

**Verzeichnis der Untersuchungsverfahren nach den Anforderungen der DIN EN ISO 15189****Molekularbiologische Untersuchungen (Amplifikationsverfahren)**

| Analyt (Messgröße)                                                                                                                                                                                                    | Untersuchungsmaterial<br>(Eingangsmaterial; Testmaterial) | Untersuchungstechnik                                                                       | Anweisung / Version                    |
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| Aderhautmelanom<br>( <i>BAP1, BRAF, CYSLTR2, EIF1AX, GNA11, GNAQ, KIT, NRAS, PLCB4, SF3B1</i> )                                                                                                                       | genomische DNA; DNA                                       | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Akute myeloische Leukämie (AML) ( <i>ASXL1, CEBPA, DNMT3A, FLT3, IDH1, IDH2, KIT, NOTCH1, NPM1, RUNX1, SETBP1, SF3B1, SRSF2, TET2, TP53, U2AF1</i> )                                                                  | genomische DNA; DNA                                       | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| B-Zell Lymphom<br>( <i>CARD11, CD79B, CREBBP, CXCR4, EZH2, GNA13, MYD88, PIM1, PRDM1, SOCS1, STAT6, TNFAIP3, TNFRSF14</i> )                                                                                           | genomische DNA; DNA                                       | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Bronchialkarzinome<br>( <i>AKT1, ALK, BRAF, CDKN2A, CTNNB1, EGFR, ERBB2, HRAS, KEAP1, KRAS, MAP2K1, MET, NRAS, PIK3CA, RET, ROS1, SMAD4, STK11, TP53</i> )                                                            | genomische DNA; DNA                                       | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Chronische lymphatische Leukämie (CLL)<br>( <i>ATM, BCOR, BIRC3, BRAF, BTK, EGR2, FBXW7, KRAS, MYD88, NOTCH1, NRAS, PLCG2, POT1, SAMHD1, SF3B1, TP53, XPO1</i> )                                                      | genomische DNA; DNA                                       | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| CUP-Syndrom (Cancer of unknown primary)/Targetable Cancer Mutations (TCM)<br>( <i>ALK, BRAF, BRCA1, BRCA2, EGFR, ERBB2, FGFR1, FGFR2, FGFR3, FGFR4, HRAS, IDH1, KIT, KRAS, MET, NRAS, PDGFRA, PIK3CA, RET, ROS1</i> ) | genomische DNA; DNA                                       | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |

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| Endometriumkarzinom<br>( <i>BRAF, BRCA1, BRCA2, CTNNB1, KRAS, PIK3CA, POLD1, POLE, PTEN, TP53</i> )                                                                                               | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Cholangiokarzinom<br>( <i>BRAF, BRCA1, BRCA2, ERBB2, FGFR2, IDH1, IDH2, KRAS, NRAS</i> )                                                                                                          | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Gastrointestinaler Stromatumor (GIST)<br>( <i>BRAF, KIT, PDGFRA</i> )                                                                                                                             | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Glioblastom<br>( <i>AKT1, APC, BAP1, BCOR, BRAF, CDKN2A, CDKN2B, CDKN2C, EGFR, FGFR1, GNA11, GNAQ, H3F3A, IDH1, IDH2, KIT, KRAS, MET, NOTCH1, NRAS, PDGFRA, PIK3CA, PTEN, STAG2, TERT, TP53</i> ) | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Gliom<br>( <i>BRAF, CDKN2A, CDKN2B, IDH1, IDH2, TERT, TP53</i> )                                                                                                                                  | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Harnblasen-/Urothelkarzinom ( <i>CDKN2A, CTNNB1, ERBB2, FGFR1, FGFR2, FGFR3, FGFR4, HRAS, KRAS, NRAS, PIK3CA, SF3B1, TERT, TP53</i> )                                                             | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Kolorektales Karzinom<br>( <i>AKT1, APC, BRAF, EGFR, ERBB2, HRAS, KRAS, MAP2K1, NRAS, PIK3CA, POLD1, POLE, TP53</i> )                                                                             | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Kutanes T-Zell Lymphom<br>( <i>ARID1A, BCOR, CARD11, CD28, DNMT3A, MSC, NCOR1, PLCG1, RHOA, SETD2, STAT3, STAT5B, TET2, TP53</i> )                                                                | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Mammakarzinom<br>( <i>AKT1, BRCA1, BRCA2, ERBB2, ESR1, PALB2, PIK3CA, PTEN</i> )                                                                                                                  | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |

