

# Calprotectin for Orthopaedics



LYFSTONE

**Few diagnostic tools are available for diagnostic procedures relating to prosthetic joint infection (PJI). Available diagnostic test holds either insufficient diagnostic accuracy, or are not cost-effective for the health care system.**

In patients with painful joints, the orthopaedic consultant must consider the possibility of infection, and calprotectin LFD offers an easy and cost-effective approach for PJI diagnostics.

Calprotectin (CLP) is a novel PJI biomarker for use in synovial fluid biopsies. CLP is abundantly present in neutrophils (like Alpha-defensine, Synovasure). Presence of neutrophils is a hallmark of acute PJI, and a massive release of CLP occurs upon encounter with pathogens.

Elevated levels of CLP have been demonstrated to hold excellent diagnostic precision for both acute and chronic PJI, with excellent negative prediction value (NPV) for ruling out infection in suspected PJI patients <sup>(1)</sup>.

**Intended use:**

The Calprotectin for Synovial Fluid test is a method for the risk stratification of infection in suspected periprosthetic joint infection (PJI) patients by determination of Calprotectin levels in human synovial fluid samples in combination with the dedicated Lyfstone™ smartphone application. The test is intended as a diagnostic aid for screening of suspected PJI patients in a patient near setting or a laboratory. The test is for professional use only.

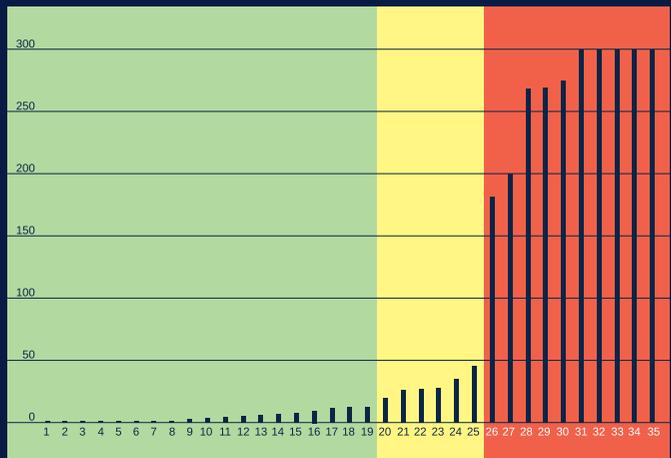
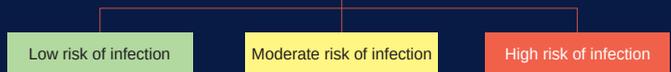
**References**

1: Wouthuyzen-Bakker, M., Ploegmakers, J. J. W., Kampinga, G. A., Wagenmakers-Huizenga, L., Jutte, P.C. and Muller-Kobold, A.C. (2017). "A potential biomarker to exclude a prosthetic joint infection.". The Bone and Joint Journal, 99(B): 660-665.



**PATIENT WITH PAIN**

Joint fluid sample, diluted and tested  
PoCT test for Calprotectin



In-house study on performance of CLP test in synovial fluid biopsies. Results correspond to measured Calprotectin levels in samples documented in the literature

- To our knowledge, this is the first CE-IVD approved test system to aid in exclusion of PJI.
- The test is an easy, fast and quantitative Point of Care test (POCT) designed to give results within 15 minutes.
- Synovial CLP is a biomarker that can be easily implemented in diagnostic for patients with a suspicion of PJI.
- With its high specificity and negative predictive value, synovial CLP can be used to exclude PJI.
- **The CLP test is CE-IVD labelled**

**Interpretation of results:**

- The range of Calprotectin measurements using the device is 14-300 mg/L
- Samples with lower or higher concentrations than 14/300 mg/L <14 mg/L or >300 mg/L
- The App has a risk stratification colour (green, yellow, red) read-out.
  - Green – LOW risk for infection, calprotectin levels <14 mg/L
  - Yellow – MODERATE risk for infection, calprotectin levels between 14- < 50 mg/L
  - Red – HIGH risk for infection, calprotectin levels ≥50 mg/L
- Measurements of <14 mg/L will be interpreted as LOW risk of infection and >300 mg/L will be interpreted as HIGH risk of infection

## LYFSTONE MISSION STATEMENT

Lyfstone AS is a med-tech company developing informative and functional biomarkers for the orthopaedic market.

Our mission is to provide the orthopaedic health care professionals with better tools to make informed decisions and delivering the best patient care.

We aim to offer an easy, fast and quantitative Point of Care testing (POCT) platform for a selected range of orthopaedic biomarkers. The POCT is designed to give results within 15 minutes, and will help in detection of infection, both pre- and post-op, and aids towards a more accurate treatment.

We collaborate with hospitals and researchers in Norway, UK, Belgium and USA.

PHONE: + 47 77 61 11 12  
POST@LYFSTONE.COM  
WWW.LYFSTONE.COM

Further readings and references, see

**lyfstone.com**



P.B. 6430  
SCIENCE PARK TROMSØ  
9294 TROMSØ NORWAY