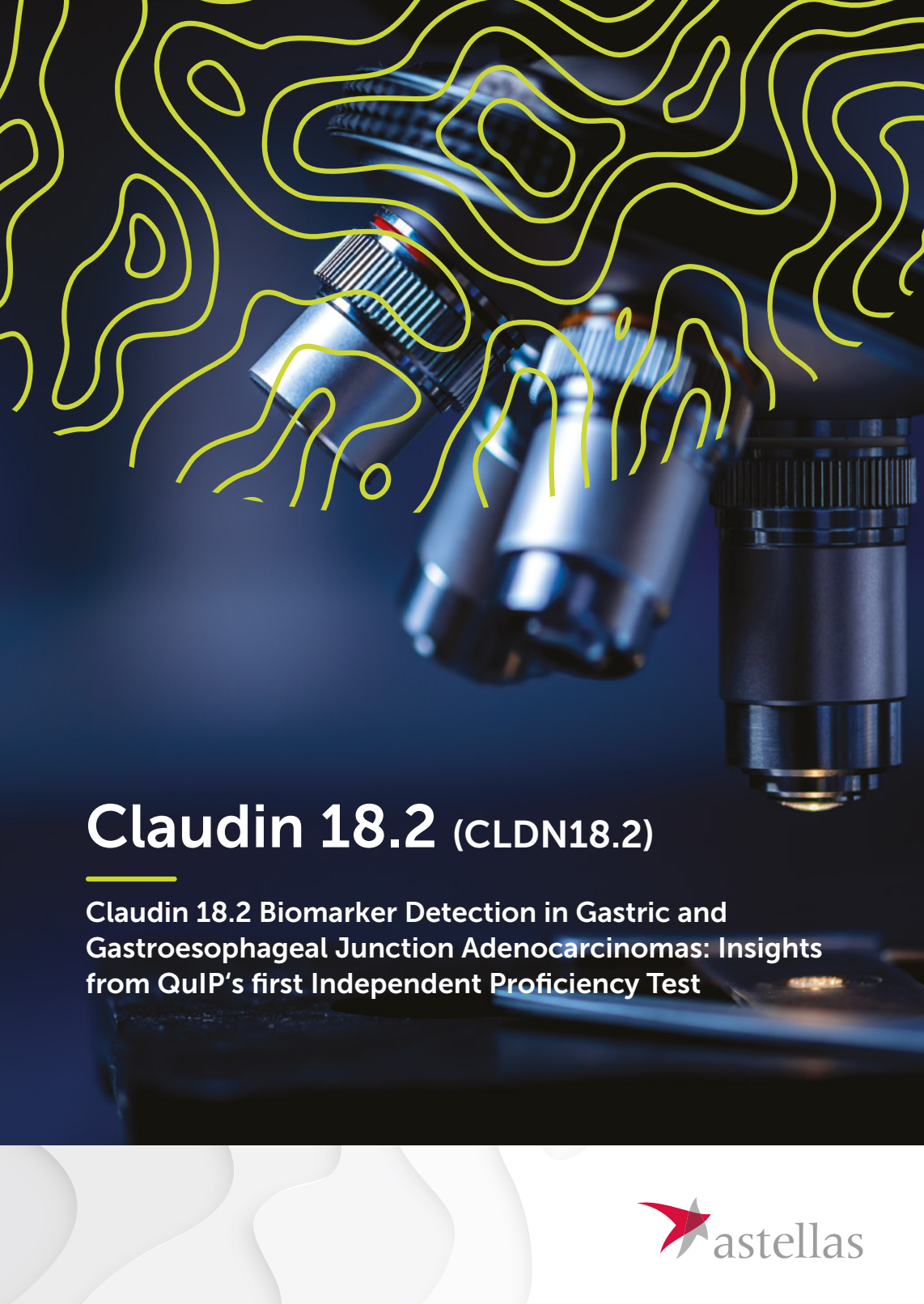


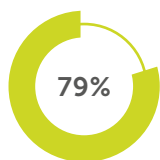
A close-up, low-angle shot of a microscope's objective lenses, which are metallic and have a ribbed texture. The background is dark blue. Overlaid on the image are several bright yellow, hand-drawn contour lines that meander across the top and middle of the frame, resembling a topographic map.

