Annex 1

TB/DR-TB diagnostics class definition

1. **Low complexity automated NAATs** (LC-aNAATs) for TB diagnosis and detection of resistance to H/R (e.g. Xpert Ultra, TrueNAT, Standard M10, IRON-qPCR, etc).
2. **Low complexity manual** (LC-mNAATs) **NAATs** for TB diagnosis (e.g.TB-LAMP).
3. **Moderate complexity automated** NAATs (MC-aNAATs) for detection of pre-XDR-TB and XDR-TB (e.g. Bruker-Hain Fluorotype)

	LC-mNAATs	**LC-aNAATs**	**MC-aNAATs**
Reagents	Reagents are enclosed in multiple disposable sealed containers not requiring special storage conditions.	Most reagents are enclosed in a disposable sealed container not requiring special storage conditions.	Reagents are enclosed in single/multiple disposable sealed containers requiring special storage conditions.
Steps	May require an initial manual specimen treatment step followed by three distinct steps: DNA extraction, PCR amplification and results visualization.	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	May require an initial manual specimen treatment step before transfer the specimen for automated processing Automated DNA extraction; Automated real-time PCR
Pipetting	Multiple pipetting steps (max 10) are included from processed sample to the result generation.	Either no or only one pipetting step is included in the process.	Either no pipetting steps or only one pipetting step included in the process.
Result report	Automated or manual	Automated	Automated
Infrastructure	No special laboratory infrastructure is needed	No special laboratory infrastructure is needed	Laboratory-specific infrastructure needed
Skills	Basic technical skills (basic pipetting, precision not critical, etc.)	Basic technical skills (basic pipetting, precision not critical, etc.)	Technically qualified with laboratory-specific skills (multi-step procedure or precision important)