

AFIAS

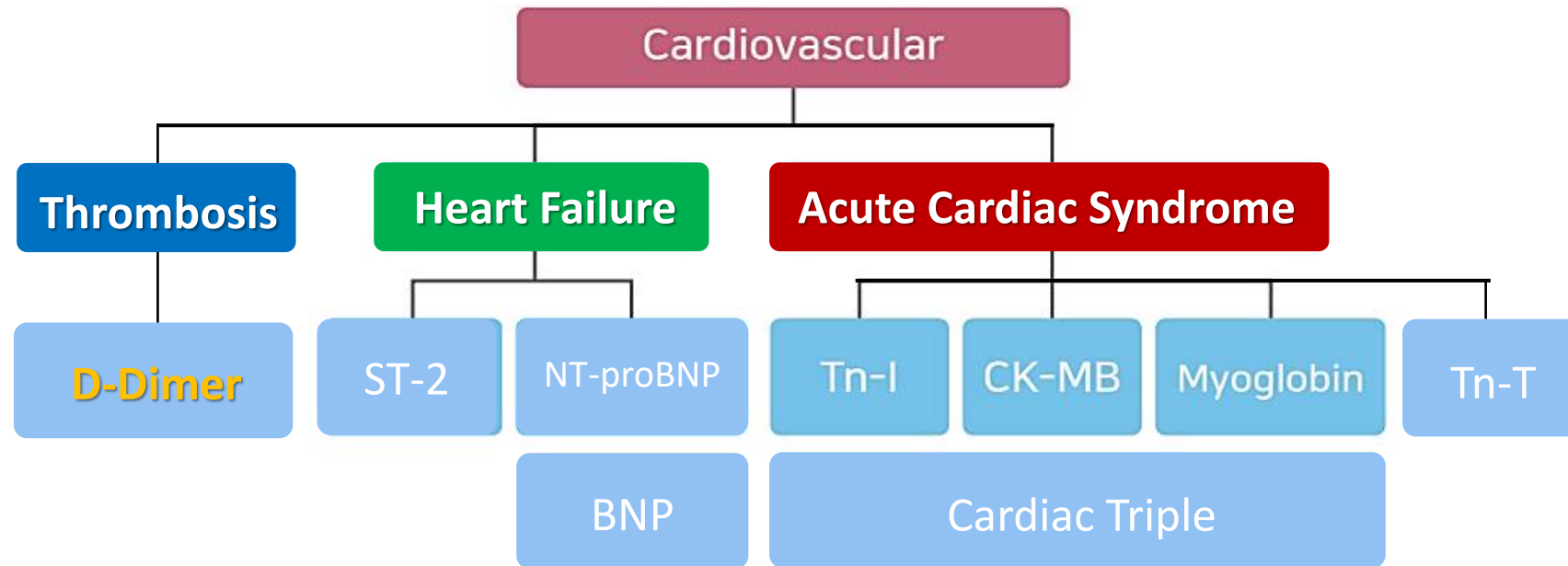
Comparability Study-Clinical evaluation

Comprehensive Cardiovascular Panels of Boditech Med Inc.

D-Dimer

Marketing Team
Last Updated: 220329

Cardiovascular Panels of Boditech Med Inc.



AFIAS D-Dimer Specifications

Intended use:

Specifications: -

Measurement range: 50 – 10,000 ng/mL

Cut-off: 500 ng/mL

Test time: 12 minutes

Reference instrument:

