

PLA descriptor guidelines and examples

Specify all of the following elements in the descriptor, as applicable. No proprietary information should be included. See provided examples for details on PLA code descriptor formatting.

- Disease type (eg, oncology, autoimmune, tissue rejection)
- Chemical(s) analyzed (eg, DNA, RNA, protein, antibody)
- Number of markers (eg, number of genes, number of proteins)
- Methodology(s) (eg, microarray, real-time [RT]-PCR, in situ hybridization [ISH], enzyme linked immunosorbent assays [ELISA])
- Number of functional domains (if indicated)
- Specimen type (eg, blood, fresh tissue, formalin-fixed paraffin embedded tissue)
- Algorithm result type (eg, prognostic, diagnostic)
- Report (eg, probability index, risk score)

Examples of descriptors

MAAA descriptor example:

- Oncology (breast), mRNA, microarray gene expression profiling of 70 content genes and 465 housekeeping genes, utilizing fresh frozen or formalin-fixed paraffin-embedded tissue, algorithm reported as index related to risk of distant metastasis
- * Note that up to 10 analytes should be included in the descriptor

Infectious Disease / Microbiology example:

- Infectious disease (*Aspergillus* species), real-time PCR for detection of DNA from 4 species (*A. fumigatus*, *A. terreus*, *A. niger*, and *A. flavus*), blood, lavage fluid, or tissue, qualitative reporting of presence or absence of each species

GSP descriptor example:

- Nuclear encoded mitochondrial genes (eg, neurologic or myopathic phenotypes), genomic sequence panel, must include analysis of at least 100 genes, including *BCS1L*, *C10orf2*, *COQ2*, *COX10*, *DGUOK*, *MPV17*, *OPA1*, *PDSS2*, *POLG*, *POLG2*, *RRM2B*, *SCO1*, *SCO2*, *SLC25A4*, *SUCLA2*, *SUCLG1*, *TAZ*, *TK2*, and *TYMP*
- * Note that up to 10 analytes should be included in the descriptor

Molecular Pathology (other than GSP or MAAA) descriptor example:

- Oncology (ovarian), serum, analysis of 39 glycoproteins by liquid chromatography with tandem mass spectrometry (LC-MS/MS) in multiple reaction monitoring mode, reported as likelihood of malignancy

Chemistry descriptor example:

- Neurology (prion disease), cerebrospinal fluid, detection of prion protein by quaking-induced conformational conversion assay, qualitative