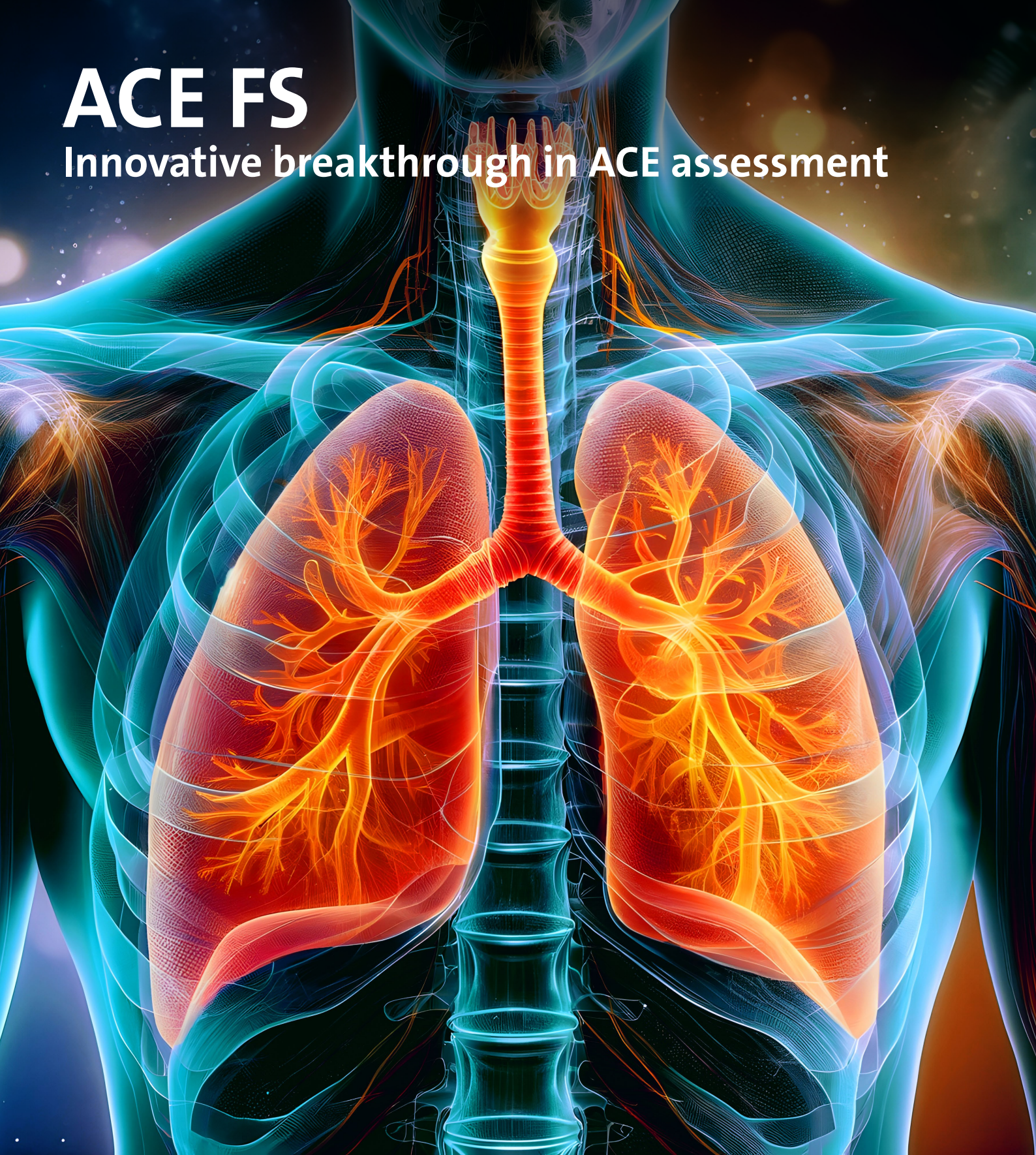


ACE FS

Innovative breakthrough in ACE assessment



DiaSys. Specialties beyond routine testing.

