

IHC/ISH Validation Checklist (HTL)

Change in fixative or retrieval requires:

- Parallel testing with known controls.
- Document pre-analytics: cold ischemia, start/stop times, fixative type/lot/pH.
- Optimize retrieval (buffer pH, time, temp) per marker; avoid over-retrieval.
- Assess morphology & background; quantify signal-to-noise.
- Update validation docs/SOPs; authorized sign-off.
- Consider on-slide controls for multiplex; check decalc effects.