PUBLICATION HIGHLIGHT: *High Sensitivity and Detection in Serum*

Details taken from: Afsahi, S., et al. **Novel Graphene-Based Biosensor for Early Detection of Zika Virus Infection**. *Biosensors and Bioelectronics*. 2017. doi:10.1016/j.bios.2017.08.051. Read the open access paper.

Agile™ R100

Unparalleled sensitivity to *push the limits.*

Agile R100 is a portable label-free graphene biosensor that has drastically widened the detection limits of binding interactions. The proprietary Field Effect Biosensing (FEB) technology on which it is based is an electrical technique that enables cost-effective, robust, portable form factors that can be applied in life science research, drug discovery applications, and diagnostic platforms.

PAPER SUMMARY

- Agile R100 detected Zika viral antigen in buffer using monoclonal antibodies developed by the CDC at **18 ng/mL**, an exceptional level of sensitivity unmatched by any portable device.
- Additional measurements showed detection of Zika viral antigen in simulated **human serum** at a CV% in line with specs set by the Clinical Laboratory Standards Institute (CLSI). At 500 ng/mL, this represents the ability to detect **clinically-relevant levels of antigen in serum.**
- Agile R100 is the only graphene-based portable biosensor of its kind. Its affordability, small size, high sensitivity, and ability to detect in serum make it an ideal on-site platform for PK/PD studies, and a candidate for development as an early-stage medical diagnostic test that can be run by the healthcare provider.

OVERVIEW

The Zika virus, a mosquito-borne infection, has been shown to be a cause of microcephaly and other severe fetal brain defects. For pregnant women, it is especially important to reliably identify Zika virus infection in a timely manner, but current methods can take weeks to return test results.

In this publication, the compact and portable Agile R100 demonstrated a clinically-relevant level of sensitivity and ability to detect in serum, making it a potential methodology to identify Zika infection promptly, at the location of the patient.

MATERIALS AND EQUIPMENT

- Agile R100 label-free biosensor
- Laptop with Agile Plus software
- NHS Agile Biosensor Chips
- Anti-Zika NS1 mouse mAb 6B1 developed by the CDC
- Phosphate buffered saline (PBS) pH 7.4.
- Amino-polyethylene glycol pH 7.4.
- 1M Ethanolamine pH 8.5.
- ZIKV NS1 recombinant antigen
- Simulated human serum

METHODS AND PROCEDURE

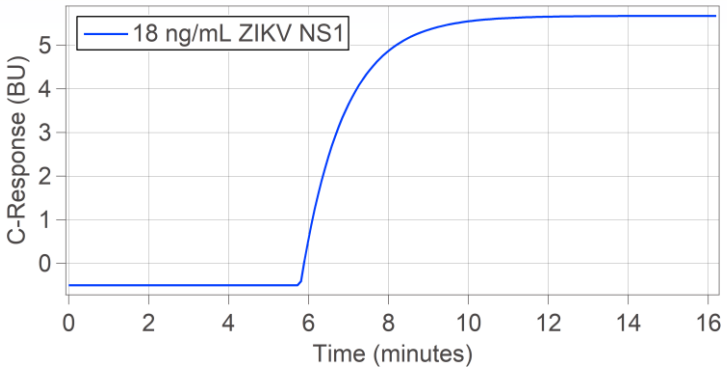
Agile biosensor chips were functionalized with the target, anti-Zika NS1 mouse mAb 6B1 developed by the Centers for Disease Control (CDC). Anti-Zika NS1 was diluted to a working concentration of 14.6 nM in 1X phosphate buffered saline (PBS) pH 7.4. During immobilization and measurement, 75 µL of all solutions were used on the biosensor chips and incubation steps took place at room temperature. The software was calibrated to baseline in 1X PBS pH 7.4 for 60 s. Anti-Zika NS1 was immobilized on the surface by incubating for 15 min. Residual active NHS groups were first quenched using 3 mM amino-PEG5-alcohol (amino-PEG) pH 7.4 before a final quench with 1 M Ethanolamine pH 8.5. Each quench step was done for 15 min each, followed by several washes in 1X PBS pH 7.4. The high concentration of PEG used during blocking leads to both covalently-linked PEG to the graphene surface and absorbed-PEG to the rest of the chip surfaces, providing a stable block on the graphene against non-specific interactions at the surface.

Measurements were performed in an assay buffer of 1X PBS pH 7.4 or a dilution of simulated serum for spike-in measurements at 1:10 and 1:100 of serum to 1X PBS pH 7.4. Immediately after immobilization, the biosensor chips were calibrated in assay buffer for 5 min. The ZIKV NS1 recombinant antigen was diluted in assay buffer to the desired concentration. Each concentration was applied to individual biosensor chips for at least 5 min to generate a sensor response.

*Afsahi, S., et al. **Towards Novel Graphene-Enabled Diagnostic Assays with Improved Signal to Noise Ratio.** *MRS Advances.* 2017. doi:10.1557/adv.2017.431.

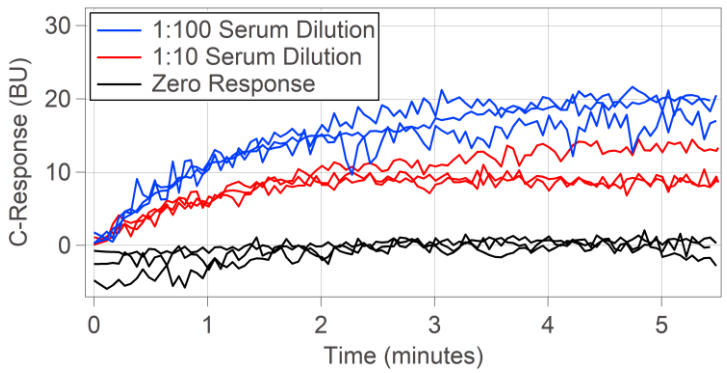
RESULTS AND DISCUSSION

The figure below shows the Agile biosensor response in buffer for 18 ng/mL ZIKV NS1.



A previous publication compares this measurement to Biolayer Interferometry (BLI), an alternative label-free technique. Agile R100 showed detection of Zika antigen at 10 times lower concentration than on Octet RED96, a BLI system (Afsahi et al., 2017*), using the same antibody-antigen binding pair.

Spike-in measurements in simulated serum were performed to demonstrate the potential of the platform and assay for diagnostic purposes. The figure below shows the sensor response of 2 dilutions in triplicate. According to the CLSI, the CV% for in vitro diagnostics should be ≤20%, and ≤ 10% is considered a reliable test. At 1:10 dilution, the CV% is 19.89%, while at 1:100 dilution, the CV% is 9.17%. The ability to detect in serum at 500 ng/mL, a clinically-relevant level of sensitivity, suggests the ability of Agile R100 to be developed into a valuable platform for PK/PD studies or on-site diagnostics.



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