

## WHITEPAPER

# Biomarker-Based Molecular Support in Inflammatory Dermatoses and Cutaneous T-Cell Lymphoma

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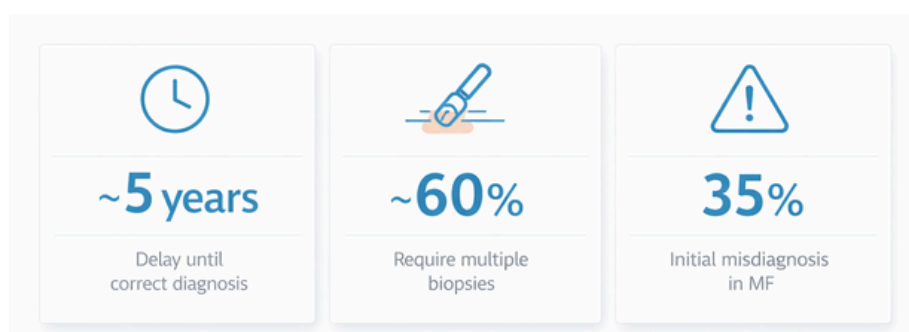
## Background

Diagnosing inflammatory skin diseases can be challenging. **Psoriasis, eczema, and early cutaneous T-cell lymphoma (CTCL)**, particularly **Mycosis Fungoides (MF)**, often present with similar clinical and histological features, especially in early disease stages. As a result, distinguishing between these conditions can be difficult even for experienced dermatologists and dermatopathologists.

Accurate diagnosis is essential because **psoriasis, eczema, and MF are driven by distinct biological mechanisms** and therefore require different therapeutic regimens. Misclassification may lead to ineffective therapy, delayed appropriate treatment, or prolonged disease burden for patients. Clinical evaluation and histopathology remain the foundation of dermatological diagnosis. However, in early or atypical cases these methods may not provide a clear answer.

**Molecular diagnostics adds an objective layer of information** by measuring disease-specific gene expression patterns directly from skin biopsy samples. These molecular signatures can support diagnostic decisions when conventional methods reach their limits. Dermagnostix has developed PCR-based molecular assays designed to integrate into the dermatology diagnostic workflow and provide targeted molecular support in diagnostically challenging cases.

## Diagnostic Challenges in Inflammatory Skin Diseases



Delayed diagnosis of psoriasis by up to 5 years.<sup>1</sup>



Psoriasis & atopic dermatitis overlap and require multiple biopsies and repeated reassessments.<sup>2</sup>



35% of MF patients (**3,5 out of 10**) is initially diagnosed as psoriasis.<sup>3</sup>



## Diagnosis isn't a matter of opinion

Dermagnostix elevates dermatology from surface-level observation to deep molecular diagnostics.



### Clinical Evaluation

Diagnosis begins with a clinical assessment by a dermatologist, considering lesion morphology, distribution, disease history, and prior treatments. Because many inflammatory dermatoses share similar clinical features, the diagnosis may remain uncertain.

### Histopathology

If uncertainty persists, a skin biopsy is examined by a dermatopathologist. Histopathology is the diagnostic gold standard but can be inconclusive in early disease stages, overlapping inflammatory patterns, or therapy-modified lesions.

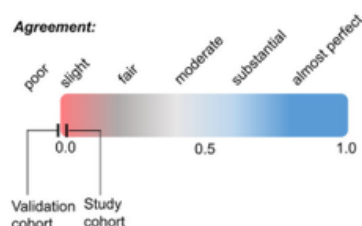
### Molecular Diagnostics

Molecular diagnostics analyzes gene expression in biopsy tissue. Because psoriasis, eczema, and MF have distinct molecular signatures, PCR-based biomarker assays can provide objective information that complements clinical and histological assessment in challenging cases.

