CLDN18.2 Reporting Status by IHC

Developed collaboratively by the CLDN18.2 Expert Committee, the following template can help you generate and integrate CLDN18.2 reporting into your current protocols.

Scoring algorithm

Percentage of tumour cells demonstrating moderate-to-strong (2+/3+) membranous CLDN18-specific staining.

Percentage of tumour cells with membranous staining

Tumour cells with moderate staining (2+): _____

Tumour cells with strong staining (3+): _____

Total tumour cells with moderate-to-strong (2+/3+) staining: _____ (Sum of 2 lines above)

CLDN18.2 status

(Select one)

Inconclusive Positive (≥75% tumour staining)

_____ Negative (<75% tumour staining)

CLDN18.2 testing method (Protein expression by immunohistochemistry)

(Select one)

 HC IVD-approved test:
 (Specify test/vendor)

 Laboratory-developed test:
 (Specify test/vendor)

Notes

The CLDN18.2 Expert Committee is comprised of some of the world's leading pathologists, including Matteo Fassan, MD, PhD, Takeshi Kuwata, MD, PhD, Kristina A. Matkowskyj, MD, PhD, Christoph Röcken, MD, and Josef H. Rüschoff, MD. The members of the committee have been contracted as paid advisors through Astellas Pharma Inc. and have received compensation for their time.

IHC = Immunohistochemistry G/GEJ = gastric/gastroesophageal junction CLDN = claudin IVD = in vitro diagnostics HC = Health Canada

