Annex 1: Class criteria for near point-of-care nucleic acid amplification tests (NPOC-NAATs) and low-complexity nucleci acid amplification tests (LC-aNAATs)

Class		**NPOC-NAATs**	**LC-aNAATs**
Purpose		Detection of TB with or without drug resistance detection	Detection of TB and rifampicin resistance
Principle of action		Nucleic acid amplification testing	Nucleic acid amplification testing
Complexity	**Reagents**	All reagents are enclosed in disposable sealed containers not requiring special storage requirements.	Most reagents are enclosed in disposable sealed containers not requiring special storage requirements.
	Skills	Basic technical skills.	Basic technical skills.
	Pipetting	Either no, or only one, pipetting step in the process, not requiring precision.	Either no, or only one, pipetting step in the process, that may require precision.
	Testing procedure	Maximum three steps with optional equipment that come with a UPS or are battery operated (preferable) • May require an initial minimal specimen treatment step before transferring the specimen into the disposable sealed container for automated processing • Automated DNA extraction • PCR amplification/Results visualization	May include more than three steps with powered equipment and optional batteries. • May require an initial manual specimen treatment step before transferring the specimen into the disposable sealed container for automated processing • Automated DNA extraction • Automated real-time PCR/Results generation
	Operating Environment	Temperatures up to 50°C with up to 90% humidity. Dust protection not required.	Temperatures up to 40°C with up to 70% humidity. It is important to adequately protect optics from dust.
Type of test result reporting		Automated or manual	Automated
Setting of use		No laboratory infrastructure required (i.e. peripheral microscopy centres, primary health clinics, mobile units)	Basic laboratory (no special infrastructure needed)