LYFSTONE

CALPROTECTIN FOR SYNOVIAL FLUID

A RAPID TEST FOR RISK STRATIFICATION OF INFECTION IN PERIPROSTHETIC PATIENTS

INSTRUCTIONS FOR USE

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LIST OF CONTENT

1	**INTENDED USE**		4
2	**BACKGROUND**		4
3	**PRINCIPLE OF THE TEST**		6
4	**MATERIALS**		6
	4.1	Reagents and components supplied within the box	6
	4.2	Materials and equipment required but not supplied	7
5	**IT-Components**		7
	5.1	Set-up of a clinic and initiation of the Lyfstone® CLP reader system	7
	5.2	Registration of a clinic in the Lyfstone® CLP system	7
	5.3	User profiles and privileges in the Lyfstone® CLP system	8
	5.4	Lyfstone® user profiles	9
	5.5	Creating and adding new users with different user privileges in The Lyfstone® Calprotectin for Synovial Fluid system:	10
	5.6	Manage users	10
	5.7	Management of data in clinic interface	10
6	**STABILITY AND STORAGE**		11
7	**PREPARATION**		11
	7.1	Running the test	11
	7.2	Sampling	11
8	**TEST PROCEDURE**		12
9	**QUALITY CONTROL**		13
10	**INTERPRETATION OF RESULTS**		13
11	**PERFORMANCE CHARACTERISTICS**		14
12	**LIMITATIONS OF THE PROCEDURE**		16
13	**CONTRAINDICATIONS**		16
14	**PRECAUTIONS AND WARNINGS**		17
15	**DISPOSIAL CONSIDERATIONS**		17
16	**REFERENCES**		18
17	**ORDERING INFORMATION**		19

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CALPROTECTIN FOR SYNOVIAL FLUID -A RAPID TEST FOR RISK STRATIFICATION OF INFECTION IN PERIPROSTHETIC PATIENTS

1 INTENDED USE

The Lyfstone® Calprotectin for Synovial Fluid test is a method for risk stratification of infection in suspected periprosthetic joint infection (PJI) patients by determination of the calprotectin (CLP) level 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.

2 BACKGROUND

Calprotectin is a biomarker closely associated with leucocytes in general and is present in high volumes in neutrophil cells [1-4]. Calprotectin is also produced by infiltrating monocytes and macrophages, where calprotectin is released upon phagocytosis [5]. In neutrophils, calprotectin is stored intracellularly and are released upon activation of the cell by danger signals from the immune system (danger associated molecular patterns (DAMP). Upon encounter with a pathogen, neutrophils have several strategies to fight infection [4,6]. Ultimately leading to the release of high levels of calprotectin [1,2,4,6]. Activation of neutrophils, and release of calprotectin, can be for any reason causing activation of the complement system and aseptic inflammatory responses [4]. The calprotectin level in synovial fluid do not merely reflect the level of leucocytes and neutrophils present in the fluid, but the calprotectin level is correlated to the white blood cell (WBC) content. Calprotectin is likely to reflect the number of activated cells and surpass the diagnostic accuracy of total WBC counts and neutrophil percentage for PJI diagnosis. In fact, the level of calprotectin is significantly elevated in the synovial fluid of patients with acute joint pathology, and measurement of calprotectin is an excellent strategy to assist the diagnostic decision making concerning the patient flow of suspected joint revision patients.

Wouthuyzen-Bakker and co-workers (2017) demonstrated that a calprotectin level of 50 mg/L in the synovial fluid has very good diagnostic accuracy for PJI, supported by area under the curve values of more than 0.9 [7]. This breakpoint produced a negative predictive value (NPV) of 95% for all 42 patients in the study, meaning that calprotectin levels below 50 mg/L is a very efficient marker for ruling out the presence of infection. The ability to rule out infection was even better in patients suffering from chronic PJI where sub-groups analysis demonstrated NPV of 97% [7].