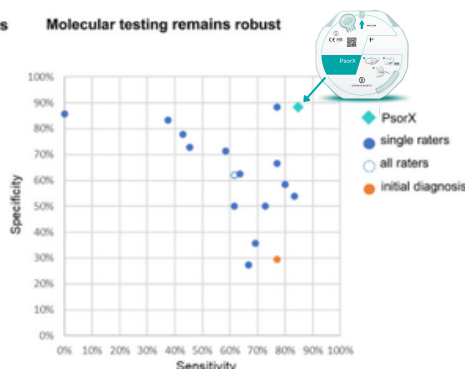
Schmitt et al. (2026): Diagnostic concordance of dermatopathology and PCR in differentiating eczema from psoriasis



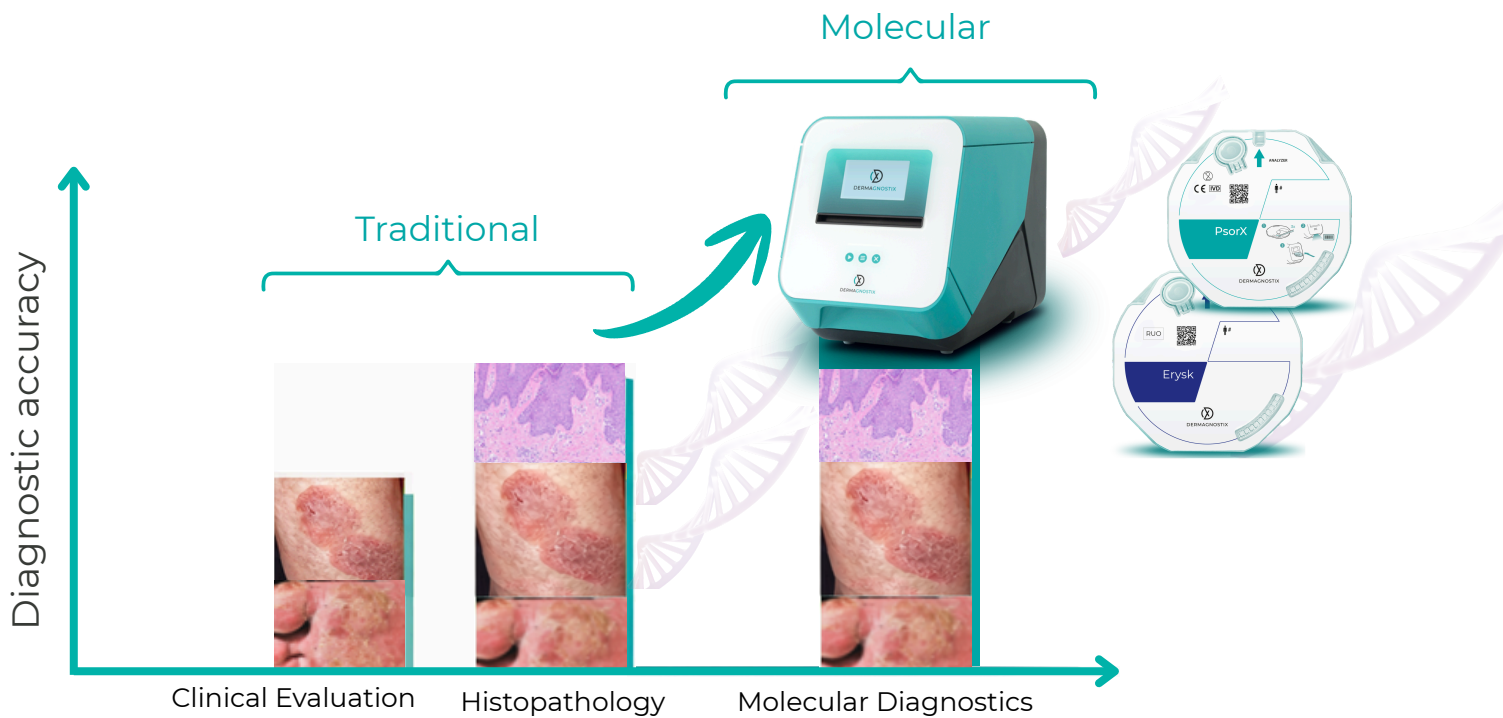
Pathologists disagree substantially in ambiguous cases



Molecular testing remains robust



PsorX-LabDisk maintained outstanding sensitivity and specificity, even in diagnostically ambiguous cases, while dermatopathological assessments showed low diagnostic concordance.



