

## AggreGuide A-100 Liquid Quality Control (LQC) Kit



The AggreGuide A-100 Liquid Quality Control (LQC) Kit is used without blood, and permits the User to verify correct operation of the AggreGuide A-100 AA Assay and ADP Assay cartridges in the AggreGuide A-100 Instrument as part of a laboratory quality control program. The LQC Kit contains both negative control and positive control liquid samples. When pipetted into Assay cartridges the negative control shows signal that is representative of aggregation of platelets, indicative of the absence of platelet dysfunction due to anti-platelet medications. The positive control shows signal representative of the absence of platelet aggregates, indicative of the presence of platelet dysfunction due to anti-platelet medications.

### Contents of the LQC Kit:

- |  |   |
|--|---|
| 1 Vial of Positive Control liquid suspension (1mL) | 10 Special pipette tips                       |
| 1 Vial of Negative Control liquid suspension (1mL) | Package Insert and Certificate of Conformance |

### Items Required but not Provided:

- Pipettor 20 – 200  $\mu$ L, set to 200  $\mu$ L
- AggreGuide A-100 Instrument
- AggreGuide A-100 ADP Assay cartridge, and/or AA Assay cartridge

### Storage and Handling of the LQC Kit:

Do not allow the LQC Kit liquid materials to freeze; keep the Kit within a temperature range of +15 to +25 °C. The expiration date for the LQC is printed on the vials containing the liquid control sample suspensions. Do not use any material that is past its expiration date.

Once a vial is opened, samples must be drawn and used within 30 minutes.

There is a nominal volume of 1000 $\mu$ L of liquid suspension in each vial. However, only four draws of 200 $\mu$ L should be used for control measurements. Once the four draws are removed from the vial, discard the vial and remaining liquid.

### Procedure for quality control testing using the LQC Kit:

1. Make sure that the AggreGuide A-100 Instrument is turned on and has passed its warm-up and internal controls sequence, as seen by the prompt "Insert empty cartridge and press 'Ready' after the startup count-down timer.
2. It is suggested that the QC2 quality control cartridge (furnished with the instrument) is used to conduct the QC2 test prior to proceeding with the LQC testing. The frequency of this testing can be as frequently as the laboratory determines is necessary to meet its quality control program requirements.

3. Before beginning the LQC quality control assays, it is important to thoroughly agitate the LQC liquid samples. **NOTE—this is different than when testing with blood.** The LQC Control Samples contain non-biologic particles that represent blood constituents, and the vials must be vigorously agitated to re-suspend all of the components of the liquid. This can be done with a vortex mixer, or by firmly grasping the vial between index finger and thumb. Vigorously shake the vial 10 or more times over three seconds. The liquid suspension will have some froth, but there should be no dark residue within the vial on the bottom or sides of the glass.
4. In most ways, LQC testing is conducted using the same software settings as if running a blood sample. Prepare the A-100 and test cartridge:
  - a. Select a cartridge from the cartridge lot to be tested, insert it into the A-100 Instrument sample chamber.
  - b. Press the 'Ready' button. When the cartridge passes the first set of internal testing, the A-100 will prompt with "Enter Test Data".
  - c. Select the Agonist from the drop down box to match the cartridge type, (AA or ADP).
  - d. Enter the Cartridge ID, Study, Patient ID and Operator name. It is suggested that the assay cartridge lot number be entered into the Study Name field, and the LQC Kit lot number be entered into the Patient ID field. (These entries will help in quickly filtering for and finding these results later.)
  - e. You are prompted to press 'Ready' when you are done entering the Test Data-- do not press 'Ready' yet.
5. Load the liquid control sample into the cartridge to be tested.
  - a. Set your pipettor to 200µL. (**This volume is different than when using blood in an actual test**).
  - b. Affix one of the Special pipette tips to the pipettor.
  - c. Before opening the Control sample vial, invert it five times rapidly. (**This is different than when using a blood sample in an actual test**). Immediately open the vial cap and draw 200 µL of the sample into the pipette tip.
  - d. Carefully place the end of the pipette tip onto the landing zone of the cartridge over the loading hole. Tilt the pipettor across the center of the cartridge to facilitate pipetting by making a seal with the loading hole of the cartridge. (See **Figure 1**).
  - e. Slowly dispense the 200 µL of the Control liquid into the cartridge. It is important to begin the pipetting process very slowly, so that the initial fluid will enter the filling hole instead of overflowing. While filling, watch carefully to see that only the fluid and not air is delivered into the assay cartridge. When loading is complete, a small amount of overflow liquid should be visible at the vent hope opposite the loading hole. (See **Figure 2**).
  - f. Put the pipettor down, and carefully remove the cartridge from the A-100 Instrument so that the cartridge can be inspected for air bubbles. (See **Figure 3**, and also page 20 of the **A-100 User's Manual**). If an air bubble is present, discard the cartridge and try again.
6. If the cartridge with loaded control liquid is free of bubbles, replace it into the A-100 instrument. Press 'Ready', and when the prompt reads "Place sample into cartridge and press 'Ready'" press the 'Ready' button again.
  - a. The assay should begin. Once the A-100 instrument states "Collecting Data" inspect the graph for signs that a bubble is in the cartridge per page 21 of the **A-100 User's Manual**.
  - b. When the assay is complete, the instrument will display the result in the PAI box. Record the result. A sample quality control log entry is shown at the end of this set of instructions
  - c. Press 'Save'. The A-100 Instrument will prompt you to remove the cartridge. Remove and discard the cartridge, then press 'Ready'. The Instrument is ready for the next assay.