Inflammation is closely related to infection as both processes recruit immune cells to sites of trauma and tissue damage [4,8,9]. Neutrophils are recruited to infections, whereas elevated levels of activated monocytes/macrophages are associated with aseptic loosening [8-9]. In the particle debris paradigm of aseptic loosening, wear and tear on the joint implant generate debris and formation of small particles which induce tissue damage and inflammation. The immune response recruit monocytes to remove this debris by phagocytosis [8-9]. Monocytes and immature macrophages have a membrane form of calprotectin, and presence of calprotectin-positive cells in the joint also reflects the influx of mononuclear phagocytes [5]. Debris from joint implants activates monocytes/macrophages and activated monocytes shed calprotectin during phagocytosis and attachment to the endothelium [5]. Activated immune cells ultimately leads to degradation of the bone, making the implant unstable and loose [8].

The Lyfstone® Calprotectin for Synovial at the Cleveland Clinic was tested towards three major definitions of PJI. Using 2013 Musculoskeletal Infection Society criteria, the POC test demonstrated a sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and area under the curve (AUC) of 98.1%, 95.7%, 94.5%, 98.5%, and 0.969, respectively. Using the 2018 ICM, the POC test demonstrated a sensitivity, specificity, PPV, NPV, and AUC of 98.2%, 98.5%, 98.2%, 98.5%, and 0.984, respectively. Using the 2019 proposed European Bone and Joint Infection Society criteria, the POC test demonstrated a sensitivity, specificity, PPV, NPV, and AUC of 93.2%, 100.0%, 100.0%, 94.2%, and 0.966, respectively [10].

3 PRINCIPLE OF THE TEST

The Lyfstone® Calprotectin for Synovial Fluid test is based on dilution of a synovial fluid sample in a provided *Sample Diluent* tube. The level of calprotectin is determined by running the diluted sample on the provided lateral flow immunoassay cassette specific for calprotectin.

The sample is added to the sample well of the test cassette and reacts with gold-conjugated antibodies which binds calprotectin. Calprotectin and conjugated antibody complexes travel together along the membrane and bind to calprotectin-specific antibodies immobilized on the test line. This immobilization causes the test line to form. Gold-conjugated antibody without any bound antigen is immobilized on the control line. After ended incubation time the concentration of calprotectin in the sample is calculated by means of the Lyfstone® smartphone application (Lyfstone Reader). The color intensity is proportional with the concentration of calprotectin in the sample.

4. MATERIALS

4.1 REAGENTS AND COMPONENTS SUPPLIED WITHIN THE BOX

A) One / Five Sample diluent tubes	S*ample diluent* tube prefilled with 2 ml calprotectin *Sample diluent* Buffer. The tube is designed to dilute 20 µl of synovial fluid sample and give a 1:101 extract.
B) One / Five Rapid test pouches	Tests individually sealed in aluminium foil with desiccant bag.
C) One / Five Support frames	Rectangular plastic frame with a slot for placement of the rapid test cartridge labelled with a design that allows the smartphone app to identify the position of the control and test line and read the test result.
D) Package leaflet	Quick Instructions, directions to online Instructions For Use

4.2 MATERIALS AND EQUIPMENT REQUIRED BUT NOT SUPPLIED

- Pipettes suitable for pipetting 20 µl and 80 µl
- Aerosol-filter pipette tips
- Timer (optional, also available in app)

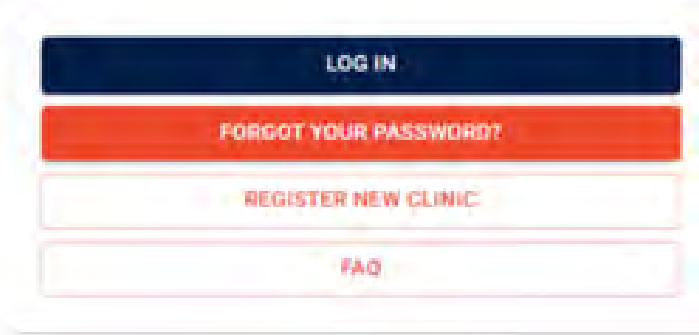
5. IT-COMPONENTS

Lyfstone® Reader Android or Apple app	For reading the test cassette
https://portal.lyfstone.com	For registration of users and data-handling

Before Lyfstone® Calprotectin for Synovial Fluid can be used, a user account must be registered at https://portal.lyfstone.com. Activation of the user account is described below. **The Lyfstone® Reader** app is available at Google play and iTunes App Store.

