IMPACT Control Set – For Research Use Only

REF HB-2131-FG

Guide to Symbols

REF Catalogue No.

Contains sufficient for <n> tests

Consult accompanying documents

Use By Date

Store at 2-8°C

LOT Batch – Lot Code

IFU122-RUO Version 0

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IMPACT Control Set – For Research Use Only

GB Handling Instructions

Section 1: Manufacturer:
Hart Biologicals Ltd. 2 Rivergreen Business Centre, Queens Meadow, Hartlepool. UK. TS25 2DL.

Section 2: Identification of the Reagent:
IMPACT Control Set – For Research Use Only (HB-2131-FG) comprises of:
2 x IMPACT Baseline Control Vial
1 x IMPACT Low Control Vial
1 x IMPACT High Control Vial

Section 3: Intended use:
Hart Biologicals IMPACT Control Set – For Research Use Only, is intended to be used as a two-level impedance quality control test to verify performance of the IMPACT analyser, prior to testing samples. For use by trained professionals only.
Each IMPACT Control Set – For Research Use Only comprises of two IMPACT Baseline Control Vials and an IMPACT Low Control and an IMPACT High Control vial.
Within the IMPACT analyser software there is QC Test selection, refer to IMPACT Operator's Manual for test guidance. Two tests are available, LQC Low and LQC High. Within each test the IMPACT Baseline Control solution is firstly added to create a baseline signal. Then within the LQC Low test, the IMPACT Low Control Vial is used to create a low impedance response within the range of 5-20 ohms. Whereas within the LQC High test, the IMPACT High Control Vial is used to create a high impedance response within the range of 35-60 ohms.
LQC Low and LQC High results can be verified for each IMPACT analyser channel (6), prior to testing samples.
For ease of identification, each QC solution has a different colour as stated below:

- IMPACT Baseline Control Vial – Clear Colourless
- IMPACT Low Control Vial – Clear Pale Red
- IMPACT High Control Vial – Clear Pale Blue

Section 4: Principles of the examination method:
IMPACT utilises whole blood impedance aggregometry (WBIA), an established technology for platelet function testing that has been widely used for many years. It is a rapid and standardised option for platelet function testing. [1-5] The method is impedance (electrical resistance) aggregometry and is non optical.[3] The analyser can be used to test platelet function and for antiplatelet studies.[3,5] Test principle is that platelets adhere to small wires suspended in the blood sample and the impedance between the wires as the platelets adhere and aggregate is measured and plotted.[3] In the IMPACT aggregation trace, the impedance is measured numerically in ohms and displayed graphically and numerically on the screen. Two measurements are performed in parallel in each test cell to provide internal verification and assurance.
IMPACT Control Set – For Research Use Only, is intended to be used as a two-level impedance quality control test to verify performance of the IMPACT analyser, prior to testing samples. QC tests should be performed in accordance with the IMPACT Operator's Manual. Each solution within the IMPACT Control Set – For Research Use Only is provided liquid stable and ready to use. Each vial should be prewarmed at 37°C to provide optimum test conditions.

Section 5: Traceability of values assigned to calibrators and trueness-control material:

No control material is currently available for platelet aggregation testing. However, IMPACT Control Set – For Research Use Only is provided for verification of the IMPACT analyser, with two level impedance quality control.

Section 6: Components:
IMPACT Control Set – For Research Use Only (HB-2131-FG) comprises of:
2 x IMPACT Baseline Control Vial (3.6ml)
1 x IMPACT Low Control Vial (1.7ml)
1 x IMPACT High Control Vial (1.7ml)

Each kit provides sufficient volume to perform 6 LQC Low and 6 LQC High tests on the IMPACT analyser. Typically, this would allow QC of each channel (6).

Section 7: Additional required equipment
IMPACT Operator's Manual - Research Use Only – IFU123-RUO
IMPACT Analyser – For Research Use Only (HB-2116-FG)
IMPACT Test Cells 5 x 12 For Research Use Only (HB-2117-FG)

Section 8: Reagent preparation:
IMPACT Control Set – For Research Use Only, is provided liquid stable and ready for use. Each vial within the kit, fits the prewarming station of the IMPACT analyser and should be placed into position, ready for pre-warming to 37°C prior to testing. Refer to IMPACT Operator's Manual.

Section 9: Storage and shelf life after first opening:
Unopened vials - 3 years @ 2-8°C
Opened vials - 2 Weeks @ 2-8°C

The vial label carries the expiry date of the control from the date of manufacture.

Once the expiry date is reached the product must be discarded using standard laboratory waste procedures. Outer box packaging may be recycled.

Section 10: Warnings and precautions:
For Research Use Only.

According to REACH (EC) No. 1907/2006 and CLP Regulation (EC) No. 1272/2008, IMPACT Control Set – For Research Use Only, product is not classifiable as hazardous.

