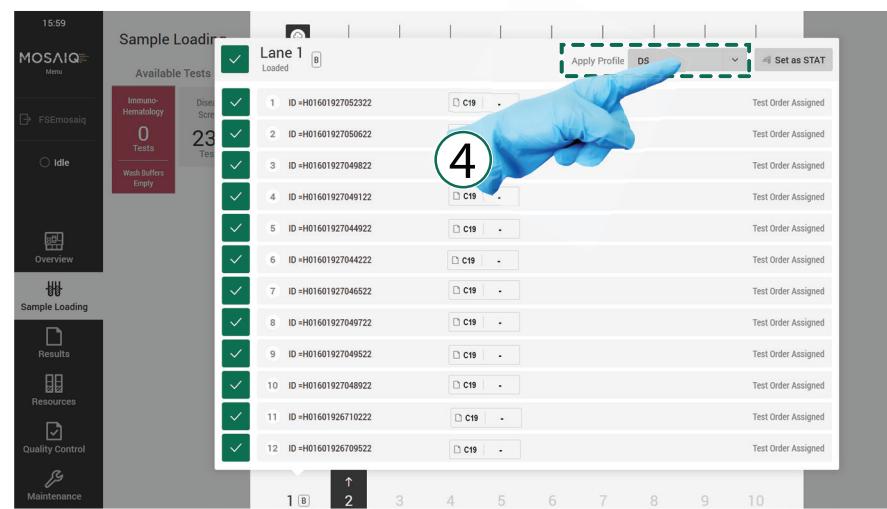
2 - Tap on the arrow next to **Apply Profile** to open the list with all selectable test profiles.

3 - Select the test for each lane and each sample tube if the tests are different.

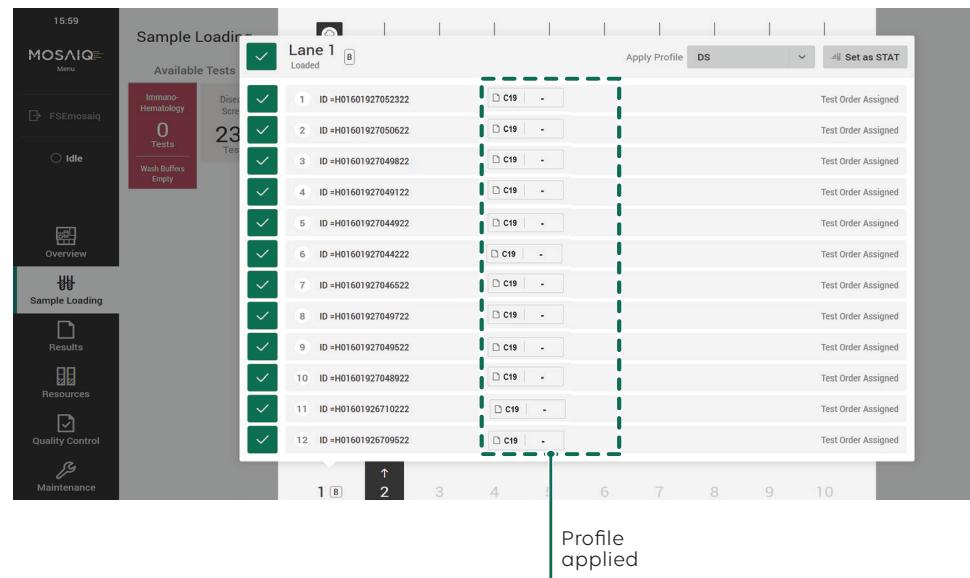
4 - ④ Select the desired test profile from the list.

5 - The chosen test profile is shown in the grey box.

6 - Tap on the grey box with the test profile to assign it to the marked sample tubes.



7 - All lanes are displayed with the selected profile.



8 - If necessary, repeat the procedure for the other sample tubes.

9 - To close the rack details view, tap on the dimmed background or a main navigation item when you have finished.

## 8.7 INDIVIDUAL TEST ORDER ASSIGNMENT

This section provides step-by-step instructions on how to assign a specific test order for an individual sample tube.

- 1 - To perform a different test order on each of the samples in a sample rack, select the given sample number on the rack.
- 2 - Tick the appropriate box under the **Test Orders** list to apply the relevant test

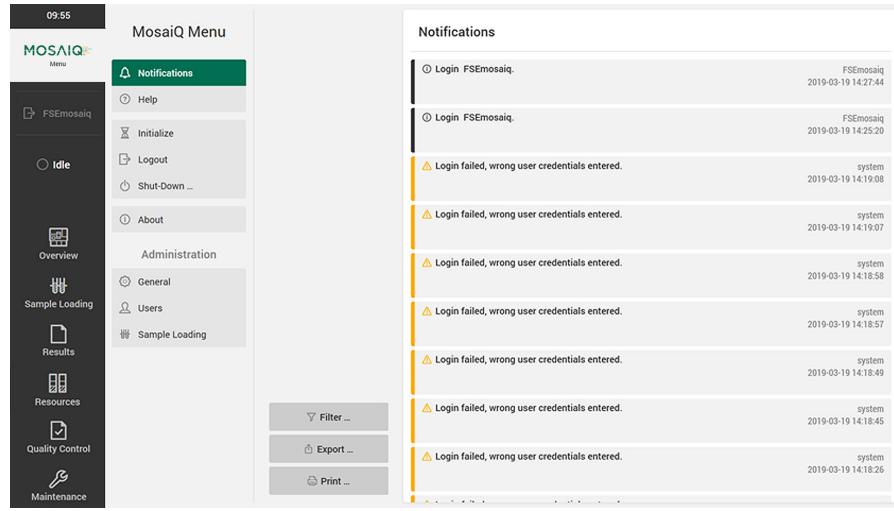
(individual test assignment)

- 3 - Once all test orders have been applied, return to the sample loading screen.
- 4 - Control available resources please refer to [chapter 7.2.3](#) of this manual before starting the run.
- 5 - Tap on the **Add to Process** button to start processing.



(starting of the assay process)

Once sampling has started, navigate to the **Notifications** screen.

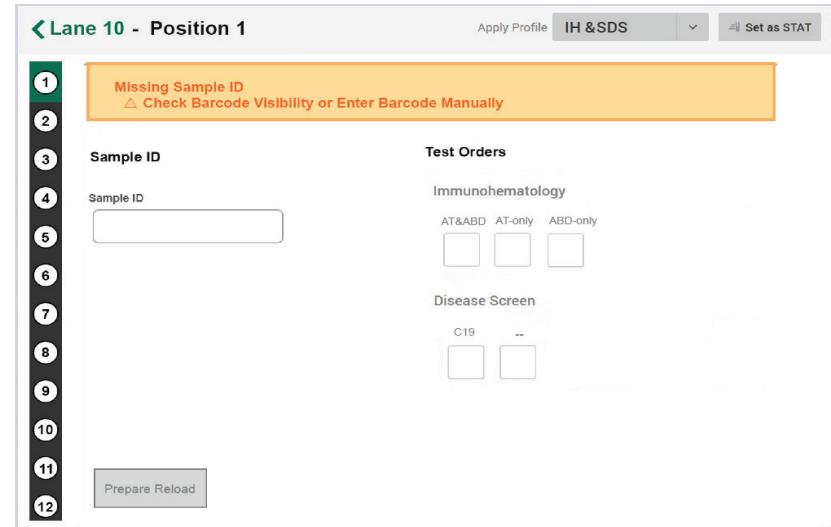


(notifications list)

- 6 - Select the Menu icon in the navigation bar to monitor **MosaiQ 125** progress.
- 7 - Do not remove or add any sample racks that are being pipetted by the **MosaiQ 125**. This will result in a software crash and a loss of results and potentially damage the pipettor module.

## 8.8 BARCODE READING ERRORS

In some cases, the barcode on a sample tube cannot be read. A warning message is displayed. The following screen is displayed if there is a barcode reading error.



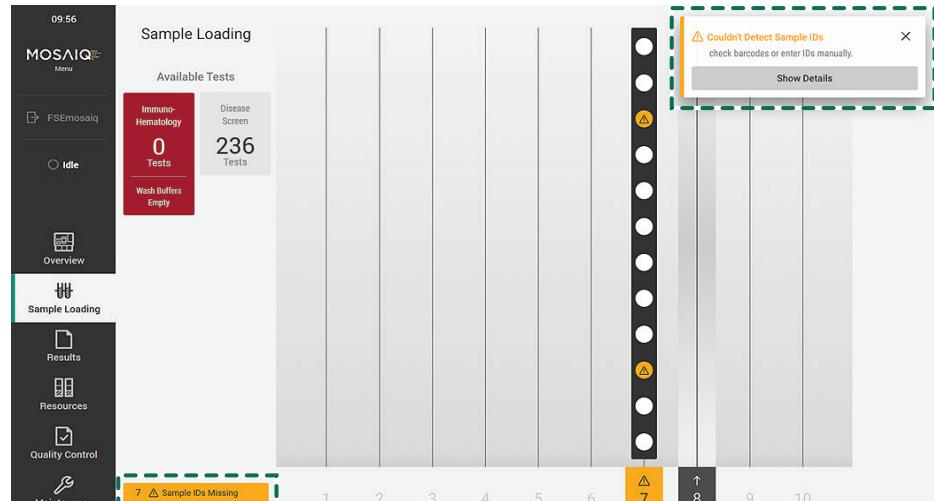
(missing sample ID message)

### 8.8.1 CHECK BARCODE LABELS

This section explains how to check barcode labels and provides step-by-step troubleshooting instructions in the event of barcode reading errors.

- 1 - Note the affected sample tube position(s).
- 2 - Remove the affected sample rack.
- 3 - Ensure that the barcode labels face outwards (open side of the sample rack).
- 4 - Check the barcodes of the affected sample tubes.
- 5 - Insert the sample rack again.

An error message stating **Missing Sample ID** will come into view above the sample barcode number. The barcode can then be entered manually, as described in the next section.



### 8.8.2 EDIT SAMPLE ID(S)

This section provides step-by-step instructions on how to modify the sample ID manually.

- 1 - To edit the sample ID of the affected sample tube(s), tap on **Show Details** in the error message.
- 2 - Enter the sample ID in the **Sample ID** field (double entry).
- 3 - If necessary, tap on the next marked sample tube.
- 4 - When you have finished, tap on the grey screen area.

#### INFO

If the sample ID has been successfully identified by the **MosaiQ 125**.  
The Sample ID cannot be modified manually.

#### NOTICE

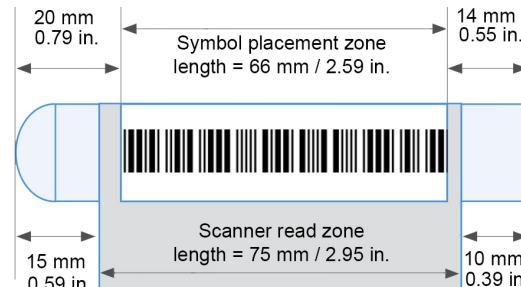
When the sample ID has been entered manually, a pencil symbol is displayed on the assay information strip beside the Sample ID.



## 8.9 BARCODE SPECIFICATIONS

### 8.9.1 LABEL

The barcodes used on the tubes must satisfy the CLSI AUTO2-A2 requirements. The barcodes must also satisfy at least quality level C.



(barcode label dimensions)

#### Max. length of barcode

Symbol placement zone 66 mm (2.59 in.)

Scanner read zone 75 mm (2.95 in.)

### 8.9.2 FORMAT AND STANDARD

The **MosaiQ 125** can support this barcode format and standard:

- Code 128 is a high-density linear barcode symbology. It can encode all 128 characters of ASCII (American Standard Code for Information Interchange).
- GS1 (General Specifications Standard) requires that barcodes shall have a quality of ANSI "Grade C. The measurements are based on a scale of 0-4 and expressed as a letter grade (A, B, C, D or F), based on the guidelines status in each category. A grade C or higher should allow correct scanning of barcodes at first rack insertion.
- ISBT 128 (International Society of Blood Transfusion) is the global standard for the terminology, identification, coding and labeling of medical products of human origin.

### 8.9.3 NUMBER OF CHARACTERS SUPPORTED

The MosaiQ Software support 5 to 25 characters.

## 8.10 SAMPLE TUBE REQUIREMENTS

Only the sample tube references listed below have been tested for use in the **MosaiQ 125**.

Sample tubes	
1	Greiner, 12ml, ref 160101
2	Greiner, 10ml, ref 136101
3	Greiner, 5ml, ref 115101
4	Greiner, 4ml, ref 109001
5	BD vacutainer, 2 ml, ref 367841
6	BD vacutainer, 4 ml, ref 368860
7	BD vacutainer, 6ml, ref 367864

### INFO

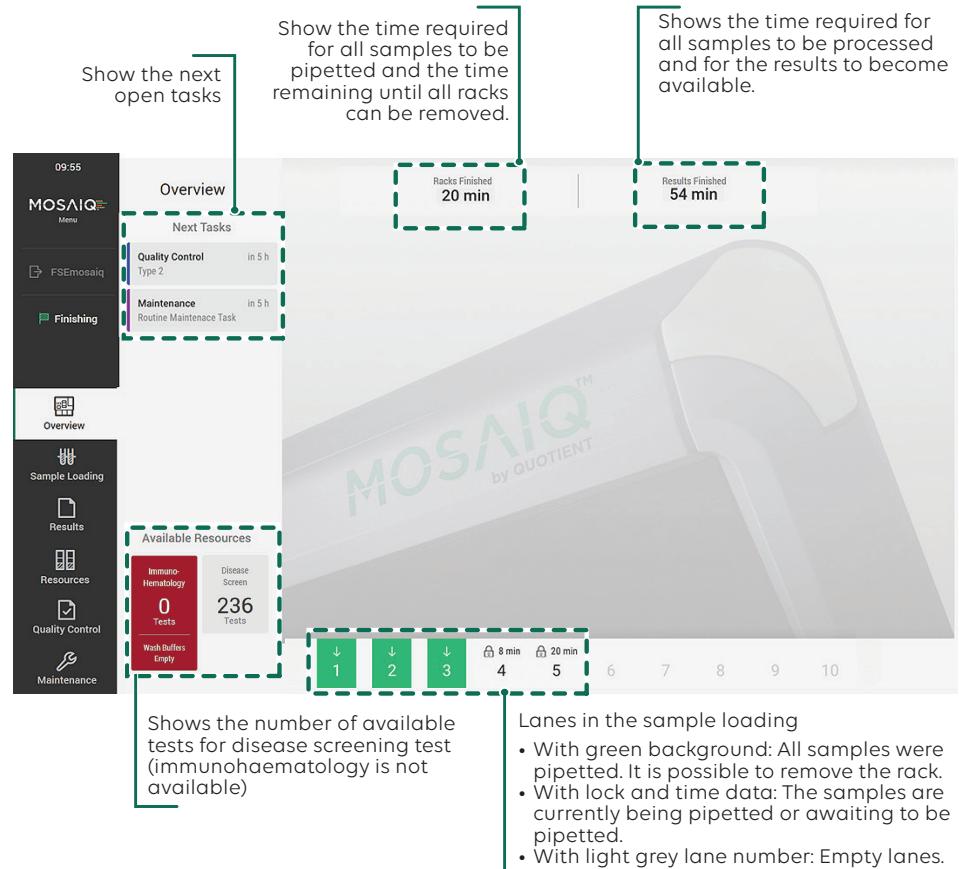
For other sample tubes, please contact your local technical representative to verify the compatibility.

## 8.11 SAMPLE TESTING MONITORING

This section explains how to carry out and monitor a test run using the graphical user interface. It also provides information on end-of-run procedures and test results.

### 8.11.1 OVERVIEW

The diagram below provides an overview of test run operations.



(overview screen during operation)

### 8.11.2 END OF A RUN

The Covid19 and other assay SDS processing time is 34 minutes.

- Before starting a run, the **Idle** message is displayed on the touch screen below the user name.



(MosaiQ 125 "idle" status)

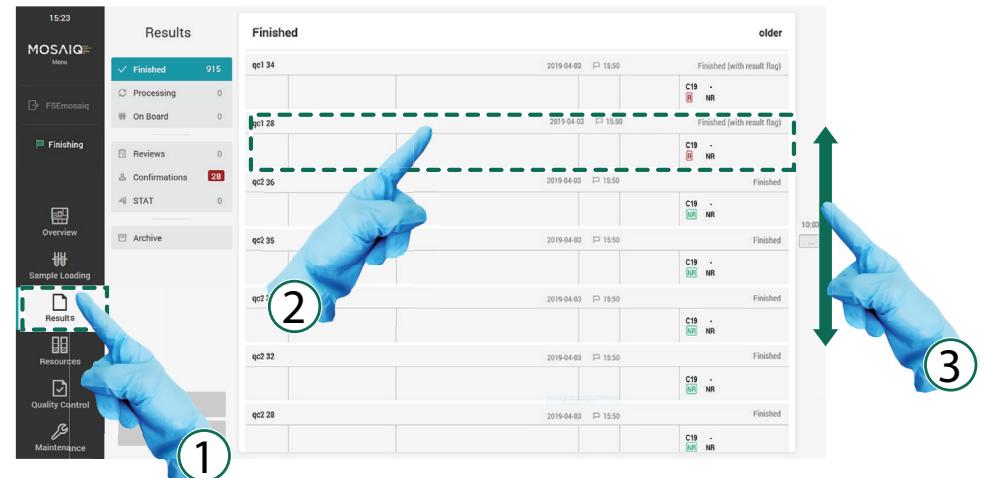
- Once a run has started, different messages such as **Maintenance** (during maintenance operation), **Processing** (while **MosaiQ 125** is performing assays) and **Finishing** (while **MosaiQ 125** is finishing the assays) appear transiently. When the run is completed, the initial **Idle** message is displayed steadily.
- Once a rack has been loaded and samples have been pipetted, the rack can be replaced by a new rack in the same lane:
  - Navigate back to the **Sample Loading** icon.
  - When the upward facing arrow below the corresponding lane has turned green , the rack can be removed, and a new rack can be loaded.

### 8.12 COVID19 TEST RESULTS

A successful test run will generate test results. The following section provides step-by-step instructions on how to read the test results of each sample.

The user can read the test results of each sample.

- ① Tap on the **Results** icon in the navigation bar.
- ② On the **Finished** sub menu, tap on the desired test result to show the details of the results.
- ③ Scroll down to see older test results, scroll up to see the most recent test results



(selecting test result)

## SAMPLE LOADING AND TESTING / COVID19 TEST RESULTS

On the finished test results screen the operator can see at a glance which test results are available or failed as well as the tests that require retesting or confirmation. The same sample ID may have several test results with different status.

The colors indicate the status of these test results as described below:

Test results status	
Test results are available	qc2.33 2018-08-16 19:05 ✓ Finished 
Test has failed	2018-01-12 10:59 ⚡ Cancelled - Data Reduction Error 

For detailed explanations on the interpretation of the results, please refer to the **MosaiQ COVID-19 Antibody Magazine** IFU.

### Report (non-reactive results)

The **Report** screen shows a detailed overview for a C19 non-reactive result.

The screenshot shows the MosaiQ software interface. On the left is a dark sidebar with icons for Overview, Sample Loading, Results, Resources, Quality Control, and Maintenance. To its right is a light-colored main area. At the top of the main area, a blue header bar says 'Finished' with a back arrow. Below it is a section titled 'Report' with a sub-section 'Disease Screen'. Under 'Reported Result', it shows 'C19 - NR'. It lists the operator as 'FSEmosaiq', the rack as 'A-Rack, Lane 6, POS 1 #1', the magazine ID as '009132', and the magazine lot as '1100035182'. It also details the reagents used: 'Detection Reagent 2 (9070900)', 'Enhancement Reagent 1 (9071000)', and 'Enhancement Reagent 2 (9100901)'. At the bottom of the main area are buttons for 'Re-Send to LIS' and 'Print ...'.

(Non-reactive C19 detailed result report)

### Report (reactive results)

The **Report** screen shows a detailed overview for a reactive C19 result.

This screenshot is identical to the one above, showing the MosaiQ software interface for a reactive C19 result. The main difference is in the 'Reported Result' section, where it shows 'C19 - R' instead of 'C19 - NR', indicating a reactive result. The rest of the information (operator, rack, magazine ID, magazine lot, and reagents) remains the same.

(reactive C19 detailed result report))

## SAMPLE LOADING AND TESTING / COVID19 TEST RESULTS

### Confirmations

On the **Results** screen, the **Confirmations** button shows the number of tests that require retesting to confirm reactive results for C19.

1 - Tap on **Confirmations** to see the tests that require retesting.

The screenshot shows the MOSAIQ interface with the 'Results' module selected. On the left, a sidebar lists various modules: FSEmosaiq, Finishing, Overview, Sample Loading, Results (selected), Resources, Quality Control, and Maintenance. The main area displays a table titled 'Finished' with 915 entries. A blue-gloved hand points to the 'Confirmations' button in the top navigation bar, which has a red badge indicating 28 pending items. The table includes columns for ID, Date, Time, and Result status (C19 + or NR).

(confirmation screen)

2 - On the list select the result you want to retest.

The screenshot shows the MOSAIQ interface with the 'Confirmations' module selected. The sidebar remains the same. The main area displays a table of confirmed samples. A blue-gloved hand points to a specific row for 'sample3333' with a red badge of 28. This row is highlighted with a dashed green border. The table includes columns for ID, Date, Time, and Status (Confirmation Pending).

(retesting a sample)

## 8.13 REPEATING TESTING BY “DATA REDUCTION ERROR” OR “TECHNICAL ERROR”

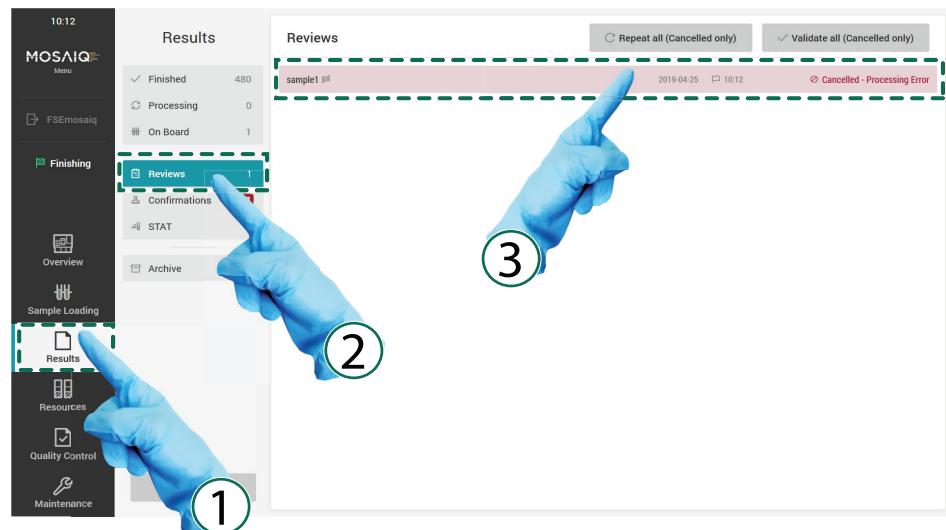
When a result is marked as “**Data Reduction Error**”, or “**Technical Error**”, the test has been failed and no results can be generated.