### **Interpreting the results:**

- The LQC Kit contains a Positive Control Sample Vial and a Negative Control Sample Vial.
- The Positive Control Sample is used to perform a QC test for the system in the case of platelet dysfunction.
  - Results less than or equal to 4 PAI are expected due to the lack of simulated platelet aggregates in the Positive Control Sample fluid.
    - The Positive Control should provide a PAI result that is  $\leq 4$  PAI (includes result "LOW") when used with an AA Assay Cartridge.
    - The Positive Control should provide a PAI result that is  $\leq 4.0$  PAI (includes result "LOW") when used with an ADP Assay Cartridge.
  - Results of greater than 4 PAI are not expected when using the Positive Control Sample fluid.

- If a Positive Control Sample results in an AA Assay result that is >4 PAI, the Positive Control Sample should be rerun with another AA Assay Cartridge. If the result of the second Positive Control Sample AA Assay is >4 PAI contact Technical Support (866-800-1955).
    - If a Positive Control Sample results in an ADP Assay result that is >4.0 PAI, the Positive Control Sample should be rerun with another ADP Assay Cartridge. If the result of the second Positive Control Sample ADP Assay is >4.0 PAI contact Technical Support (866-800-1955).
  - The Negative Control Sample is used to perform a QC test for the system in the case of no platelet dysfunction.
    - Results greater than or equal to 5 PAI are expected due to the presence of simulated platelet aggregates in the Negative Control Sample fluid.
      - The Negative Control should provide a PAI result that is  $\geq 5$  PAI (includes result "HIGH") when used with the AA Assay Cartridge.
      - The Negative Control should provide a PAI result that is  $\geq 5.0$  PAI (includes result "HIGH") when used with the ADP Assay Cartridge.
    - Results less than 5 PAI are not expected when using the Negative Control Sample fluid.
      - If a Negative Control Sample results in an AA Assay result that is <5 PAI, the Positive Control Sample should be rerun with another AA Assay Cartridge. Please refer to troubleshooting section at the end of this package insert. If the result of the second Positive Control Sample AA Assay is >5 PAI contact Technical Support (866-800-1955).
      - If a Positive Control Sample results in an ADP Assay result that is <5.0 PAI, the Positive Control Sample should be rerun with another ADP Assay Cartridge. Please refer to troubleshooting section at the end of this package insert. If the result of the second Positive Control Sample ADP Assay is <5.0 PAI contact Technical Support (866-800-1955).
  - It is recommended that both Positive and Negative Control Samples be tested with both AA and ADP Assays.
    - A summary of the expected results from the recommended LQC test is shown:

Expected LQC Test Results	AA Assay	ADP Assay
Positive Control Sample	$\leq 4$ PAI or "LOW"	$\leq 4.0$ PAI or "LOW"
Negative Control Sample	$\geq 5$ PAI or "HIGH"	$\geq 5.0$ PAI or "HIGH"

### Troubleshooting:

In the event of unexpected LQC results, it is recommended that the following actions be performed or items checked.