5.1 SET-UP OF A CLINIC AND INITIATION OF THE LYFSTONE® READER SYSTEM

To implement the system in clinical practice, a clinic (database) must be registered and accounts with user privileges must be assigned to staff members by the clinic administrator.



▲ **Figure 1:**
Front page at https://portal.lyfstone.com

5.2 REGISTRATION OF A CLINIC IN THE LYFSTONE® SYSTEM

Registration of a Clinic (database) is conducted at:
https://portal.lyfstone.com

At the website, click the "**Register a new clinic**" tab at the bottom line (Figure 1).

▲ **Figure 2.**
Registration form at
https://portal.lyfstone.com

Prior to registration a functional e-mail and contact information regarding the clinic must be available (Figure 2). Following registration, a clinic verification at Lyfstone® will be conducted, and as soon as this verification is completed, a link will be sent to the provided e-mail address. Normally, this is conducted within the next business day.
Please read and accept the end-user agreements to activate the clinic and user profile.

5.3 USER PROFILES AND PRIVILEGES IN THE LYFSTONE® CALPROTECTIN SYSTEM

Once the clinic is activated, the Clinic Admin (provided e-mail) can start the registration of additional users such as laboratory technicians, physicians, and other relevant personnel.

There are three (3) different user profiles with different user privileges. Table 1 gives an overview of the different user privileges assigned to each profile. One person (e-mail account) can hold multiple user profiles.

▼ **Table 1.**
Overview user profiles and privileges in **The Lyfstone® Calprotectin for Synovial Fluid** system

User types in Lyfstone® CLP system	Clinic Admin	Lab Tester	Bedside Tester
Register Clinics	X		
Register Lab Tester	X		
Register Bedside Tester	X		
View all patient's test results	X	X	X
Web access	X	X	X
Perform test on Lyfstone® app	X	X	X

