

Zika Virus Assay External Quality Controls

Not for IVD use

Intended Use

The Zika Virus Assay External Quality Controls (Zika EQCs) are external quality controls that may be used in conjunction with Zika Virus assays to assist in monitoring assay performance.

Summary and Explanation of the Test

The single-use Zika EQCs are designed to assist in monitoring assay performance by providing an independent reference material. Frequent testing of independent quality controls provides a means of monitoring the performance of the assay performed in the laboratory. Routine use of controls enables laboratories to monitor day-to-day performance of test kits and operator variation, and can assist in identifying increases in random or systematic error.

Reagents and Materials Provided

Note: For information on any hazard and precautionary statements that may be associated with reagents, refer to the Safety Data Sheet Library at www.hologic.com/sds.

Zika Virus Assay External Quality Controls Kit, for approximately 1000 tests, Cat. No. PRD-04093-D

Zika Virus Assay External Quality Controls

(store at -15°C to -35°C upon receipt)

Component	Quantity
Zika Negative External Quality Control <i>A HEPES buffered solution containing detergent.</i>	15 x 1.3 mL
Zika Positive External Quality Control <i>A HEPES buffered solution containing detergent and a Zika virus RNA transcript.</i>	15 x 1.3 mL

Warnings and Precautions

- Not for IVD use.
- Each Zika EQC is designed for use in a single replicate. Excess material in each vial is to be appropriately discarded according to local, state, and federal regulations.
- Use routine laboratory precautions. Do not pipette by mouth; do not eat, drink or smoke in the laboratory work area. Wear disposable gloves and a laboratory coat when handling Zika EQCs. Wash hands thoroughly after handling.
- Avoid microbial and ribonuclease contamination of Zika EQCs. Use of filtered, disposable pipette tips is strongly recommended.

Reagent Storage

Store the Zika EQCs between -15°C and -35°C.

Reagent Preparation

Thaw single-use Zika EQCs at room temperature (15°C to 30°C). Throughout the thawing process, gently invert each tube to mix thoroughly to avoid foaming. Ensure tube contents are fully thawed prior to use. Do not use the Reagent Preparation Incubator (RPI) to thaw the Zika EQCs. Once thawed, use Zika EQCs within 8 hours. Do not refreeze.

Note: *If gelling occurs, gel must be dissolved prior to use and within the 8 hour thaw period at room temperature. To expedite the dissolution of gel, warm the EQCs at 15°C to 30°C in a water bath. Periodically remove the EQCs from the water bath to gently invert until gel is dissolved.*

Procedure

The Zika EQCs have been designed for quality assurance and the purpose of monitoring assay performance.

The Zika EQCs are provided as single-use vials and should be placed on the Panther system using the same instructions as are used for samples. See the *Panther System Operator's Manual* for additional procedural information.

Expected Results

The Zika Negative External Quality Control is designed to produce a Nonreactive/Negative result under normal assay usage. The Zika External Positive Quality Control is designed to produce a Reactive/Positive result under normal assay usage.

Limitations

- A. Zika EQCs must not be substituted for the mandatory positive and negative calibrators provided with the Zika Virus assay kit or proficiency panels.
- B. Deviations from these procedures may produce unreliable results. Adverse shipping and/or storage conditions of Zika EQCs and/or reagents may produce unreliable results.
- C. Zika EQCs must not be used to determine run validity or to interpret results.



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