

# Technology Offer



## Predictive diagnostic marker to differentiate Spondyloarthritis (SpA) from Rheumatoid Arthritis (RA)

### Benefits and value

- Growth Differentiation Factor 15 (GDF15), is a novel marker that allows to discriminate SpA patients from other inflammatory arthritic diseases, in particular RA-patients.
- GDF15 can be measured in serum and synovial fluid.
- GDF15 concentrations are not related to conventional biochemical markers and thus represent an independent method for diagnosis.

### Description

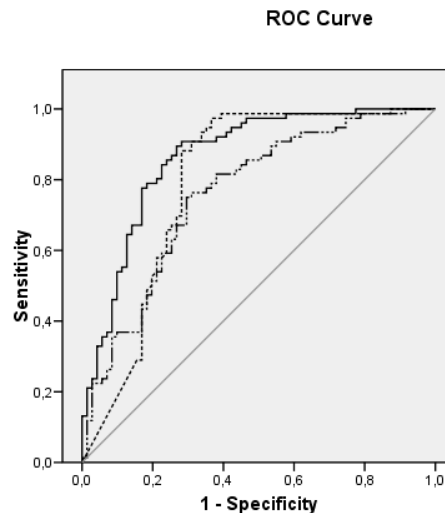
An innovative diagnostic marker has been validated to assist in the diagnosis of patients with clinical signs of inflammatory joint disease. The marker has been proven to create an added value to conventional diagnostic tools in several patient cohorts.

The marker allows discrimination of SpA patients from other inflammatory rheumatic diseases, such as RA, by measurement of GDF15 serum concentrations. Additional diagnostic value may be created by combining serum and synovial fluid analysis. The highly specific ACPA-tests are well known to diagnose RA-patients. However, these test are characterized by a rather low sensitivity. The use of GDF15 may is a clear complementary tool to increase specificity and overall performance of existing diagnostic tests.

### Proof of concept

A primary study was conducted to compare GDF15 serum levels in the most frequently diagnosed inflammatory joint diseases, RA and SpA. SpA patients (502 pg/ml, n=69) showed significantly ( $p < 0,001$ ) lower concentrations to RA patients (992 pg/ml, n=39).

To validate the diagnostic power of the serum marker, GDF15 serum concentration was evaluated in a consecutive cohort of patients diagnosed with RA (n=71) or SpA (n=76). A ROC-curve was established to discriminate SpA from RA patients, using a commercially available ACPA test (dotted line), GDF15 (mixed line) and a combination of GDF15 and ACPA (full line). The highest AUC was found for the GDF15/ACPA combination, clearly indicating the additional value of GDF15 in a diagnostic setting.



In a second retrospective study, patients from two cohorts who currently have a clear diagnosis based on clinical criteria, were re-screened to compare the use of ACPA scoring, either alone or in combination with GDF15 to differentiate patients between RA and SpA.

	% of SpA with SpA diagnosis (sensitivity)	% RA with SpA diagnosis (specificity)
<i>cohorte 1</i>		
ACPA + GDF15	85%	9%
ACPA	94%	38%
<i>cohorte 2</i>		
ACPA + GDF15	86%	25%
ACPA	97%	42%

Conclusion: based on ACPA alone, the sensitivity for SpA diagnosis is very high, however the specificity is low. Inclusion of GDF15 as marker clearly enhances specificity, with only a small decrease in sensitivity.

## IP-position

PCT patent application WO2010/094709

## Collaboration type

- License for use of GDF15 as a diagnostic marker for SpA
- (Joint) development of a new GDF15 diagnostic assay.
- Validation of GDF15 diagnostic assays in patient cohorts.

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