

Oncology Diagnostics

66 applications across the cancer-care journey

[Referenced research inventory](#)

A source-linked companion to Ahead of ESMO 2026 (2): Emerging Oncology Diagnostics and the Next Wave of IVD Innovation. Five care stages, established and emerging clinical applications, and the underlying evidence sources.

Research perimeter. This is a curated inventory of **66 application classes**: **36** M1 (routine-established), **18** M2 (selective/conditional), **5** M3 (product-authorised for a defined use), and **7** M4 (emerging/evaluation). It is not a count of unique commercial tests or independently proven treatment strategies. Additional research frontiers, including spatial profiling and proteogenomics, are outside this 66-item denominator.

How to read the evidence. One or two linked sources accompany each application. They document the stated method or representative indication; they do not constitute blanket endorsement, validation of every commercial product, or confirmation of regulatory status in all jurisdictions. Some records remain subject to full intended-use and maturity review. Clinical limits are highlighted where material.

Maturity key **M1** routine-established · **M2** selective/conditional · **M3** product-specific authorisation · **M4** emerging/evaluation

01 Risk assessment and inherited cancer predisposition (4)

1.1 Hereditary germline cancer risk testing

Example: BRCA1/2; Lynch syndrome gene panels

M1 · Evidence: [\[01\]](#) [\[02\]](#)

Scope: Index-case genetic-risk testing in defined hereditary-risk contexts.

1.2 Cascade familial-variant testing

Example: Known familial pathogenic variant testing in relatives

M1 · Evidence: [\[02\]](#)

1.3 Polygenic risk scores

Example: Breast cancer polygenic risk scores

M4 · Evidence: [\[03\]](#)

Scope: Risk-score utility and calibration depend on the population and screening pathway.

1.4 Infection-associated cancer risk testing

Example: HBV testing in infection-associated hepatocellular cancer risk

M1 · Evidence: [\[04\]](#) [\[05\]](#)

Scope: HBV-related hepatocellular cancer risk; population and prevention setting matter.

02 Early detection and screening (9)

2.1 HPV screening

Example: High-risk HPV DNA testing

M2 · Evidence: [\[06\]](#) [\[07\]](#)

Scope: Cervical screening programmes specify ages, intervals and triage.

2.2 Faecal occult blood screening

Example: Faecal immunochemical test (FIT)

M2 · Evidence: [\[06\]](#) [\[07\]](#)

2.3 Multi-cancer early detection (MCED)

Example: Cell-free DNA methylation/fragmentation MCED blood assays

M4 · Evidence: [\[08\]](#) [\[09\]](#)

Scope: NHS-Galleri did not meet its primary late-stage-cancer endpoint; FDA advisory vote is not approval.

2.4 Multi-target stool DNA screening

Example: Stool DNA plus immunochemical haemoglobin components

M3 · Evidence: [\[10\]](#)

Scope: US-authorized stool-DNA method; distinct from a FIT-only test.

2.5 PSA-based prostate screening / risk assessment

Example: PSA testing with MRI as downstream contextual follow-up

M4 · Evidence: [\[11\]](#)

Scope: M4 describes risk-adapted screening strategy, not PSA assay maturity.

2.6 H. pylori screen-and-treat prevention

Example: H. pylori antigen / breath-based IVD (high-incidence gastric settings)

M4 · Evidence: [\[12\]](#)

Scope: Screen-and-treat prevention depends on gastric-cancer prevalence and programme design.

2.7 FIT symptomatic primary-care triage

Example: Faecal immunochemical test for symptomatic colorectal-cancer pathways

M1 · Evidence: [\[13\]](#)

Scope: Low FIT cannot override persistent clinical concern.

2.8 HPV screening reflex triage

Example: Reflex cytology, extended HPV genotyping or p16/Ki-67 dual-stain

M2 · Evidence: [\[14\]](#)

2.9 Blood-based colorectal cancer screening

Example: FDA-approved cfDNA blood test, Guardant Shield

M3 · Evidence: [\[15\]](#)

Scope: US FDA-authorized product for specified population; EU status is separate.