### INFO

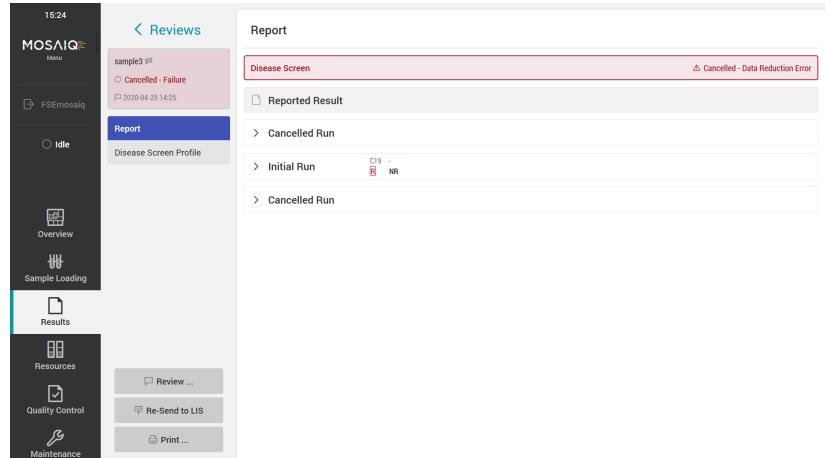
On each microarray there are several control probes showing that the assay is reacting as expected. All control probes must have an appropriate reaction for the test to be interpreted by the MosaiQ Software. The failure of one or more of these control probes during the image analysis will provide a “Data Reduction Error” message instead, meaning that no result can be generated.

To check the details of the test impacted

- ① Tap on the **Results** icon in the navigation bar.
- ② Tap on the **Review** sub menu.
- ③ Tap on the desired test result to show the details of the results.

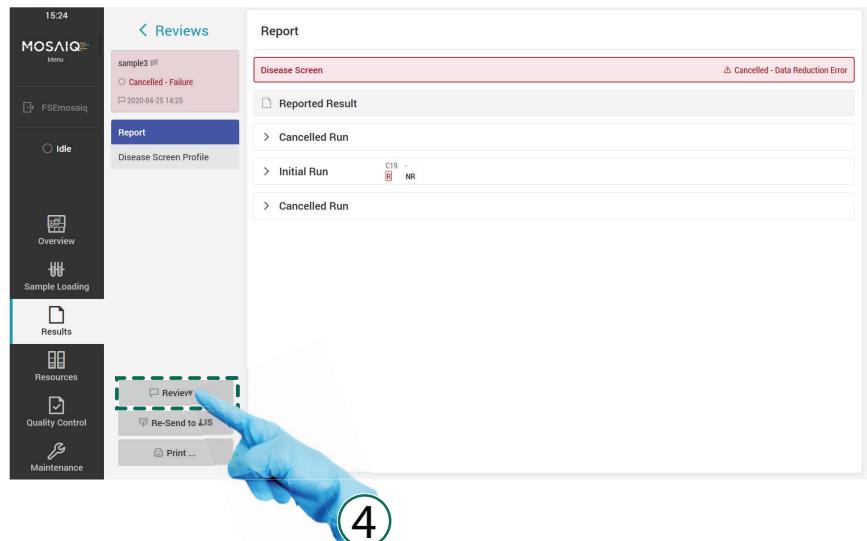


(review screen)



(test results report in collapsed view)

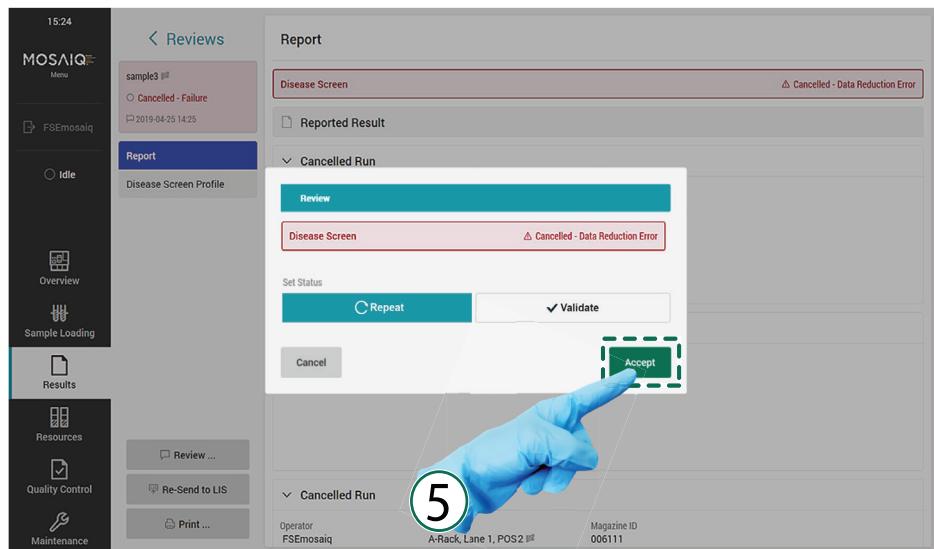
- ④ Tap on the test result message or on **Review** button to decide if you want to repeat the test.



(test results review)

- ⑤ On the review pop up window, tap on the **Accept** button to repeat the test.

Before retesting verify the level of the MosaiQ system reagents as this might have been the cause of this error.

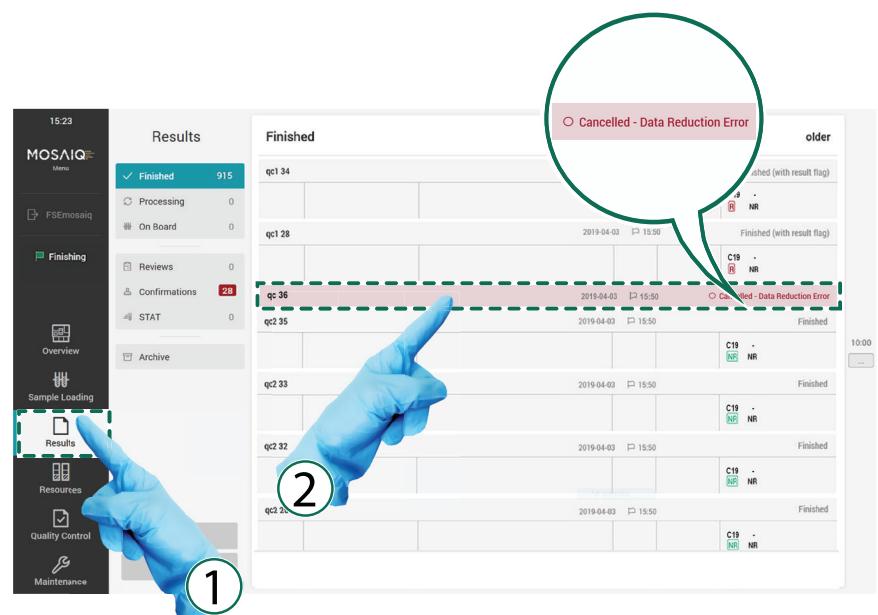


## 8.14 TEST RESULTS FLAGS

This section explains how to find test results flags and their definition.

On the **Results** screen.

- ① Tap **Results** on the navigation bar
- ② Select the result that has a flag you want to check and tap on its line.



## SAMPLE LOADING AND TESTING / TEST RESULTS FLAGS

- ③ The following screen displays the results details and the flag name.

The screenshot shows the MosaiQ software interface. On the left is a vertical navigation bar with icons for Home, Overview, Sample Loading, Results, Resources, Quality Control, and Maintenance. The main window has a title bar "Report" and a sub-section "Disease Screen". A pink banner at the top right indicates a "Cancelled - Data Reduction Error". Below this, a section titled "Reported Result" displays detailed information: Operator FSEmosaiq, Rack A-Rack, Lane 6, POS 3, Magazine ID 009132, Reagents Detection Reagent 2 (9070900), Loaded on 2019-04-03 15:00, Magazine LOT 1100035182, Enhancement Reagent 1 (9071000), Processed on 2019-04-03 15:50, and Enhancement Reagent 2 (9100901). At the bottom are buttons for "Re-Send to LIS" and "Print ...".

(test result details with the result flag)

### Flags definitions for SDS tests

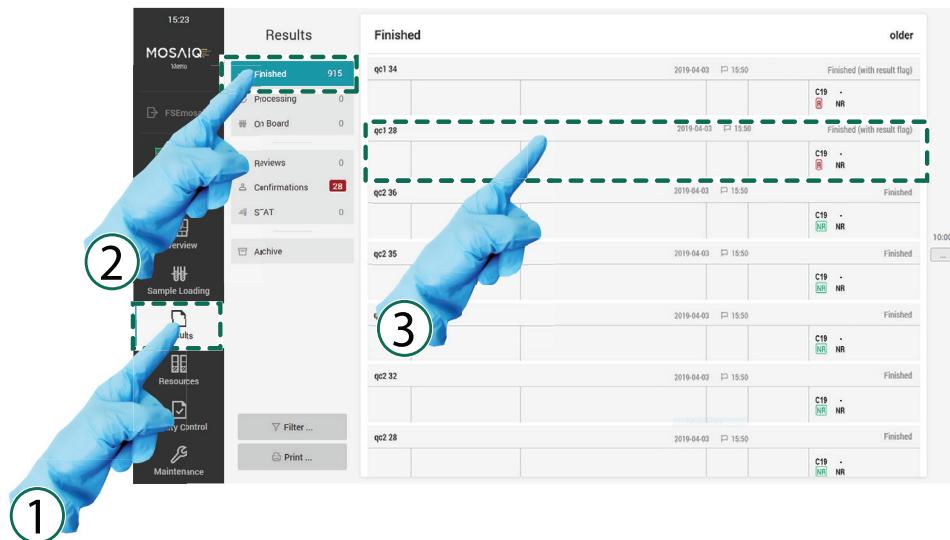
#	Flags	Type
1	Data Reduction Error	There is no data returned.
2	Processing Error	Issue during sample aspiration and/or dispensing

For detailed information about SDS flags, please refer to the **MosaiQ COVID-19 Antibody Magazine IFU**.

## 8.15 REVIEWING RESULTS

In some cases, it is necessary to review a result. To do this, start a two-stage review process.

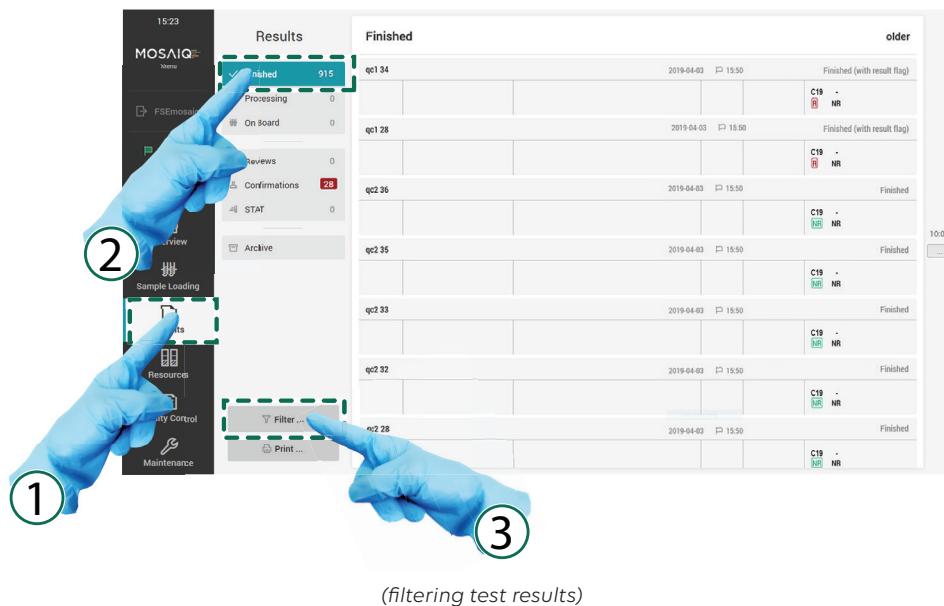
- ① Tap on the **Results** icon in the navigation bar.
- ② If necessary, tap on the **Finished** button or another result menu entry.
- ③ Tap on the desired test result to show the details.



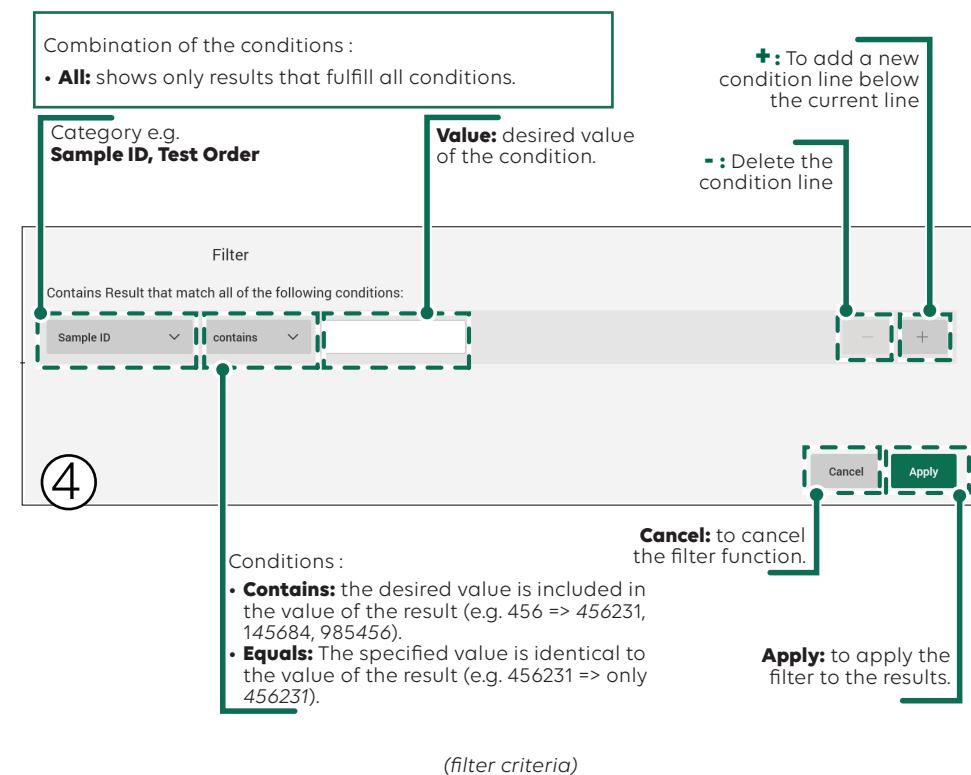
## 8.16 FILTERING OF TEST RESULTS

This section provides step-by-step instructions on how to filter the test results using different criteria.

- ① Tap on the **Results** icon in the navigation bar.
- ② Tap on the **Finished** button or another result menu entry.
- ③ Use the **Filter** function to focus on the most important results.



- ④ The following screen appears:

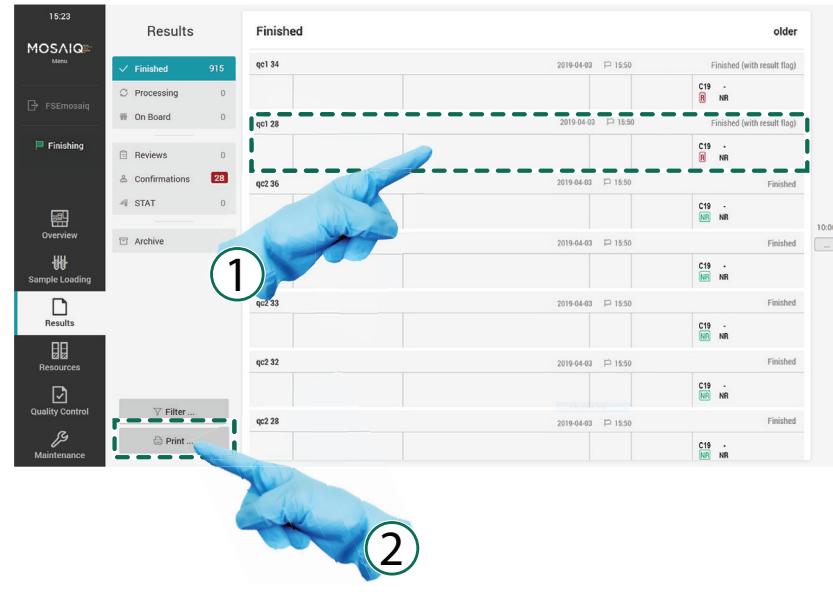


## 8.17 PRINTING TEST RESULTS

This section explains how to print test results using the graphical user interface.

To print the test results:

- ① Select and tap on the test to be printed.
- ② Tap on **Print**.



(printing test results)

There are 2 possible print options:

1- Print all finished results:

- On **Finished** screen, tap on **Print**.

2- Print individual result:

- On **Finished** screen, tap on the selected result and tap on **Print**.

### NOTICE

# **9. QUALITY CONTROL**

<b>9.1</b>	<b>QUALITY CONTROL METHOD</b>	<b>111</b>
<b>9.2</b>	<b>QUALITY CONTROLS PREPARATION</b>	<b>111</b>
<b>9.3</b>	<b>QUALITY CONTROLS LOADING AND RUNNING</b>	<b>112</b>
<b>9.4</b>	<b>QUALITY CONTROLS RESULTS</b>	<b>114</b>

This section provides information on **MosaiQ 125** quality controls (QC).

QC are used to ensure that **MosaiQ 125** performance is acceptable.



### NOTICE

The current MosaiQ Software version does not allow to run QC using the "**Quality Control**" functionality that is displayed on the **Navigation Bar**.

To run QC, please follow the instructions provided below.

## 9.1 QUALITY CONTROL METHOD

In this section we describe how to run QC using the **MosaiQ 125**.

The laboratories must validate their own quality control method and quality control material for the assays performed by **MosaiQ 125**.

### NOTICE

Perform QC testing of the **MosaiQ 125** at LEAST once a day or as per laboratory and regional specific requirements mandate.

## 9.2 QUALITY CONTROLS PREPARATION

Before loading any QC material into the **MosaiQ 125**:

- Follow the instructions for use of the QC material.
- Let the QC material reach the room temperature (if required).
- Transfer the QC material into a standard 5 ml test tube that is compatible with the **MosaiQ 125** rack.

### NOTICE

- We recommend the use of a volume of 1,5 mL QC material, using a standard 5 ml test tube. The minimum volume of QC material required for one QC run is 0,5 mL.
- Cap the tube securely for cold storage or transfer the uncapped tube for imminent use on the **MosaiQ 125**.

- Create a barcode label that is readable by the **MosaiQ 125** (as described in [chapter 8.9](#)) for each appropriate QC material and apply it on the prepared tube. This will allow the **MosaiQ 125** to process the QC material as a normal sample (as described in [chapter 8.3](#)).



(transferring the QC material into a MosaiQ 125 compatible labeled test tube)

### INFO

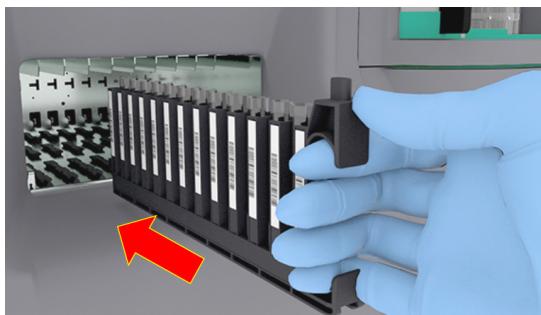
To verify the compatibility of tubes with the **MosaiQ 125** rack, please contact your local technical representative.

### 9.3 QUALITY CONTROLS LOADING AND RUNNING

Before loading the QC into the **MosaiQ 125**:

Make sure that the **MosaiQ 125** is ready for running tests (check for required maintenance tasks, resources, waste capacity).

- 1 - Place the uncapped QC tube in a standard rack, as described in [chapter 8.3](#) of this manual.
- 2 - Tap on the **Sample Loading** icon in the navigation bar
- 3 - To use a different lane, tap on the desired empty lane number (e.g. lane 1)
- 4 - Wait until the light on the chosen lane blinks slowly
- 5 - Insert the rack carefully into the selected lane and slide it in. Follow the instruction on how to insert the rack into the **MosaiQ 125** as described in [chapter 8.4](#) of this manual.



(inserting of a sample rack)

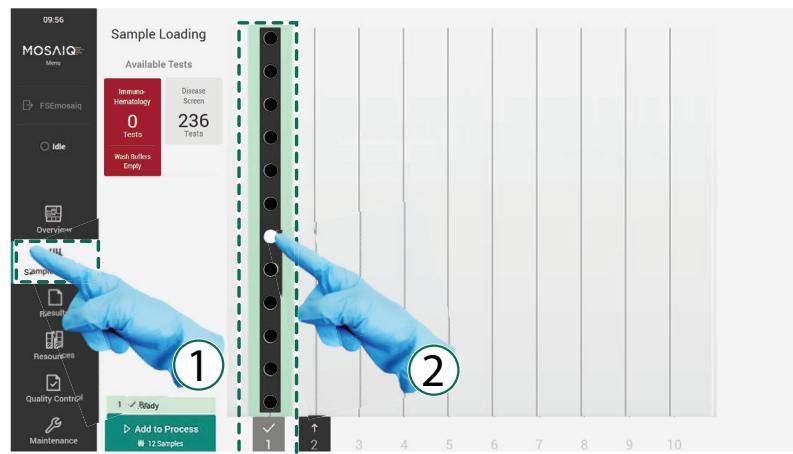
- 6 - Press the sample rack briefly against the pressure of the spring, until you hear a click.
- 7 - The barcode of the QC tube is read automatically as the sample rack is inserted into the **MosaiQ 125**.



(inserted sample rack)

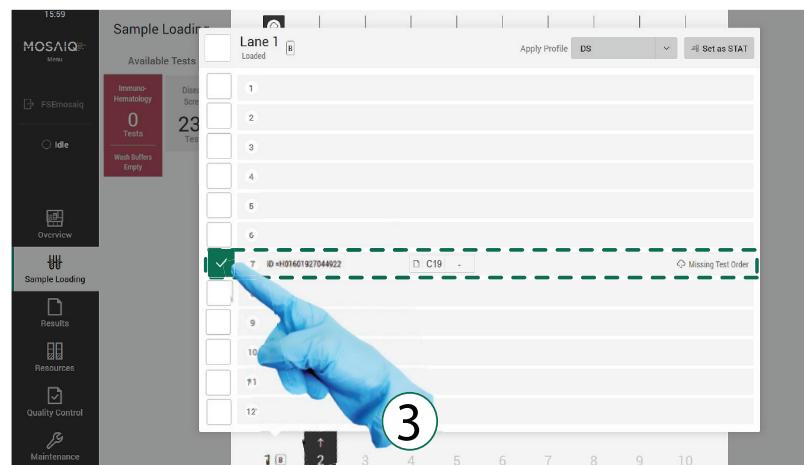
Proceed to a manual test assignment

- 1 - ① Tap on the **Sample Loading** icon.
- 2 - ② Tap one of the lanes (Lanes 1-10) to view tube details



(viewing the sample tube details)

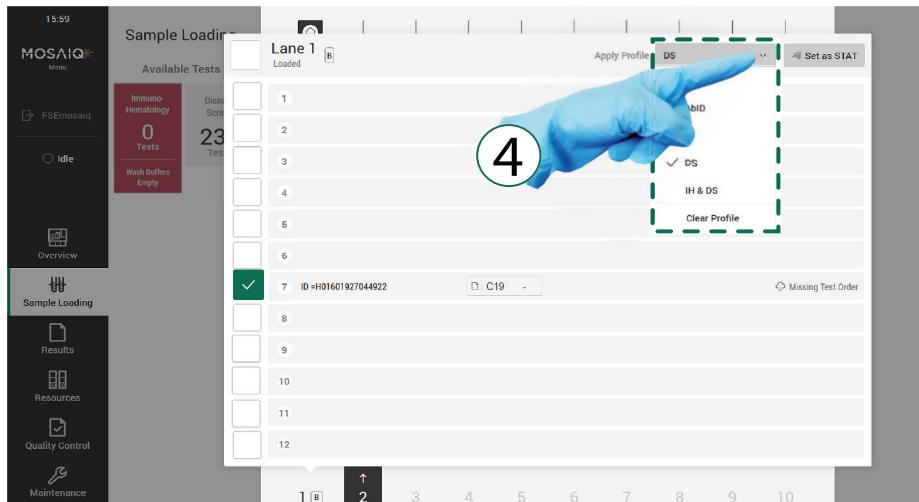
- 3 - ③ Select the tube with the QC material, tap the tick box next to the lane headline.