1. Check instrument by performing the QC2 procedures as instructed in the **A-100 User's Manual**. This will allow verification that the instrument electronics and optics are working correctly.
2. Verify that a pipetter set to 200 $\mu$ L is used along with the pipette tips included in the LQC Kit for LQC Testing.
3. Repeat LQC testing with another LQC Kit. Ensure that the replacement LQC Kit is within its shelf life date. This will check to see if the LQC Kit controls are working as expected.
4. Contact AggreDyne Technical Support (866-800-1955) if the problem is not resolved.

### Sample Quality Control Log:

A sample quality control log format is provided as a guideline. Each laboratory should adapt this sample quality control log to conform to the quality requirements of the individual laboratory. The recommended format is shown in the example of data entries provided in *italics*:

A-100 Liquid Quality Control (LQC Kit) Quality Control Log										Expected Results (PASS Criteria):	
Facility Name:		<i>Example Hospital</i>								Positive Control 4 PAI or less	
Laboratory:		<i>Central Laboratory</i>								Negative Control 5 PAI or greater	
Date	Shift	Time	Operator	Instrument SN	Assay Type	Assay Lot Number	Control Type	Control Lot Number	Assay Result	PASS/FAIL	QC Initials
<i>1/1/2020</i>	<i>7a-3p</i>	<i>7:00am</i>	<i>sample</i>	<i>2G00000</i>	<i>AA</i>	<i>20AA000</i>	<i>Positive</i>	<i>20LQC000</i>	<i>"Low"</i>	<i>PASS</i>	<i>ABC</i>
<i>1/1/2020</i>	<i>7a-3p</i>	<i>7:05am</i>	<i>sample</i>	<i>2G00000</i>	<i>AA</i>	<i>20AA000</i>	<i>Negative</i>	<i>20LQC000</i>	<i>7 PAI</i>	<i>PASS</i>	<i>ABC</i>
<i>1/1/2020</i>	<i>7a-3p</i>	<i>7:10am</i>	<i>sample</i>	<i>2G00000</i>	<i>ADP</i>	<i>20ADP000</i>	<i>Positive</i>	<i>20LQC000</i>	<i>"Low"</i>	<i>PASS</i>	<i>ABC</i>
<i>1/1/2020</i>	<i>7a-3p</i>	<i>7:15am</i>	<i>sample</i>	<i>2G00000</i>	<i>ADP</i>	<i>20ADP000</i>	<i>Negative</i>	<i>20LQC000</i>	<i>8.1 PAI</i>	<i>PASS</i>	<i>ABC</i>

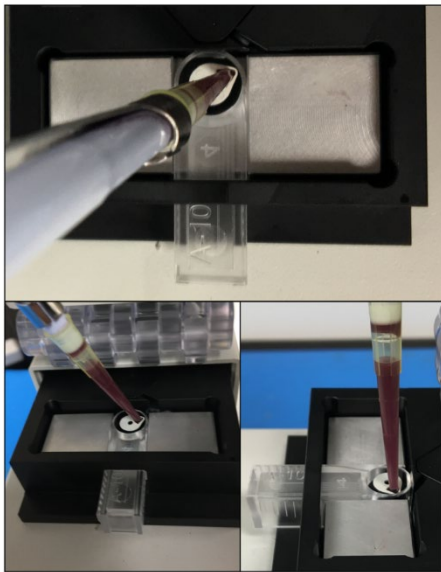


59° F to +77° F  
(+15° C to +25° C)