5.4 LYFSTONE® USER PROFILES

Clinic Admin

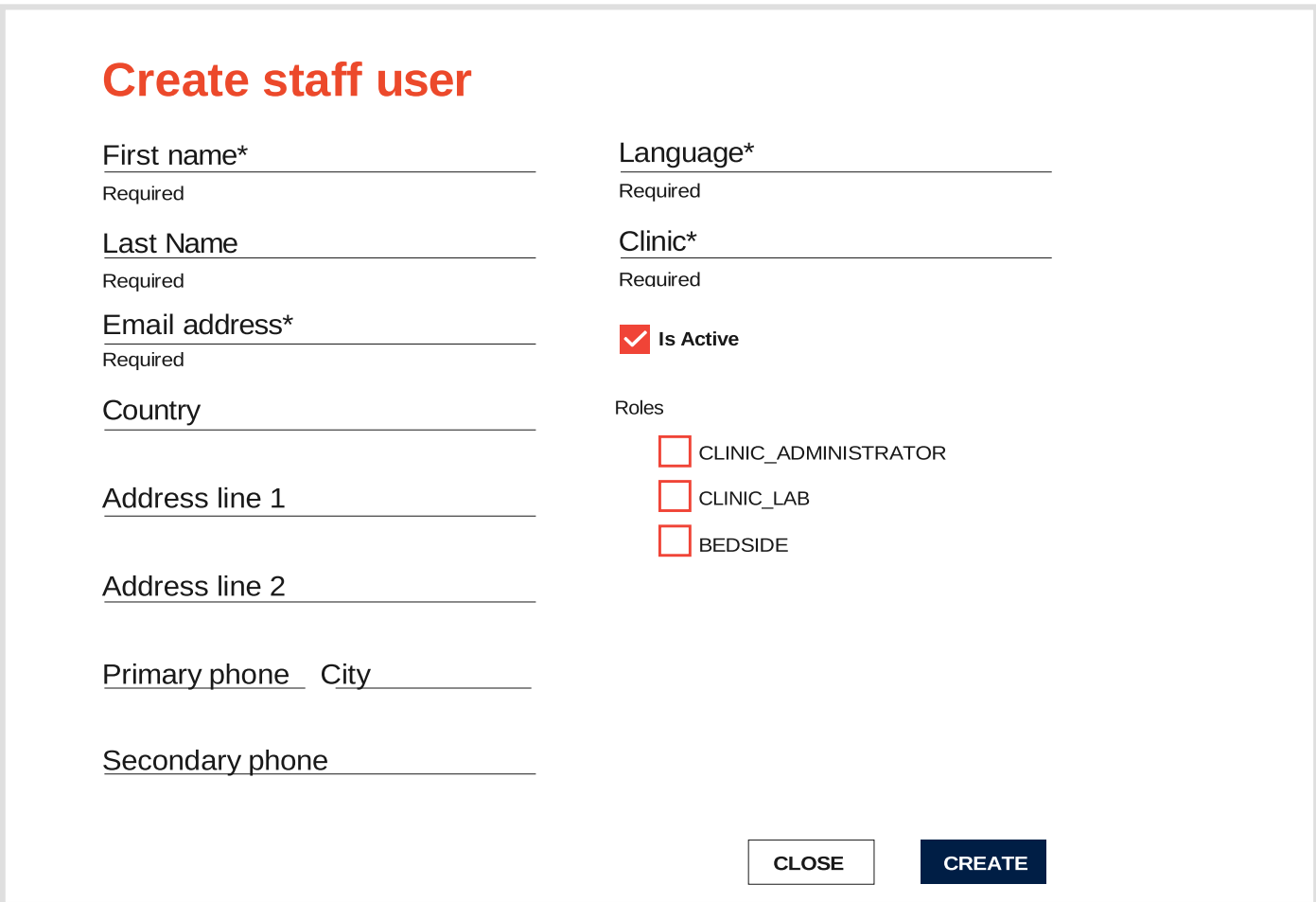
Clinic Admin is the only user profile with permission to create and edit other staff users at the clinic and have the permission to see any results.

Lab Tester

Lab Tester is the person conducting the test. This function gives access to all patients and patient results. This role gives opportunity to skip instructions in the app.

Bedside Tester

Bedside Tester is the person who is next to the patient conducting the test. This function gives access to all patients and patient results.
This role displays instructions in the app without possibility to skip it.



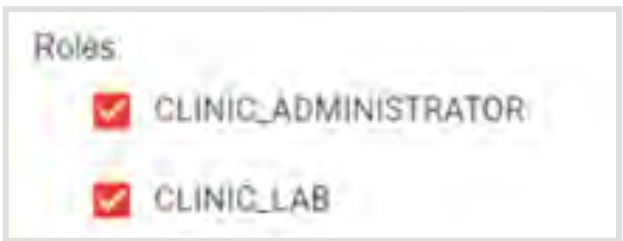
▲ **Figure 3.** Staff User registration form at https://portal.lyfstone.com

5.5 CREATING AND ADDING NEW USERS WITH DIFFERENT USER PRIVILEGES IN THE LYFSTONE® CALPROTECTIN FOR SYNOVIAL FLUID SYSTEM:

Log in as *Clinic Admin* at https://portal.lyfstone.com.
Click "**Staff users**" and "**Create user**" and fill in required fields (Figure 3).
Select the applicable user under Groups. The new user will receive an e-mail to set a password to log in to at https://portal.lyfstone.com.
Clinic Lab and *Bedside users* can download the Lyfstone® Reader application from AppStore or Google Play store when they have completed setting the password for their account.