(sample tube with QC material ID)

## QUALITY CONTROL / QUALITY CONTROLS LOADING AND RUNNING

- 4 - The tube is marked with a tick mark.
- 5 - Tap on the arrow next to **Apply Profile** to open the list with all selectable test profiles.
- 6 - Select the test for each lane and each sample tube if the tests are different
- 7 - ④ Select the desired test profile from the list.
- 8 - The chosen test profile is shown in the grey box.
- 9 - Tap on the grey box with the test profile to assign it to the marked QC tube.



- 10 - The corresponding lane is displayed with the selected profile.
- 11 - To close the rack details view, tap on the dimmed background or a main navigation item when you have finished.

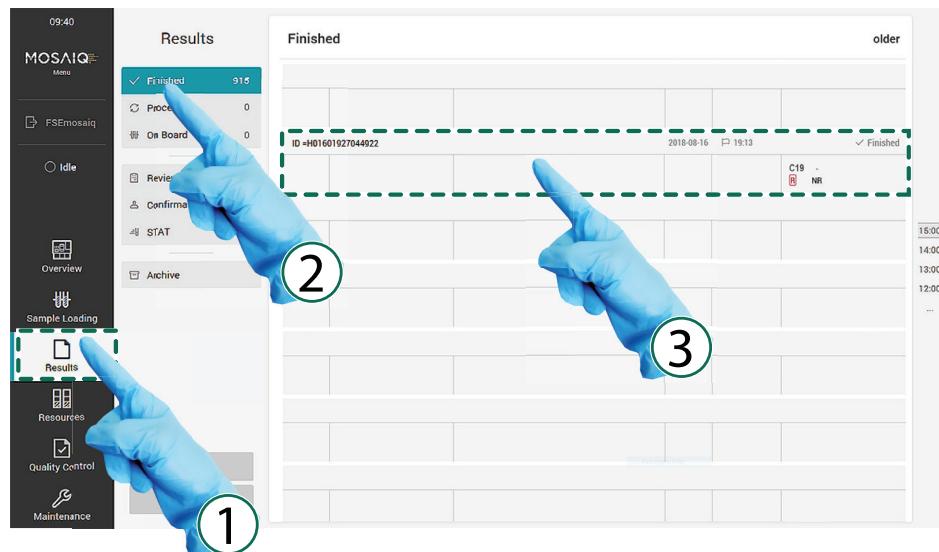
- 12 - Tap on the **Add to Process** icon to run the QC.



## 9.4 QUALITY CONTROLS RESULTS

The quality controls are successful when the expected QC results are aligned with the QC given characteristics. Please read carefully the instructions for use provided with your QC material. To review the QC results:

- ① Tap on the **Results** icon in the navigation bar.
- ② If necessary, tap on the **Finished** button.
- ③ Tap on the QC test result to show the details.



### NOTICE

The interpretation of the QC results is provided in the **MosaiQ COVID-19 Antibody Magazine** IFU.

For **SDS(C19)**, there two possible reports:

- **C19 non-reactive result**
- **C19 reactive result**

# 10. MOSAIQ 125 SHUTDOWN

To shut down the **MosaiQ 125** safely, please follow this procedure.

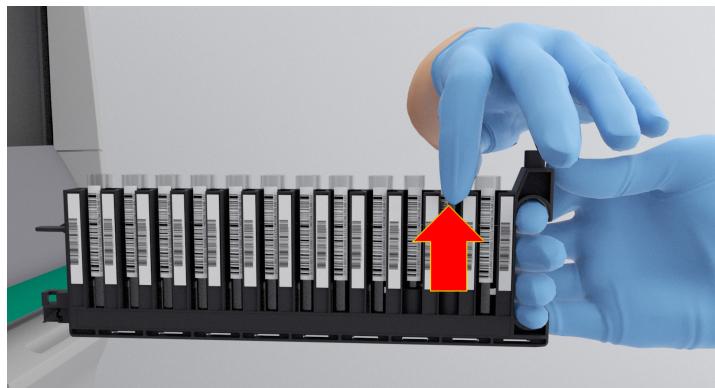
## 10.1. REMOVAL OF REMAINING MATERIAL AND WASTE

- 1 - Remove all racks from the **MosaiQ 125**.



(removing the sample rack)

- 2 - Remove all samples from the racks.



(removing the sample tubes)

- 3 - Empty the liquid canister and solid waste container, if necessary. Discard the waste following the procedure.



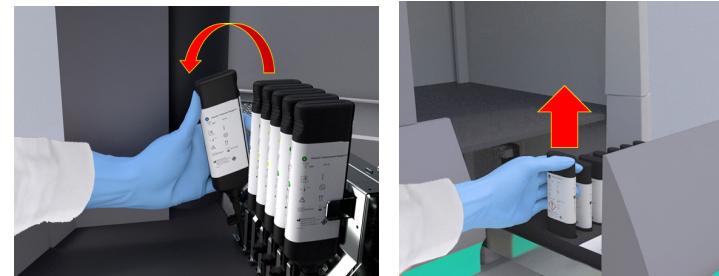
(removing the liquid and solid wast)

- 4 - Remove any empty magazines from the carousel.



(removing the remaining magazines)

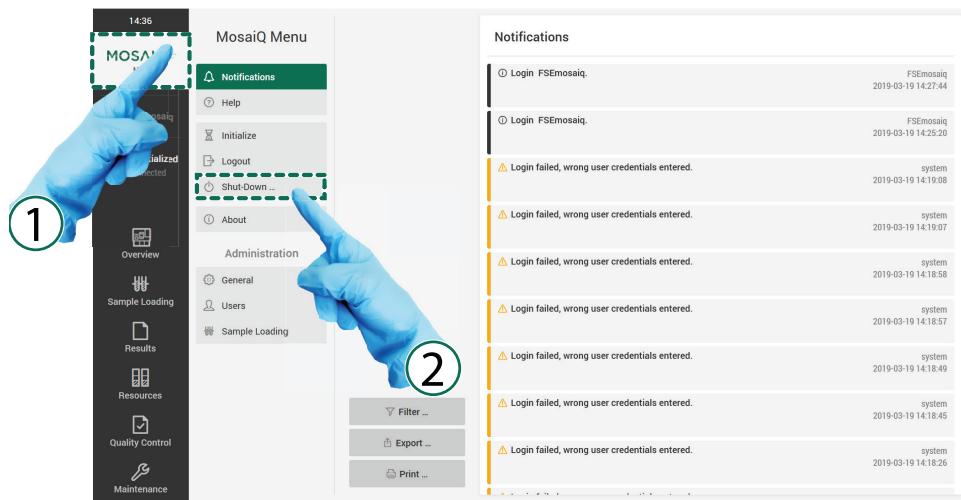
- 5 - Remove any empty reagents bottles.



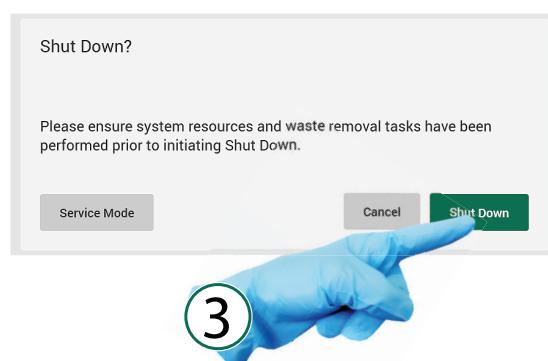
(removing the remaining reagent bottles)

### 10.2. SHUTING DOWN THE MOSAIQ 125

- ① Tap on the **Menu** icon.
- ② Tap on the **Shut Down** button.



- ③ Confirm to shut down and wait until the PC has shut down (touch screen is black).



- ④ Switch off the **MosaiQ 125**.



#### NOTICE

Perform the cleaning maintenance tasks of the **MosaiQ 125** as required.  
Please refer to [chapter 12](#) of this manual .

# 11. ADVANCED FUNCTIONS

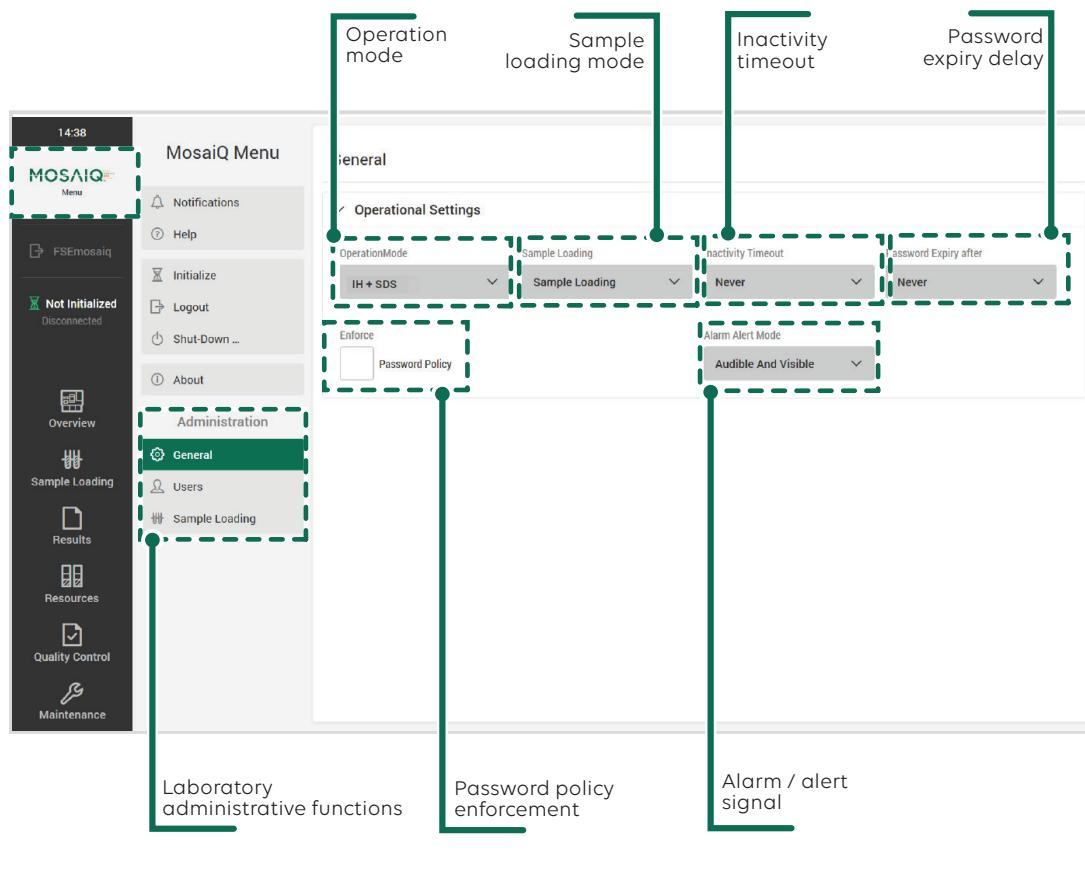
<b>11.1 GENERAL SETTINGS</b>	<b>118</b>	<b>11.2 USERS ROLES</b>	<b>121</b>
11.1.1 OPERATION MODE	119	11.3.1 ADD A NEW USER ACCOUNT	123
11.1.2 INACTIVITY TIME-OUT	119	11.3.2 DEACTIVATE A USER ACCOUNT	124
11.1.3 PASSWORD POLICY ENFORCEMENT	120	11.3.3 DELETE A USER ACCOUNT	124
11.1.4 ALARM / ALERT MODE	120	11.3.4 RESET A USER'S PASSWORD	125
		11.3.5 SAMPLE PROFILE SETTING	126

This section provides information about the advanced functions accessible with laboratory administrator rights available on the **MosaiQ 125**. Only the laboratory administrator is authorized to access certain software/system configurations.

## 11.1 GENERAL SETTINGS

On this screen you can modify several functionalities on the dedicated scroll button:

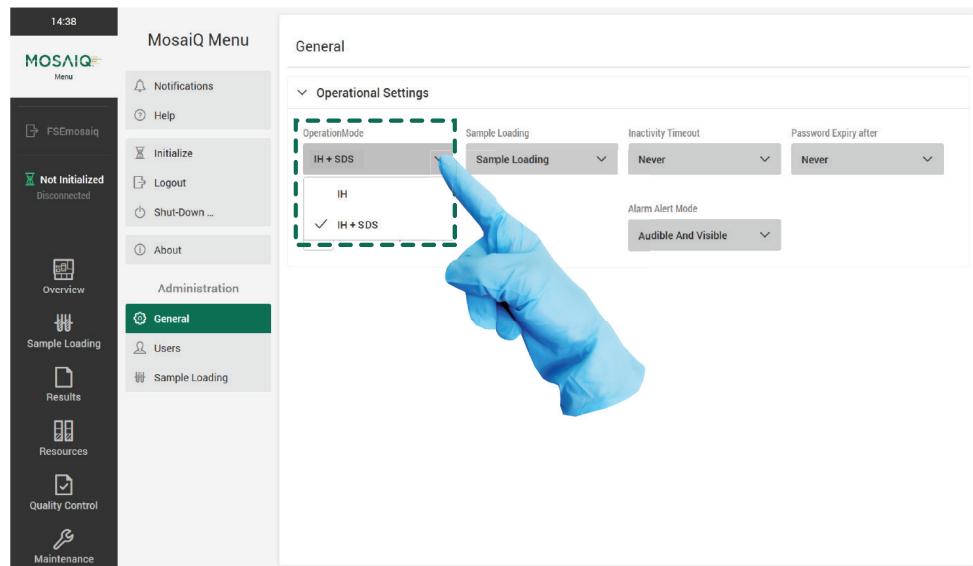
- The kind of operational mode (SDS only available),
- Sample loading (set as default)
- Inactivity timeout,
- Password expiry delay
- Password policy enforcement
- Alarm / alert mode



### 11.1.1 OPERATION MODE

From this scroll button you can select the type of assays the **MosaiQ 125** can run:

- IH only (not available)
- IH and DS



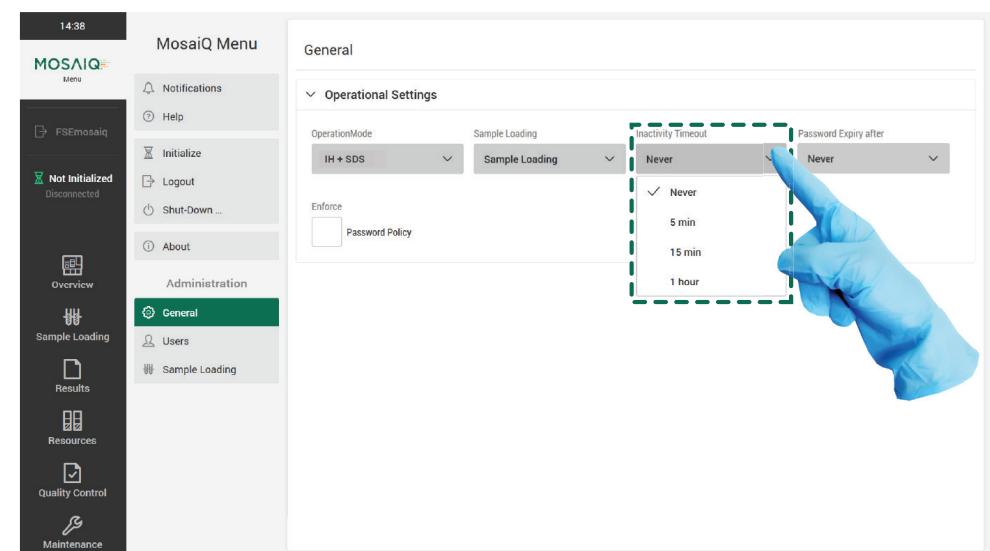
(operation mode selection)

**NOTICE**

Please, consider that SDS (Serological Disease Screening) is limited to Covid19 assay only.

### 11.1.2 INACTIVITY TIME-OUT

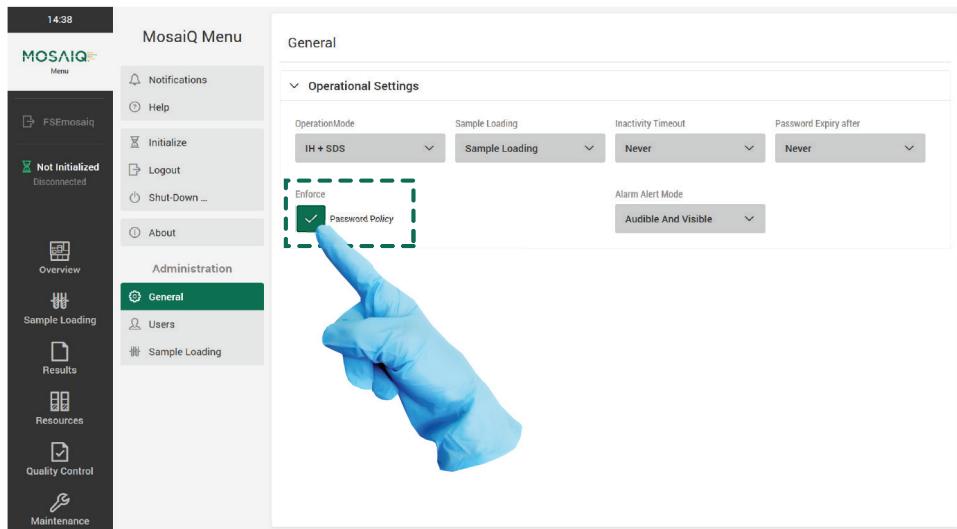
This function allows you to set the time-out delay. After a selected period of time, the **MosaiQ 125** will automatically log the user out.



(inactivity timeout selection)

### 11.1.3 PASSWORD POLICY ENFORCEMENT

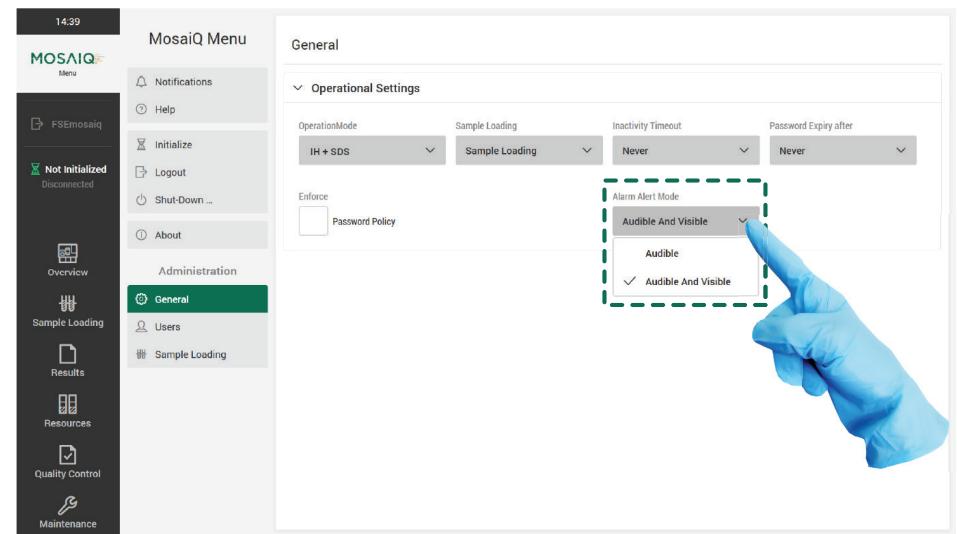
To enforce the password security this function allows the laboratory administrator to determine the required password characteristics (password length and special characters).



(enforcing password policy selection)

### 11.1.4 ALARM / ALERT MODE

By tapping on this scroll button you can select the Alarm/Alert mode, when the **MosaiQ 125** displays a notification:



(alarm / alert mode selection)

- The audible mode: The user is alerted by a sound
- The audible and visible mode: The user is alerted by a sound and the blinking light on the **MosaiQ 125** top right cover, as described in [chapter 5.2](#).

## 11.2 USERS ROLES

The access rights determine who can perform certain operations.

The **MosaiQ 125** provides for three roles with different levels of access rights:

- Operator,
- Laboratory administrator,
- Local technical representative.

The table below provides a breakdown of who can perform specific operations according to their level of access rights.

Tasks			
	Operator	Laboratory Administrator	Local technical representative
Normal operation <ul style="list-style-type: none"> <li>• Load/remove samples</li> <li>• Load/remove resources</li> <li>• Start sample tests</li> <li>• Show sample test results</li> <li>• Start QC tests</li> <li>• Show QC test results</li> <li>• Start maintenance tasks</li> </ul>	Yes	Yes	Yes
Review QC test results	Read only	Read only	Yes
Review sample test results	Read only	Read only	Yes
Set application settings	No	Yes	Yes
Set general settings	No	Yes	Yes
Set LIS settings	No	No	Yes
Set resources settings	No	Yes	Yes
Set sample loading settings	No	Yes	Yes

Refer to the "[APPENDIX](#)" of this manual for more details on the users role and access rights

## 11.3 USER ADMINISTRATION

User administration makes it possible to add, edit and deactivate user accounts. Each user must be assigned to one role, which defines the associated access rights.

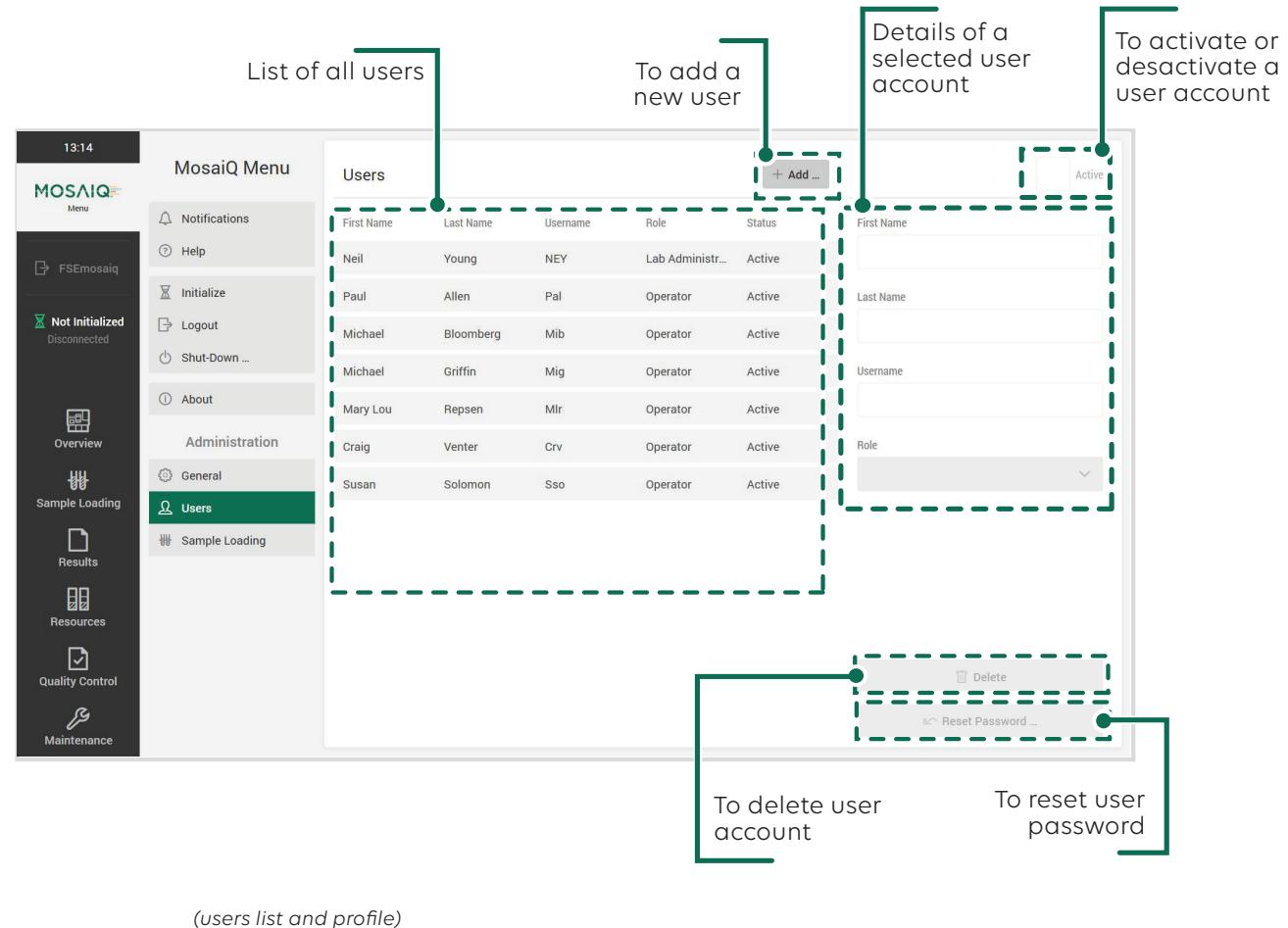
The diagram below explains how to:

- View a list of all user accounts,
- Create a new user account,
- Print out the list of users,
- View the details of a selected user account.