## Psoriasis versus eczema: The urgent need for objective diagnostic data

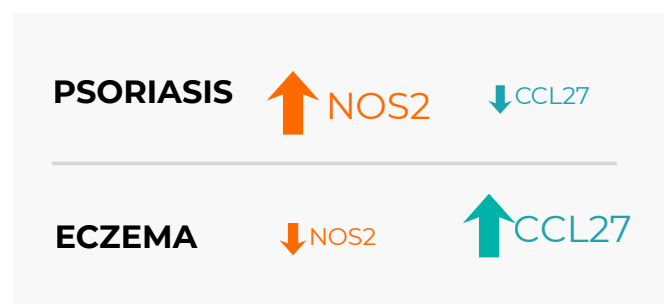
Psoriasis and eczema are among the most common inflammatory skin diseases. Although they are clinically distinct entities, they **can appear very similar** in certain stages or anatomical locations.

Similarly, the **use of artificial intelligence for diagnostic purposes remains limited** at present, as the quality and standardization of available datasets are often insufficient to ensure robust and generalizable performance, supporting the urgent need for objective diagnostic tools.<sup>4</sup>

**At the molecular level, however, both diseases are driven by different inflammatory pathways** that lead to characteristic gene expression profiles.<sup>5</sup> Two biomarkers have proven particularly useful in distinguishing these diseases:

- NOS2 (Nitric Oxide Synthase 2): Highly expressed in psoriatic lesions, stress-induced molecule with multiple functions on immune and metabolic processes.

- CCL27 (Chemokine (C-C motif) ligand 27): Strongly expressed in eczema, involved in recruiting immune cells to the skin in allergic inflammation.



The reciprocal expression of these biomarkers forms the molecular backbone of PsorX-LabDisk, enabling **robust discrimination** between the two most common chronic inflammatory dermatoses.

## PsorX-LabDisk:

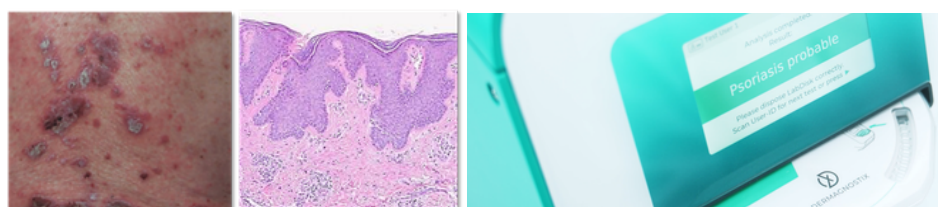
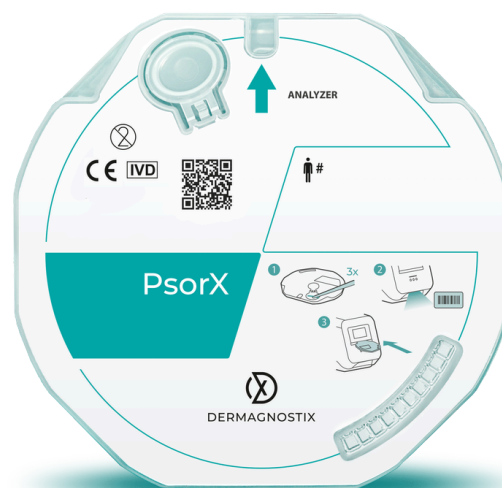
### Molecular Differentiation of Psoriasis and Eczema

#### Clinical Value

PsorX-LabDisk supports dermatopathologists in situations such as:

- ambiguous histological findings
- therapy-modified biopsies
- conflicting clinical information
- confirmation before initiating systemic therapy

By adding molecular data to clinical and histological findings, the test contributes to a more confident diagnostic decision.