5.6 MANAGE USERS

To customize **The Lyfstone® Calprotectin for Synovial Fluid** system for small and larger clinics, Staff users in a clinic can have more than one role.
Log in as *Clinic Admin.* click "**Manage user accounts**".
Add functionality/permission to a user under Groups (Figure 4).



◄ **Figure 4:** Edit user panel in the Lyfstone® Calprotectin for Synovial Fluid system.

5.7 MANAGEMENT OF DATA IN CLINIC INTERFACE

Log in to: https://portal.lyfstone.com - You will find the performed test in table "**Test Results**". *Lab Tester* and *Bedside tester* can view and manage the results. (Figure 5).

▲ **Figure 5:** Test Results

6. STABILITY AND STORAGE

When stored unopened at 2 – 8°C, kit reagents are stable up to the expiry date stated on the label. The reagents can be transported in ambient temperature but avoid exposure to high temperatures and direct sunlight.

7. PREPARATION

7.1 RUNNING THE TEST

Test cassettes, *Sample Diluent* device and sample can be used directly from the refrigerator. Avoid running the test at elevated temperatures (≥30 °C), as this can give falsely elevated measurements.

The first time the test is performed, the *Clinic Admin* must register at https://portal.lyfstone.com. It is important that this information is registered prior to performing the first test.

Make sure that the **Lyfstone® Reader app** is installed on your smartphone and check that login is successful before you start the procedure.

7.2 SAMPLING

- Synovial Fluid (SF) should be collected in sterile sample tubes without additives or in EDTA tubes with a final EDTA concentration of <5.4 mg/ml (EDTA tube filled at least 1/3 of full volume).
- SF must NOT be collected and stored in sample collection tubes containing Heparin or Citrate.
- Arthrocentesis should be performed following the clinics procedures.
- The calprotectin measurement must be conducted within 2 hours if the sampled SF is stored at ambient temperature or within 10 hours if the SF is transferred directly to 2-8 °C after sampling.
- The assay tolerates presence of up to 20% blood in the synovial fluid.

8 TEST PROCEDURE

1) Take one rapid test cassette, one sample diluent tube and the support frame from the kit.
2) Inspect the integrity of the test pouch
3) Log in on the Lyfstone® app (Lyfstone Reader)
4) Open the test pouch and place test in the support frame
5) Make a 101x dilution by adding 20 µl synovial fluid to the Sample Diluent tube
6) Invert the tube 10x to homogenize the solution
7) Add 80 µl extracted sample to the round well of the test cassette and incubate at room temperature for exactly 15 minutes
   a. Important: Normally you will see the applied liquid move in the cartridge window. If this is not observed within 15 seconds, a new test cassette must be used.
8) Following the 15 minutes of incubation there is a 2-minute window to make the measurement using the Lyfstone® app.
   a. Hold the smartphone above the sample and align the screen layout with the support frame
   b. The measurement is conducted automatically when the system finds the QR-code.
   c. The Calprotectin concentration and the risk stratification group of the sample is displayed on the screen.
9) Provide sample ID to the sample result
10) Save the measurement.
   a. The saved measurement is automatically transferred to a protected database.
   b. Be mindful with patient identifiable data
   c. Store patient sensitive data in the Lyfstone® app in accordance with your institutional guidelines.

Important: Internet connection is required during login to the app and during transfer of test results to the portal. If losing the internet connection, the results will be transferred to the portal when the internet connection is restored.

9 QUALITY CONTROL

- The control and test lines should be clear and well defined. If the lines are missing or the quality of the lines is not acceptable, the software will be unable to detect the test line, and/or an error message will appear. A new test should be performed if this occurs.
- If the QR-code is damaged, the cassette will not be detected by the software and an error message will appear.

10 INTERPRETATION OF RESULTS:

- The range of calprotectin measurements using the device is 14-300 mg/L.
    - The quantitative calprotectin measurement range is 24-300 mg/L
    - Calprotectin measurements between 14 and 24 mg/L gives a qualitative readout that report “Between 14 and 24 mg/L”
- Samples with lower or higher concentrations than 14/300 mg/L are displayed as <14 mg/L or >300 mg/L.
- The App has a risk stratification color (green, yellow, red) read-out.