Stago STA[®]-Liatest[®] D-Di

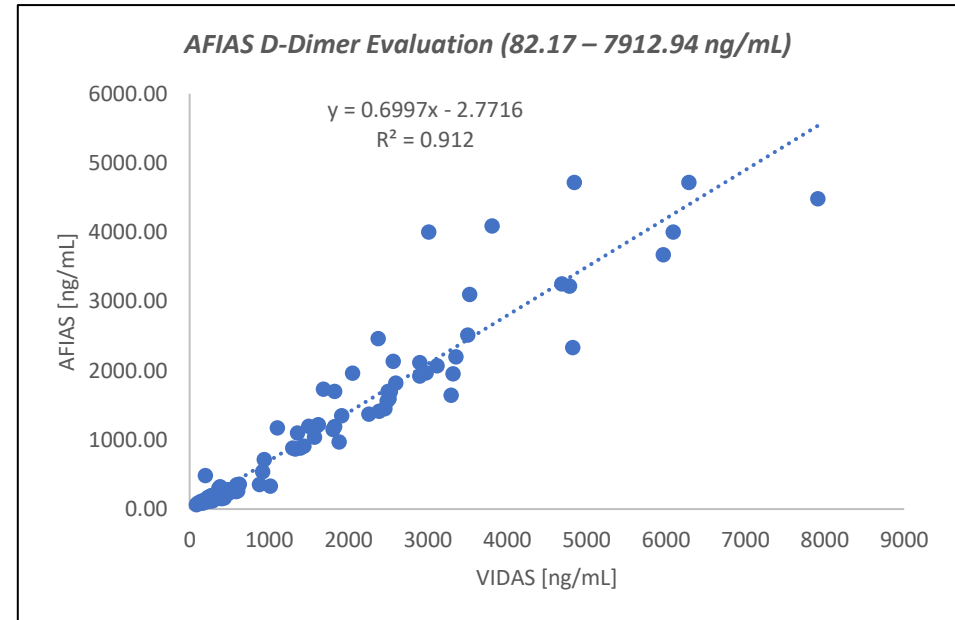
Shelf-life: 20 months

Sample volume: 100 µL

Sample type: WB/Plasma (Sodium citrate)

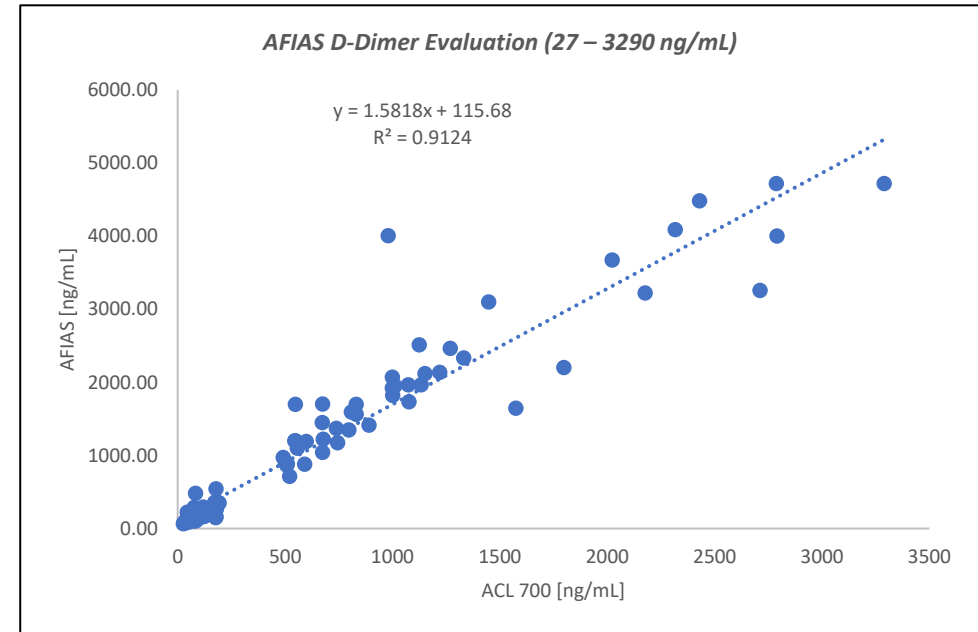
D-Dimer: External evaluation (1)

- 1) Date: 2016.11
- 2) Replica: n=1
- 3) Sample type: Plasma 121 ea.
- 4) Sample state: Fresh
- 5) Sample range: 0.822 – 7.91 ug/ml
- 6) Reference analyzer: mini-VIDAS Exclusion II
- 7) Result
 - R square =0.912
 - Slop = 0.6997