### Special access rights

**INFO**

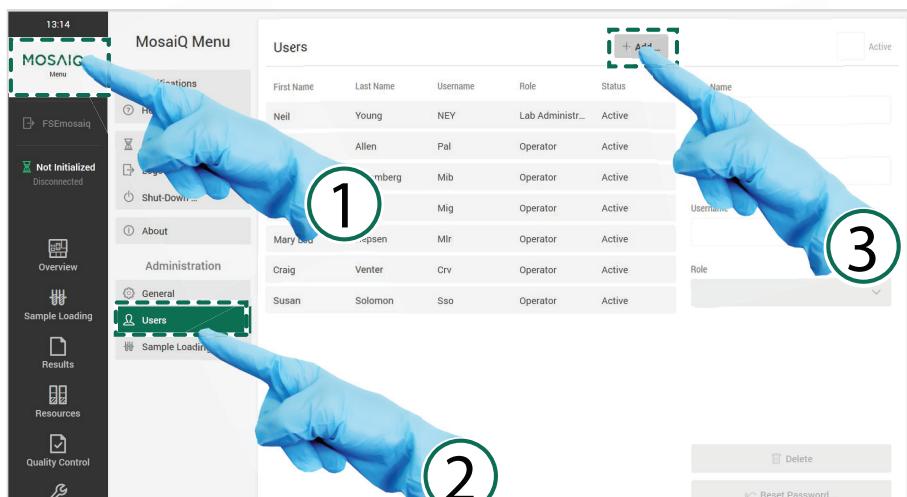
In most cases, special access rights are required for the described functions.



### 11.3.1 ADD A NEW USER ACCOUNT

This section provides step-by-step instructions on how to add a new user account.

- ① Tap on the **Menu** button
- ② Tap on the **Users** button
- ③ Tap on the **+ Add** button to create a new user account.



(adding a new user)

- ④ Fill in the appropriate fields.

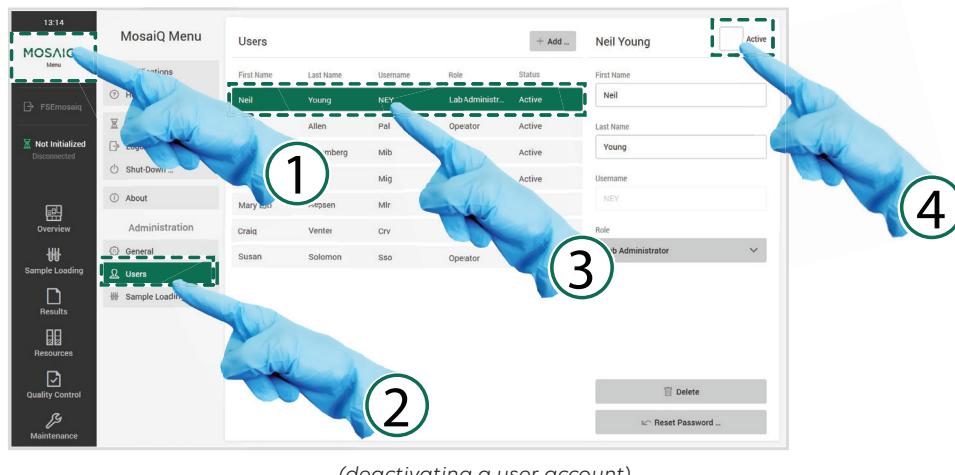
- Choose the appropriate role of the user.
- All changes will be saved automatically.
- Tap on the **Add** button to apply the new user account.

(creating a new user profile)

### 11.3.2 DEACTIVATE A USER ACCOUNT

This section provides step-by-step instructions on how to deactivate a user account.

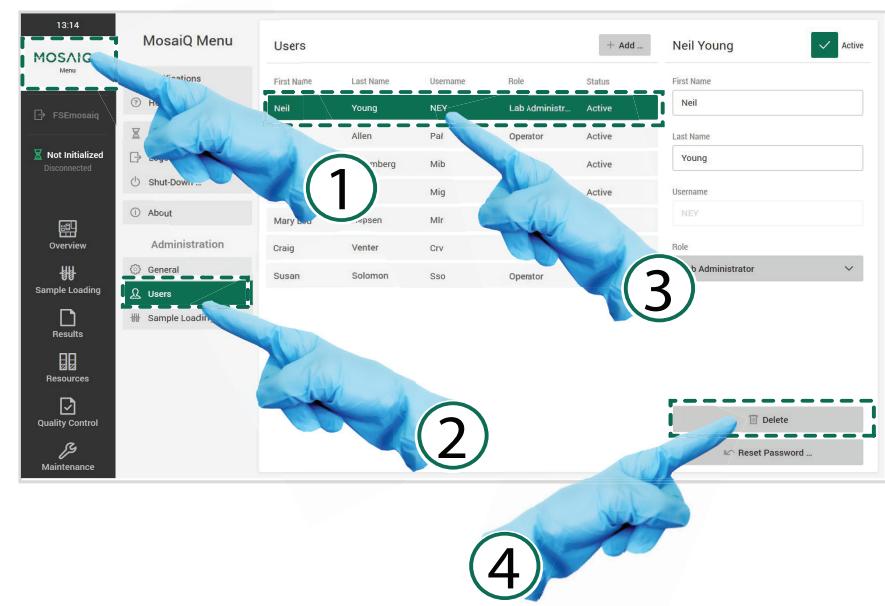
- ① Tap on the **Menu** button screen to access to the administration sub-menu.
- ② Tap on the **Users** button,
- ③ Select the appropriate user account from the list.
- ④ Tap on the **Active** button to deactivate the user account.



### 11.3.3 DELETE A USER ACCOUNT

This section provides step-by-step instructions on how to delete a user account.

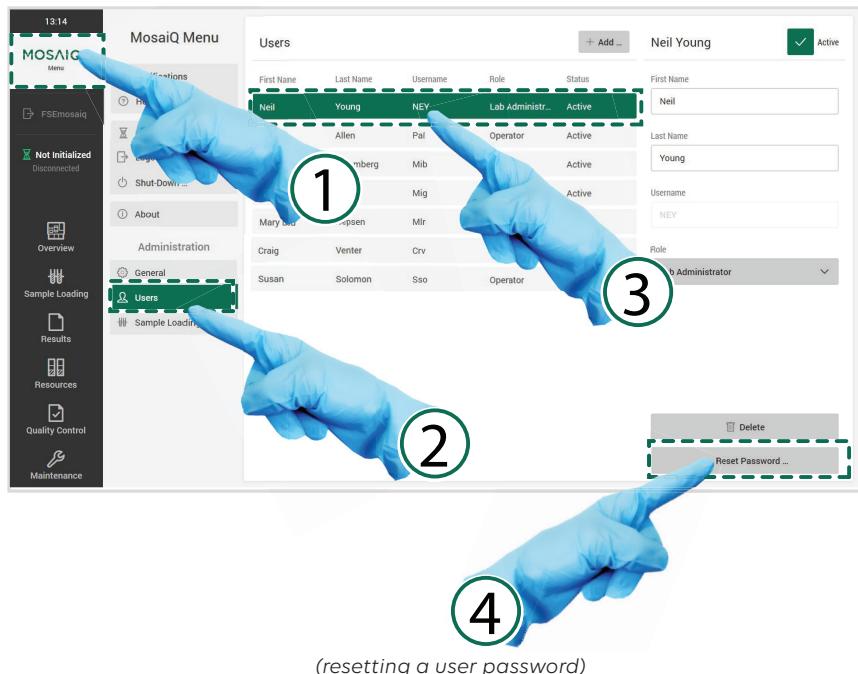
- To delete the selected user account,
- ① Tap on the **Menu** button screen to access to the administration sub-menu.
  - ② Tap on the **Users** button,
  - ③ Select the appropriate user account from the list.
  - ④ Tap on the **Delete** button.



### 11.3.4 RESET A USER'S PASSWORD

This section provides step-by-step instructions on how to reset a user password.

- ① Tap on the **Menu** button screen to access to the administration sub-menu.
- ② Tap on the **Users** button,
- ③ Select the appropriate user account from the list.
- ④ Tap on the **Reset** button.



- ⑤ A pop up window appears to tap a new temporary password.

5

Reset Password

Minimum Length: 7 Characters  
Required Characters: at least 1 Capital Letter (e.g. A.B.C...), at least 1 small character (e.g.a.b.c...), at least one numeric character and at least 1 special character (e.g.!\$,\$%,?...)

New Password

Cancel      Reset Password

(creating a new temporary password)

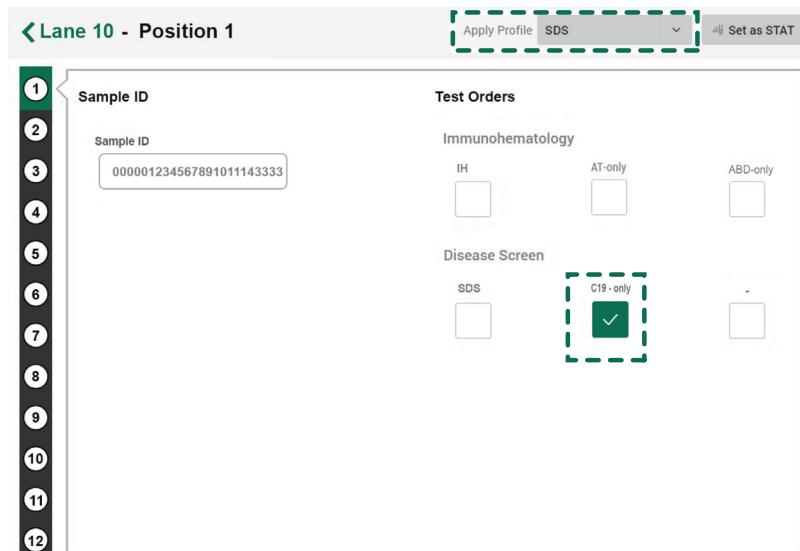
#### NOTICE

A temporary password can be entered in a dialogue box.  
The user must enter and confirm a new password at the next login.

### 11.3.5 SAMPLE PROFILE SETTING

With this setting, the laboratory administrator can select and edit the type of test to be used on the **MosaiQ 125**.

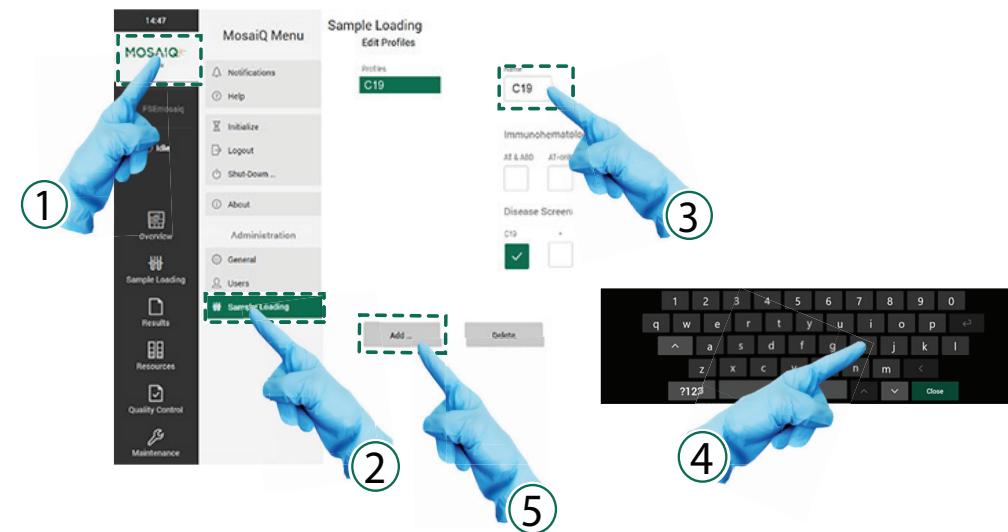
By setting the profile, each time a sample is loaded on the **MosaiQ 125**, only this selected sample profile (SDS available / C19 only) will be available on the **Sample Loading** dialog screen.



(sample profile in the sample loading dialog window)

To set a sample profile:

- ① Tap on the **Menu** button screen to access to the administration sub-menu.
- ② Tap on the **Sample Loading** button,
- ③ Tap on the profile **Name** field to activate automatically the virtual keyboard and select the tests in the tick box (Disease Screen / C19 only).
- ④ Tip the name of the profile on the virtual keyboard.
- ⑤ Tap on the **Add** button to implement the new profile



(editing a sample profile)

# 12. MAINTENANCE

## 12.1 SAFETY AND TIPS ABOUT MAINTENANCE AND CLEANING 128

12.1.1 ELECTRIC SHOCK OR MECHANICAL INJURY BY MAINS POWER SUPPLY	128
12.1.2 DEFECTS IN THE LIQUID SYSTEM	128
12.1.3 UNAPPROVED OR IMPROPER MAINTENANCE WORK	128

## 12.2 SAFETY AND TIPS ABOUT DISPOSAL AND DECONTAMINATION 129

12.2.1 CLEANING, DISINFECTION OR DECONTAMINATION	129
12.2.2 DISPOSAL OF NON-CONTAMINATED PARTS	129
12.2.3 HANDLING OF DECONTAMINATION SOLUTIONS	129

## 12.3 MAINTENANCE SCREEN PRESENTATION 130

## 12.4 PREVENTIVE MAINTENANCE TO BE PERFORMED BY THE USER 130

12.4.1 BEFORE PERFORMING MAINTENANCE TASKS	131
12.4.2 CLEANING AND DISINFECTION STEPS	131

## 12.5 CLEANING SOLUTIONS TO BE USED 131

## 12.6 DAILY MAINTENANCE TASKS 132

12.6.1 DAILY MAINTENANCE TASKS OVERVIEW	133
12.6.2 INITIALIZE SYSTEM	134
12.6.3 MAINTENANCE PRIMING	134
12.6.4 PRIME SAMPLE DILUENT 2	134
12.6.5 SHIFT START	134

## 12.7 WEEKLY MAINTENANCE 135

12.7.1 WEEKLY MAINTENANCE TASKS OVERVIEW	136
12.7.2 CLEANING OF THE PIPETTOR PROBES	138
12.7.3 CLEANING OF THE REAGENT DRAWER BLACK INSERT AND REAGENT BOTTLE DOCKING STATION	139
12.7.4 CLEANING OF THE EXTERNAL SURFACES OF THE MOSAIQ 125	139
12.7.5 CLEANING OF THE REAGENT CARRIAGE	139
12.7.6 CLEANING OF THE EXTERNAL COVERS OF THE INCUBATION RING	139
12.7.7 CLEANING OF THE REAGENT DOOR	139
12.7.8 CLEANING OF THE MAGAZINE STATION	140
12.7.9 CLEANING OF THE COMPUTER WORKSTATION	140
12.7.10 CLEANING OF THE SAMPLE STATION (EXTERNAL)	140
12.7.11 CLEANING OF THE TOUCH SCREEN	140
12.7.12 CLEANING OF THE SURROUNDING FLOOR AREA	140

## 12.8 MONTHLY MAINTENANCE TASKS 141

12.8.1 MONTHLY MAINTENANCE TASKS OVERVIEW	141
12.8.2 CLEANING OF THE LIQUID WASTE AND WATER SPILL TRAYS	142
12.8.3 CLEANING OF THE SOLID WASTE CONTAINER	142
12.8.4 CLEANING OF THE LIQUID WASTE CANISTER (EXTERNAL)	142
12.8.5 CLEANING OF THE WATER CANISTER (EXTERNAL)	142
12.8.6 LIQUID WASTE CANISTER (INTERNAL SOAKING)	142
12.8.7 WATER CANISTER (INTERNAL SOAKING)	142
12.8.8 SAMPLE RACK (SOAKING)	142

## 12.9 GUI MAINTENANCE TASKS OVERVIEW 143

This section provides information on how to maintain the **MosaiQ 125**.

The **MosaiQ 125** requires periodic maintenance tasks that must be performed at different stages of the **MosaiQ 125** use. Tasks are required on a daily, weekly and monthly basis.

The maintenance tasks can also be performed as needed.

Each maintenance task requires a dedicated cleaning product, method and frequency to guarantee optimal system performance.

There are maintenance tasks that will be performed by local technical representative only. These tasks are not described in this manual. For more information, please contact your local technical representative.

Please be aware of the safety measures that are described in this chapter before performing any maintenance task.

## 12.1 SAFETY AND TIPS ABOUT MAINTENANCE AND CLEANING

This section provides information about how to perform maintenance and cleaning operations safely and effectively. Please read this section carefully before performing maintenance or cleaning operations on the **MosaiQ 125**.

Any spills must be cleaned up immediately.

The spills containing or potentially containing chemical and/or biological components must be cleaned up immediately and the area sanitized by spraying 70% alcohol.

All potentially contaminated materials or materials used for cleaning must be disposed of in the biological waste container.



Any spills must be cleaned up immediately.

The spills containing or potentially containing chemical and/or biological components must be cleaned up immediately and the area sanitized by spraying 70% alcohol.

All potentially contaminated materials or materials used for cleaning must be disposed of in the biological waste container.

### 12.1.1 ELECTRIC SHOCK OR MECHANICAL INJURY BY MAINS POWER SUPPLY



There is a risk of electric shock or mechanical injury if the **MosaiQ 125** is not disconnected from the mains power supply before performing some maintenance. Please read the maintenance instructions carefully. Additionally, there is the danger that the **MosaiQ 125** could start and cause injury (e.g. contusions, cuts etc.) to the person working on the **MosaiQ 125**.

- Switch off the **MosaiQ 125**, disconnect it from the mains power supply to prevent it from restarting.
- Make sure that no one is working on the **MosaiQ 125** and that all covers are attached and closed before reconnecting the **MosaiQ 125** to the mains power supply.
- Only start cleaning, disinfection, decontamination, maintenance or repair work when the **MosaiQ 125** is disconnected from the mains power supply..

### 12.1.2 DEFECTS IN THE LIQUID SYSTEM



Defective or leaky tubes, valves or pumps may lead to deterioration of pipetting and accuracy of final results.

- Check the **MosaiQ 125** for isolated drops of liquid and pooling of liquid on surfaces.
- Check the tubes, valves and pumps periodically.

### 12.1.3 UNAPPROVED OR IMPROPER MAINTENANCE WORK



Unapproved or improper maintenance work may result in serious personal injury and material damage.

- Follow all safety instructions in this section.
- Only perform the maintenance procedures described in this manual.
- Closely follow the steps contained in the individual instructions.
- Only use the parts mentioned in the instructions to carry out maintenance work.
- Tests and maintenance specified by the manufacturer will be performed to ensure the safe operation and the proper functioning of the **MosaiQ 125**.
- All service and maintenance operations that are not described in this instruction manual will be performed by the local technical representative.
- Any changes made to the **MosaiQ 125** that are not authorized by the manufacturer will void the manufacturer warranty.

## 12.2 SAFETY AND TIPS ABOUT DISPOSAL AND DECONTAMINATION

This section provides information on cleaning (disinfection/decontamination), disposal of non-contaminated parts and handling of decontamination products. Please read this information carefully before carrying out any cleaning or disposal operations.

### Infectious waste

#### WARNING

Potentially infectious material and all parts that may come in contact with potential infectious material may expose a risk to the health of individuals and may cause severe environmental contamination.

- Strictly follow the local and national provisions, legislation and laboratory regulations.

### Misuse of battery

#### WARNING

The product contains an internal lithium manganese dioxide, vanadium pentoxide, or alkaline battery or rechargeable battery. There is risk of fire and explosions which can lead to burns if the battery pack is not handled properly.

- Do not attempt to recharge the battery.
- Do not expose to temperatures higher than 60 °C (140 °F).
- Spare batteries must match the values (nominal voltage, nominal current, and type) specified by the manufacturer.
- Dispose of used batteries according to the local and national provisions or legislation.

### 12.2.1 CLEANING, DISINFECTION OR DECONTAMINATION

This section provides information on how to clean, disinfect and decontaminate the **MosaiQ 125**. It also provides information on the recommended cleaning products.

#### NOTICE

Comply with the following instructions during cleaning, disinfection or decontamination. Failure to follow these instructions may expose a risk to the health of individuals.

- Disinfect or decontaminate components using a suitable disinfection or decontamination method, as described in this manual.
- Always follow the instructions provided with the product being used.
- Follow the routine cleaning maintenance procedures provided in this manual.

- For external surfaces of the **MosaiQ 125**, only use liquid cleaning, disinfection or decontamination solutions with a moistened cleaning wipe.
- Only use cleaning solution with proven efficiency, disinfection or decontamination solutions and methods, as described in [chapter 12.4](#) of this manual.
- Avoid having cleaning, disinfection or decontamination solutions come in contact with bearings and guides. These products may cause the greasy film to dissolve.
- Do not use cleaning, disinfection or decontamination solutions near the circuit boards, light barriers and acrylic surfaces.
- Unless explicitly stated in the maintenance procedure, do not pour or spray liquid cleaning, disinfection or decontamination solutions inside the **MosaiQ 125**.
- Do not autoclave canisters and components for the water or waste.

### 12.2.2 DISPOSAL OF NON-CONTAMINATED PARTS

- Strictly follow the local and national provisions, legislation and laboratory regulations.

### 12.2.3 HANDLING OF DECONTAMINATION SOLUTIONS

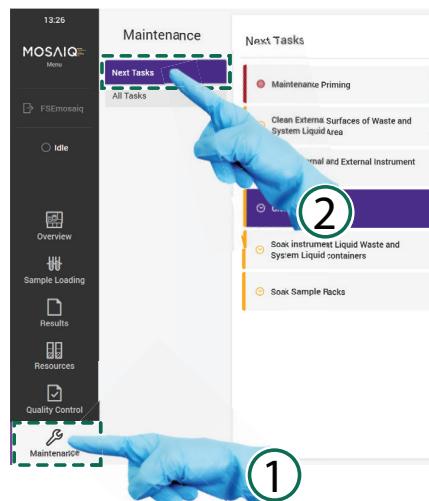
This section explains how to handle decontamination products. Pay careful attention when handling decontamination products. These products are hazardous, please read the product label and/or instructions for use.

- Strictly follow the local and national provisions, legislation and laboratory regulations.
- Do not mix bleach or decontamination liquid with alcohol.
- Do not use improper decontamination products.
- Only use 70% alcohol (i.e. Isopropanol) to decontaminate the external parts of the **MosaiQ 125**.
- Only use decontamination liquid in accordance with the User Manual.

