Evidence-based Comparison of the

Synovasure® Alpha Defensin ELISA Test

and Alpha Defensin Lateral Flow Test

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Diagnostics

Overview:

Alpha defensin biomarker testing is the first test specifically designed and validated for use, as an adjunct to additional tests, in the diagnosis of periprosthetic joint infection (PJI). The test detects human alpha defensins in the synovial fluid of persons with a total joint replacement. Alpha defensins are antimicrobial peptides released by activated neutrophils in response to infection.

There are two test options available: an ELISA test (available via laboratory) and a lateral flow device.

Synovasure Alpha Defensin ELISA Test

Synovasure Alpha Defensin ELISA test is a validated laboratory service performed by trained personnel in a certified laboratory (ie. CLIA (US), DAkkS (Germany), UKAS (UK)) with, typically, a 24–48 hours result turnaround. The Synovasure Alpha Defensin ELISA test is available in the US via CD Laboratories and in the EU via partner labs, the Fenner Lab (Germany) and Golden Jubilee National Laboratory (UK).

Synovasure Alpha Defensin Lateral Flow Test

Synovasure Alpha Defensin Lateral Flow Test utilizes the same anti-microbial peptide to detect the immune response to infection as the ELISA test, but returns results in 10 minutes. The Synovasure Alpha Defensin Lateral Flow Test is available for use in numerous countries throughout the world.

Clinical Validation

In numerous clinical studies, both Synovasure Alpha Defensin test options demonstrated high levels of clinical performance through high sensitivity and specificity (see data table below).

Synovasure Alpha Defensin ELISA Test

Study	N	Sensitivity	Specificity
Rothman Institute[1]	149	97% (36/37)	96% (107/112)
Mayo Clinic[2]	61	100% (19/19)	95% (40/42)
Cleveland Clinic[3]	78	100% (24/24)	98% (53/54)
Endo Klinik[4]	156	97% (28/29)	97% (123/127)
Cleveland Florida[5]	70	97% (34/35)	97% (34/35)
Charite – Universitatsmedizin Berlin[6]	71	85% (11/13)*	98% (57/58)
Multi-center Study[7]**	369	93% (113/122)	98% (241/247)
Combined	**954**	**95% (265/279)**	**97% (655/675)**

Synovasure Alpha Defensin Lateral Flow

Study	N	Sensitivity	Specificity
Multi-center Study[7]**	288	94.3% (50/53)	94.5% (222/235)

Note: Excludes samples with >20% blood

* Includes patients with a draining sinus
** Mayo Clinic, Cleveland Clinic – Florida, Sinai Hospital of Baltimore

Lateral Flow Studies: Understanding the Differences

Several studies have been published that assess the performance of the Synovasure Alpha Defensin Lateral Flow device. A number of factors can influence the performance and results of these studies, for example:

- Using small sample sizes especially with low numbers of PJI positives[8–10] can misrepresent performance of the test
- Potential misuse of LF device such as improper dilution of samples[8] - user should always follow the manufacturer's instructions for use
- Use of criteria different from MSIS as the reference method
- Inclusion of joints with spacers[9]

ELISA Test vs. Lateral Flow Test

In a multi-center prospective clinical study, no statistically significant difference was shown between Synovasure Alpha Defensin ELISA Test and Synovasure Alpha Defensin Lateral Flow Test.[7]

Furthermore, two published clinical studies performed a comparison between the tests:

- Gehrke, *et al.*, demonstrated a 94.8% accuracy between the ELISA and Lateral Flow Test.[11]
- Balato, *et al.*, concluded that "The diagnostic accuracy of the two alpha-defensin assessment methods is comparable".[12]

The Synovasure Alpha Defensin ELISA Test and the Synovasure Alpha Defensin Lateral Flow Test perform nearly equivalent with no statistically significant difference. The tests achieve a sensitivity and specificity of 94% or greater, which can be seen from the clinical studies for both.

References

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2377.2-GLBL-en-Issue Date-2024-06