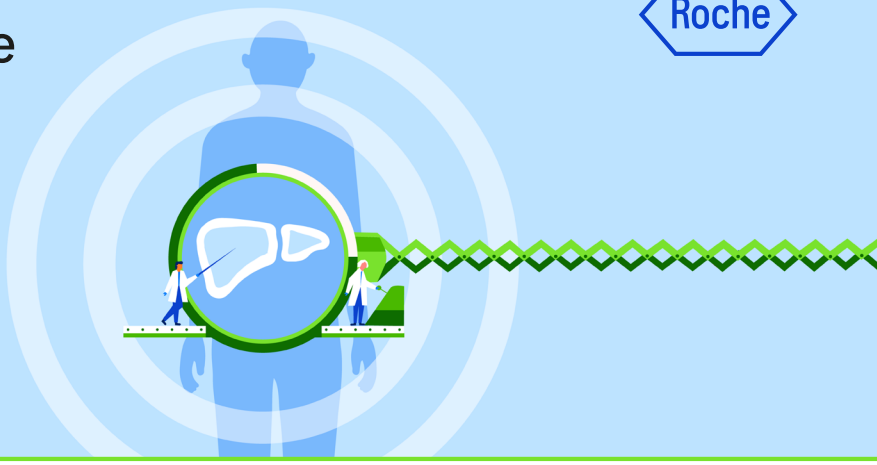
navify® Algorithm Suite

GAAD

GAAD test for the aid in diagnosis of Hepatocellular Carcinoma (HCC). Supporting our mission to stop chronic liver disease.



Cases of hepatocellular carcinoma (HCC) are on the rise, especially in developed countries.[1] Occurring almost exclusively in patients with chronic liver disease,[2] HCC is the most common form of liver cancer, accounting for nearly 90% of liver cancers, and is also the third leading cause of cancer death.[3–5]

HCC is often not symptomatic until the later stages, at which the 5-year survival rate can be less than 5%, meaning growing numbers of patients with liver cancer are progressing silently towards a lower chance of survival.[3,6]

The opportunity

We need to diagnose HCC earlier. In fact, in high-risk groups, biannual screening has decreased HCC mortality by 37%.[7]
With high sensitivity and specificity for differentiating early stage HCC and benign chronic liver disease, the GAAD Algorithm aids in the diagnosis of HCC (early and all stages).[8]

Using GAAD to amplify all stage HCC signs

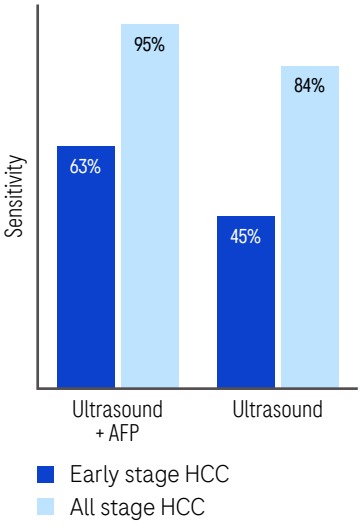
Although **ultrasound** is a widely used surveillance tool with proven clinical utility for HCC, when used alone, it only has a **sensitivity of 45%** in early stage diagnosis.[9]

In a multicenter evaluation study, **GAAD** has a **specificity of 93.7%** and a **sensitivity of 70.1% and 83.1%** for early stage and all stages of HCC detection, respectively.[10]

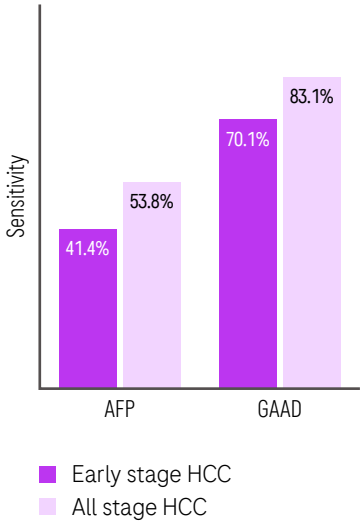
Results from a research study conducted in Taiwan and supported by Roche showed that the combination of **GAAD and ultrasound** leads to a **sensitivity of 92.5%** for all stages of HCC detection.[11]

HCC early and all stages – diagnostic sensitivity of different methods

Results from a meta-analysis[9]



Results from GAAD multicenter evaluation study[10]



navify®

Roche

CE 0123 **CE mark**
Class C IVDR

On market

- **Gender (at birth)**
- **Age**
- **Elecsys® AFP**
- **Elecsys® PIVKA-II**

GAAD*

Gender, Age, AFP, DCP (PIVKA-II).
Aid in diagnosis for HCC (early and all stages).