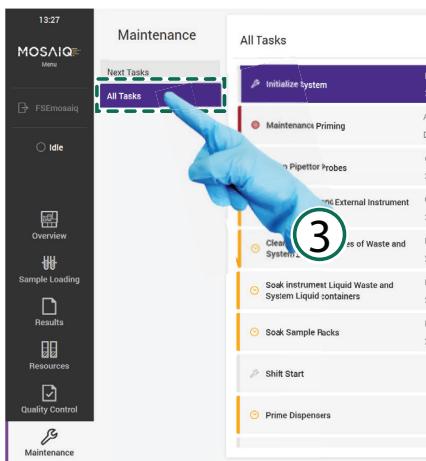
## 12.3 MAINTENANCE SCREEN PRESENTATION

To view the maintenance tasks:

- ① Tap on the **Maintenance** menu.
- ② Tap on **Next Tasks** to see which are the upcoming maintenance tasks.
- ③ Tap on **All tasks** to see all maintenance tasks and their corresponding periodicity.



(to see the next maintenance tasks)



(to see the all maintenance tasks)

In front of each maintenance task, a symbol indicates its specificity.

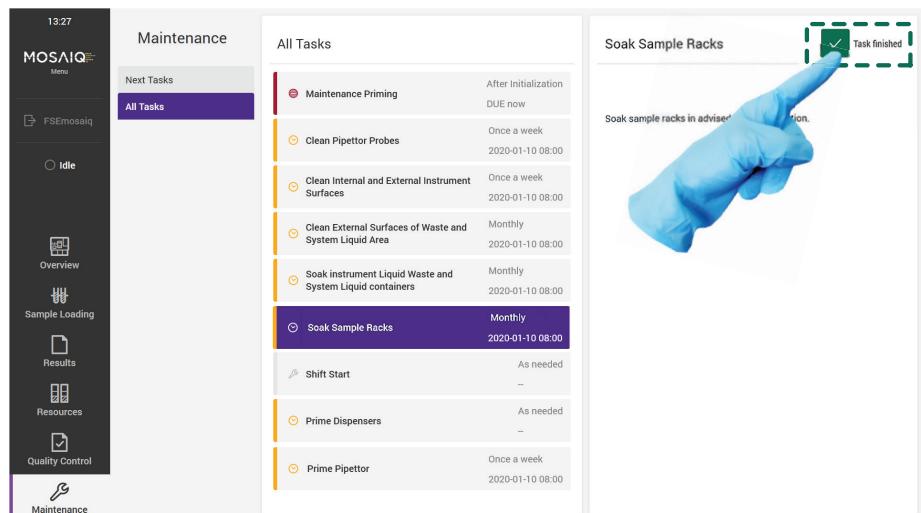
### Maintenance task symbols

	Periodic : Daily, weekly, monthly or as needed <i>(The date and time written below the periodicity information indicates the last time the task has been performed (JJJJ-MM-DD / HH:MM).</i>	<b>Daily</b> Once a week Monthly As needed
	Mandatory : The <b>MosaiQ 125</b> can not be used until this task is completed.	<b>DUE now</b>
	As needed.	<b>As needed</b>

## 12.4 PREVENTIVE MAINTENANCE TO BE PERFORMED BY THE USER

This section explains how to carry out preventive maintenance on the **MosaiQ 125**. Before using the **MosaiQ 125**, make sure that all maintenance tasks have been performed at the recommended frequencies. To do so:

- 1 - Tap on the **Maintenance** menu.
- 2 - Tap on the **Next Due** button to make sure that all tasks have been performed correctly.
- 3 - Some maintenance tasks (that are not performed by the **MosaiQ 125**) need to be confirmed by the user by tapping on the **Task Finished** button, on the top right corner of the **Maintenance** screen.



(maintenance screen with the "task finished" button)

## 12.4.1 BEFORE PERFORMING MAINTENANCE TASKS

Check that the minimum volumes for the resources for the MosaiQ 125 have been met, before performing the maintenance tasks.

- Reagents and system liquid,
- Available capacity in the waste canister.

For more information to check resources levels please refer to [chapter 7.2.2](#).

## 12.4.2 CLEANING AND DISINFECTION STEPS

This paragraph contains the information and instructions of the proper cleaning and disinfection of the **MosaiQ 125** to be carried out by the user. Personal Protective Equipment (PPE) must be worn in accordance with local regulations and guidance when performing the **MosaiQ 125** maintenance

Comply with the following aspects during cleaning and disinfection operations. Failure to do so can result in breakdowns or damage to the **MosaiQ 125** and may expose a risk to the health of individuals:

- Do not use the cleaning solution near circuit boards, light barrier or barcode reader.
- Do not spray the cleaning solution inside the **MosaiQ 125**.
- Always spray the cleaning solution onto a soft lint-free wipe to clean internal parts of the **MosaiQ 125**.
- You may spray the cleaning solution on the external surfaces where it is safe to do so (away from all ports, outlets and connections). Another option is to spray cleaning solution onto a lint-free wipe, which can then be used to clean the **MosaiQ 125**.
- Do not autoclave containers and components for the system liquid or waste.
- Make sure that before cleaning the **MosaiQ 125**, all samples, reagents and magazines have been removed.

The users with the required access rights should perform each maintenance task in accordance with the recommended frequency as described below:

## 12.5 CLEANING SOLUTIONS TO BE USED

The **MosaiQ 125** is designed such that the majority of cleaning activities can be performed following local guidelines and common laboratory cleaning agents.

We recommend to use either 70% Ethanol (EtOH) or Isopropyl alcohol (IPA) for cleaning of external surfaces and 0.5 M Sodium Hydroxide (NaOH) for pipettor cleaning.

All cleaning solutions for internal use should instead be sprayed onto a lint free wipe outside the **MosaiQ 125** first and then target surfaces wiped gently.

### Use only the following products for cleaning and disinfection purposes:

- 70% alcohol (i.e. Isopropanol),
- 2% Decon® / Virkon®,
- 5% Bleach,
- 0.5 M NaOH (Sodium Hydroxide),
- DI Water (Deionized Water),
- Cleaning wipes / Lint free multi-surface wipes.

 **WARNING**  
Do not use bleach for cleaning of all internal **MosaiQ 125** surfaces. The impact of bleach vapor may have an impact on functional testing.

 **WARNING**  
Never mix cleaning products.

## 12.6 DAILY MAINTENANCE TASKS

This section provides information on maintenance tasks that must be performed on a daily basis. System priming is an essential step to ensure that each module is ready to operate correctly. Failure to carry out priming may result in inaccurate results. Please read this information carefully before you begin.

Check that all resources conditions of the **MosaiQ 125** are met before performing maintenance tasks.

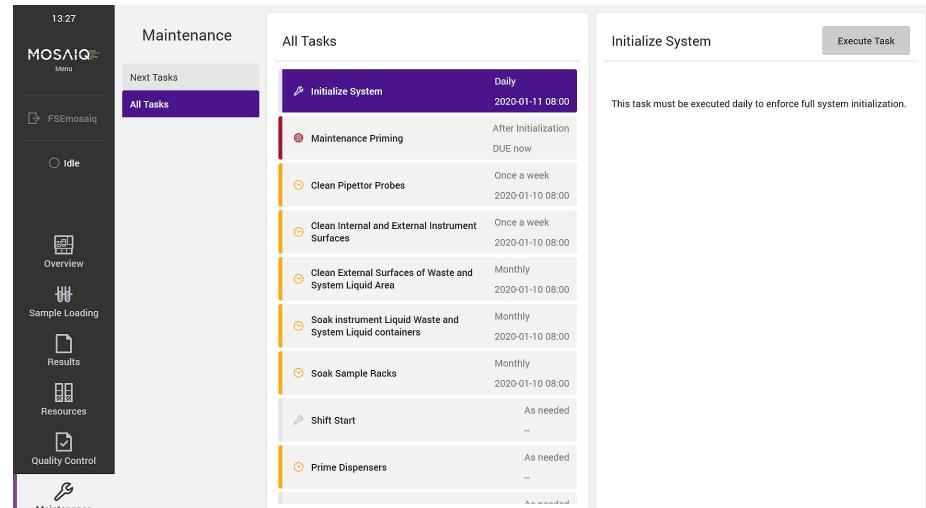
- Reagents and system liquid,
- Available capacity in the waste canister.

For more information to check resources levels please refer to [chapter 7.2.2](#).

The daily maintenance tasks must be executed to ensure each module is primed and ready to operate correctly.

### On the touch screen

- 1 - Select the **Maintenance** icon from the list on the main menu.
- 2 - Tap on the corresponding icon displayed in the middle of the touch screen to prime each module sequentially.
- 3 - For each module, select **Execute Task** on the right side of the screen to start the maintenance task.
- 4 - While performing the maintenance task, a hourglass symbol and the term **Maintenance** will appear on the left side of the screen.
- 5 - Once the task is finished, the term **Idle** will reappear.



(maintenance screen)

### NOTICE

Processing is blocked during priming operations.

## 12.6.1 DAILY MAINTENANCE TASKS OVERVIEW

<b>After turning on the MOSAIQ 125</b>			
User Manual chapter	Tasks	Time	Instructions / information
<b>12.6.2</b>	<b>Initialize System</b> (Initialization of the MosaiQ System)	<b>3 to 5 minutes</b>	<b>Execute this task (mandatory) to initialize the MosaiQ System</b>
<b>12.6.3</b>	<b>Maintenance Priming (x2)</b> (Priming of the wash modules and pipettor verification)	<b>5 to 10 minutes</b>	<b>Execute this task 2 times (mandatory after the System Initialization)</b>  it performs the priming of the wash modules to avoid any bubbles in the lines and generate fresh reconstituted wash buffers
<b>12.6.4</b>	<b>Prime Sample Diluent 2 (x3)</b> (Priming of MosaiQ Sample Diluent 2)	<b>1 to 3 minutes</b>	<b>Execute this task three consecutive times to avoid any bubble in the MosaiQ Sample Diluent 2 lines (as needed).</b>
<b>12.6.5</b>	<b>Shift Start</b> Archiving results	<b>1 to 2 minutes</b>	<b>Execute this task to archive results (as needed)</b>

## 12.6.2 INITIALIZE SYSTEM

This maintenance task is required prior to any sample processing. It takes up to 5 minutes to initialize all components. Initialization of the **MosaiQ 125** happens automatically after switching it on. This task is mandatory.

**On the touch screen:**

- 1 - Tap on **Maintenance** on the navigation bar.
- 2 - Tap on **Init System**.
- 3 - Tap on **Execute Task** on the right side of the screen to start the maintenance.

**NOTICE**

The initialization of the **MosaiQ 125** is required every 8 hours.  
Empty the liquid waste containers.

## 12.6.3 MAINTENANCE PRIMING

This maintenance task primes all washer lines and refills the intermediate container with diluted wash buffer. It needs to be executed after each initialization. Ensure MosaiQ wash buffers are plugged-in.

**On the touch screen:**

- 1 - Tap on **Maintenance** on the navigation bar.
- 2 - Tap on **Maintenance Priming**.
- 3 - Tap on **Execute Task** on the right side of the screen to start the maintenance.

## 12.6.4 PRIME SAMPLE DILUENT 2

This maintenance task primes the **MosaiQ Sample Diluent 2**, to avoid or remove any bubbles from the lines. To be performed as needed.

For an optimal result please perform this task three times consecutively.

**On the touch screen:**

- 1 - Tap on **Maintenance** on the navigation bar.
- 2 - Tap on **Prime Diluent 2**.
- 3 - Tap on **Execute Task** on the right side of the screen to start the maintenance.

## 12.6.5 SHIFT START

By performing this maintenance task, all results provided during the previous shift are saved in the archive. To be performed as needed.

**On the touch screen:**

- 1 - Tap on **Maintenance** on the navigation bar.
- 2 - Tap on **Shift Start**.
- 3 - Tap on **Execute Task** on the right side of the screen to start the maintenance.

## 12.7 WEEKLY MAINTENANCE

This section provides information on maintenance tasks that must be performed on a weekly basis. Please be aware of the maintenance tasks safety and precautions below.

### MosaiQ 125 internal Chassis

The term "internal chassis" refers to the interior of the **MosaiQ 125** where certain system components are housed that require cleaning on a weekly basis.

For application of solutions for cleaning of internal surfaces (i.e. loading bay, turntable) users MUST avoid spraying reagents directly onto **MosaiQ 125** surfaces to reduce the risk of aerosols coming into contact with electrical components.

### Safety and precautions

 **WARNING**

Unless specified, any cleaning/disinfection operation performed on the **MosaiQ 125** by the user must be carried out with the power supply cord disconnected from the power source.

For the cleaning and disinfection of the internal chassis of the **MosaiQ 125** and accessories, use a clean wipe that does not leave any residues and on which you spray a sufficient quantity of cleaning solution (IPA). Take a new clean wipe when necessary.

 **WARNING**

Improper cleaning of the optical surfaces (e.g. scanners, sensors, lenses) could generally degrade the quality of images, data, etc. Do not touch any optical surfaces. If necessary, only clean the optical surfaces with a soft and lint-free wipe and do not use any aggressive detergents or other cleaning solutions (i.e. alcohol).

## 12.7.1 WEEKLY MAINTENANCE TASKS OVERVIEW

This table provides an overview of the weekly maintenance tasks with a short description. Please read the details for each maintenance task in the corresponding chapter.

The table is split in three sections:

- Maintenance tasks that must be performed when **MosaiQ 125** is connected to the mains power supply and on.
- Maintenance tasks that can be performed when **MosaiQ 125** is connected to the mains power supply or not.
- Maintenance tasks that must be performed when **MosaiQ 125** is disconnected from the mains power supply.

When MOSAIQ 125 is ON					
User Manual chapter	Parts	Time	Location	Cleaning solutions	Instructions / information
12.7.2	Pipettor probes	20 minutes	Loading of rack in the sample station	0.5 M NaOH (Sodium Hydroxide)  Avoid: bleach	<ul style="list-style-type: none"> <li>• Fill a sample tube with Sodium Hydroxide</li> <li>• Place the tube in position 1 of a rack</li> <li>• Insert the rack in lane n°10 of the MosaiQ 125</li> <li>• Execute the task from the maintenance screen</li> </ul>
When MOSAIQ 125 is ON or OFF					
User Manual chapter	Parts	Time	Location	Cleaning solutions	Instructions / information
12.7.3	Reagent drawer black insert + Reagent bottle docking station	1 to 2 minutes	To access to this area open the reagent drawer	70% alcohol (i.e. Isopropanol)  Warm water*	<p>Wipe the surface with a lint free wipe and 70% alcohol</p> <p>* Warm water can be used for salt crystal removal but needs to be followed with established cleaning solution.</p>
12.7.4	External surfaces of the MosaiQ 125.	3 to 5 minutes	External	Avoid: Aerosols, Bleach, Strong Alkaline or Acidic Solutions.	

**WARNING**

All of these cleaning / disinfection operations must be carried out with the power supply cord disconnected from the power source.

**WARNING**

Never mix cleaning products.

**When MOSAIQ 125 is disconnected from the mains**

User Manual chapter	Parts	Time	Location	Cleaning solutions	Instructions / information
12.7.5	Reagent Carriage (all accessible surfaces)	1 to 2 minutes	To access this area open the reagent door	70% alcohol (i.e. Isopropanol)	Wipe the surface with a lint free wipe and 70% alcohol
12.7.6	External Covers of the incubation ring	1 to 2 minutes		Warm water*	* Warm water can be used for salt crystal removal but needs to be followed with established cleaning solution.
12.7.7	Reagent Door (both sides)	1 to 2 minutes			
12.7.8	Magazine Station (magazine door and 4 magazine carousel positions)	1 to 2 minutes	To access to this area open the Magazine Station door	Avoid: Aerosol Cleaners, Bleach, Strong Alkaline or Acidic Solutions.	
12.7.9	Computer Workstation (including power button)	1 to 2 minutes	To access this area open the Water Drawer		
12.7.10	Sample Station (external and inner surfaces)	3 to 5 minutes	External	70% alcohol, water	Wipe the surface with a lint free wipe 70% alcohol, water.
12.7.11	Touch Screen	2 to 3 minutes		Avoid: Aerosol Cleaners, Bleach	

## 12.7.2 CLEANING OF THE PIPETTOR PROBES

The inner and outer surface cleaning of the sample pipettor is aimed at preventing sample build-up and thus carryover over time. Subsequent washing with system liquid should remove all residual cleaning fluid so that future test orders are not compromised.

### WARNING

Bleach MUST NOT be used as replacement solution due to the high risk of residue remaining in the pipettor probe prior to test processing.

### NOTICE

As the pipettor maintenance is also performed partially by the **MosaiQ 125** for 15 minutes, you can meanwhile do other maintenance tasks that are safe when the **MosaiQ 125** is connected to the mains. For example, on the external parts and inside the drawers (solid and liquid waste, system liquid and reagent drawer).

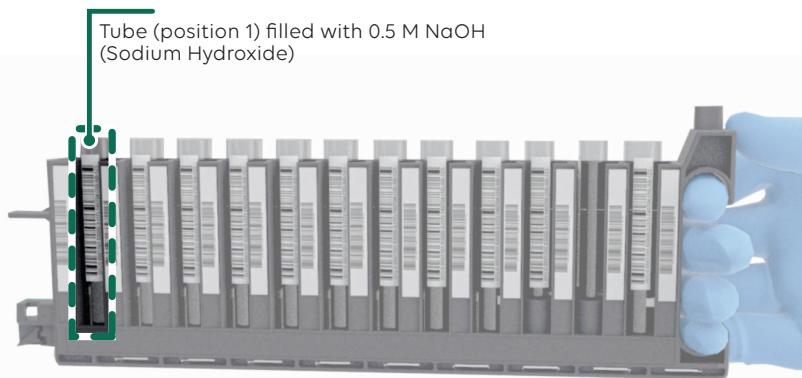
### NOTICE

On completion of the cleaning, the remaining NaOH should be discarded as per local guidelines. This reagent should NOT be poured into MosaiQ liquid waste as it may react with other components of the liquid waste.

This task performs an intensive cleaning of the pipettor probes.

To perform the cleaning:

- Fill a sample tube with a small volume ( $\geq 5\text{mL}$ ) 0.5 M NaOH (Sodium Hydroxide) and place it in position number 1 on a MosaiQ rack.

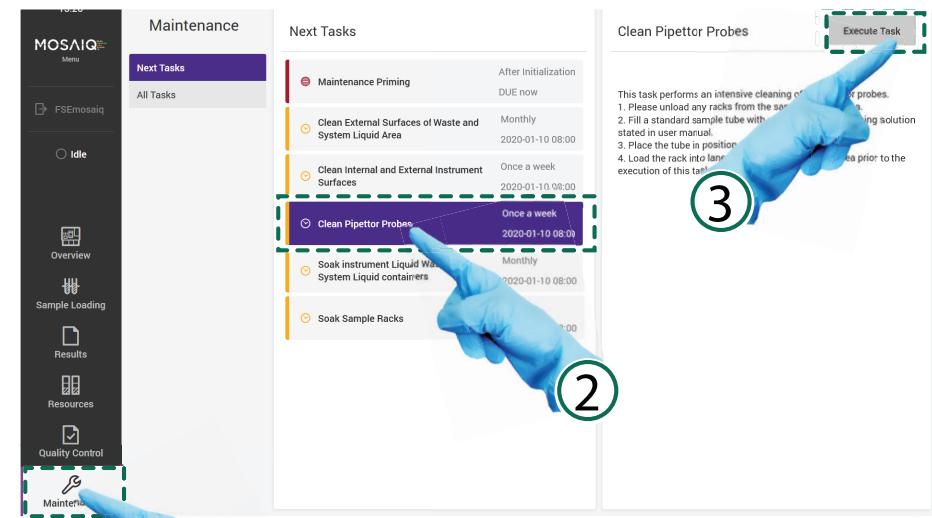


(sample tube in position one on the sample rack)

- Slide the rack into the lane number 10 in the sample station.

- On the touch screen:

- Tap on **Maintenance** on the navigation bar.
- Tap on the **Clean Pipettor Probes** task
- Tap on the **Execute Task** button.



(executing a maintenance task)

### 12.7.3 CLEANING OF THE REAGENT DRAWER BLACK INSERT AND REAGENT BOTTLE DOCKING STATION

To clean the inside of the reagent drawer:

- 1 - Open the reagent drawer.
- 2 - Remove any reagent bottle from the drawer.
- 3 - Wipe the surface of the black insert of the reagent drawer with a lint free wipe and 70% alcohol.
- 4 - If any salt crystal is present, use warm water to remove it.
- 5 - Close the reagent drawer.



(inside of the reagent drawer)

More information about the reagent drawer, please refer to [chapter 5.8](#) of this manual.

To remove the reagent bottles from the reagent drawer, please refer to [chapter 7.3.5](#) of this manual.

### 12.7.4 CLEANING OF THE EXTERNAL SURFACES OF THE MOSAIQ 125

The external surfaces (covers and drawers) can be cleaned when the **MosaiQ 125** is not operating.

External **MosaiQ 125** covers spray 70% alcohol on a lint free wipes then clean the **MosaiQ 125** surface, however care should be taken when cleaning the **MosaiQ 125** touch screen and PC.

- 1 - Close all drawers.
- 2 - Wipe the surface of the external covers and drawers with a lint free wipe and 70% alcohol.

### 12.7.5 CLEANING OF THE REAGENT CARRIAGE

The reagent carriage is located in the process module compartment and supports the detection and enhancement reagent bottles. It should be cleaned weekly.

#### WARNING

Disconnect the **MosaiQ 125** power cord from the mains before carrying out this cleaning/disinfection operation..

To clean the reagent carriage:

- 1 - Be sure that the **MosaiQ 125** is not connected to the mains power supply.
- 2 - Open the reagent door.
- 3 - Remove all detection and enhancement reagent bottles from the reagent carriage.
- 4 - Wipe all accessible surfaces of the reagent carriage with a lint free wipe and 70% alcohol.

More information about the reagent carriage please refer to [chapter 5.9.1](#) of this manual.

To remove detection and enhancement reagent bottles form the reagent carriage please refer to [chapter 7.3.3](#) of this manual.

### 12.7.6 CLEANING OF THE EXTERNAL COVERS OF THE INCUBATION RING

Clean the incubation ring covers weekly.

To clean the incubation ring covers:

- 1 - Be sure that the **MosaiQ 125** is not connected to the mains power supply..
  - 2 - Open the reagent door.
  - 3 - Wipe the surface of the incubation ring covers with a lint free wipe and 70% alcohol.
- More information about the incubator please refer to [chapter 5.9.3](#) of this manual.

### 12.7.7 CLEANING OF THE REAGENT DOOR

The reagent door is controlled by software and cannot be opened when the **MosaiQ 125** is operating, but it can be opened when the **MosaiQ 125** is in **Idle** mode. For safety reasons disconnect the **MosaiQ 125** from the mains power supply..

#### WARNING

Disconnect the **MosaiQ 125** power cord from the mains power supply. before carrying out this cleaning/disinfection operation..

To clean the reagent door:

- 1 - Be sure that the **MosaiQ 125** is not connected to the mains power supply..
- 2 - Open the reagent door until it reaches its locked open position.
- 3 - Wipe the internal surfaces of the reagent door with a lint free wipe and 70% alcohol.
- 4 - Close the reagent door and wipe the external surface of the reagent door with a lint free wipe and 70% alcohol.

## 12.7.8 CLEANING OF THE MAGAZINE STATION

The magazine station door is controlled by software and cannot be opened when the **MosaiQ 125** is operating, but it can be opened when the **MosaiQ 125** is in **Idle** mode. For safety reasons DO NOT clean the magazine station door when the **MosaiQ 125** is connected to the mains power supply..

