PCR*opsis*™ Concentrator

(NOT FOR RESALE)

INTENDED USE (in vitro diagnostic use)

PCR*opsis*™ Concentrator is intended for concentrating DNA, proteins, and / or cells from clinical samples.

PRINCIPLES OF THE PROCEDURE

PCR*opsis*™ Concentrator consists of a proprietary substrate engineered to selectively absorb water from clinical samples without the use of equipment as a means of concentrating components within the sample. This is achieved through the use of a sterile, water absorbing substrate core where the substrate surface minimally binds to DNA, proteins, and cells. PCR*opsis*™ Concentrator allows for the concentration of samples without the need for centrifugation or vacuum, and thereby streamlines automated sample processing.

WARNINGS & PRECAUTIONS

For in vitro Diagnostic Use.

- Observe approved biohazard precautions and aseptic techniques to prevent contamination of the product. To be used only by adequately trained and qualified personnel.
- Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. "Standard Precautions"[1-4] and institutional guidelines should be followed in handling all potentially bio-hazardous materials.
- Sterilize all biohazard waste including specimens, containers and mediums after their use.
- Directions should be read and followed carefully.
- Do not re-pack.
- The use of this product in association with a rapid diagnostic kit, diagnostic instrumentation or used in a manner not intended should be validated by the user.
- Do not ingest.

Storage: This product is ready for use and no further preparation is necessary. The product should be transported and stored in a dry environment in its original container at ~25˚C until used. Do not overheat or freeze prior to use. Improper storage will result in a loss of efficacy. Do not expose the product to organic solvents or samples with a pH lower than 5 or greater than 9. This may alter the surface chemistry and affect the functionality of the product. Do not use after expiration date, which is printed on the label.

Product Deterioration: This product should not be used if (1) there is evidence of damage or contamination to the product, (2) there is evidence of liquid in the product, (3) the color of the substrate has changed from white hazy to yellow, (4) the expiration date has passed, or (5) there are other signs of deterioration.

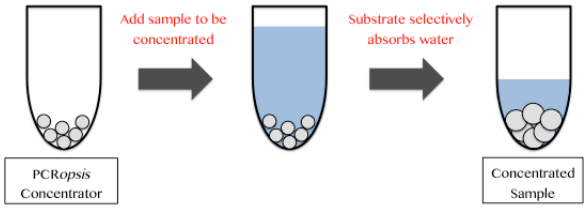
PROCEDURES

Materials Provided: PCR*opsis*™ Concentrator (bulk substrate or pre-loaded tubes)

Materials Required But Not Provided: Pipette with tips and test sample

Test Procedure: Proper specimen collection, transport and storage is critical for successful nucleic acid amplification. For specific guidance regarding specimen collection procedures, consult published reference manuals.[5-11] Clinical specimens should be collected as soon as possible after the clinical onset of disease. Highest viral titers are present during the acute illness.

1. Add 0.5 ~ 2 mL of sample to be concentrated into 2 mL tube containing ~15 PCR*opsis*™ Concentrator substrate beads
    1. Thoroughly mix sample with dried substrates for best results
2. Let sample incubate at room temperature for 2 ~ 20 minutes depending on your desired level of sample concentration
3. Remove concentrated supernatant into a fresh tube by sliding the pipette tip along the edge of the tube to the bottom of the tube to prevent clogging tips
4. Use concentrated supernatant in desired applications



Quality Control: All lots of PCR*opsis*™ Concentrator are tested for microbial contamination and the ability to absorb water. If aberrant quality control results are noted, patient results should not be reported.

RESULTS

Results obtained will partially depend on proper and adequate specimen collection, transport and processing in the laboratory. The use of PCR*opsis*™ Concentrator with samples containing noticeable levels of lysed red blood cells, high levels of fat, and / or noticeable microbial growth (i.e., contamination) may result in unreliable results.

LIMITATIONS OF THE PROCEDURE

- Performance characteristics of PCR*opsis*™ Concentrator were validated using diluted human plasma spiked with genomic DNA. The use of alternative samples may affect the performance of the product.
- The product has not been validated for concentrating RNA
- Concentrated samples may contain concentrated levels of PCR inhibitors that may interfere with direct PCR applications if these inhibitors are not removed

- Repeated freezing and thawing of test specimens may reduce the detection of desired gene targets.
- Follow recommended guidelines for specimen collection, transport and storage as this may affect the ability to amplify gene targets.

PERFORMANCE CHARACTERISTICS

The performance of PCR*opsis*™ Concentrator was tested with 50% diluted human plasma spiked with genomic DNA. The ability of the product to concentrate the sample >50% within 10 minutes at room temperature, concentrate proteins assessed by SDS-PAGE, and concentrate DNA assessed through PCR were the main endpoints of the study.

AVAILABILITY – NOT FOR RESALE

Cat. #	Description
266384	PCR*opsis*™ Concentrator, 384 units (~5,760 substrate beads)
2661536	PCR*opsis*™ Concentrator, 1536 units (~23,040 substrate beads)
266850	PCR*opsis*™ Concentrator, 50x 2 mL tubes (1 unit / tube)
2668250	PCR*opsis*™ Concentrator, 250x 2 mL tubes (1 unit / tube)

MANUFACTURER

Entopsis, Inc., 7600 NW 69th Ave, Medley, FL 33166, USA info@entopsis.com

REFERENCES

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Glossary of Symbols Used