03 Tumour diagnosis and characterisation (16)

3.1 Histopathology and cytology

Example: H&E tissue pathology; cytological examination

M1 · Evidence: [\[16\]](#)

3.2 Immunohistochemistry (IHC)

Example: ER, PR, HER2, MMR proteins; PD-L1 in selected uses

M1 · Evidence: [\[17\]](#) [\[18\]](#)

Scope: Biomarker-specific interpretation, thresholds and tumour indications differ.

3.3 MMR immunohistochemistry in colon cancer

Example: MSI/MMR testing in stage II localised colon cancer; stage III for Lynch syndrome assessment

M1 · Evidence: [\[19\]](#)

Scope: MMR role is defined by disease stage and clinical question.

3.4 In situ hybridisation / FISH

Example: HER2 amplification; selected fusion/rearrangement assays

M1 · Evidence: [\[17\]](#)

3.5 Haematological malignancy immunophenotyping

Example: Flow cytometry; cytogenetic and molecular classification

M1 · Evidence: [\[20\]](#)

3.6 Tissue comprehensive genomic profiling

Example: NGS DNA/RNA panels in advanced cancer

M1 · Evidence: [\[21\]](#)

3.7 Gene-expression prognostic assays

Example: 21-gene recurrence score in early HR+ breast cancer

M1 · Evidence: [\[22\]](#) [\[23\]](#)

3.8 DNA methylation classification

Example: CNS tumour methylation classifier

M2 · Evidence: [\[24\]](#) [\[25\]](#)

Scope: WHO CNS classification incorporates molecular methods in specified tumour diagnoses.

3.9 Computational pathology and AI-assisted interpretation

Example: Paige Prostate cancer-region detection assistance

M3 · Evidence: [\[26\]](#) [\[27\]](#)

Scope: Authorisation refers to Paige Prostate, not to AI pathology broadly.

3.10 Germ cell staging laboratory markers

Example: AFP, beta-hCG, LDH for germ-cell tumour staging

M1 · Evidence: [\[28\]](#)

3.11 Thyroid cancer diagnostic markers

Example: Calcitonin for selected suspected medullary thyroid carcinoma

M2 · Evidence: [\[29\]](#)

3.12 Adnexal mass risk-assessment markers

Example: CA-125 with clinical risk assessment for selected adnexal masses

M2 · Evidence: [\[30\]](#)

Scope: CA-125 contributes to selected adnexal-mass risk models; not a standalone diagnosis.

3.13 Clinical variant interpretation / genomic reporting

Example: Interpretation of variants and somatic / germline laboratory reports

M1 · Evidence: [\[31\]](#) [\[32\]](#)

3.14 Monoclonal protein assessment in myeloma

Example: Serum protein electrophoresis (SPEP), serum/urine immunofixation

M1 · Evidence: [\[33\]](#)

3.15 LDH in metastatic melanoma staging

Example: Serum LDH for AJCC melanoma stage IV classification

M2 · Evidence: [\[34\]](#)

3.16 Urine cytology for bladder cancer

Example: Urine cytology in selected urothelial cancer diagnostic pathways

M2 · Evidence: [\[35\]](#)

Scope: Urine cytology has defined strengths and sensitivity limitations.

04 Treatment decisions and safety (22)

4.1 Predictive biomarker assays / companion diagnostics

Example: HER2 IHC/ISH; EGFR; ALK; PD-L1; MSI/dMMR

M1 · Evidence: [\[36\]](#) [\[17\]](#)

Scope: Eligibility is tumour-, drug- and companion-diagnostic-specific.

4.2 Targeted somatic PCR / fusion tests

Example: BRAF V600; EGFR; RET fusion assays

M1 · Evidence: [\[36\]](#)

4.3 Plasma ctDNA molecular genotyping

Example: Selected advanced NSCLC and other actionable genotyping

M1 · Evidence: [\[37\]](#)

Scope: A negative plasma finding may require tissue testing in selected indications.