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| Mastozytose<br>(ASXL1, CBL, EZH2, IDH1, IDH2, JAK2, KIT, KRAS, NRAS, RUNX1, SF3B1, SRSF2, TET2)                                                                                                                       | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Melanom<br>(BRAF, CDKN2A, HRAS, KIT, KRAS, NRAS, MAP2K1, PDGFRA, PIK3CA, TERT)                                                                                                                                        | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Meningeom<br>(AKT1, BAP1, BRAF, CDKN2A, CDKN2B, FGFR3, IDH1, IDH2, MET, NOTCH2, PIK3CA, PTEN, TERT, TP53)                                                                                                             | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Myelodysplastische Neoplasie (MDS)<br>(ASXL1, BCOR, CBL, CEBPA, DNMT3A, ETV6, EZH2, FLT3, IDH1, IDH2, MLL/KMT2A, KRAS, NPM1, NRAS, PTPN11, RUNX1, SETBP1, SF3B1, SRSF2, STAG2, TP53, U2AF1)                           | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Myeloproliferative Neoplasien (MPN)<br>(ABL1, ASXL1, CALR, CBL, CEBPA, CSF3R, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, JAK3, KIT, KRAS, MPL, NOTCH2, NPM1, NRAS, PTPN11, RUNX1, SETBP1, SF3B1, SRSF2, TET2, TP53, U2AF1) | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| NK-LGL-Leukämie (NK-LGLL)<br>(ASXL1, ATM, CCL22, DNMT3A, STAT3, STAT5B, TET2, TNFAIP3)                                                                                                                                | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Ovarialkarzinom<br>(BRCA1, BRCA2)                                                                                                                                                                                     | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Pankreaskarzinom<br>(BRAF, BRCA1, BRCA2, CDKN2A, CTNNB1, ERBB2, GNAS, KRAS, PALB2, PIK3CA, SMAD4, TP53, VHL)                                                                                                          | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |

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| Peritonealkarzinom<br>( <i>BRCA1, BRCA2</i> )                                                                                                                                             | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Prostatakarzinom<br>( <i>BRCA1, BRCA2, PTEN</i> )                                                                                                                                         | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Schilddrüsenkarzinom<br>( <i>BRAF, EGFR, ERBB2, HRAS, KRAS, MET, NRAS, PIK3CA, RET, STK11, TERT, TP53</i> )                                                                               | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Spitz-Tumor<br>( <i>BAP1, BRAF, CDKN2A, HRAS, KIT, MAP2K1, MAP3K8, NRAS, PTEN, TERT</i> )                                                                                                 | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Tubenkarzinom<br>( <i>BRCA1, BRCA2</i> )                                                                                                                                                  | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| T-Zell Lymphom<br>( <i>ABCC9, ARID1A, ATM, BCOR, CARD11, CD28, DNMT3A, FYN, IDH2, JAK1, JAK3, KMT2D, MSC, NCOR1, PLCG1, PTEN, RHOA, SETD1B, SETD2, STAT3, STAT5B, STAT6, TET2, TP53</i> ) | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |
| Urachuskarzinom<br>( <i>APC, BRAF, EGFR, ERBB2, KIT, KRAS, MAP2K1, MET, NRAS, PIK3CA, PTEN, TP53</i> )                                                                                    | genomische DNA; DNA | Sonden – Panel<br>(PCR, Sonden-Hybridisierung, Capture-PCR),<br>Hochdurchsatzsequenzierung | AA_7-027R; Rev. 4<br>AA_7-017R, Rev. 7 |

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| <p>HaSo_Complete<br/>(ABCC9, ABL1, AKT1, ALK, APC, ARID1A, ASXL1, ATM, BAP1, BCOR, BIRC3, BRAF, BRCA1, BRCA2, BTK, CALR, CARD11, CBL, CCL22, CD28, CD79B, CDKN2A, CDKN2B, CDKN2C, CEBPA, CREBBP, CSF3R, CTNNB1, CUL3, CXCR4, CYSLTR2, DNMT3A, DPYP, EGFR, EGR2, EIF1AX, ERBB2, ESR1, ETV6, EZH2, FBXW7, FGF6, FGFR1, FGFR2, FGFR3, FGFR4, FLT3, FYN, GNA11, GNA13, GNAQ, GNAS, H3F3A, HRAS, IDH1, IDH2, JAK1, JAK2, JAK3, KEAP1, KIT, KMT2A, KMT2D, KRAS, MAP2K1, MAP3K8, MET, MPL, MSC, MYB, MYBL1, MYD88, NCOR1, NF2, NFE2L2, NOTCH1, NOTCH2, NPM1, NRAS, PALB2, PDGFRA, PIK3CA, PIM1, PLCB4, PLCG1, PLCG2, POLD1, POLE, POT1, PRDM1, PTEN, PTPN11, RB1, RET, RHOA, ROS1, RUNX1, SAMHD1, SETBP1, SETD2, SF3B1, SMAD4, SMARCA4, SOCS1, SRSF2, STAG2, STAT3, STAT5B, STAT6, STK11, TERT, TET2, TNFAIP3, TNFRSF14, TP53, U2AF1, VHL, XPO1)</p> | <p>genomische DNA; DNA</p> | <p>Sonden – Panel<br/>(PCR, Sonden-Hybridisierung, Capture-PCR),<br/>Hochdurchsatzsequenzierung</p> | <p>AA_7-027R; Rev. 4<br/>AA_7-017R, Rev. 7</p> |
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