GBS Nucleic Acid Assay Control Instruction for Use

[REF & SPECIFICATIONS]

REF	CRM1020802-1	
SPECIFICATIONS	1 SET	
	1 Positive Control	1 Negative Control
REF	**CRM1020802-5**	
SPECIFICATIONS	5 SETs	
	5 Positive Controls	5 Negative Controls

[INTENDED USE]

The product is used with procedures of GBS Nucleic Acid Test Card designed for Thiolase (atoB) gene of Group B Streptococcus(GBS) DNA in vaginal swab samples, for purposes of monitoring test performance and evaluating laboratory testing accuracy.

[PRINCIPLES OF THE PROCEDURE]

The Positive Control contains GBS DNA fragment , thus it can be used to evaluate test proficiency and accuracy through the full process because GBS require extraction and amplification.

The product contains DNA fragment with sequences comprising the GBS partial genome.

The Positive Control and Negative Control also contain DNA fragment with sequences from human β-actin gene (ACTB).

The product does not have assigned values. Specific performance will vary among different manufacturers' assays, different procedures, different lot numbers, and different laboratories.

[WARNINGS AND PRECAUTIONS]

For in vitro diagnostic use.

Handle all specimens, samples and controls as potentially infectious. Follow universal precautions when handling the product.

Wear suitable protective clothing, gloves and eye/face protection when handling the contents of the kit.

Clean any spillage by immediately wiping up with 0.5% sodium hypochlorite solution or 75% ethanol.

Avoid microbial and cross contamination of the product when opening and closing the product. Follow Good Laboratory Practice procedures.

Perform the test in an area with adequate ventilation.

Do not use the product beyond the expiration date.

Dispose of containers and unused contents in accordance with local regulatory requirements. Do not empty the controls into drains.

Wash hands thoroughly after handling.

[STORAGE INSTRUCTIONS]

2°C~28°C storage, valid for 13 months.

The production date is shown on the package label.

[PROCEDURE]

Process the product according to the instructions for unknown specimens provided by the test kits or the laboratory's standard operating procedures.

INSTRUCTIONS FOR USE

1.Wash hands before performing the test.

2.Before opening the tube, confirm that the lyophilized bead is at the bottom of the tube. If the bead were dislodged, hold the top of the tube and flick downward to pull the lyophilized bead to the bottom of the tube.

3.Unscrew the tube caps to open the tubes. Gently transfer the lyophilized bead from Positive Control Vial or Negative Control Vial into the Nucleic Acid Releasing Agent 02 tube, then mix thoroughly by shaking upside down or on a vortex mixer until the bead dissolves completely.

4.Transfer the reconstituted control to a testing card as if it was a patient sample and tested as described in the Sample Testing section in the Instruction for Use of GBS Nucleic Acid Test Card. Reconstituted controls must be tested immediately.

NOTE: TEST PROCEDURES provided by manufacturers of test kits must be followed closely. Deviations from procedures recommended by test kit manufacturers may produce unreliable results.

[QUALITY CONTROL]

Since the product does not have assigned values, it is recommended that each laboratory validate the use of each lot of product with each specific assay system prior to its routine use in the laboratory.

[EXPECTED RESULTS]

Results	
Positive Control	Negative Control
Positive	Negative

If the control does not perform as expected, please contact our Technical Support Team via service@pluslife.com or contact the local distributor.

[LIMITATIONS OF THE PROCEDURE]

The product is provided for quality assurance purposes and must not be used for calibration or as a primary reference preparation in any test procedures.

[REFERENCES]

1. Green IV GA, Carey RN, Westgard JO, Carten T, Shablesky LA, Achord D, Page E, and Le AV. Quality control for qualitative assays: quantitative QC procedure designed to assure analytical quality required for an ELISA for hepatitis B surface antigen. Clin. Chem. 43:9 1618-1621, 1997.

2. CLSI. Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline-Third Edition. CLSI document C24-A3. Wayne, PA: Clinical and Laboratory Standards Institute; 2006.

3. Statistical Quality Control for Quantitative Measurements: Principles and Definitions; Approved Guideline– Second Edition. NCCLS document C24-A2, 1999.

[MANUFACTURER]

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[Explanation of Symbols]

CE	CE Mark	EC REP	Authorized Representative in the European Community
CONTROL -	Negative control	CONTROL +	Positive control
	Consult instructions for use	LOT	Batch Code
	Use by		Keep dry
	Temperature Limits		Date of manufacture
	Manufacturer		Do not use if package is damaged and consult instructions for use
	Do not re-use		Keep away from sunlight
REF	Catalogue number		Contains sufficient for<n> tests
IVD	In Vitro Diagnostic Medical Device		

Version: A/1

Date: May., 2022