### WARNING

Disconnect the **MosaiQ 125** power cord from the mains power supply. before carrying out this cleaning/disinfection operation..

To clean the magazine station:

- 1 - Be sure that the **MosaiQ 125** is not connected to the mains power supply.
- 2 - Open the magazine station door.
- 3 - Remove any magazine from the magazine station.
- 4 - Wipe all surfaces of the magazine carousel (all four positions) with a lint free wipe and 70% alcohol.
- 5 - Close the magazine station and wipe the external surface of the magazine station door with a lint free wipe and 70% alcohol.

More information about the magazine station, please refer to [chapter 5.4](#) of this manual.

To remove magazines, form the magazine station, please refer to [chapter 7.3.1](#) of this manual.

## 12.7.9 CLEANING OF THE COMPUTER WORKSTATION

The computer is located in the water drawer. DO NOT perform the cleaning of the computer workstation when the **MosaiQ 125** and the computer workstation are connected to the mains.

### WARNING

Disconnect the **MosaiQ 125** power cord from the mains power supply. before carrying out this cleaning/disinfection operation..

To clean the computer workstation:

- 1 - Be sure that the **MosaiQ 125** and the computer workstation are not connected to the mains power supply.
  - 2 - Open the water drawer.
  - 3 - Wipe the surface of the computer workstation and the **ON/OFF** button with a lint free wipe and 70% alcohol.
  - 4 - Close the water drawer.
- More information about the computer workstation, please refer to [chapter 5.7.2](#) of this manual.

## 12.7.10 CLEANING OF THE SAMPLE STATION (EXTERNAL)

External part

The external part of the sample station is equipped with a laser barcode scanner and requires attention when cleaning of this area.

### Handling and Cleaning the optical Surfaces:

#### NOTICE

Improper handling and cleaning of optical surfaces (e.g. scanners, lenses, sensors) could generally degrade the quality of images, data, etc.

- Do not touch any optical surfaces with anything other than soft lint-free wipes that can be used for cleaning.
- Use a commercially available lens cleaner to clean optical surfaces, never use any aggressive detergents or solutions (e.g. acetone).

To clean the external part of the sample station:

- 1 - Wipe the surface with a lint free wipe and 70% alcohol.

## 12.7.11 CLEANING OF THE TOUCH SCREEN

The touch screen is a sensitive part and it requires attention regarding the cleaning product to be used.

### Damage of touch screen while cleaning

#### NOTICE

Improper cleaning could damage the touch screen surface.

- Use a soft and lint-free wipe with neutral detergent or with ethanol to clean the touch screen.
- Do not use any chemical solvent, acidic or alkali solution.

## 12.7.12 CLEANING OF THE SURROUNDING FLOOR AREA

Please follow the laboratory internal safety and cleaning instructions.

- 1 - Any spills must be cleaned up immediately.
- 2 - Spills containing or potentially containing chemical and/or biological components must be cleaned up immediately and the area sanitised by spraying 70% alcohol.
- 3 - All potentially contaminated materials or materials used for cleaning must be disposed of in the biological waste container.

## 12.8 MONTHLY MAINTENANCE TASKS

This section provides information on maintenance tasks that must be performed on a monthly basis.

Please be aware of the maintenance tasks safety and precautions.

### 12.8.1 MONTHLY MAINTENANCE TASKS OVERVIEW

This table provides an overview of the monthly maintenance tasks with a short description. Please read the details for each maintenance task in the corresponding chapter.

These maintenance tasks can be performed when **MosaiQ 125** is connected to the mains or not.



Never mix cleaning products.

When MOSAIQ 125 is ON or OFF					
User Manual chapter	Parts	Time	Location	Cleaning solutions	Instructions / information
12.8.2	Liquid Waste & Water Spill Trays	3 to 5 minutes	Liquid Waste Drawer & Water Drawer	multi-purpose cleaning solution (Bleach 5% or Virkon 2%, or 70% alcohol or Decon 2%)  Warm water *	Wipe the surface with a multi-purpose cleaning solution.  * Warm water can be used for salt crystal removal but needs to be followed with established cleaning solution.
12.8.3	Solid Waste Container surfaces	2 to 3 minutes	Waste Drawer		
12.8.4	Liquid Waste Canisters (external surfaces)	1 to 2 minutes	To be removed from Waste Drawer		
12.8.5	Water Canisters (external surfaces)	1 to 2 minutes	To be removed from Water Drawer		
12.8.6	Liquid Waste Canister (internal soaking)	Minimum 2 hours	To be removed from the Waste Drawer	Bleach 5%	Soak the canister with Bleach and rinse before use.
12.8.7	Water Canisters (internal soaking)	Minimum 2 hours	To be removed from the Water Drawer	Virkon 2% or Decon 2%  Avoid: Bleach	Soak the canister with Virkon or Decon and rinse before use.
12.8.8	Sample Racks (soaking)	Minimum 2 hours	To be removed from Sample Station	Bleach 5% or Virkon 2%  Avoid: Strong Alkaline or Acidic Solutions	Soak the racks in Bleach or Virkon, rinse and let dry before use.

## 12.8.2 CLEANING OF THE LIQUID WASTE AND WATER SPILL TRAYS

The spill trays of both the water and the liquid waste containers need to be cleaned once a month.

To clean the spill trays:

- 1 - Open the water drawer and the waste drawer.
- 2 - Remove all water canisters and all liquid waste canisters.
- 3 - Wipe the surface with bleach, or 70% alcohol or Virkon® or Decon®.

## 12.8.3 CLEANING OF THE SOLID WASTE CONTAINER

The solid waste container must always contain a waste bag.

### WARNING

The container has sharp parts, be careful not to hurt yourself during cleaning.

**To clean the solid waste container:**

- 1 - Slide opened the solid waste drawer and remove the biological waste bag from the solid waste container and put it in the box destined for the disposal of such waste.
- 2 - Wipe the solid waste container inside and outside with bleach or 70% alcohol or Virkon® or Decon®.
- 3 - After cleaning, put a new biological hazard waste bag in the solid waste container and slide the container into the **MosaiQ 125**.

## 12.8.4 CLEANING OF THE LIQUID WASTE CANISTER (EXTERNAL)

External surface of the liquid waste canister

To clean the external surface of the liquid waste canister:

- Wipe the surface with bleach, or 70% alcohol or Virkon® or Decon®.

## 12.8.5 CLEANING OF THE WATER CANISTER (EXTERNAL)

External surface of the water canister

To clean the external surface of the water canister:

- Wipe the surface with bleach, or 70% alcohol or Virkon® or Decon®.

## 12.8.6 LIQUID WASTE CANISTER (INTERNAL SOAKING)

Soaking the internal surface of the liquid waste canister

The periodic soaking of the liquid waste canister needs to be performed to reduce the risk of microbial build-up over time. Users should perform as per local guidelines and procedures used for similar instrumentation, taking care to ensure all residual cleaning solution is flushed out prior to re-use.

For liquid waste canisters we recommend the use of bleach 5%:

- 1 - If the container is full, empty the water directly into the drain.
- 2 - Fill the container with water and add the appropriate concentration of bleach.
- 3 - Let the canister soak a minimum of two hours.
- 4 - Then empty the canister into the drain.
- 5 - Fill the canister with tap water and rinse it
- 6 - Repeat this procedure several times if there are any visual deposits or residue before replacing it in the **MosaiQ 125**.

## 12.8.7 WATER CANISTER (INTERNAL SOAKING)

Soaking the internal surface of the water canister

The periodic soaking of the water canister needs to be performed to reduce the risk of microbial build-up over time. Users should perform as per local guidelines and procedures used for similar instrumentation, taking care to ensure all residual cleaning solution is flushed out prior to re-use.

For water canisters we recommend the use of Virkon® or Decon®:

- 1 - If the container is full, empty the water directly into the drain.
- 2 - Fill the container with the appropriate concentration 0.1 M NaOH (2% of Virkon® or Decon®).
- 3 - Let the canister soak a minimum of two hours.
- 4 - Then empty the canister into the drain.
- 5 - Rinse the canister thoroughly with water. Repeat this step at least three times, until there are no visual deposits or residue.
- 6 - Finally, rinse the canisters with purified water before filling the tank with purified water and replacing it in the **MosaiQ 125**.

## 12.8.8 SAMPLE RACK (SOAKING)

To soak the MosaiQ rack:

- 1 - Remove all tubes from the racks.
- 2 - Let the racks in bleach or Virkon® soak a minimum of two hours.
- 3 - Rinse the racks and let them dry before use.

## 12.9 GUI MAINTENANCE TASKS OVERVIEW

This section describes the maintenance tasks provided by the GUI.

### Procedure

- 1 - Tap on the **Maintenance** icon in the navigation bar.
- 2 - Tap on a task to show details.
- 3 - Tap on the **Execute Task** button to execute the maintenance task.
- 4 - Follow the instructions.

### Tasks

Task	Description	Frequency
<b>Initialize System</b>	Initializes the <b>MosaiQ 125</b> .	Daily required after <b>MosaiQ 125</b> start
<b>Maintenance Priming</b>	Primes the washer module 1 and washer module 2, and generates fresh diluted wash buffers.  Solutions used: <ul style="list-style-type: none"><li>• <b>MosaiQ Wash Buffer 1</b></li><li>• <b>MosaiQ Wash Buffer 2</b></li></ul>	After <b>MosaiQ 125</b> initialization
<b>Clean Pipettor Probes</b>	Cleaning of the pipettor probes  Solution used: <ul style="list-style-type: none"><li>• Sodium Hydroxide (0.5 M NaOH)</li></ul>	Required once a week
<b>Clean Washer Prime troughs</b>	Incubation ring priming wells cleaning (these wells are not visible to users)  Solutions used: <ul style="list-style-type: none"><li>• <b>MosaiQ Wash Buffer 1</b></li><li>• <b>System liquid</b></li></ul>	As needed, follow the indications on the <b>MosaiQ 125</b>
<b>Prime Wash Buffer 1</b>	Primes the <b>MosaiQ Wash Buffer 1</b> pumps in the reconstitution drawer. Only if a reagent bottle is installed.	As needed, follow the instructions on the <b>MosaiQ 125</b>
<b>Prime Wash Buffer 2</b>	Primes <b>MosaiQ Wash Buffer 2</b> pumps in the reconstitution drawer.  Only if a reagent bottle is installed.	As needed, follow the indications on the <b>MosaiQ 125</b>

Task	Description	Frequency
<b>Shift start</b>	Starts the archiving of results, quality control results and maintenance tasks.	As needed, follow the indications on the <b>MosaiQ 125</b>
<b>Prime Detection Reagent 1</b>	Primes the <b>MosaiQ Detection Reagent 1</b> dispensers on the reagent priming trough. Only if a reagent bottle is installed.	As needed, follow the indications on the <b>MosaiQ 125</b>
<b>Prime Detection Reagent 2</b>	Primes the <b>MosaiQ Detection Reagent 2</b> dispensers on the reagent carriage. Only if a reagent bottle is installed.	As needed, follow the indications on the <b>MosaiQ 125</b>
<b>Prime Sample Diluent 1</b>	Primes the <b>MosaiQ Sample Diluent 1</b> pumps in the samples diluent reservoir. Only if a reagent bottle is installed.	As needed, follow the indications on the <b>MosaiQ 125</b>
<b>Prime Sample Diluent 2</b>	Primes the <b>MosaiQ Sample Diluent 2</b> pumps in the samples diluent reservoir. Only if a reagent bottle is installed.	As needed, follow the indications on the <b>MosaiQ 125</b>
<b>Prime Dispensers</b>	Primes all dispensers ( <b>MosaiQ Detection Reagent 1</b> , <b>MosaiQ Detection Reagent 2</b> , <b>MosaiQ Enhancement Reagent 1</b> , <b>MosaiQ Enhancement Reagent 2</b> ) on the reagent carriage.  Only if a reagent bottle is installed.	As needed, follow the indications on the <b>MosaiQ 125</b>
<b>Prime Enhancement Reagent 1</b>	Primes <b>MosaiQ Enhancement Reagent 1</b> dispensers on the reagent carriage. Only if a reagent bottle is installed.	As needed, follow the indications on the <b>MosaiQ 125</b>
<b>Prime Enhancement Reagent 2</b>	Primes <b>MosaiQ Enhancement Reagent 2</b> dispensers on the reagent carriage. Only if a reagent bottle is installed.	As needed, follow the indications on the <b>MosaiQ 125</b>
<b>Prime Pipettor</b>	Wash the outside and the inside of both pipettor probes with system liquid.	As needed, follow the indications on the <b>MosaiQ 125</b>

Task	Description	Frequency
<b>Prime Wash Buffers and Sample Diluents</b>	<p>Primes <b>MosaiQ Wash Buffer 1</b> and <b>2</b> pumps in the reconstitution drawer and <b>MosaiQ Sample Diluent 1</b> and <b>2</b> sample diluent pumps in the intermediate reservoirs.</p> <p>Only if a reagent bottle is installed.</p>	As needed, follow the indications on the <b>MosaiQ 125</b>
<b>Prime Wash Module 1</b>	<p>Primes all the liquid lines at washer module 1.</p> <p>Solutions used:</p> <ul style="list-style-type: none"> <li>• <b>MosaiQ Wash Buffer 1</b></li> <li>• <b>MosaiQ Wash Buffer 2</b></li> </ul>	As needed, follow the indications on the <b>MosaiQ 125</b>
<b>Prime Wash Module 2</b>	<p>Primes all the liquid lines at washer module 2.</p> <p>Solutions used:</p> <ul style="list-style-type: none"> <li>• <b>MosaiQ Wash Buffer 1</b></li> <li>• System liquid</li> </ul>	As needed, follow the indications on the <b>MosaiQ 125</b>

# 13. TROUBLESHOOTING AND ERROR OVERVIEW

<b>13.1 INTRODUCTION</b>	<b>146</b>	<b>13.3 FREQUENT OPERATIONAL WARNING MESSAGES</b>	<b>149</b>
13.1.1 MESSAGE EVENTS	146	13.3.1 MOSAIQ 125 FAILS TO INITIALIZE	149
13.1.2 WARNING EVENTS	146	13.3.2 UNABLE TO ADD TO PROCESS DUE TO WASTE LEVEL	149
13.1.3 CRITICAL EVENTS	146	13.3.3 SYSTEM LIQUID LEVEL SHOWN IN RESOURCES DOES NOT APPEAR CORRECT	150
13.1.4 FATAL EVENTS	146		
<b>13.2 ERRORS RELATED TO PROCESS MODULES</b>	<b>147</b>	<b>13.4 MOSAIQ 125 ERROR CODES</b>	<b>151</b>
13.2.1 MAGAZINE STATION	147		
13.2.2 SAMPLE STATION	147		
13.2.4 MICROARRAY LOADING	147		
13.2.5 SAMPLE ADDITION	147		
13.2.6 PIPETTOR	147		
13.2.7 REAGENT CARRIAGE	148		
13.2.8 WASHING MODULES	148		
13.2.9 REAGENT DOOR	148		
13.2.10 REAGENT DRAWER	148		
13.2.11 WATER DRAWER	148		

This section provides information on how to troubleshoot common errors that may arise when using the **MosaiQ 125**.

## 13.1 INTRODUCTION

The **MosaiQ 125** presents four events classes from the lowest severity up to the highest.

- Message Events
- Warning Events
- Critical Events
- Fatal Events

### 13.1.1 MESSAGE EVENTS

#### **Message Events type 1**

Events are classified as a message when they just contain information for transparency purposes and do not fall in one of the other classes with a higher severity (no failure).

#### **Message Events type 2**

These messages give information related to the **MosaiQ 125**, state or transitions. They are usually not necessary for the user and they do not require any action.

### 13.1.2 WARNING EVENTS

#### **Warning Events type 1**

An event is classified as a warning to indicate a low severity issue. Typically a module has detected an exceptional state, but could recover safely on its own.

#### **Warning Events type 2**

These warning events give indication to the user to perform something (e.g. fill level), it can also indicate that a problem has been solved, or that a state has been changed.

### 13.1.3 CRITICAL EVENTS

Depending on the severity of an error, the user can resolve a problem by following the recovery instruction for each error message.

#### **Critical error**

An event is classified as a critical error, when an error condition affects test order processing, but processing can continue for unaffected test orders. User intervention might be required.

- Critical errors will provide information, they are displayed on the screen when they are detected by the **MosaiQ 125**. Errors messages and descriptions can be reviewed by tapping on the **Notifications** button from the MosaiQ Menu, as described in the [chapter 6.2.3](#) of this manual.
- Critical errors do not lead to a **MosaiQ 125** crash, but they warn the user that something must be corrected to run the **MosaiQ 125** correctly.
- Critical errors can cause jobs to be cancelled... For any reason a specific sample cannot be run or must be canceled. In this case no result will be generated.
- As part of the critical errors, if a failure occurs due to not detecting the positive controls, this will be described as a "**Data Reduction Error**". This error maybe due to several reasons and require some investigation.
- Critical errors can be caused by a pipetting error due to a Liquid Level Detection (LLD), or Optical Liquid Verification (OLV) error.

### 13.1.4 FATAL EVENTS

Depending on the cause, the user might be able to resolve the problem by following the troubleshooting instructions and re-initializing the **MosaiQ 125**.

#### **Fatal error**

An event is classified as a fatal error when an error may cause the **MosaiQ 125** to crash and generates error flags.

- Fatal errors are the most severe errors because they generate a crash on the **MosaiQ 125**.
- Fatal errors cause the loss of all samples that are currently being processed. That means that the user needs to redo all tests that have been initiated when the fatal error occurred. To check the assays impacted by this fatal error, go to the **Results** screen, the affected assays are tagged with a processing error message in the **Review** section.
- When a fatal error occurs, the user has to check and troubleshoot the cause of the crash and re-initialize the **MosaiQ 125**.

## 13.2 ERRORS RELATED TO PROCESS MODULES

Each process module has its own related possible errors and troubleshooting instructions. Please carefully follow the instructions provided.

### 13.2.1 MAGAZINE STATION

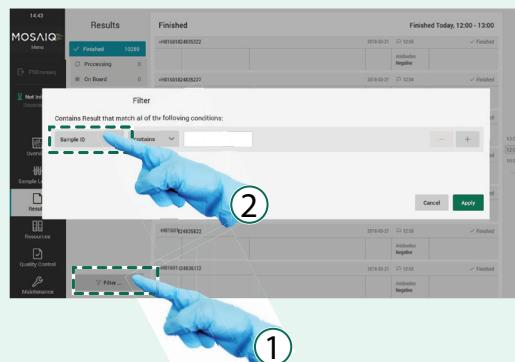
Error message(s)	Severity	Recovery	Possible cause(s)
Target position not reached	FATAL ERROR	Reinitialize the <b>MosaiQ 125</b>	Closing Magazine door. - Too slow. - Not in one movement.

### 13.2.2 SAMPLE STATION

Error message(s)	Severity	Recovery	Possible cause(s)
Unexpected software error. Application must be closed	FATAL ERROR	Reinitialize the <b>MosaiQ 125</b> & Use a different sample ID	Manual entry of Sample ID. - When a sample ID that has been used before is manually entered again.

#### Mitigation

Search for result ID on the result overview using the filter.



### 13.2.4 MICROARRAY LOADING

Error message(s)	Severity	Recovery	Possible cause(s)
Target position not reached	FATAL ERROR	Reinitialize the <b>MosaiQ 125</b> .	- Mechanism that pushes the microarrays out of the Magazine. - Magazine Red Cap (on top of the microarrays) is stuck and blocks the microarrays.
Surveillance Sensor Inactive Before Start Of Motion	FATAL ERROR	Reinitialize the <b>MosaiQ 125</b> If not able to initialize, move the gripper.	

### 13.2.5 SAMPLE ADDITION

Error message(s)	Severity	Recovery	Possible cause(s)
Processing error	CRITICAL ERROR	- Check the sample and/or Sample diluent bottle is correctly plugged in. - Re-prime Sample Diluent if <b>MosaiQ 125</b> is in idle mode.	Low sample or sample diluent volume (IH/SDS).
		- Power off, restart the system and reinitialize the <b>MosaiQ 125</b> . - Prime sample diluent.	All samples with processing error - might be related to sample diluent. Not enough priming of sample diluent /Air bubbles (IH/SDS).

### 13.2.6 PIPETTOR

Error message(s)	Severity	Recovery	Possible cause(s)
Target position not reached	FATAL ERROR	- Check the tubing / re-adjust it if required (blue coil around the tubing) and reinitialize the <b>MosaiQ 125</b> .	Pipettor tubing getting caught on the rail.

### 13.2.7 REAGENT CARRIAGE

Error message(s)	Severity	Recovery	Possible cause(s)
Data Reduction Error (DRE)	CRITICAL ERROR	- Check detection and enhancement reagents bottles. - Replace the bottles. - Prime the dispenser.	There might be a leakage due to a reagent bottle (DDC) failure.
			Failure on dispensing

### 13.2.8 WASHING MODULES

Error message(s)	Severity	Recovery	Possible cause(s)
Three consecutive aspiration failures	FATAL ERROR	- Check the pump tubing – both aspirate (red tubing) and dispense (clear tubing). - Extra priming.  - Reinitialize the <b>MosaiQ 125</b> .	Pipettor tubing getting caught on the rail.

### 13.2.9 REAGENT DOOR

Error message(s)	Severity	Recovery	Possible cause(s)
Target position not reached	FATAL ERROR	Reinitialize the <b>MosaiQ 125</b> .	The interlock is not detecting that the reagent door is closed.

### 13.2.10 REAGENT DRAWER

Error message(s)	Severity	Recovery	Possible cause(s)
Conductivity out of range	FATAL ERROR	Empty reservoir and prime; always empty the reservoir from the side.	Reagent bottles not pugged in correctly.
		New sensor needed; - Empty reservoir and prime. Always empty the reservoir from the side.	Liquid level sensor broken.
Flooding sensor	FATAL ERROR	Tray to be removed and clean. Dry the sensor thoroughly.	Leakage from the bottle.
Conductivity out of range (Wash buffers)	FATAL ERROR	Tubing to be cleaned or exchange.	Crystallization inside the tubing.
Processing error (Sample Diluents)	CRITICAL ERROR		

### 13.2.11 WATER DRAWER

Error message(s)	Severity	Recovery	Possible cause(s)
Resource limitation	CRITICAL ERROR or FATAL ERROR	Check the connection and check the system liquid tube is not damaged.	10L canister not correctly plugged to intermediate canister.

### 13.3 FREQUENT OPERATIONAL WARNING MESSAGES

During processing, warning messages will display on the screen. Each of these messages requires an action to continue operating the **MosaiQ 125**.