Green	**LOW** risk for infection, calprotectin levels <14 mg/L[1]
Yellow	**MODERATE** risk for infection, calprotectin levels between 14- < 50 mg/L [2]
Red	**HIGH** risk for infection, calprotectin levels ≥50 mg/L[3]

The test has two clinically relevant thresholds, 14 and 50 mg/L, generating three risk categories.

- Low risk for infection (green). Calprotectin levels below 14 mg/L (semi quantitative determination).
- Moderate risk for infection (Yellow). Calprotectin levels between 14 and 50 mg/L
- High risk for infection (Red). Calprotectin levels above 50 mg/L.

Using the 50 mg/L threshold Warren et al. [10.] reported the performance for detecting PJI using three separate definitions for PJI (Table 2).
These definitions were:

- 2013 Musculoskeletal Infection Society (MSIS-13)
- 2018 Intentional Consensus Meeting (ICM-18)
- The 2019 proposed European Bone and Joint Infection Society criteria (EBJIS Criteria)

Table 2.
Performance characteristics of LYFCAL005 at 50mg/L

Criteria	Sensitivity	Specificity	Negative prediction value	Positive prediction value	Area under the curve
MSIS13	98.1%	95.7%	98.5%	94.5%	0.969
2018 ICM	98.2%	98.5%	98.5%	98.2%	0.984
EBJIS criteria	93.2%	100.0%	94.2%	100.0%	0.966

The quantitative measurement allows the clinical end user to assess the levels of calprotectin in the joint, and interpretation should be conducted with the consideration of the level of variation reported for the assay.

The 50 mg/L has a better diagnostic accuracy for PJI compared to the 14 mg/L threshold.

For additional information please consult publications at NCBI PubMed for research papers on synovial calprotectin levels.

Only results obtained by the Lyfstone reader app are valid.

11 PERFORMANCE CHARACTERISTICS

- Appearance: the synovial fluid should be without presence of blood and precipitations
- Assay range is from 14 mg/L to 300 mg/L
- Quantitative range is from 24 mg/L to 300 mg/L
- Level of blank is 0 mg/L

- Limit of detection is 2.99 mg/L
- Recovery is 100,12%, ranging between 75-115%
- Precision: Inter-assay CV – 24,6%, Intra-assay CV – 20,4 %.,
- Method agreement: R2 values of 0,98 (20-100 mg/L) and 0,84 (<20, >100 mg/L). The correlation coefficients were 0,99 and 0,91, respectively. All method agreement was conducted with the CalproLAB ALP ELISA kit, production number CALP0170 (Calpro AS).
- Interfering substances: The substances in table 3 were investigated for interfering effects at 1x and 3x expected biological levels. With 95% confidence, presence of hemoglobin in the synovial fluid was found to cause an elevated measurement signal at 66.5 mg/ml and above.

Table 3.
Substances that has been investigated for interfering effects

Substance	Concentration	Interference
Rheumatoid factor	60 IU	Not detected
Hemoglobin	66.5 mg/ml	20.4%
Bilirubin - unconjugated	0.36 mg/ml	Not detected
Bilirubin - conjugated	0.51 mg/ml	Not detected
Hemoglobin/unconjugated bilirubin combination	40/0.36 mg/ml	Not detected
Hemoglobin/conjugated bilirubin combination	40/0.51 mg/ml	Not detected
Triglyceride	12.6 mg/ml	Not detected
Hyaluronic acid	8 mg/ml	Not detected
Metal Ion Cobalt	0.15 mg/ml	Not detected
Metal Ion Chromium	0.15 mg/ml	Not detected
Metal Ion Titanium	0.15 mg/ml	Not detected
Bone cement	10 mg/ml	Not detected
UHMW Polyethylene	10 mg/ml	Not detected
K2 Potassium EDTA	5.4 mg/ml	Not detected
K3 Potassium EDTA	5.4 mg/ml	Not detected

