

IHC / ISH Pre-analytic Validation Checklist

Validation element	Document / acceptance
Specimen types and fixation windows	_____
Fixative type, pH, lot, and temperature	_____
Tissue thickness and cold ischemia	_____
Processing and decalcification conditions	_____
Positive, negative, and reagent controls	_____
Retrieval conditions and detection chemistry	_____
Representative markers / probes	_____
Concordance or acceptance criteria	_____
Known limitations and rejection criteria	_____
Approvals, effective date, and change control	_____

Bridge any meaningful change in fixative, processor schedule, decalcifier, retrieval, antibody/probe, detection system, instrument, or scoring method according to local quality requirements.