4.4 Resistance genotyping at progression

Example: ESR1 / EGFR resistance alterations in plasma or tissue

M1 · Evidence: [\[37\]](#) [\[38\]](#)

Scope: Targeted resistance testing applies only where the alteration changes management.

4.5 Pharmacogenetic toxicity-risk assays

Example: DPYD genotype / DPD phenotype before fluoropyrimidines

M1 · Evidence: [\[39\]](#)

4.6 Baseline blood counts and chemistry

Example: CBC, coagulation, liver/kidney function, albumin prior to definitive therapy in localised colon cancer

M1 · Evidence: [\[49\]](#)

4.7 Blood counts and chemistry during treatment

Example: Serial CBC and organ-function tests for toxicity monitoring during anti-cancer therapy

M1 · Evidence: [\[40\]](#)

Scope: A fluorouracil label supports one regimen example; monitoring must follow the specific medicine.

4.8 Therapeutic drug monitoring (TDM)

Example: High-dose methotrexate plasma levels

M1 · Evidence: [\[41\]](#)

4.9 Oral targeted-treatment TDM

Example: Imatinib plasma concentration monitoring

M4 · Evidence: [\[42\]](#)

Scope: Imatinib exposure-guided monitoring has consensus support but variable uptake.

4.10 HRD predictive biomarker testing

Example: Homologous recombination deficiency in ovarian cancer for treatment selection

M1 · Evidence: [\[36\]](#)

4.11 Tumour mutational burden measurement

Example: Tumour mutational burden-high (TMB-H), selected treatment contexts

M2 · Evidence: [\[36\]](#)

Scope: TMB testing is applicable only in defined therapeutic settings.

4.12 Predictive germline cancer testing

Example: Germline BRCA1/2 for PARP inhibitor eligibility

M1 · Evidence: [\[01\]](#) [\[36\]](#)

4.13 Germline follow-up of somatic tumour findings

Example: Germline testing of selected tumour-detected variants

M2 · Evidence: [\[43\]](#)

4.14 Irinotecan toxicity pharmacogenomics

Example: UGT1A1 genotyping in selected irinotecan regimens

M2 · Evidence: [\[44\]](#)

Scope: UGT1A1 dose implications are regimen-specific; universal pretesting is not established.

4.15 Thiopurine toxicity pharmacogenomics

Example: TPMT genotype/phenotype and NUDT15 for mercaptopurine in ALL

M1 · Evidence: [\[45\]](#)

4.16 Pre-therapy infectious serology

Example: HBsAg, anti-HBc, anti-HBs prior to high-risk immunosuppression

M1 · Evidence: [\[46\]](#)

4.17 Immune-related endocrine toxicity assessment

Example: TSH/free T4, cortisol, glucose in checkpoint inhibitor management

M1 · Evidence: [\[47\]](#)

4.18 Cardio-oncology cardiac biomarker safety tests

Example: Troponin and BNP/NT-proBNP, risk-stratified

M1 · Evidence: [\[48\]](#)

4.19 Fluorouracil therapeutic drug monitoring

Example: Plasma 5-FU exposure monitoring in selected infusion regimens

M2 · Evidence: [\[49\]](#)

Scope: Specialist guidance concerns specific 5-FU infusion regimens.

4.20 Busulfan pharmacokinetic monitoring

Example: Busulfan concentration / exposure in conditioning for transplant

M2 · Evidence: [\[50\]](#)

4.21 AML genetic predictive and risk markers

Example: FLT3, NPM1, IDH1/2

M2 · Evidence: [\[51\]](#)

4.22 CLL genetic prognostic / predictive assessment

Example: TP53 disruption; IGHV mutation status

M2 · Evidence: [\[52\]](#)

05 Monitoring and follow-up (15)

5.1 CEA follow-up after colon cancer

Example: Serum CEA during follow-up after resection of localised colon cancer

M1 · Evidence: [\[19\]](#)

5.2 PSA after prostate-cancer treatment

Example: Serial PSA following prostate-cancer treatment

M1 · Evidence: [\[53\]](#)

Scope: PSA follow-up intervals and actions depend on previous treatment and risk.