#### Scientific Evidence

| Publication                                                                                                                                                                                                                    | Key message                                                                                                                                                                                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Schmitt, A., et al. "Diagnostic Concordance of Dermatopathology and PCR in Differentiating Eczema from Psoriasis." Journal of the European Academy of Dermatology and Venereology. (2026).                                     | Low agreement in dermatopathology ( $\kappa = 0.31$ ; 76.9% accuracy), whereas molecular diagnostics achieves >86% accuracy and high sensitivity (92.9%), making it superior, especially in unclear cases. |
| Bentz, P., et al. "Molecular Diagnostics in Hand Dermatoses: Clinical Findings and Health-Related Quality of Life in a 3-Year Follow-Up Cohort Study." Dermatology and Therapy (2026): 1-10.                                   | Molecular diagnostics increase diagnostic accuracy, enable more targeted therapies, and improve long-term disease outcomes and quality of life.                                                            |
| Papeleu, J., et al.: "From tissue to target: Molecular diagnostics in difficult-to-diagnose psoriasis and eczema." Journal of the European Academy of Dermatology and Venereology (2025)                                       | PsorX provides additional diagnostic value in 86% of cases of ambiguous inflammatory dermatoses.                                                                                                           |
| Gellrich, F., et al.: "Rapid Molecular Differentiation of Psoriasis and Atopic Dermatitis using Skin Biopsy Samples in Clinical Routine: Impact on Therapeutic Decision-Making." Poster presented at EADV Congress 2025, Paris | PsorX serves as a decision-making tool in diagnostically ambiguous cases, including following IL-36 $\gamma$ IHC.                                                                                          |

## Scientific Evidence

| Publication                                                                                                                                                                                                                                                              | Key message                                                                                                                                                |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Fischer, F., et al.: "Gene Expression–Based Molecular Test as Diagnostic Aid for the Differential Diagnosis of Psoriasis and Eczema in Formalin-Fixed and Paraffin-Embedded Tissue, Microbiopsies, and Tape Strips." <i>Journal of Investigative Dermatology</i> (2023). | Validation of the NOS2/CCL27 classifier in FFPE, microbiopsies, and tape strips from a total of 213 patients                                               |
| Bauer, A., et al. "S2k guideline diagnosis, prevention, and therapy of hand eczema." <i>JDDG: Journal der Deutschen Dermatologischen Gesellschaft</i> 21.9 (2023): 1054-1074.                                                                                            | Mention of the NOS2/CCL27 classifier as a diagnostic tool in the current S2k guideline "Diagnosis, prevention, and treatment of hand eczema (HE)"          |
| Böhner, A., et al. "The neglected twin: Nummular eczema is a variant of atopic dermatitis with codominant TH2/TH17 immune response." <i>Journal of Allergy and Clinical Immunology</i> (2023).                                                                           | Application of the NOS2/CCL27 Classifier in 36 patients with nummular eczema.                                                                              |
| Dickel, H., et al. "German S1 guideline: Contact dermatitis." <i>JDDG: Journal der Deutschen Dermatologischen Gesellschaft</i> 20.5 (2022): 712-734.                                                                                                                     | Recommendation of NOS2/CCL27 in the S1 guideline on contact dermatitis.                                                                                    |
| Stoffel, E., et al. "Analysis of anti-tumour necrosis factor-induced skin lesions reveals strong T helper 1 activation with some distinct immunological characteristics." <i>British Journal of Dermatology</i> 178.5 (2018): 1151-1162.                                 | Application of the NOS2/CCL27 classifier to 19 patients with eczematous and psoriasiform conditions for diagnostic classification.                         |
| Brunner, P., et al.: "Early-onset pediatric atopic dermatitis is characterized by TH2/TH17/TH22-centered inflammation and lipid alterations." <i>Journal of Allergy and Clinical Immunology</i> 141.6 (2018): 2094-2106.                                                 | Application of the NOS2/CCL27 Classifier in 19 children with atopic dermatitis.                                                                            |
| Garzorz-Stark, N., et al.: "A novel molecular disease classifier for psoriasis and eczema." <i>Experimental dermatology</i> 25.10 (2016): 767-774.                                                                                                                       | Validation of the NOS2/CCL27 classifier in 129 patients with classic and specific forms of psoriasis and eczema, with sensitivity and specificity of >95%. |
| Quaranta, M., et al.: "Intraindividual genome expression analysis reveals a specific molecular signature of psoriasis and eczema." <i>Science translational medicine</i> 6.244 (2014): 244ra90-244ra90.                                                                  | Validation of the NOS2/CCL27 classifier in 53 patients (psoriasis n=25, eczema n=28).                                                                      |