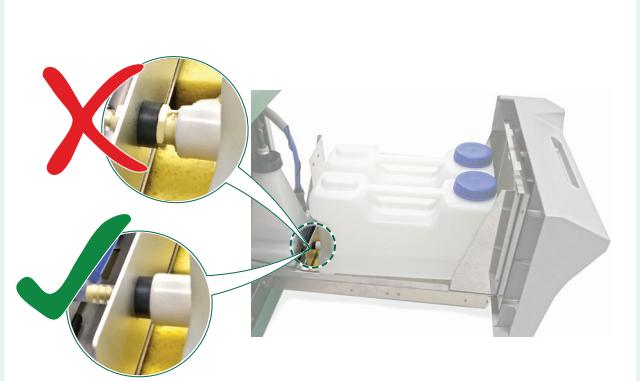
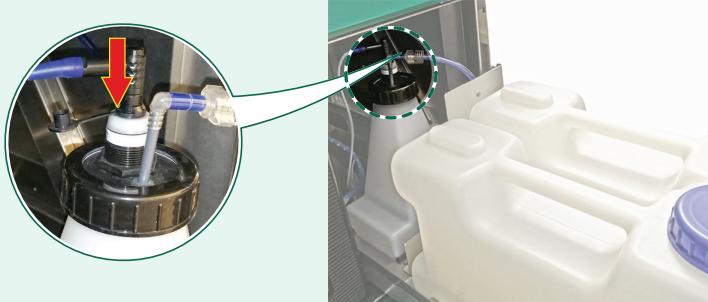
#### 13.3.1 MOSAIQ 125 FAILS TO INITIALIZE

Messages on the screen	Actions
"Please check doors"	<ol style="list-style-type: none"> <li>Check magazine station door and reagent door are closed properly.</li> <li>If error repeats, contact your local technical representative.</li> </ol>
"Please insert solid waste box"	<ol style="list-style-type: none"> <li>Check solid waste box is fully pushed in.</li> <li>If error repeats, contact your local technical representative.</li> </ol>
"Initialization not possible Cancel initialization"	<ol style="list-style-type: none"> <li>Is Status <b>Disconnected</b>?</li> <li>If not, reboot computer workstation.</li> <li>Check <b>MosaiQ 125</b> is on.</li> <li>Blinking blue LED</li> <li>Check if the blue LED is flashing (this can be viewed through the process modules door).</li> <li>Reboot PC.</li> <li>If it still disconnected, shutdown the computer workstation.</li> <li>Turn off <b>MosaiQ 125</b>.</li> <li>Wait 30 secs.</li> <li>Turn on the computer workstation.</li> <li>If error repeats, contact local technical representative.</li> </ol>

#### 13.3.2 UNABLE TO ADD TO PROCESS DUE TO WASTE LEVEL

Messages on the screen	Actions				
"Warning not enough waste resource"	<ol style="list-style-type: none"> <li>Ensure waste canisters are empty.</li> <li>Verify sensor connected properly (as shown).</li> </ol> 				
<table border="1"> <tr> <td><b>Not correct</b></td> <td><b>Correct</b></td> </tr> <tr> <td>The connector is not fully plugged on the canister.</td> <td>The connector is correctly plugged on the cannister</td> </tr> </table>		<b>Not correct</b>	<b>Correct</b>	The connector is not fully plugged on the canister.	The connector is correctly plugged on the cannister
<b>Not correct</b>	<b>Correct</b>				
The connector is not fully plugged on the canister.	The connector is correctly plugged on the cannister				
<ol style="list-style-type: none"> <li>Verify system status shows connected in resources screen.</li> <li>If error repeats, contact your local supplier technical service representative.</li> </ol>					

### 13.3.3 SYSTEM LIQUID LEVEL SHOWN IN RESOURCES DOES NOT APPEAR CORRECT

Messages on the screen	Actions
Wrong system liquid level indication	<p>1. Ensure water canisters are fitted properly (as shown)</p>  <p><b>Not correct</b> The connector is not fully plugged on the canister.</p> <p><b>Correct</b> The connector is correctly plugged on the canister.</p>
	<p>2. Re-seat sensor connector</p>  <p>Correct when the connector is correctly plugged on the canister.</p>
	<p>3. If error repeats, contact your local technical representative.</p>

**INFO**

All error messages and their recommended actions are described in the user software.

## 13.4 MOSAIQ 125 ERROR CODES

If for any reason the **MosaiQ 125** displays an error message with its event ID (digital number) it can be identified in this table.

For all other error codes that are not listed below, please contact the technical support.

The table shows

- The event ID, listed and classified in numerical order
- The short description of the event
- The severity of the event
- The event recovery

EventID	Message	Severity	Event Recovery
032.000.00096	Shaking amplitude out of range.	Critical	If this error happens repeatedly, or for more information, please contact technical support.
209.000.00011	Command terminated abnormally.	Fatal	Subsequent error message to a fatal error message, please verify associated error messages. If the problem reoccurs, please contact technical support.
209.000.00014	Command not allowed in this state. Perhaps another command is in process.	Critical	Subsequent error message to a fatal error message, please verify associated error messages. If the problem reoccurs, please contact technical support.
209.000.00034	Initialization of <b>MosaiQ 125</b> has failed.	Critical	Ensure instructions were followed as specified in the user manual to initialize <b>MosaiQ 125</b> . If the problem reoccurs, please contact technical support.
209.000.00035	<b>MosaiQ 125</b> off-line.	Fatal	The MosaiQ Software does not communicate with <b>MosaiQ 125</b> . Ensure the <b>MosaiQ 125</b> is powered ON.
209.000.00036	<b>MosaiQ 125</b> stopped by command.	Message	<b>MosaiQ 125</b> was stopped by user action. Re-start the <b>MosaiQ 125</b> .
209.000.00054	Please insert solid waste box.	Fatal	Please load the solid waste container now.
209.000.00055	Both liquid waste canisters are removed.	Fatal	Ensure at least one empty Liquid Waste canister is connected and re-initialize <b>MosaiQ 125</b> . At least one Liquid Waste canister must to be connected when <b>MosaiQ 125</b> is processing.

EventID	Message	Severity	Event Recovery
209.000.00080	Internal error memory nearly full. Please collect data with SSW and erase error memory.	Warning	Please contact technical support.
210.000.00162	Overpressure detected found by probe (ADPM)	Critical	If this error happens repeatedly, or for more information, please contact technical support.
210.000.00163	Pressure threshold exceeded by probe (ADPM)	Critical	If this error happens repeatedly, or for more information, please contact technical support.
210.000.00164	Insufficient volume detected by probe (OLV)	Critical	<b>MosaiQ 125</b> did not detect liquid in the tube, please verify there is sufficient volume and no bubbles in the tube. If the problem reoccurs, please contact technical support.
210.000.00165	Not enough liquid found by probe (LLD)	Critical	<b>MosaiQ 125</b> did not detect liquid in the tube, please verify there is sufficient volume and no bubbles in the tube. If the problem reoccurs, please contact technical support.
210.000.00166	No liquid found by probe (LLD)	Critical	<b>MosaiQ 125</b> did not detect liquid in the tube, please verify there is sufficient volume and no bubbles in the tube. If the problem reoccurs, please contact technical support.
210.000.00167	Clot detected by probe (ADPM)	Critical	<b>MosaiQ 125</b> could not aspirate sample. Please verify there is no clot in the sample and reload. If the problem reoccurs, please contact technical support.
213.000.00066	Backup solid waste is full. <b>MosaiQ 125</b> halted.	Fatal	Please load an empty solid waste container now.
213.000.00067	Solid waste Container is full. <b>MosaiQ 125</b> halted.	Fatal	Please empty the solid waste now.
213.000.00069	Solid waste intermediate container is nearly full.	Warning	Please load an empty solid waste container now.
213.000.00070	Solid Waste Intermediate Container is full. <b>MosaiQ 125</b> will stop soon.	Critical	Please load an empty solid waste container now.
213.000.00071	Solid waste container is nearly full.	Warning	Please load an empty solid waste container now.

## TROUBLESHOOTING AND ERROR OVERVIEW / MOSAIQ 125 ERROR CODES

EventID	Message	Severity	Event Recovery
213.000.00072	Solid waste container is full. <b>MosaiQ 125</b> will stop soon.	Critical	Please load an empty solid waste container now.
213.000.00078	Both bottles of WB1 or WB2 are either empty or no bottles are plugged in.	Fatal	Ensure <b>MosaiQ Wash Buffer 1</b> and <b>MosaiQ Wash Buffer 2</b> are correctly loaded and have sufficient volume. Re-initialize the MosaiQ 125.
213.000.00079	Both bottles of LISS or PBS are either empty or no bottles are plugged in.	Fatal	Ensure <b>MosaiQ Sample Diluent 1</b> and <b>MosaiQ Sample Diluent 2</b> are correctly loaded and have sufficient volume. Re-initialize the <b>MosaiQ 125</b> .
213.000.00083	Reagent bottles are empty or insufficient reagent bottles are plugged in.	Fatal	Ensure all required MosaiQ reagent bottles are correctly loaded and have sufficient volume. Re-initialize the <b>MosaiQ 125</b> .
213.000.00084	Wash buffer conductivity out of range while processing.	Fatal	Please contact technical support.
225.000.00051	Liquid waste is full. <b>MosaiQ 125</b> will halt soon.	Critical	Please reload an emptied waste canister at the inactive Liquid Waste slot now.
225.000.00052	Liquid waste is too full. <b>MosaiQ 125</b> has been halted.	Fatal	Please reload an emptied waste canister at the inactive liquid waste slot now.
226.000.00032	Initialization Timeout	Fatal	Please restart system.
256.000.00006	Unexpected software error. Application must be closed.	Fatal	Please contact technical support
256.000.00010	A timeout has been reached while waiting for a response from the <b>MosaiQ 125</b> .	Fatal	Shut down MosaiQ Software and <b>MosaiQ 125</b> . Re-start the <b>MosaiQ 125</b> .
256.000.00015	System restart required to apply configuration changes correctly.	Warning	Finish system configuration and then restart the system immediately.
257.000.00000	General database error.	Fatal	Please contact technical support
257.000.00001	Failed to connect to the database.	Fatal	Please contact technical support
257.000.00002	Microsoft SQL Server is not ready to accept new client connections.	Fatal	Please contact technical support

EventID	Message	Severity	Event Recovery
257.000.00003	No database available or connection not possible.	Fatal	Please contact technical support
257.000.00004	The current database is not compatible to the application database.	Fatal	Please contact technical support
257.000.00005	Invalid SQL Server configuration. FileStream feature is not available.	Fatal	Please contact technical support
258.000.00001	Sample rack type '{0}' loaded on lane {1} is not supported.	Warning	Use a supported rack type or contact technical support
258.000.00002	Invalid QC product loaded on lane {0} position {1}. Loaded item is ignored.	Warning	Load only valid QC products on a QC rack.
258.000.00003	Duplicate QC product loaded on lane {0} position {1}. Loaded item is ignored.	Warning	Please double check the barcodes.
258.000.00004	The QC product loaded on lane {0} position {1} expires soon.	Warning	Please replace the QC sample.
258.000.00005	The QC product loaded on lane {0} position {1} has expired.	Warning	Please replace the QC sample.
258.000.00006	Duplicate Sample ID '{0}' rejected on lane {1} position {2}. Sample already loaded on lane {3} position {4}.	Warning	Please remove sample tube and check sample identification.
258.000.00007	No or invalid Sample ID on lane {0} position {1}.	Warning	Please remove sample tube and check sample identification.
258.000.00008	Rack loaded in wrong lane {0}.	Warning	Please remove rack and re-load on lane indicated for loading.
258.000.00010	Rack '{1}' removed from lane {0} has {2} sample(s) with pending test orders.	Warning	Please re-load rack to process pending test orders.
258.000.00011	Locked rack '{1}' removed from lane {0}.	Critical	Please review corresponding canceled results.

## TROUBLESHOOTING AND ERROR OVERVIEW / MOSAIQ 125 ERROR CODES

EventID	Message	Severity	Event Recovery
258.000.00013	Error loading rack on lane {0}.	Critical	Please re-load rack. If the problem reoccurs, please contact technical support.
258.005.00001	{0} magazine in slot {1} expires soon.	Warning	Please replace the magazine.
258.005.00002	{0} magazine in slot {1} has expired.	Warning	Please replace the magazine.
258.006.00001	{0} in slot {1} expires soon.	Warning	Please replace the reagent bottle.
258.006.00002	{0} in slot {1} has expired.	Warning	Please replace the reagent bottle.
258.006.00003	{0} in slot {1} is in use and must not be removed.	Fatal	Please reload the reagent bottle and re-initialize the <b>MosaiQ 125</b> .
258.006.00004	Wash buffer {0} conductivity out of range. Contact service technician.	Warning	Please contact technical support
258.006.00005	Dispense problem for bottle in slot {0} detected.	Warning	Please replace the reagent bottle when unlocked. If the problem reoccurs, please contact technical support.
258.007.00001	{0} in slot {1} expires soon.	Warning	Please replace the reagent bottle.
258.007.00002	{0} in slot {1} has expired.	Warning	Please replace the reagent bottle.
259.000.00006	A job was not found in the database.	Fatal	Please contact technical support
259.000.00010	Job canceled.	Critical	Please review corresponding canceled results.
259.000.00012	System stopped and job canceled.	Critical	Please contact technical support
260.000.00000	Coordinate file could not be loaded.	Fatal	Please contact technical support
260.000.00001	A general <b>MosaiQ 125</b> control error has been discovered.	Fatal	Please contact technical support
260.000.00004	<b>MosaiQ 125</b> halted!	Fatal	Initialize the <b>MosaiQ 125</b> .
263.000.00001	The liquid waste level is running high.	Warning	Please reload an emptied waste canister at the inactive liquid waste slot soon.
263.000.00002	The liquid waste is full.	Critical	Please reload an emptied waste canister at the inactive liquid waste slot now.
263.000.00003	The system liquid canister is running low.	Warning	Please replenish the system liquid canisters soon.

EventID	Message	Severity	Event Recovery
263.000.00004	The system liquid canister is empty.	Critical	Please replenish the system liquid canisters now.
263.000.00005	The solid waste level is running high.	Warning	Please empty the solid waste soon.
263.000.00006	The solid waste is full.	Critical	Please empty the solid waste now.
266.000.00003	Unknown fatal error: {0}	Fatal	Please contact technical support
271.000.00001	No response to query for work-order for SID {0} within {1} seconds.	Message	Verify that <b>MosaiQ 125</b> is connected to LIS and a test order is assigned to the sample. If the problem reoccurs, please contact technical support.
271.000.00004	Error while transmitting data to LIS.	Warning	Verify that <b>MosaiQ 125</b> is connected to LIS. If the problem reoccurs, please contact technical support.
271.000.00008	MosaiQ LIS module could not be started.	Warning	Verify that <b>MosaiQ 125</b> is connected to LIS. Re-start <b>MosaiQ 125</b> . If the problem reoccurs, please contact technical support.
271.000.00009	MosaiQ LIS module could not be stopped.	Warning	Please contact technical support
271.000.00010	MosaiQ LIS module received an invalid message (unsupported message type or structure error).	Warning	Please contact technical support
271.000.00011	MosaiQ LIS module received an order message for a not supported assay.	Warning	Ensure test order sent to MosaiQ is a supported assay. If the problem reoccurs, please contact technical support
271.000.00012	MosaiQ LIS module received an order message with an invalid sample id.	Warning	Ensure sample id used is correct. If the problem reoccurs, please contact technical support
274.000.00020	Maintenance task '{0}' failed.	Critical	Ensure instructions were followed as specified in the user manual. If the problem reoccurs, please contact technical support.
279.000.00018	Login failed, wrong user credentials entered.	Warning	Ensure correct user name and password were entered. If the problem reoccurs, contact the laboratory administrator or technical support.
279.000.00019	Login failed user account {0} has been disabled.	Warning	Please contact laboratory administrator or technical support.

## TROUBLESHOOTING AND ERROR OVERVIEW / MOSAIQ 125 ERROR CODES

EventID	Message	Severity	Event Recovery
279.000.00020	Login failed user {0} has no roles.	Warning	Please contact laboratory administrator or technical support.
279.000.00021	Login failed, user {0} has no rights to break the lock.	Warning	Please contact laboratory administrator or technical support.

# 14. CYBERSECURITY

<b>14.1 DEFINITION</b>	<b>156</b>	<b>14.9 RECOMMENDATION</b>	<b>158</b>
<b>14.2 USER TRAINING AND EDUCATION</b>	<b>156</b>	<b>14.10 IDENTIFICATION OF POSSIBLE INSTALLATION / CONNECTION SCENARIOS</b>	<b>159</b>
<b>14.3 IDENTIFICATION OF THREATS AND HAZARDS</b>	<b>156</b>	14.10.1 SCENARIO 1 – STAND ALONE OR DIRECT CONNECTION OF THE MOSAIQ TO A LIS VIA RS232	159
<b>14.4 PASSWORD</b>	<b>157</b>	14.10.2 SCENARIO 2 - CONNECTION OF THE MOSAIQ TO A LOCAL NETWORK – LIS ON NETWORK OR DIRECTLY CONNECTED	160
<b>14.5 EXTERNAL MEDIA AND DEVICES</b>	<b>157</b>		
<b>14.7 INCIDENT RESPONSE</b>	<b>157</b>		
<b>14.8 DEFINITION</b>	<b>158</b>		

## 14.1 DEFINITION

Cybersecurity is variously defined but can be thought of as the protection of information systems, computers and other hardware, and the software and data that runs on these devices.

Most cyber risk issues will fall into one of these categories, which are made for better understanding of why a particular technical control or process has been implemented.

**Confidentiality** prevents sensitive data from being seen or accessed by the wrong people while ensuring that those that have legitimate need to access the data can do so.

**Integrity** means ensuring that data remains accurate and consistent for its life cycle.

**Availability** refers to the importance of keeping computer systems available and accessible when required by the activity.

## 14.2 USER TRAINING AND EDUCATION

The users are responsible for information security.

The risks can be limited by regularly educating **MosaiQ 125** users on cybersecurity best practices.

- Make cybersecurity training and awareness mandatory for all personnel.
- **Ensure that all personnel understand their roles and responsibilities with regard to cybersecurity.**
- Users must not install unauthorized applications.
- Users must not use any unauthorized media or device.
- Strictly follow the security recommendations.

### NOTICE

This policy applies to all employees, contractors, and anyone who has permanent or temporary access to this systems and hardware.

## 14.3 IDENTIFICATION OF THREATS AND HAZARDS

This section identifies the different threats and hazards that impact the cybersecurity.

Type of threat Source	Description
ADVERSE	<p>Individuals, groups, organizations or states that seek to exploit the organization's dependence on cyber resources.</p> <ul style="list-style-type: none"> <li>• Infection: A malware (virus, worm, etc.) is introduced in the system causing unexpected behavior ranging from benign to critical.</li> <li>• Corruption: Executable files, Data files or Database files are modified in such a way that they cannot be used normally and create an unexpected behavior, an error or a software crash. This includes access rights, read only mode, name change, extension change, etc.</li> </ul>
ACCIDENTAL	<p>Erroneous actions taken by individuals in the course of executing their everyday responsibilities.</p> <ul style="list-style-type: none"> <li>• Deletion: The file is deleted or moved to another location.</li> <li>• Data manipulation: Data inside a file are changed or deleted in such a way that the file will be used normally causing the system to use wrong data.</li> <li>• Copy: Critical files are copied. Can be analytical data files or system data files.</li> </ul>
STRUCTURAL	<ul style="list-style-type: none"> <li>• Failure: equipment, environmental controls, or software due to aging, resource depletion, or other circumstances which exceed expected operating parameters.</li> <li>• OS Updates: Uncontrolled OS updates can cause operation of the system in a non-validated configuration.</li> </ul>
ENVIRONMENT	<p>Natural disasters and failures of critical infrastructures on which the organization depends, but which are outside of the control of the organization.</p> <ul style="list-style-type: none"> <li>• Natural or man-made disaster</li> <li>• Unusual Natural Event (e.g. sunspots)</li> <li>• Infrastructure Failure/power outage</li> </ul>

## 14.4 PASSWORD

- Only allow legitimate and trained employees to access to the **MosaiQ 125** system with a password.
- Implement an account management process.
- Limit the number of privileged accounts to those who have a legitimate activity requirement.
- Establish a process for revoking system access by disabling accounts immediately upon termination of an employee or contractor. Disabling instead of deleting accounts allows preservation of audit trails should an investigation be necessary.
- Require that all employee accounts have strong passwords, which contain letters, numbers, and special characters. Ensure that they are changed every 90 days, and that the previous 15 passwords are not allowed to be used as a new password.

**NOTICE**

The **MosaiQ 125** automatically disconnects the user after a predetermined (user setting) period of inactivity.

## 14.5 EXTERNAL MEDIA AND DEVICES

Laboratory users must not connect any device (e.g. USB stick) to the MosaiQ computer as there is a risk of malware infection.

**WARNING**

Never use the **MosaiQ 125** and connections for a purpose other than the intended purpose of Quotient.

The use of the system for other purposes can make the system vulnerable to software viruses.

- The utilization of the USB port is strictly reserved to the Quotient Suisse SA authorized service personnel only.

**INFO**

Users cannot access to any data of the **MosaiQ 125** computer using the USB port.

## 14.7 INCIDENT RESPONSE

When a cybersecurity incident occurs, it is time to take action and mitigate – as quickly as possible – any threat to the confidentiality, integrity, and availability of an organization's information assets.

Cyber incident management helps mitigate the risks associated with internal and external threats, as well as helping an organization maintain regulatory compliance where required. An organization must be prepared to handle incidents that may originate from a variety of sources. Sources for cybersecurity incidents include:

Insiders who act with malicious intent, trusted insiders whose acts cause damage by mistake, and attacks from cyber criminals.

The following are some of the objectives of cybersecurity incident management:

- Prevent cybersecurity incidents before they occur.
- Minimize the impact of cybersecurity incidents to the confidentiality, availability, or integrity.
- Mitigate threats and vulnerabilities as cybersecurity incidents are occurring.
- Improve cybersecurity incident coordination and management.

## 14.8 DEFINITION

The definitions below are based on the International Standard for Information Security Incident Management.

### **Cybersecurity Event**

An identified occurrence of a system, service, or network state, indicating a possible breach of information security, failure of controls, or a previously unknown situation that may be security relevant.

### **Cybersecurity Incident**

A single or a series of unwanted or unexpected information security events that have a significant probability of compromising business operations and threatening information security.

### **Cybersecurity Incident Management**

The processes for detecting, reporting, assessing, responding to, dealing with, and learning from cybersecurity incidents.

### **Incident Response**

The actions taken to protect and restore the normal operational conditions of an information system and the information stored in it when a cybersecurity incident occurs.

### **Incident Response Team**

A team of appropriately skilled and trusted members of the organization that handles incidents during their lifecycle.

## 14.9 RECOMMENDATION

Once a cyber incident has been detected, immediately contact your legal counsel and Quotient Suisse SA for guidance on initiating these ten steps:

- Record the date and time when the breach was discovered.
- Alert and activate everyone on the response team to begin executing the preparedness plan.
- Secure the premises around the area where the data breach occurred to help preserve evidence.
- Stop additional data loss. Take affected computer systems off-line.
- Document everything known about the breach.
- Interview those involved in discovering the breach and anyone else who may know about it.
- Review protocols regarding disseminating information about the breach for everyone involved in this early stage.
- Assess priorities and risks based on what you know about the breach.
- Inform the proper authorities, including your regulator.
- Notify law enforcement, if needed, to begin an in-depth investigation.

## 14.10 IDENTIFICATION OF POSSIBLE INSTALLATION / CONNECTION SCENARIOS

This section describes the different possible environments of the **MosaiQ 125**, how it is connected to the outside and the various paths that could be taken by data in the system.

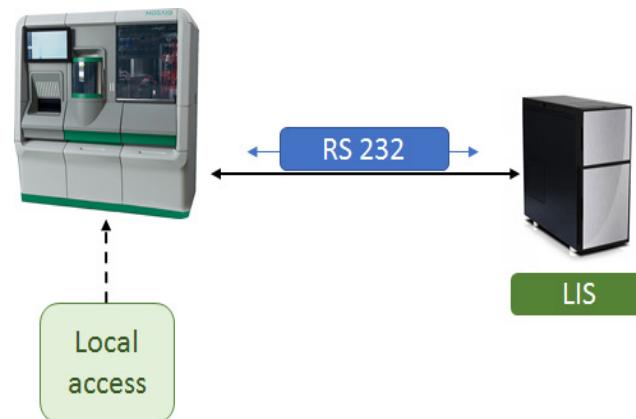
#	Type	Interface	Description
1	Local	GUI	Touch screen
2	Local	USB port	USB stick, external drive, printer MosaiQ Software Update, MosaiQ data update (Assay, Configuration)
3	Local	Barcode scanner	Sample / QC barcodes
4	Remote	LIS via RS232	Direct LIS connection via serial point to point
5	Remote	LIS via TCP/IP	LIS connection using the laboratory network
6	Wireless	RFID	Product RFID tags
7	Protocols	TCP/IP	LIS

**NOTICE**

For more information about LIS connection, please contact your local technical representative.