Claudin 18.2 (CLDN18.2)

Claudin 18.2 Biomarker Detection in Gastric and Gastroesophageal Junction Adenocarcinomas: Insights from QULP's first Independent Proficiency Test

For successful participation in the OPT, participating institutes had to correctly categorize (i.e., submit a result that was concordant with the reference value) for > 90% of cases.

Key Takeaways

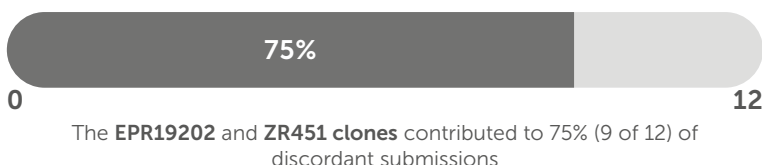


of institutes correctly evaluated **CLDN18.2 status** in $\geq 90\%$ of cases in the OPT



of institutes correctly evaluated **CLDN18.2 status** in $\geq 90\%$ of cases without the CLDN18.2-specific **EPR19202 and ZR451 clones**

- Main factor for accurate analysis was the choice of an appropriate antibody clone.
- The 43-14A clone detects both CLDN18.1 and CLDN18.2 isoforms and was associated with optimal staining results. When evaluating G/GEJ tumour tissue, staining can be attributed to the presence of CLDN18.2 due to localisation in certain tissue types.
- Interpretation errors were not a main contributing factor.
- The main source of errors was false negative results.



Optimized staining protocols and the use of CLDN18 antibody clones with high analytical performance will lead to accurate diagnosis of CLDN18.2 status. Continual monitoring of biomarker testing quality through EQA programs, regardless of antibody used, is necessary to ensure accuracy of patient test results.

Performance Overview

A total of 79.2% (42 out of 53) participating institutes successfully passed the IPT.

- Among the CLDN18-specific antibodies, **the CLDN18 (43-14A)** clone was the most frequently utilized and demonstrated consistent performance, with no significant technical or interpretive issues reported.
- In the evaluation of CLDN18.2-specific antibodies, significant issues were identified with staining quality. Two antibody clones were found to account for 75% of the unsuccessful submissions:
 - **EPR19202 clone:** Achieved a 0% success rate (0 out of 5 participants), due to low sensitivity and weak staining intensity.
 - **ZR451 clone:** Reached a 56% success rate (5 out of 9 participants), but exhibited low staining specificity.

Key Considerations

- Accurate determination of CLDN18.2 status relies on the use of **well-optimized staining protocols** and **high-performance antibody clones**.
- To ensure reliable patient test results, **it is essential to maintain ongoing quality control through external quality assurance programs**, regardless of the antibody clone employed.

Abbreviations:

CLDN – Claudin; **ab** – antibody; **IPT** – Independent Proficiency Test; **OPT** – Open Proficiency Test; **LDT** – Laboratory-Developed Test; **UKSH** – University Medical Center Reference-Holstein.

Reference: Röcken C, Höhn AK, Neumann J, Schildhaus HU, Singer S, Clauditz TS, Quaas A, Jöhrens K. Concordance of laboratory assays for claudin 18.2 in gastric cancer tissue samples: independent proficiency testing and a descriptive non-interventional study. Virchows Arch. 2025 Jun 28.

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Think You've Mastered Claudin 18.2?

Put your knowledge to the test with 15 interactive, expert-curated cases on the **Claudin 18.2** website (www.cldn182.pl)

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TO ACCESS
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WEBSITE**