

ASSESSMENT OF THE KIT REPORT

Dynamiker *Aspergillus* Galactomannan Assay

Date of performance: 14/01/2015 to 29/01/2015

Objective: Assessment of the Dynamiker *Aspergillus* Galactomannan KIT by the commercial brand Dynamiker Biotechnology (DNK) for its possible commercialization.

Features of the equipment assessed: ELISA, Ref: DNK 1402-1, Lot 141001, Expiry Date: October 2015.

Tests performed:

- Reproducibility of the standard curve during time
- External assessment using patient samples (Hospital Universitario La Fe)
- Compatibility

Description of the assay:

In order to perform the tests we proceed to run the standards and controls according to the given protocol. This test is carried out on different dates so as to study the reproducibility.

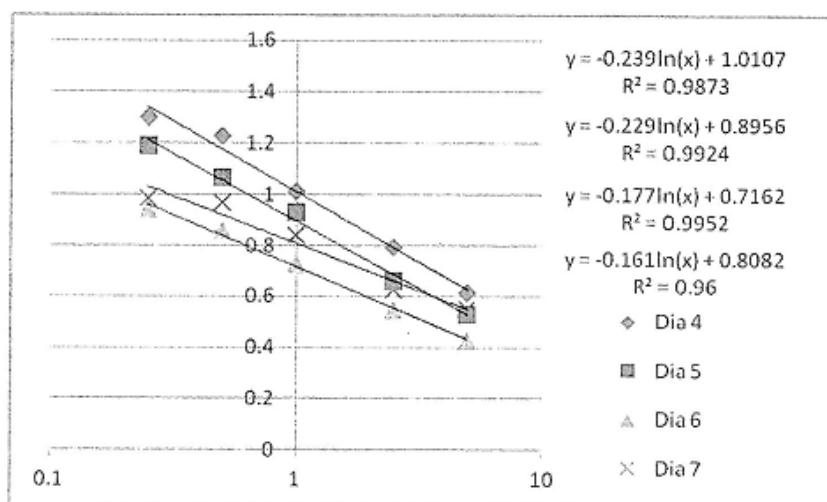
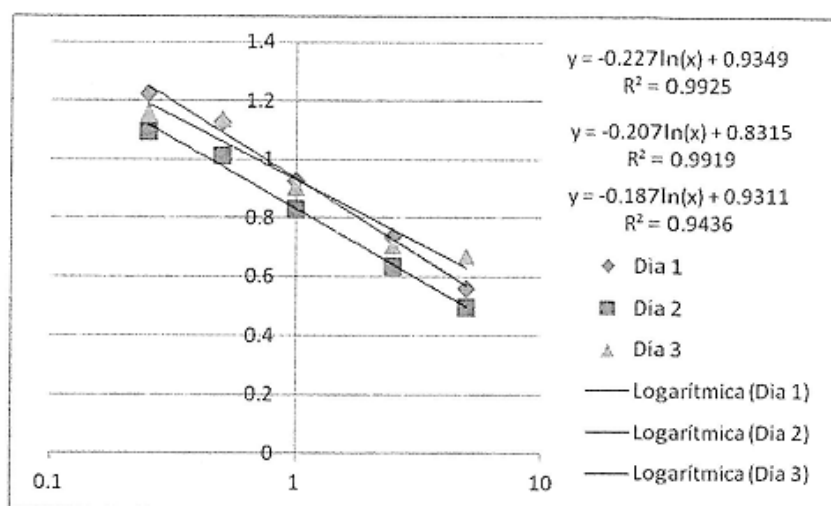
Results:

1. Reproducibility:

SAMPLE	Concentration µg/ml	O.D Day 1	O.D Day 2	O.D Day 3	O.D Day 4	O.D Day 5	O.D Day 6	O.D Day 7	%VC
Standard I	0,25	1,225	1,094	1,159	1,303	1,191	0,943	0,987	11,45
Standard II	0,5	1,129	1,012	1,138	1,227	1,067	0,858	0,967	11,62
Standard III	1	0,925	0,829	0,904	1,011	0,929	0,726	0,839	10,39
Standard IV	2,5	0,736	0,634	0,704	0,793	0,662	0,547	0,627	11,99
Standard V	5	0,558	0,496	0,667	0,613	0,527	0,428	0,549	14,13
Control A		0,689	0,8	0,752	0,751	0,593	0,41	0,603	20,36
Control B		1.256	1,087	1,151	1,224	1,139	0,875	0,935	13,00

The coefficient of variation (CV) of the optical density (OD) is within the range that we normally set in our protocols (except in the case of Control A) and therefore we can state that the standards are repetitive along time.

As follows we show the curves obtained with standards and the galactomannan concentration on controls A and B.



	□ Day 1	□ Day 2	□ Day 3	□ Day 4	□ Day 5	□ Day 6	□ Day 7
Control A	3,045	1,168	2,703	3,084	3,946	6,050	3,601
Control B	0,231	0,278	0,295	0,394	0,330	0,392	0,452

With the exception of Control A which is out of range on days 2 and 6 (it should be between 2.5 and 5ug/ml) taking the CV close to 40%. If we do not take into consideration these two aforementioned days it would be close to 20%.

2. Tests with clinical samples.

	Bio-Rad	Dynamiker
Positive Samples	23	23
Negative Samples	8	8

Total agreement with the Bio-Rad reagent kit was found.

Conclusions/Comments about the results:

- In reference to the reproducibility of the test we can consider that it is in fact repetitive during time, while the high level of Control A can be attributed to OD on a specific day which should be discarded and would then be within range.
- In reference to the exact agreement with Bio-Rad we would have no objections, we would use this data for the final report, resend it to the hospital and compare again with Bio-Rad using more samples.