### 14.10.1 SCENARIO 1 – STAND ALONE OR DIRECT CONNECTION OF THE MOSAIQ TO A LIS VIA RS232

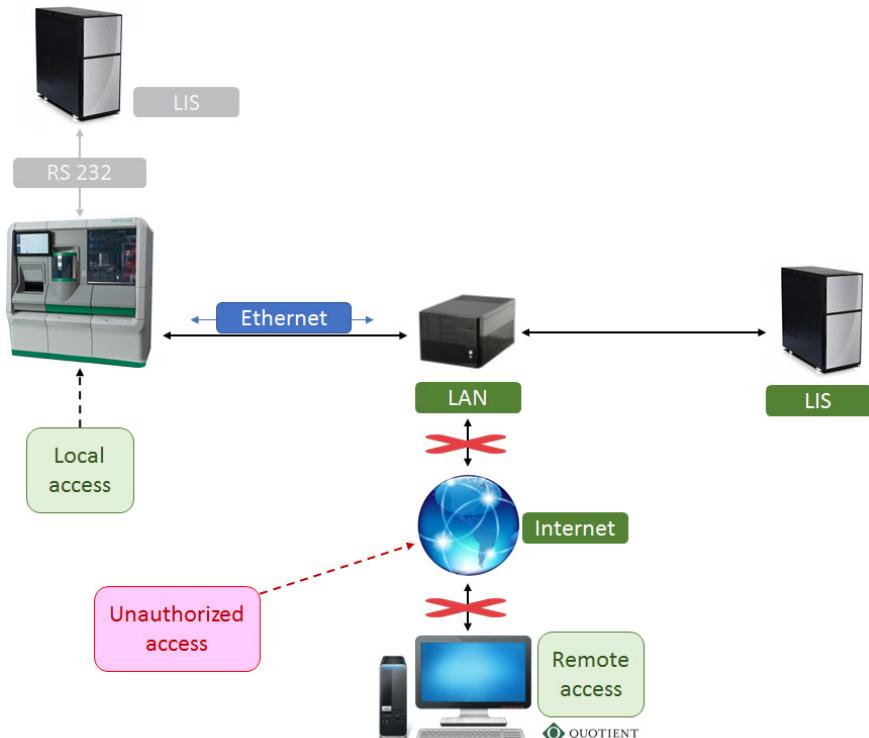
A stand-alone **MosaiQ 125** or the connection of the MosaiQ to a LIS using a RS232 serial link limits the vulnerabilities to those that are related to a direct local access to the **MosaiQ 125**.



(MosaiQ 125 stand-alone connection)

### 14.10.2 SCENARIO 2 - CONNECTION OF THE MOSAIQ TO A LOCAL NETWORK – LIS ON NETWORK OR DIRECTLY CONNECTED

The connection of the MosaiQ to a LIS through the Laboratory local area network can potentially create vulnerabilities related to local access to the **MosaiQ 125**. The vulnerabilities that are related to a direct physical access to the **MosaiQ 125** must be considered.



(MosaiQ 125 network connection)

# 15. INSTALLATION AND REMOVAL OF THE MOSAIQ 125

## 15.1 MOSAIQ 125 INSTALLATION

### ⚠ CAUTION

- The installation of the **MosaiQ 125** and its connection to external devices (e.g. printer) must be executed by Quotient Suisse SA authorized service personnel only.
- Improper installation can cause damage or malfunctions.

After the installation is completed, the user receives the qualification documentation (IQ, OQ) attesting the installation of the **MosaiQ 125** has been performed properly.

### INFO

Installation Qualification (IQ) verifies that the **MosaiQ 125** has been installed and configured according to the manufacturer's specifications or installation checklist.

Operational qualification (OQ) is performed after meeting each protocol of IQ. OQ's purpose is to determine that the **MosaiQ 125** performance is consistent with the user requirement specification within the manufacturer specified operating ranges. In action, this means identifying and inspecting equipment features that can impact final product quality.

Please note, the enclosed Microsoft software license terms for the Microsoft Windows embedded operating system.

### INFO

Microsoft software license terms EULA (End-User License Agreement). The EULA specifies in detail the rights and restrictions which apply to the use of the software.

## 15.2 REMOVAL OF THE MOSAIQ 125

### ⚠ CAUTION

- Removal must be executed by Quotient Suisse SA authorized service personnel only.
- Improper removal can cause damage or malfunctions.
- After a displacement (within the laboratory) of the **MosaiQ 125**, a re-installation is required. If omitted, this can cause damage or irregular pipetting performance of the **MosaiQ 125**.

## 16. WARRANTY

For further information about the warranty, refer to the sales contract.

Read the type label on the back side of the **MosaiQ 125** to determine its serial number.



(type label localization)

## 17. CONTACT QUOTIENT

To contact Quotient, please write to:

### **GREAT BRITAIN**

QUOTIENT  
5 James Hamilton Way  
Milton bridge  
Penicuik  
EH26 0BF  
Tel: + 44 0131 658 5700

### **UNITED STATES OF AMERICA**

QUOTIENT  
301 South State Street  
Suite S-204  
Newtown  
Pennsylvania  
18940 USA  
Tel: + 00 1 215 4978820

### **SWITZERLAND**

QUOTIENT SUISSE SA  
Business Park Terre Bonne  
Route de Crassier 13  
1262 Eysins, Switzerland  
Tel: + 41 22 716 98 00

For customer service information please refer to :

<https://quotientbd.com/login>

# 18. TECHNICAL DATA

<b>18.1 POWER REQUIREMENTS</b>	<b>165</b>	<b>18.9 MOSAIQ 125 MEMORY</b>	<b>167</b>
<b>18.2 LASER OF THE BARCODE SCANNER</b>	<b>165</b>	<b>18.10 RFID TAG AND READER SPECIFICATIONS</b>	<b>168</b>
<b>18.3 COMPUTER WORKSTATION AND CONNECTIONS</b>	<b>165</b>	18.10.1 RFID TAG SPECIFICATIONS	168
<b>18.4 INSTALLATION DIMENSIONS AND WEIGHT</b>	<b>166</b>	18.10.2 RFID READER SPECIFICATIONS	168
<b>18.5 SPACE REQUIREMENT</b>	<b>166</b>	<b>18.11 OUTPUT</b>	<b>168</b>
<b>18.6 ENVIRONMENTAL CONDITIONS</b>	<b>167</b>		
<b>18.7 NOISE</b>	<b>167</b>		
<b>18.8 PACKAGING</b>	<b>167</b>		

This section provides all technical specifications for the **MosaiQ 125**.

**INFO****Specifications**

Values are achieved under optimal conditions and can vary depending on environmental conditions, **MosaiQ 125** status and processing conditions. Specifications are subject to change without notice.

## 18.1 POWER REQUIREMENTS

This section provides the power requirements to operate the **MosaiQ 125** safely and effectively.

<b>Voltage</b>	100 V - 240 V
<b>Frequency</b>	50 - 60 Hz
<b>Input current</b>	6 - 2.5 A
<b>Power consumption</b>	Mean 400 W (600 W max.)
<b>Fuses</b>	Primary T6.3 AH/250 VAC

## 18.2 LASER OF THE BARCODE SCANNER

This section provides technical specifications for the laser barcode scanner.

<b>Class</b>	Class 2 laser product
<b>Maximal output radiation</b>	1.3 mW
<b>Maximal pulse duration</b>	110 µs
<b>Wavelength</b>	650 nm

## 18.3 COMPUTER WORKSTATION AND CONNECTIONS

This section provides the technical specifications for the computer and the associated connections.

<b>Processor</b>	Intel Core i7
<b>Memory (RAM)</b>	16 GB DDR4
<b>Hard disk</b>	1 TB
<b>Ports</b>	1 LAN port USB 3.0 ports USB 2.0 ports 1 Display-Port
<b>Monitor/Graphic card</b>	Resolution: 1920 x 1080 pixels 17.3 inch, touch screen
<b>Operating system</b>	Microsoft® Windows®10 (US English)

## 18.4 INSTALLATION DIMENSIONS AND WEIGHT

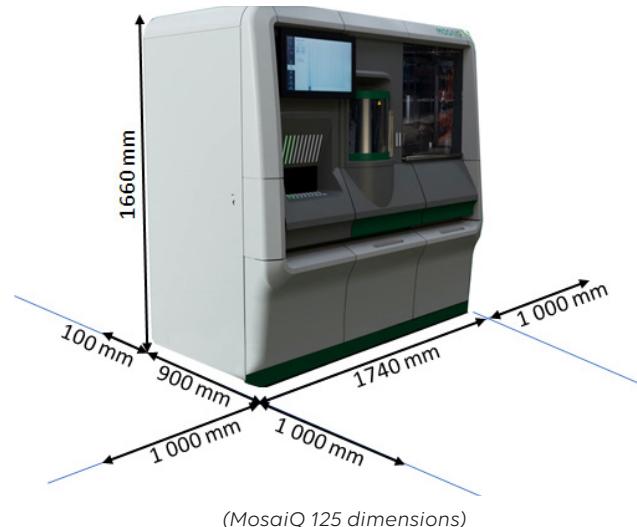
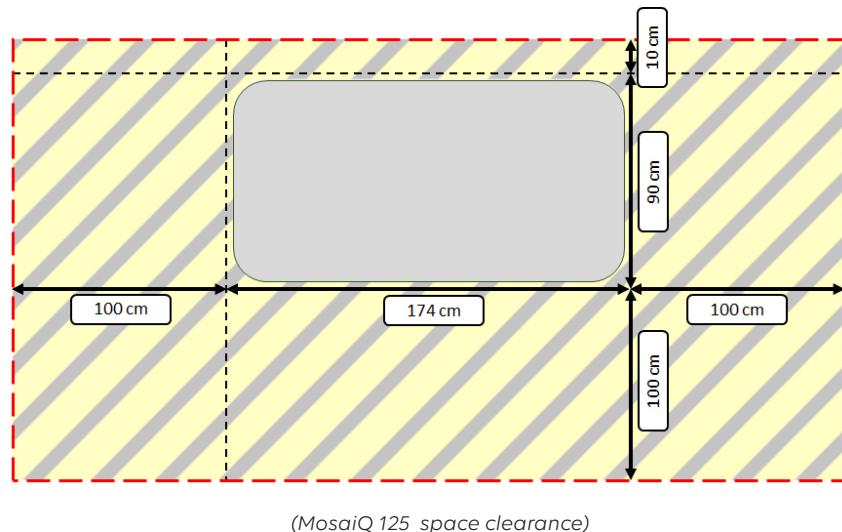
This section provides the technical specifications for the dimensions and weight of the **MosaiQ 125**. Please read this information carefully before installing the **MosaiQ 125**.

<b>Width:</b>	Closed: 174 cm (68.51 in) Opened (only for servicing): 354 cm (139.38 in)
<b>Depth:</b>	Closed: 90 cm (35.44 in) Opened: 165 cm (64.97 in)
<b>Height:</b>	166 cm (65.36 in)
<b>Weight</b>	285 kg (628.3 lb)

## 18.5 SPACE REQUIREMENT

To guarantee a safe use please follow this space clearance around of the **MosaiQ 125**.

<b>Width:</b>	374 cm (147,25 in)
<b>Depth:</b>	200 cm (78,74 in)



## 18.6 ENVIRONMENTAL CONDITIONS

The following table shows the range of environmental conditions required to operate the system safely.

<b>Environmental Conditions</b>	The system is made for Indoor use only.
<b>Temperature</b>	Operating: 16°C to 32°C (60.8°F to 89.6°F) Storage: 5°C to 40°C (41°F to 104°F) Transport: -10°C to 55°C (14°F to 131°F)
<b>Humidity</b>	Operating: 15% - 80% non-condensing Storage: 10% - 85% non-condensing Transport: 10% - 90% non-condensing
<b>Pollution Degree</b>	2
<b>Installation Class</b>	2
<b>Limit Class</b>	Class A (For industrial use. Domestic use restricted)
<b>Sunlight</b>	No direct sunlight May mislead optical sensors and affect performance
<b>Altitude</b>	Up to 2000 m (6562 ft) above mean sea level
<b>Dust</b>	No excessive dust

## 18.7 NOISE

This section provides information about noise generated by the **MosaiQ 125**.

- 47 dBA is the maximum noise level measured at 1 m (39.4 in) around the device
- 59 dBA is the maximum noise level in the user's working area at 25 cm (9.8 in) from the device.

## 18.8 PACKAGING

This section provides information about how the **MosaiQ 125** is packaged as well as the dimensions and weight of each crate.

- Number of crates: 2

### Crate 1

<b>Contents</b>	<b>MosaiQ 125</b>
<b>Dimensions (WxDxH)</b>	180 cm x 105 cm x 200 cm (70.87 in x 41.34 in x 78.75 in)
<b>Weight</b>	500 kg (1102.4 lb)

### Crate 2:

<b>Contents</b>	Covers
<b>Dimensions (WxDxH)</b>	180 cm x 80 cm x 120 cm (70.87 in x 31.5 in x 47.25 in)
<b>Weight</b>	200 kg (441 lb)

## 18.9 MOSAIQ 125 MEMORY

This section provides information about the memory capacity of the **MosaiQ 125**. Memory enables the **MosaiQ 125** to store 30 000 test results information.

## 18.10 RFID TAG AND READER SPECIFICATIONS

The MosaiQ magazines and the MosaiQ system reagents have RFID tags that are embedded in the label for traceability, on board management. Radio Frequency Identification (RFID) system refers to a wireless system comprised of two components: tags and readers.

The RFID reader is a device that has one or more antennas that emit radio waves and receive signals back from the RFID tag. RFID readers located in different locations in the **MosaiQ 125** are used to read and write on the RFID tags.

### 18.10.1 RFID TAG SPECIFICATIONS

#### **MosaiQ system reagent bottles:**

- RFID-Chip
- Protocol: ISO/IEC 15693, ISO/IEC 18000-3 mode 1
- Type: NXPICODE SLI-X
- RFID system frequency: 13,56 MHz
- Memory: 1024 bits in total with 896 bits user configurable memory; user memory is structured in 28 blocks of 4 Bytes each
- Write cycles: min. 100.000 per lifetime
- Data retention: 50 years

#### **MosaiQ magazines:**

- RFID-Chip
- Protocol: ISO/IEC 15693, ISO/IEC 18000-3 mode 1
- Type: Infineon MyD SRF55V10P
- RFID system frequency: 13,56 MHz
- Memory: 1280 Bytes in total with 1024 Bytes user configurable memory
- Write cycles: min. 100.000 per lifetime
- Data retention: 10 years

### 18.10.2 RFID READER SPECIFICATIONS

- Operating frequency: 13.56 Mhz
- Number of channels: 1
- Product Class: Class 1 (inductive loop coil transmitter)
- Antenna: PCB, integral or external, not changeable
- Power supply: DC 24V

The maximum radio-frequency power transmitted in the frequency band(s) of CLRC663 with larger antenna used at Consumable CU board and Buffer sensor board: ~ 1,74 dB $\mu$ A/m  
The maximum radio-frequency power transmitted in the frequency band(s) of CLRC663 with tiny antenna used at DDCA: ~ -23, 42 dB $\mu$ A/m.

## 18.11 OUTPUT

Output Specification	Quantity
<b>Throughput</b>	Up to 125 microarrays per hour
<b>Time first result for SDS assay</b>	34 minutes

# 19. INDEX

## A

Administrative functions: [p.51](#)  
Advanced functions: [p.117](#)  
Appendix: [p.171](#)  
Audible warning signal: [p.52](#)

## B

Barcode error: [p.92, p.98](#)  
Barcode: [p.98, p.99, p.100](#)  
Barcode scanner: [p.36, p.141, p.165](#)  
Basic functions: [p.50](#)

## C

Camera: [p.15, p.44](#)  
Cleaning: [p.128, p.129](#)  
Cleaning solutions: [p.131](#)  
Computer and connections: [p.165](#)

## D

Decontamination: [p.25, p.129, p.130](#)  
Disposal: [p.25, p.129](#)

## E

Empty liquid waste canisters: [p.79](#)  
Empty solid waste container: [p.77](#)  
Environmental conditions: [p.169](#)  
Error codes: [p.145](#)

## F

Fill water: [p.81](#)

## G

General information: [p.5](#)  
General safety: [p.22](#)

## I

Incubator module: [p.43](#)  
Installation dimensions: [p.167](#)  
Intended use: [p.12](#)

## L

Label (sample rack): [p.20](#)  
Label (safety): [p.26](#)  
Laser: [p.149](#)  
LED status (waste drawer): [p.37](#)  
LED status (DC bottles): [p.40](#)  
LED status (DDC bottles): [p.42](#)  
Light status (sample station): [p.36](#)  
Load magazines: [p.67](#)  
Load reagents: [p.71, p.76](#)  
Load samples: [p.85](#)  
Lock screen: [p.53](#)

## M

Maintenance: [p.127](#)  
Maintenance (Daily): [p.132](#)  
Maintenance (weekly): [p.135](#)  
Material provided: [p.46](#)  
Messages (troubleshooting): [p.145](#)  
Metric system: [p.11](#)  
Microarray: [p.13, p.18](#)  
**MosaiQ 125** description: [p.29](#)

## N

Noise: [p.167](#)  
Notes: [p.9](#)  
Notifications: [p.51](#)

## O

Overview (processing sequence): [p.57](#)  
Overview (resources): [p.60](#)  
Overview (testing sample): [p.86](#)  
Electrical safety: [p.24](#)

## P

Packaging: [p.167](#)  
Pipettor: [p.45, p.139](#)  
Power requirements: [p.164](#)  
Power Switch: [p.33](#)  
Principles (quality controls): [p.111](#)  
Process modules: [p.41](#)

## Q

Qualification for operator: [p.17](#)  
Quality control: [p.20, p.110](#)

## R

Radio interference: [p.28](#)  
Removal of magazines: [p.66](#)  
Removal of DDC bottles: [p.69](#)  
Removal of DC bottles: [p.74](#)  
Removal of liquid waste: [p.79](#)  
Removal of solid waste: [p.77](#)  
Removal of water canister: [p.84](#)  
Removal of the **MosaiQ 125**: [p.161](#)

Resources: [p.60](#)

Resulting Principles: [p.15](#)  
Results (SDS): [p.101](#)  
Results reviewing: [p.108](#)

## S

Safety instructions: [p.22](#)  
Sample ID: [p.90](#)  
Sample ID missing: [p.92](#)  
Sample loading: [p.85](#)  
Shutdown: [p.115](#)  
Special types: [p.6](#)  
Sample preparation: [p.20, p.90](#)  
Symbols: [p.9](#)  
Symbols (rack status): [p.93, p.94](#)

## T

Technical data: [p.165](#)  
Terminology: [p.7](#)  
Test assignment (Automatic): [p.95](#)  
Test assignment (Manual): [p.95](#)  
Touch screen: [p.34](#)  
Typographical conventions: [p.6](#)

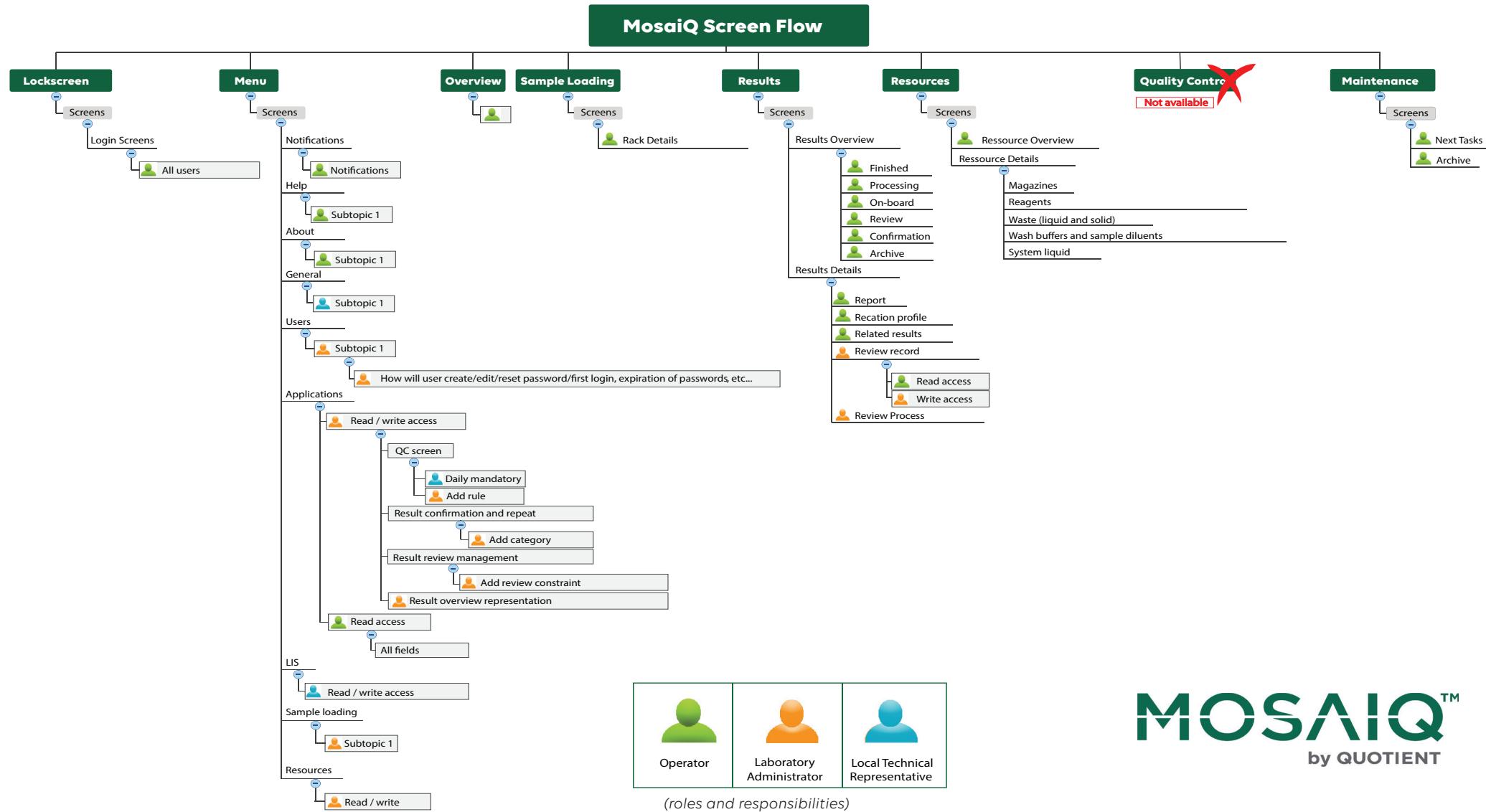
## U

Use of the **MosaiQ 125**: [p.54](#)  
User administration: [p.117](#)

## W

Warning symbols: [p.9](#)  
Weight: [p.166](#)

# 20. APPENDIX



**MOSAIQ™**  
by QUOTIENT



# MOSAIQ™

by QUOTIENT



**QUOTIENT SUISSE SA**

Business Park Terre Bonne, Route de Crassier 13, CH-1262 Eysins - Switzerland  
Tel: + 41 22 716 98 00



**QUOTIENT**

This manual is the property of Quotient Suisse SA. It may not be reproduced or transmitted in any way without prior written approval from Quotient Suisse SA.