BIOHIT

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ENGLISH

QC Cassette

for verification of fluorescence reader performance (low/high)

REF 740470 (1 cassette)

1. INTENDED PURPOSE

The QC cassette is a reusable accessory intended to verify the proper functioning and performance of the GP Reader NT (REF 740450) fluorescence immunoassay reader. The cassette provides a defined fluorescence signal response to confirm that the optical detection system of the instrument is operating as expected.

This product is intended for use by healthcare professionals in laboratory or near-patient settings, as part of routine instrument performance verification. The device does not require any sample or specimen and does not have a medical function of its own.

2. INTRODUCTION

Fluorescence immunoassay readers (also called fluorimetric lateral flow test readers) are instruments designed to detect and quantify fluorescence signals from lateral flow assays, providing accurate and objective measurements. The detection system of these instruments includes sensitive optical and electronic components, such as photosensors, precision light sources, and optical filters, whose performance may degrade over time. While these modules typically incorporate self-test and auto-calibration functions to regulate operation, periodic verification is recommended to ensure that the system continues to operate correctly. The QC Cassette is designed to facilitate this verification process in a safe, simple, and reproducible way, without the use of biological samples, reference materials, or liquids.

3. PRINCIPLE OF THE TEST

The QC Cassette contains a predefined fluorescence signal that simulates the response of a fluorimetric lateral flow test. The instrument scans the cassette and measures the intensity of the fluorescence signal. The measured value is then compared against the expected (or target) value to determine whether it falls within a defined acceptance range. This process allows verification of the correct functioning and performance of the optical detection system of the instrument, ensuring consistent, reliable and accurate operation during use.

4. WARNINGS AND PRECAUTIONS

- Always wear protective gloves when handling the cassette to prevent contamination.
- After removing a cassette for use, reseal the foil pouch to protect it from contamination and moisture.
- After measurement, reseal the foil pouch to prevent contamination and preserve product shelf life.
- Use only with the specified compatible instrument(s).
- Do not use a damaged foil pouch or cassette.
- Do not touch the optical reading window
- For *in vitro* diagnostic use only

5. CONTENTS, STORAGE AND DISPOSAL OF MATERIALS PROVIDED

5.1. Contents

Item	Quantity
Instrument QC cassette (sealed in foil pouch with desiccant)	1
Quality Control certificate	1
Instructions for use	1

5.2. Storage

Store at 2 to 30°C, keep dry, and protect from moisture, direct sunlight, dust, and contamination sources. After use, always return the cassette into the foil pouch to minimize exposure to dust, particles, and moisture.

Proper storage ensures product stability until the expiration date or until the maximum number of uses has been reached, whichever occurs first.

5.3. Disposal

Dispose of as general laboratory waste, in accordance with local or regional regulations.

6. MATERIALS REQUIRED BUT NOT PROVIDED

Disposable gloves for handling.

7. TEST PROCEDURE

If stored refrigerated, allow the QC Cassette to reach room temperature before use. Insert the QC Cassette into the instrument cassette tray. Navigate to the Instrument QC screen and tap TEST to initiate the Instrument QC procedure. The instrument will scan the QC Cassette, and the results will be displayed automatically. For complete instruction on performing Instrument QC, refer to the User Guide or the Instructions for Use specific to the instrument.

8. INTERPRETATION OF THE RESULTS

The results of the Instrument QC performed with the QC Cassette are automatically generated by the instrument's software. The result will be either PASS, indicating that the instrument is performing as intended, or FAIL, indicating that the instrument's performance has deteriorated, in which case it is advised to contact the distributor/manufacturer for further instructions.

9. PERFORMANCE CHARACTERISTICS

Characteristic	Value
Stability / Service life	12 months or 250 use cycles
Operating temperature	20 to 25°C
Maximum allowed drift from defined value	± 10%
Precision (within-run)	CV < 2%

10. TECHNICAL SPECIFICATIONS

Characteristic	Value
Cassette dimensions (L × W × H)	88 × 18 × 5.5 mm
Product box dimensions (L × W × H)	157 × 90 × 18 mm
Compatible instruments	GP reader NT (REF 740450)
Storage conditions	2 to 30°C, ≤ 80% RH, away from direct sunlight

11. DATE OF ISSUE

QC Cassette Instructions for Use

Version 1.1, 2026-03-05

12. WARRANTY

Biohit shall remedy all defects discovered in any Product (the "Defective Product") that result from unsuitable materials or negligent workmanship, and which prevent the mechanical functioning or intended use of the Product including, but not limited to, the functions specified in Biohit's specifications for the Product.

ANY WARRANTY WILL, HOWEVER, BE DEEMED AS VOID IF FAULT IS FOUND TO HAVE BEEN CAUSED BY MALTREATMENT, MISUSE, ACCIDENTAL DAMAGE, INCORRECT STORAGE OR USE OF THE PRODUCTS FOR OPERATIONS OUTSIDE THEIR SPECIFIED LIMITATIONS OR OUTSIDE THEIR SPECIFICATIONS, CONTRARY TO THESE INSTRUCTIONS.

This Biohit product has been manufactured according to ISO 13485 quality management system and has passed all relevant Quality Assurance procedures.

13. ORDERING INFORMATION

QC Cassette, REF 740470

14. REGULATORY COMPLIANCE

The QC Cassette is a Class A accessory to IVD medical device(s), complies with the Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices, and is CE marked under the sole responsibility of the manufacturer.

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer or the local distributor and the appropriate national competent authority, in accordance with applicable local regulations.

EXPLANATION OF THE SYMBOLS USED

Symbol	Title
CE	CE mark
	Temperature limit
	Keep dry
IVD	*In vitro* diagnostic medical device
REF	Catalogue number
LOT	Batch code / Lot number
	Manufacturer
	Consult instructions for use
	Use-by date (yyyy-mm-dd)
	Keep away from sunlight
21 PAP	Non-corrugated fiberboard (paperboard)
UDI	Unique Device Identifier

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