# LDT Objective checklist Template

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| **1. LDT Description** |
| *Name of the LDT* |  |
| *Clinical purpose assigned/ Intended use of the LDT* |  |
| *Clinical utility information (scientific literature, biomarker-disease association etc.)* | *Name of reference documents/files* |
| *List of items in the LDT (reagents, instruments, buffers, controls etc.) and their source (e.g. manufactured in house or commercially sourced)* | *Name of reference documents/files (where applicable)* |
| *Medical Specialty Area* |  |
| **2. Rationale for using LDT** |
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| **3. Validation Records** |
| *Analytical Validation data* | *Name of reference documents/files* |
| *Clinical Validation data* | *Name of reference documents/files* |
| *Revalidation data* | *Name of reference documents/files* |
| **4. Manufacturing Information** |
| *ISO 13485/ ISO 15189 or equivalent lab accreditation record* | *Name of reference documents/files* |
| *Manufacturing records (e.g. batch numbers, batch size, date of manufacture)* | *Name of reference documents/files* |
| *Batch testing and batch release records* | *Name of reference documents/files* |
| **5. Post-market surveillance records** |
| *Records of follow-up on user feedback/ complaints*  | *Name of reference documents/files* |
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| **Signed and dated by Lab Quality Assurance Manager and the Clinical Governance Officer (CGO) or equivalent** |  |

*The above checklist serves as a reference for clinical laboratories to develop and maintain the Objective Checklist for their LDTs. This checklist should be saved on file in the laboratory and should be submitted to HSA when required. The checklist should be maintained for 2 years after the date when the test is retired.*

*The five sections in the above checklist are the key information that the laboratory should keep on file. However, the content mentioned in each section is meant as examples. The laboratory may modify the specific contents depending on the nature and the clinical purpose of their LDTs. Some of the contents in the checklist could be applicable to multiple LDTs within the same clinical laboratory (eg: ISO 13485/ ISO 15189 or equivalent lab accreditation record) and the laboratory could maintain this as a common file and then refer this file in the checklist maintained for each LDT.*