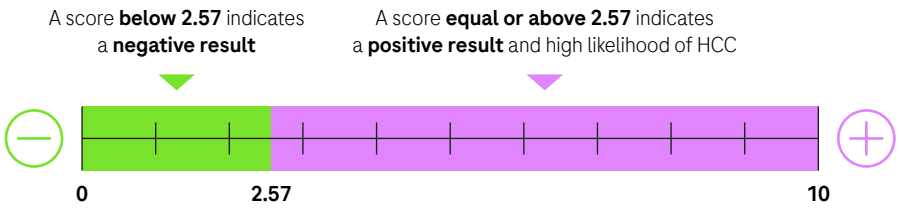
Both Elecsys® assays on a **fully automated IVD** platform[12,13]

Clinical performance validated in a multicenter evaluation study[10]

Superior performance to AFP alone[10]

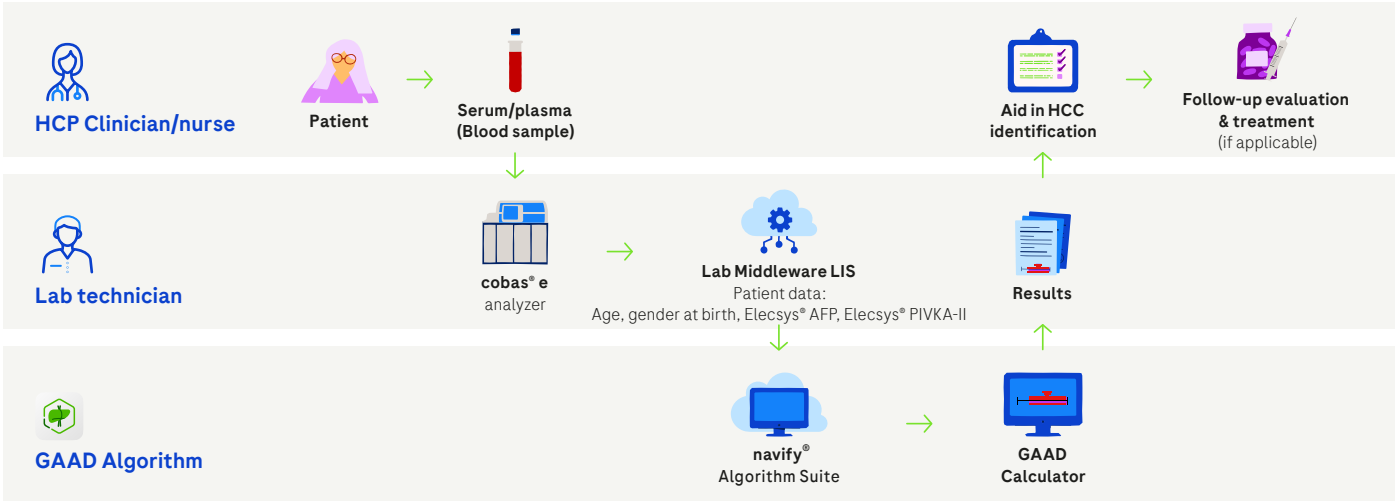
Interpreting the GAAD score

The calculated GAAD score is evaluated with a predefined cut-off 2.57. The GAAD score ranges from 0 to 10.*



Integration into your existing workflows

GAAD integrates directly into your current workflow with **navify®** Algorithm Suite.



Turn up the volume on HCC detection!

The diagnostic algorithm is ready to use right now, scan here to find out more.

GAAD is CE-marked (NB 0123). Not available in the US. Local registration status varies according to local regions. Please confirm the registration status of GAAD with your local Roche representative.

*GAAD must be interpreted in conjunction with other diagnostic findings and clinical information, and assays values must be determined from the same sample.

1. Fitzmaurice T et al. The burden of primary liver cancer and underlying etiologies from 1990 to 2015 at the global, regional, and national level: Results From the Global Burden of Disease Study 2015. JAMA Oncol 2017;3:1683–1691.
2. Bartosch B. Hepatitis B and C Viruses and Hepatocellular Carcinoma. Viruses 2010;2:1504.
3. El-Serag HB et al. Surveillance for hepatocellular carcinoma: in whom and how? Ther Adv Gastroenterol 2011;4: 5–10.
4. Llovet JM et al. Hepatocellular carcinoma. Nat Rev Dis Prim 2016;14:2:16018.
5. Bray F, Laversanne M, Sung H, Ferlay J, Siegel RL, Soerjomataram I, Jemal A. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2024 May-Jun;74(3):229-263. doi: 10.3322/caac.21834. Epub 2024 Apr 4. PMID: 38572751.
6. Kao WY et al. Prognosis of Early-Stage Hepatocellular Carcinoma: The Clinical Implications of Substages of Barcelona Clinic Liver Cancer System Based on a Cohort of 1265 Patients. Medicine (Baltimore). 2015 Oct;94(43):e1929.
7. Zhang BH et al. Randomized controlled trial of screening for hepatocellular carcinoma. J Cancer Res Clin Oncol 2004;130: 417–22.
8. GAAD Method Sheet, for Material #09964533001.
9. Tzartzeva et al. Surveillance Imaging and Alpha Fetoprotein for Early Detection of Hepatocellular Carcinoma in Patients With Cirrhosis: A Meta analysis. Gastroenterology. 2018 May;154(6):1706–1718.e1.
10. Piratvisuth T et al. Development and clinical validation of a novel algorithmic score (GAAD) for detecting HCC in prospective cohort studies. Hepatology Communications 2023 November;7(11): e0317.
11. Chung-Feng Huang et al. The clinical utility of Elecsys GAAD score the diagnosis of hepatocellular carcinoma. Poster presented at: APASL Single Topic Conference on Hepatocellular Carcinoma; 2022 June 23–25; Taipei, Taiwan.
12. Elecsys AFP Method Sheet, for Material #09015060190 and Material #09015124190.
13. Elecsys PIVKA-II Method Sheet, for Material #09015043190 and Material #09014985190.