5.3 CA-125 surveillance in ovarian cancer

Example: CA-125 in follow-up after ovarian cancer treatment

M1 · Evidence: [\[54\]](#) [\[55\]](#)

Scope: CA-125 is an optional follow-up measure; treating solely on a rise did not improve survival.

5.4 CA19-9 for pancreatic-cancer staging

Example: CA19-9 biological criterion in assessing borderline resectable pancreatic cancer

M1 · Evidence: [\[56\]](#)

5.5 ctDNA molecular residual disease companion diagnostic

Example: Signatera CDx ctDNA molecular residual disease (post-cystectomy muscle-invasive bladder cancer); serial plasma testing during 12 months

M3 · Evidence: [\[57\]](#)

Scope: Specific US bladder-cancer CDx indication; not pan-cancer use.

5.6 Molecular residual disease (MRD) and molecular relapse

Example: Tumour-informed and tumour-agnostic ctDNA assays

M4 · Evidence: [\[37\]](#) [\[57\]](#)

Scope: Broad ctDNA MRD treatment guidance remains conditional on disease and strategy.

5.7 Circulating tumour cell enumeration

Example: CTC counts in metastatic settings

M3 · Evidence: [\[58\]](#)

Scope: CTC enumeration is a prognostic aid, not a standalone therapeutic selection rule.

5.8 Differentiated thyroid cancer biochemical surveillance

Example: Serum thyroglobulin and anti-thyroglobulin antibodies

M1 · Evidence: [\[29\]](#)

5.9 Germ cell and trophoblastic tumour markers

Example: hCG (gestational trophoblastic disease); AFP/hCG in germ-cell follow-up

M1 · Evidence: [\[28\]](#) [\[59\]](#)

5.10 Acute lymphoblastic leukaemia MRD

Example: Flow cytometry, qPCR or NGS MRD in ALL

M2 · Evidence: [\[60\]](#)

5.11 Myeloma measurable residual disease (MRD)

Example: Flow cytometry or NGS MRD in multiple myeloma

M2 · Evidence: [\[61\]](#)

5.12 BCR::ABL1 quantitative molecular monitoring

Example: Standardised RT-qPCR (or validated RT-ddPCR) serial CML monitoring

M1 · Evidence: [\[62\]](#)

5.13 Cardiometabolic and cardiac late-effects monitoring

Example: Glucose/HbA1c, lipids, troponin/NP in selected survivors

M2 · Evidence: [\[48\]](#)

5.14 HPV-associated cancer molecular surveillance

Example: HPV ctDNA in oropharyngeal cancer follow-up

M4 · Evidence: [\[63\]](#)

Scope: HPV ctDNA surveillance remains investigational for outcome-directed routine care.

5.15 Myeloma biochemical response monitoring

Example: SPEP, immunofixation, serum free light chains

M1 · Evidence: [\[61\]](#)

Source register

References appear in order of first use. Each citation number links to its primary online document, regulatory record, clinical guideline or peer-reviewed paper. The reference list preserves source provenance; some referenced guidance requires further indication-level appraisal.

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Evidence and publication qualification

Inventory status. The maturity codes are those of the Persodia qualified working matrix (October 2026). Sources are linked to every row, but a source link alone does not establish the exact strength of a clinical recommendation, every analytical or regulatory requirement, or clinical utility in all indications. Source statements and intended-use claims should be checked before reuse in decisions affecting patient care, product compliance or investment.

Targeted source additions in this edition. The regimen-specific blood-count and chemistry monitoring entry now uses an official fluorouracil label. For CA-125 surveillance, the source pair distinguishes optional monitoring from the absence of survival improvement when treatment is initiated solely on a biochemical rise. These additions do not retrospectively change the frozen workbook review statuses.

Limits. FDA authorisations do not automatically translate into EU authorisations; molecular tests and screening programmes depend on defined intended uses. Maturity codes describe the particular research application, not the universal status of a technology. This document is an industry research inventory, not clinical advice.

Source: Persodia Oncology Diagnostics qualified evidence matrix, v15 (October 2026); source-register corrections and supplementary official citations, 19 October 2026. persodia.org