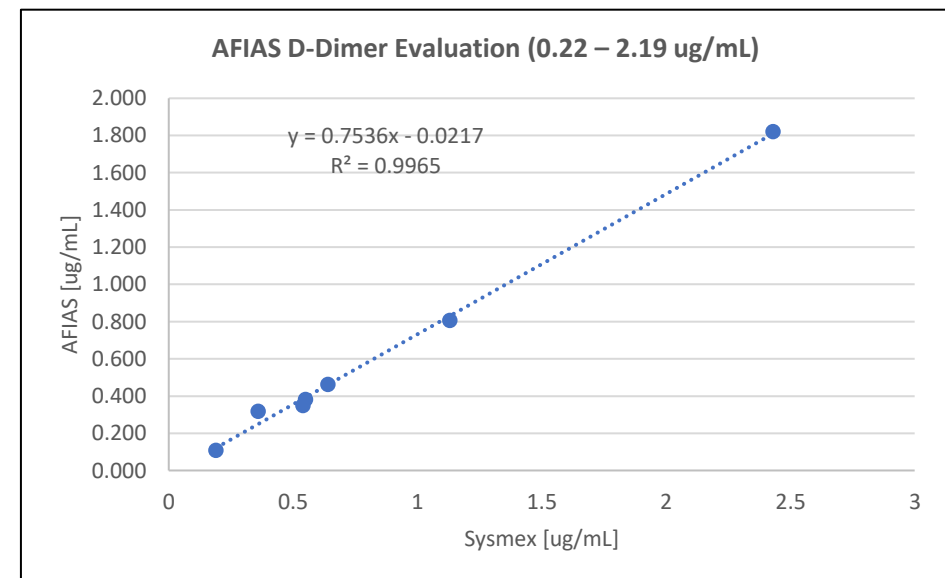
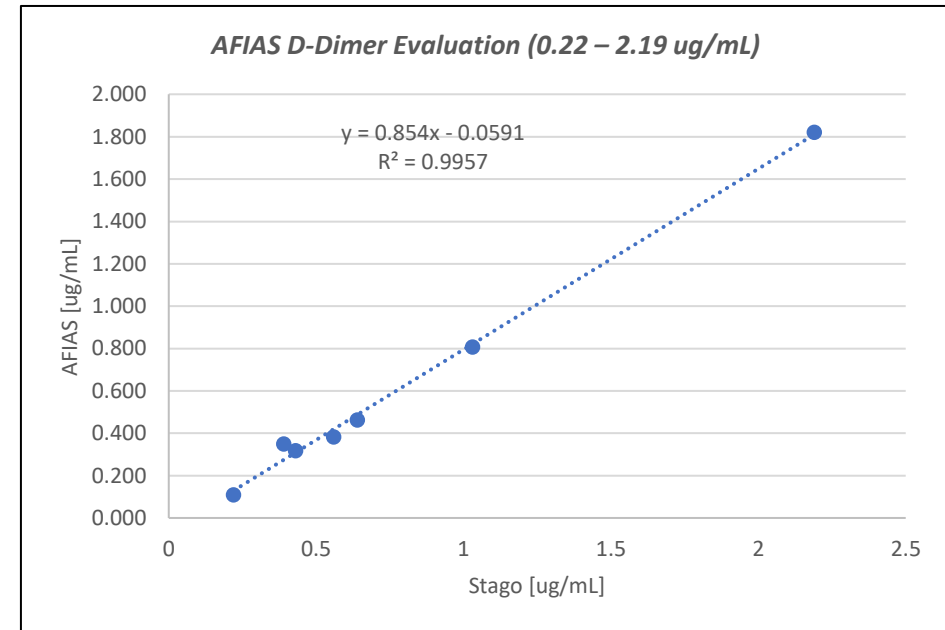
D-Dimer: External evaluation (2)

- 1) Date: 2016.11
- 2) Replica: n=1
- 3) Sample type: Plasma 104 ea.
- 4) Sample state: Fresh
- 5) Sample range: 0.27 – 3.29 ug/ml
- 6) Reference analyzer: ACL-TOP (ug/mL)
- 7) Result
 - R square =0.9124
 - Slope = 1.582



D-Dimer: External evaluation (3)

- 1) Date: 2019.03
- 2) Replica: n=1
- 3) Sample type: Plasma 7 ea.
- 4) Sample state: Fresh
- 5) Sample range: 0.22 – 2.19 ug/ml
- 6) Reference analyzer: Stago STA®-Liatest® D-Di, Sysmex
- 7) Result
 - With Stago STA
 - R square =0.9957
 - Slop = 0.854
 - With Sysmex
 - R square =0.9965
 - Slop = 0.7536



**We are always here for you!
Please contact for any
question or inquiry**

BODITECH MED INC.

-Visit our Website:

<https://www.boditech.co.kr/en>

-Brochure:

<https://www.boditech.co.kr/en/support/attachment/232/0>

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