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ACE and its clinical significance

Angiotensin-converting enzyme (ACE) is a central component of the renin-angiotensin-aldosterone system (RAAS), which plays a crucial role in maintaining circulatory homeostasis. By catalyzing the conversion of angiotensin I into angiotensin II, ACE promotes vasoconstriction [1, 2]. ACE is predominantly localized on the luminal surface of vascular endothelial cells across various organs, including kidneys, heart, brain, skin, and striated muscle. Notably, the highest ACE activity is reported in endothelium of pulmonary capillaries [3].

ACE FS is intended to be used in conjunction with other tests to confirm the diagnosis of sarcoidosis, for long-term assessment of clinically active sarcoidosis, and to monitor the efficacy of initiated drug therapy. In addition, emerging evidence suggests that ACE activity assessment in cerebrospinal fluid (CSF) may serve as a potential biomarker for the diagnosis of Alzheimer's disease [6].

ACE in sarcoidosis

Sarcoidosis is a multisystemic inflammatory disease that affects various tissues and organs, with the lungs being the most involved. This disorder is mainly characterized by formation of non-caseating inflammatory granulomas. The diagnosis of sarcoidosis is challenging, since there is no directly linked marker reported to the disease. Consequently, it is mainly diagnosed by exclusion of other granulomatous conditions. Interestingly, ACE activity has been reported to exhibit distinct patterns in patients with sarcoid granulomas compared to those with other types of granulomas, as following:

Patients diagnosed with acute sarcoidosis	→	Increased ACE activity
Patients exhibiting other granuloma types	→	Unchanged ACE activity
Treated sarcoidosis patients	→	Normalized ACE activity

Therefore, ACE activity is widely assessed as a supportive tool to diagnose sarcoidosis and to initiate timely therapy. The incidence and prevalence of sarcoidosis are influenced by several factors such as ethnicity, age, and sex, with notable variations observed across different populations and geographic regions [7].

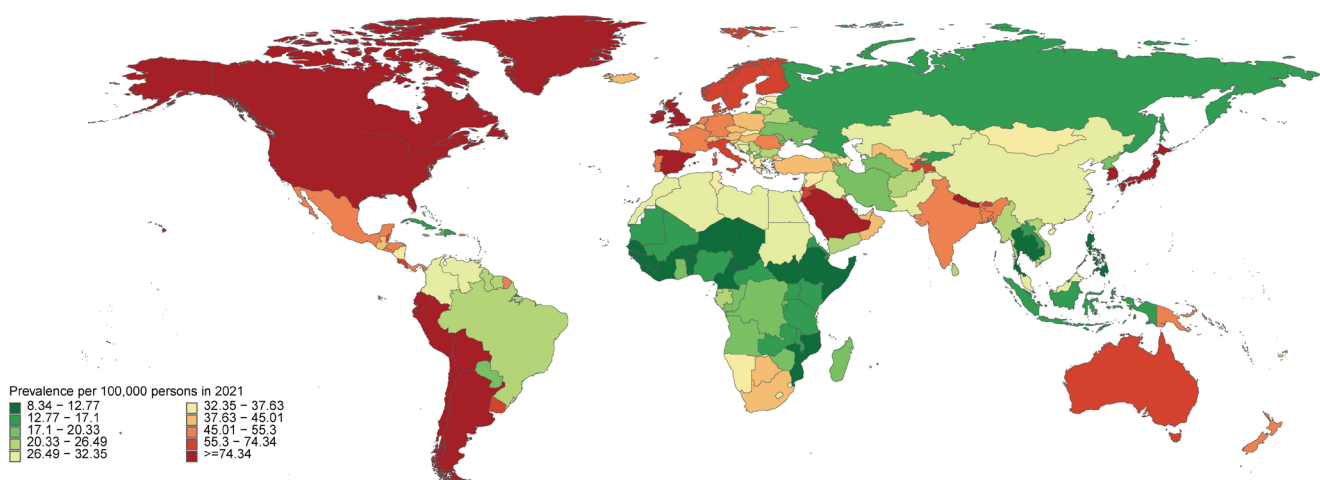


Figure 1. Sarcoidosis prevalence globally by 2021 [7].