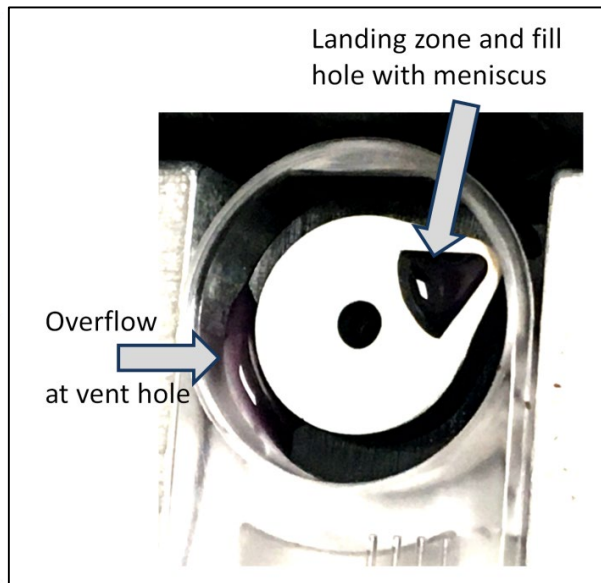


Manufactured by:  
AggreDyne, Inc.,  
10530 Rockley Road, Suite 150  
Houston, Texas, USA 77099  
866-800-1955

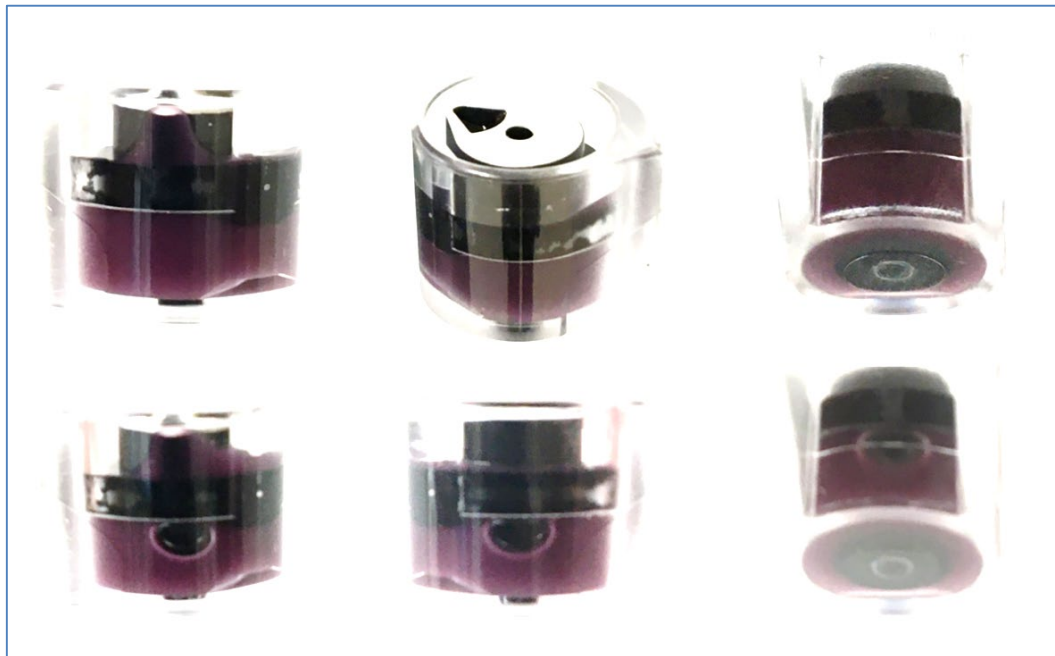
**Figures:**



**Figure 1:** Pipetting of the LQC fluid into the assay cartridge. Tilting the pipette tip allows a better connection between the tip and fill hole.



**Figure 2:** Photo of an assay cartridge cap, including the landing zone/fill hole and overflow/vent hole. Note the slight amount of fluid at each opening (seen as reflected light).



**Figure 3:** Absence (top row) and presence (bottom row) of bubbles in the assay cartridges. Bubbles, which must be avoided, can be of different sizes and appear at different locations.