IMPACT Control Set – For Research Use Only, vials, may be disposed of in accordance with laboratory procedures for hazardous waste. IMPACT Control Set – For Research Use Only Kit Packaging may be recycled in line with local regulatory requirements.

Section 11: Primary sample collection, handling and storage:
No sample material is required for the IMPACT Control Set – For Research Use only, testing.

Section 12: Examination procedure:
The IMPACT analyser is designed to ensure easy, efficient, and safe user handling. The Software User Interface is developed for the use of a touchscreen and semi-automated test programme with step by step protocol. IMPACT Operator's Manual - Research Use Only – IFU123-RUO, should be referred to.

Data entry can be performed via the integrated label scanner on the front of the IMPACT analyser or manually via an integrated keyboard.) Test volumes used during the routine IMPACT QC test protocol are stated as follows:

- 550µl IMPACT Baseline Control
- Incubation
- 260µl IMPACT Low Control / High Control

Section 13: Control Procedure:
For Research Use Only.
IMPACT Control Set – For Research Use Only should be used to verify performance of the IMPACT analyser prior to testing samples.

Section 14: Calculation of examination results:
During the IMPACT testing, results are expressed within the software interface as Area Under Curve (AUC) value, this is the measured impedance in ohms*minute. Additionally, the Maximum Slope in ohms/minute and the Maximum Aggregation in ohms are also displayed.
Within the LQC Low test, the IMPACT Low Control Vial is used to create a low impedance response within the range of 5-20 ohms. Whereas within the LQC High test, the IMPACT High Control Vial is used to create a high impedance response within the range of 35-60 ohms.
Figures 1 and 2 below, illustrate an example of the QC results.
Figure 1: LQC Low Result example trace

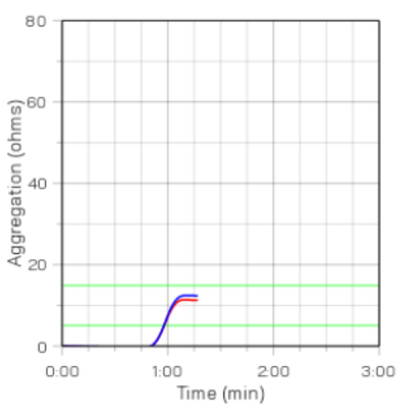
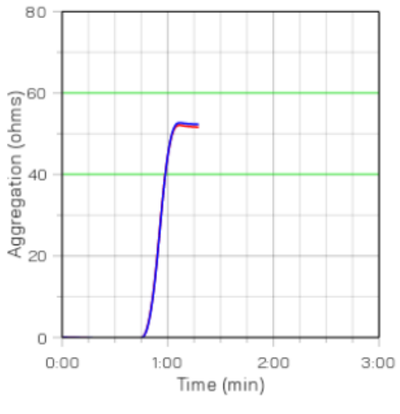


Figure 2: LQC High Result example trace



Section 15: Interpretation of results:
Within the IMPACT Software, the IMPACT Control Set – For Research Use only results, will be verified as in range or flagged as out of range. Refer to IMPACT Operator's Manual for guidance.

Section 16: Performance characteristics:

i. Analytical Performance Characteristics
For Research Use Only.

ii. Performance Characteristics
For Research Use Only.

iii. Measuring Intervals
For Research Use Only. IMPACT Control Set – For Research Use Only, can be used to test each IMPACT analyser channel. Schedule of testing can be set up to suit research facility requirements. Refer to IMPACT Operator's Manual for guidance.

Section 17: Biological reference intervals:
For Research Use Only.

Section 18: Limitations of the examination procedure:
For Research Use Only.
For use by trained professionals only.
Test incubation times may be longer where IMPACT Control Set – For Research Use Only, vials have not been prewarmed.

Section 19: Literature references:

1. Ranucci, Marco; Simioni, Paolo (20 January 2016). Point-of-Care Tests for Severe Hemorrhage: A Manual for Diagnosis and Treatment. Springer. pp. 40–42. ISBN 978-3-319-24795-3
2. Marcucci, Carlo; Schoettker, Patrick (17 September 2014). Perioperative Hemostasis: Coagulation for Anesthesiologists. Springer. pp. 54–56. ISBN 978-3-642-55004-1.3.
3. Dacie & Lewis, 'Practical Haematology', Lewis, S.M., Bain, B.J. and Bates, I. (Editors); 9th Edition, Elsevier Science Ltd., 2002, pages 380-385.
4. Kaiser AF, Neubauer H, Franken CC, et al. Which is the best anticoagulant for whole blood aggregometry platelet function testing? Comparison of six anticoagulants and diverse storage conditions. Platelets. 2011 Oct 14.
5. Aradi D, Komócsi A, Price MJ, et al. Efficacy and safety of intensified antiplatelet therapy on the basis of platelet reactivity testing in patients after percutaneous coronary intervention: systematic review and meta-analysis. Int J Cardiol. 2013;167(5):2140–8.