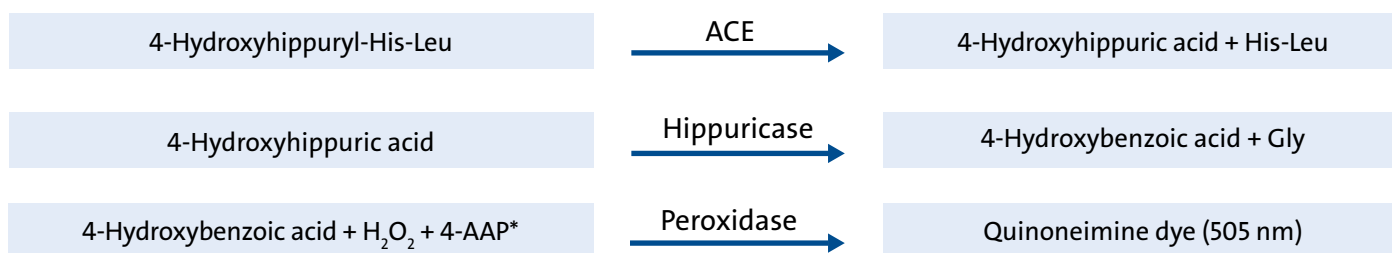
Additionally, it has to be mentioned that only 60-70% of patients reveal elevated ACE activity [8].

The heart of innovation

Currently, the FAPGG method is the only commercially available assay for ACE activity that is specifically designed for use on clinical chemistry analyzers. Despite its widespread use, this method generates low signals and is highly vulnerable to analytical errors.

DiaSys latest innovation ACE FS overcomes these limitations, offering a robust and reliable alternative for ACE activity determination. The newly defined and advanced hippuricase-based assay, which can be used on clinical chemistry analyzers, operates through a three-step enzymatic chain reaction.

A key feature of this method is the use of efficient peroxidase-based dye formation, which enables the generation of high absorbance signals and thereby ensures high linearity, excellent accuracy and precision.



*4-Aminoantipyrine

This liquid-stable, two-component assay demands only a low sample volume, making it suitable for routine clinical use. Moreover, its reduced susceptibility to analytical interference—particularly from substances like lipemia—further enhances its reliability, making it a valuable choice for ACE activity determination in clinical diagnostics.

Performance characteristics

Key performance features of ACE FS:

Feature	Outcome
Limit of quantitation (LoQ)*	5 U/L
Linearity*	5 – 175 U/L
Repeatability	≤ 1.60 %
Deviation from EQA samples	≤ 17 %

* Reference range 13.3 - 63.9 U/L [9]

Performance highlights of DiaSys ACE FS vs. leading competitor:

Parameter	DiaSys ACE FS	Leading competitor
Sample volume	6 µL	30 µL
Interfering substances:		
Bilirubin (conjugated)	30 mg/dL	6 mg/dL
Bilirubin (unconjugated)	12.5 mg/dL	4.7 mg/dL
Hemoglobin	200 mg/dL	119 mg/dL
Hemolysis	600 mg/dL	n.a.
Lipemia	1000 mg/dL	224 mg/dL
N-acetylcysteine (NAC)	500 mg/dL	n.a.
Wavelength	505 nm	340 nm*

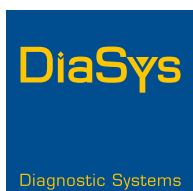
* susceptible to interfering substances (e.g. lipemia)

DiaSys leading technology in fluid-stable reagents

- Over 33 years of experience in development and production of clinical chemistry tests
- Premium service in techniques, applications, and after sales
- Quality products made-in-Germany
- High performance, ready-to-use reagents with minimized interferences, long shelf-life and on-board stability as well as traceability to international references
- Perfectly matched fluid-stable reagents, calibrators, and controls
- High-grade raw materials from traceable origin
- Processes and resources certified according to IVDR, ISO 13485 and MDSAP, fulfilling highest quality standards
- Sustainable processes and products preserve the environment

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