12 LIMITATIONS OF PROCEDURE

- Samples should be collected on sterile tubes or K2/K3 EDTA tubes (see precautions/warnings).
- The test is intended for analysis of undiluted synovial fluid. Saline flushing of the joint when sampling may compromise the test.
- Avoid excess leakage of blood into the synovial fluid. The assay tolerates up to 20% blood in the synovial fluid, at volumes above this the assay may give false results due to blood dilution or hemoglobin interference.
- If the time limit for measuring the test (15-17 minutes) is exceeded, the test must be performed from the start with a new Sample Diluent device and a new rapid test cassette.

13 CONTRAINDICATIONS

The test is a diagnostic aid and it is always important to consider differential diagnosis which might lead to an increased calprotectin level in the joint. Known differential diagnosis with increased calprotectin levels comprise:

- Metal on metal revisions
- Gross aseptic loosening
- Active inflammatory joint diseases
- Gout
- Pseudogout
- Rheumatoid arthritis
- Psoriatic arthritis

Despite the risk of increased levels of calprotectin in these pathologies, the test shows good performance as patients with these joint pathologies are included in clinical studies.

14 PRECAUTIONS AND WARNINGS

- **For CE-IVD use only.**
- **For professional use only.**
- **The test is intended as a Diagnostic aid.**
- Conduct test within 30 minutes of opening the aluminum pouch as moisture will influence the flow of the rapid test
- Inappropriate storage of products may interfere with test performance
- Inspect the pouch for holes/leakages prior to use
- Use gloves during assay preparation
- A **Safety Data Sheet (SDS)** is available at request to support@lyfstone.com
- Use calibrated pipettes only for dispensing correct volumes
- Read the **Instructions for Use** carefully before performing the test.
- Do not measure the same test cassette several times.
- Avoid carrying out the test at very dark (<10 lx) or very bright <2000 lx light conditions, as this can generate elevated measurement signals.
- Avoid carrying out the test at temperatures of 30 °C or above, as this can generate elevated measurement signals
- Do not interchange reagents from different production lots.
- Do not use reagents from other manufacturers with reagents of this test kit.
- Do not use reagents after expiry date stated on the label
- The Sample Diluent buffer contains sodium azide at less than 0.1% (w/v).
- Contact information is provided in the package insert
- A statement concerning GDPR compliance is available at request to support@lyfstone.com

15 DISPOSAL CONSIDERATIONS

Synovial fluid extracts are potentially contagious and should be treated as hazardous waste. Make sure that the *Sample Diluent* tube is completely closed after use to prevent leakage/spillage to the surroundings. All used components should be closed securely and disposed.

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17 ORDERING INFORMATION

Product code: LYFCLP001/LYFCLP005
Lyfstone® Calprotectin for Synovial Fluid
Order at your local distributor or at sales@lyfstone.com

Manufactured by
CALPRO AS
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N-1366 Lysaker, Norway
Net: www.calpro.no
Email: mail@calpro.no
Phone: +47 40 00 42 79

Symbols Key / Symbolschlüssel / Explication des symboles	
IVD	In Vitro Diagnostic Medical Device / In Vitro Diagnosticum / Dispositif médical de diagnostic in vitro
LOT	Lot Number / Chargenbezeichnung / Numéro de lot
	Expiration Date / Verfallsdatum / Date de péremption
	Storage Temperature / Lagertemperatur / Température de conservation
CE	CE Mark / CE-Zeichen / Marquage CE
REF	Catalogue Number / Katalog Nummer / Référence du catalogue
Σ n	Contains sufficient for “n” tests / Ausreichend für “n” Tests / Contenu suffisant pour “n” tests
	Do not reuse / Nicht wiederverwenden / Ne pas réutiliser
	Manufactured by / Hergestellt von / Fabriqué par
i	Follow operating instructions / Bedienungsanweisung beachten / Suivez les instructions d'utilisation

Manufactured by:
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