## Erysk-TargetDisk (RUO):

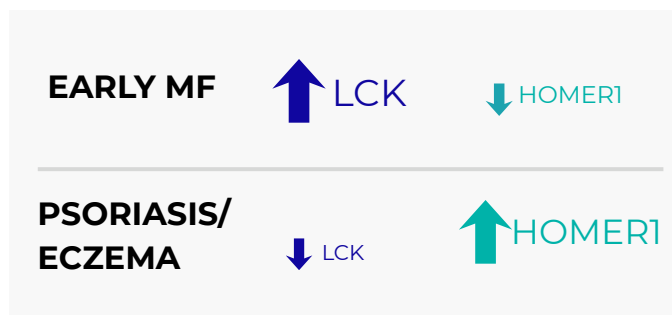
### Measurement of biomarkers of early mycosis fungoides

Early Mycosis Fungoides represents **one of the most difficult diagnostic challenges** in dermatology. Patch-stage MF can clinically and histologically **mimic inflammatory dermatoses** for years before a clear diagnosis becomes possible. Patients often undergo multiple biopsies before the disease can be definitively classified.

A survey among physicians revealed that **82% believe the diagnosis of early-stage MF is frequently delayed**, primarily due to its misclassification as a benign inflammatory dermatosis - leading to impairment of therapeutic efficacy and negative effect on patients' quality of life.<sup>6</sup>

At the molecular level, however, malignant T-cell signaling differs from benign inflammatory processes. Two biomarkers capture these differences:

- **LCK** (Lymphocyte-Specific Protein Tyrosine Kinase): Upregulated in MF, reflecting malignant T-cell signaling, while downregulated in psoriasis and eczema.
- **HOMER1**: Downregulated in MF, but highly expressed in psoriasis and eczema, representing preserved inflammatory signaling pathways in benign conditions.

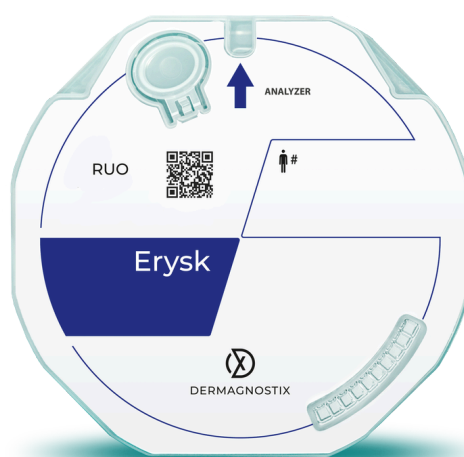


The inverse regulation of LCK and HOMER1 creates a molecular signature that aids in distinguishing MF from the benign inflammatory dermatoses.

### Clinical Value

Erysk-TargetDisk provides molecular support in cases of:

- Suspected early or patch-stage MF
- Repeated biopsies with unclear diagnosis
- Long-standing, therapy-resistant inflammatory lesions

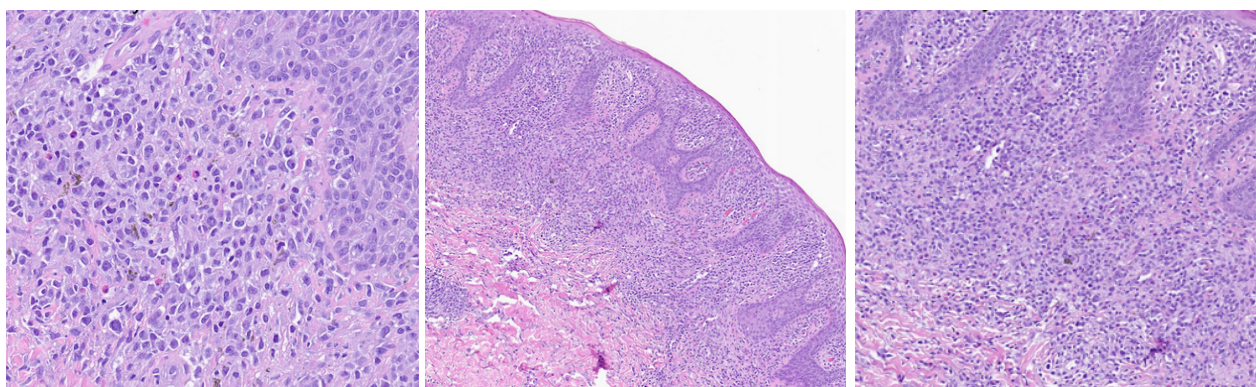


## Erysk-TargetDisk (RUO): Measurement of biomarkers of early mycosis fungoides

### Scientific Evidence

The diagnostic relevance of LCK and HOMER1 has been demonstrated:

| Publication                                                                                                                                                                                                                                            | Key message                                                                                                                                                                                                                  |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Meinel, M., et al.: "LCK and HOMER1 gene expression-based classifier distinguishes early mycosis fungoides from eczema and psoriasis." medRxiv (2025): 2025-10.                                                                                        | Development of a gene expression-based molecular classifier to reliably distinguish early mycosis fungoides (MF) from eczema and psoriasis, in order to reduce misdiagnosis, delay in treatment, and diagnostic uncertainty. |
| <b>State of the Art &amp; Guidelines</b>                                                                                                                                                                                                               |                                                                                                                                                                                                                              |
| Pimpinelli, N., et al. "Defining early mycosis fungoides." Journal of the American Academy of Dermatology 53.6 (2005): 1053-1063.                                                                                                                      |                                                                                                                                                                                                                              |
| Kempf, W., et al. "Classifications of cutaneous lymphomas and lymphoproliferative disorders: An update from the EORTC cutaneous lymphoma histopathology group." Journal of the European Academy of Dermatology and Venereology 38.8 (2024): 1491-1503. |                                                                                                                                                                                                                              |
| Dippel, E., et al. "S2k-guidelines-cutaneous lymphomas (ICD10 C82-C86): update 2021." Journal Der Deutschen Dermatologischen Gesellschaft 20.4 (2022): 537.                                                                                            |                                                                                                                                                                                                                              |



## From biomarker discovery to clinical impact

Accurate diagnosis of chronic inflammatory skin diseases and early cutaneous T-cell lymphoma such as Mycosis Fungoides can be challenging. Clinical evaluation and histopathology remain the foundation of dermatological diagnosis, but both approaches may reach their limits in early disease stages or atypical presentations.

**Molecular diagnostics provides an additional layer of information** by measuring disease-specific gene expression directly from skin biopsies. Integrated into the diagnostic workflow, molecular biomarker assays can **support dermatopathologists and clinicians in differentiating inflammatory dermatoses from malignant conditions** and in reaching more confident diagnostic decisions.

Dermagnostix molecular assays complement the dermatological diagnostic workflow by providing targeted molecular information where conventional methods reach their limits. **PsorX-LabDisk** and **Erysk-TargetDisk (RUO)** are based on Dermagnostix's Disk technology, enabling standardized and reproducible gene expression analysis directly from FFPE skin biopsies.

For more information, don't hesitate to get in touch with [info@dermagnostix.com](mailto:info@dermagnostix.com)

or visit our website to read the studies:



## References

- <sup>1</sup> Tabik, et al. Mapping opportunities for the earlier diagnosis of psoriasis in primary care settings in the UK: results from two matched case-control studies. Br J Gen Pract. 2022 Oct 27;72(724):e834-e841
  - <sup>2</sup> Brănișteanu, et al. Diagnostic and Therapeutic Challenges in Psoriasis-Atopic Dermatitis Overlap: A Retrospective Observational Cohort Study" Diagnostics 15, no. 11: 1381.
  - <sup>3</sup> Zech IM, et al. ADO congress 2024 Würzburg: Abstract #eP134
  - <sup>4</sup> Liu, et al. Artificial intelligence in psoriasis: Where we are and where we are going. Exp Dermatol. 2023;32:1884-1899.
  - <sup>5</sup> Schäbitz, et al.: "So close, and yet so far away: The dichotomy of the specific immune response and inflammation in psoriasis and atopic dermatitis." Journal of internal medicine 290.1 (2021): 27-39.
  - <sup>6</sup> Beatty, et al. The diagnosis of early-stage mycosis fungoides: Views held by experts and non-experts in cutaneous lymphoma. JDDG: Journal der Deutschen Dermatologischen Gesellschaft. 2025;23:1094-1102
- Histopathological images (access date: 01.04.2026):  
<https://www.pathologyoutlines.com/topic/skintumornonmelanocyticmycosisfungoides.html>



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