

SIBA[®] Licensing and partnering opportunities

Orion Diagnostica is seeking licensees and partnering opportunities for a novel, exclusive, IPR protected, isothermal amplification technology, SIBA[®].

The versatile technology lends itself for broad range of markets from large volume laboratory settings, to Point-of-Care (POC) as well as demanding on-the-spot field testing, and allows the development of easy-to-use products. The technology is ideal for testing pathogens in e.g. human *in vitro* diagnostics (IVD), veterinary, food, feed, or water. Results indicate that SIBA outperforms other isothermal technologies and overcomes shortcomings of PCR. SIBA technology answers to increasing demands on faster and more cost-effective testing methods.

Orion Diagnostica is interested in licensing opportunities, but also collaboration possibilities around test development, reagents, instrumentation and manufacturing.

The novel SIBA technology

- » Strand Invasion Based Amplification (SIBA[®])
- » Based on recombinase system driven invasion of target strand to enable binding of amplification primers
- » Isothermal amplification of a nucleic acid target even from crude lysates at a constant temperature of ~40°C
- » Real-time continuous reaction and detection: fast and robust
- » Time-to-results shown < 15 mins
- » High specificity
- » Both DNA and RNA targets can be detected
- » Proven to work with bacteria, viruses and eukaryotes
- » Ability to multiplex
- » Rapid assay development in < 4 weeks allowing rapid response to market needs
- » Easy and affordable instrumentation: in the field & POC as well as centralized settings
- » Solid and holistic IPR protection

SIBA – Benefits

High sensitivity

- Very low formation of artefacts allows for confidence in positive reactions with low target copies

High specificity

- Even 1–2 bp resolution
- SYBR green detection possible
- Melting curve analysis possible

Speed

- Short Time-to-Result
- Hands-on-time short due to low sample prep requirements

Robustness

- Tolerate high protein and high salt
- Temperature exact level not critical
- Dry chemistry one option

Multiplexability

- Multiple different probe/detection chemistry variants developed, some proprietary
- Also SYBR green multiplexing

Rapid assay development

- Assay development in < 4 weeks proven!

SIBA proven clinically in human IVD and also in non-human applications

Orion GenRead® C. difficile and Campylobacter IVD tests on European markets (CE marked)



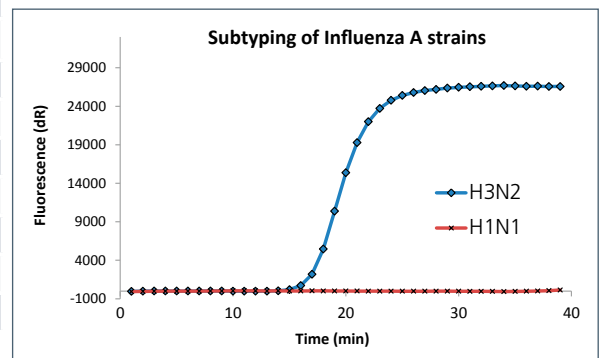
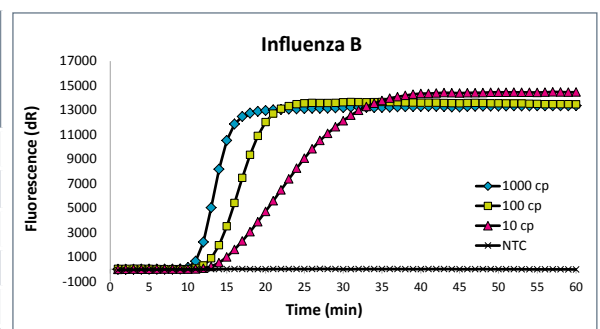
size: 22,5 x 23 x 15 (cm)
weight: 3,5 kg

Expanding the portfolio

- » Respiratory panel: Influenza A & B, RSV
- » More to follow

Superior speed and sensitivity of RT-SIBA influenza assay compared to CDC RT-PCR influenza assay; capability of subtyping influenza strains due to high specificity of SIBA

Influenza	Number of positive reactions (time of positive result)		
	cp/reaction	RT-SIBA	RT-PCR
A (H1N1)	1000	12/12 (12 min)	12/12 (54 min)
	100	12/12 (15 min)	0/12
	10	12/12 (20 min)	0/12
A (H3N2)	1000	12/12 (11 min)	12/12 (50 min)
	100	12/12 (14 min)	12/12 (52 min)
	10	12/12 (16 min)	0/12
A (H5N1)	1000	12/12 (10 min)	12/12 (51 min)
	100	12/12 (12 min)	12/12 (53 min)
	10	12/12 (15 min)	0/12
B	1000	12/12 (10 min)	12/12 (51 min)
	100	12/12 (12 min)	12/12 (53 min)
	10	11/12 (13 min)	11/12 (56 min)



For full publication, see: *Applied Microbiology and Biotechnology* 2016.
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Other applications, solid data on:

- » SIBA amplification in minced meat extract demonstrating the robustness of SIBA
- » Differentiating Robusta and Arabica coffee from roasted coffee beans with SIBA
- » Detecting GMO maize with SIBA
- » Environmental & water testing: rapid and specific analysis of environmental samples for microbial pathogens like *Legionella*
- » MRSA, Zika virus, STD ie. GC/CT

Interested?

- » Please contact us:
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- » More information and material available on the Orion Diagnostica website:
www.oriondiagnostica.com > Partnering and licensing



Orion Diagnostica develops, manufactures and markets diagnostic test systems for healthcare professionals with over 40 years of experience. Building well-being is the core of our mission. SIBA® and Orion GenRead® are registered trademarks of Orion Diagnostica Oy.

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