FOUNDATION MEDICINE®

Evidence Portfolio

FOUNDATIONONE® CDx

FOUNDATIONONE® LIQUID CDx

FoundationOne CDx

40+ FDA-approved companion diagnostic indications, 3 group indications

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FoundationOne CDx: Evidence Portfolio

Non-Small Cell Lung Cancer (NSCLC)

TUMOR TYPE	BIOMARKER(S) DETECTED	THERAPY	EVIDENCE	METHOD
Non-Small Cell Lung Cancer (NSCLC)	*EGFR* exon 19 deletions and *EGFR* exon 21 L858R alterations	EGFR Tyrosine Kinase Inhibitors (TKI) approved by FDA	• Soria et al. N Engl J Med. 2018 Jan 11;378(2):113-125 • Gilotrif® (afatinib) Prescribing Information. Boehringer Ingelheim. 2013. • Iressa® (gefitinib) Prescribing Information. AstraZeneca Pharmaceuticals; 2021. • Tarceva® (erlotinib) Prescribing Information. Genentech USA, Inc; 2016. • Tagrisso® (osimertinib) Prescribing Information. AstraZeneca Pharmaceuticals; 2021. • FDA-approved EGFR TKIs.	Clinical validity (concordance) of FoundationOne®CDx to detect EGFR exon 19 deletions and EGFR exon 21 L858R alterations in patients with advanced NSCLC who may benefit from treatment with Gilotrif® (afatinib), Iressa® (gefitinib), or Tarceva® (erlotinib) was demonstrated against cobas®EGFR v2 in a retrospective analysis. Clinical validity (concordance) of F1LCDx to detect EFGR exon 19 del and EGFR exon 21 L858R alterations in patients with NSCLC who may benefit from treatment with Tagrisso® (osimertinib) was demonstrated against the clinical trial assay in FLAURA (NCT02296125). See section 12.1 of F1CDx Technical Information www.f1cdxlabel.com.
	EGFR exon 20 T790M alterations	Tagrisso® (osimertinib)	• Mok et al. N Engl J Med. 2017 Feb 16;376(7):629-640. • Tagrisso® (osimertinib) Prescribing Information. AstraZeneca Pharmaceuticals; 2021	Clinical validity (concordance) of FoundationOne®CDx to detect EGFR T790M alterations in patients with NSCLC who may benefit from treatment with Tagrisso® (osimertinib) was demonstrated against the clinical trial assays in AURA (NCT01802632), AURA2 (NCT02094261) and AURA3 (NCT02151981) and cobas® EGFR v2. See section 12.2 of F1CDx Technical Information www.f1cdxlabel.com.
	ALK rearrangements	Alecensa® (alectinib)	• Mok et al. Ann Oncol. 2020 Aug;31(8):1056-1064. • Alecensa® (alectinib). Genentech USA, Inc.; 2021.	Clinical validity (concordance) of FoundationOne®CDx to detect ALK rearrangements in patients with NSCLC who may benefit from treatment with ALK-directed therapies was demonstrated against the clinical trial assays in samples from the ALEX study (NCT02075840, Roche study number BO28984). See section 12.4 of F1CDx Technical Information www.f1cdxlabel.com.
		Alunbrig® (brigatinib)	• Alunbrig® (brigantinib). Prescribing Information. Takeda Pharmaceutical Company Limited. 2020.	
		Xalkori® (crizotinib)	• Xalkori® (crizotinib). Prescribing Information. Pfizer Laboratories. 2021.	
		Zykadia® (ceritinib)	• Zykadia® (ceritinib). Prescribing Information. Novartis Pharmaceuticals Corporation. 2019.	
	BRAF V600E	Braftovi® (encorafenib) in combination with Mektovi®(binimetinib)	• BRAFTOVI. Prescribing Information. Array Biopharma Inc. 2023. • MEKTOVI (binimetinib) Prescribing Information. Pfizer. • Riely et al. J Clin Oncol. 2023; 41(21):3700-3711.	Clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®CDx to detect BRAF V600E alterations in patients with NSCLC who may benefit from treatment with encorafenib plus binimetinib was demonstrated in a **clinical bridging study** using samples from patients enrolled in PHAROS(ARRAY-818-202; NCT03915951). See section 12.21 of F1CDx Technical Information www.f1cdxlabel.com.
	BRAF V600E	Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib)	• Planchard et al. J Clin Oncol. 2022 Jan;17(1):103-115. • Tafinlar® (dabrafenib). Prescribing Information. Novartis Pharmaceuticals Corporation. 2021. • Mekinist® (trametinib). Prescribing Information. Novartis Pharmaceuticals Corporation. 2021.	See section 12.21 of F1CDx Technical Information www.f1cdxlabel.com.
	MET single nucleotide variants (SNVs) and indels that lead to MET exon 14 skipping	Tabrecta® (capmatinib)	• Wolf, J. N Engl J Med. 2020;383(10):944-957. • Tabrecta® (capmatinib). Package insert. Novartis Pharmaceuticals Corporation; 2020.	Clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®CDx to detect MET SNVs and indels that lead to METex14 skipping in patients with NSCLC who may benefit from treatment with capmatinib was demonstrated in a **clinical bridging study** using samples from the GEOMETRY-mono 1 (NCT02414139). See section 12.12 of F1CDx Technical Information www.f1cdxlabel.com.
	ROS1 fusions	Rozlytrek® (entrectinib)	• Drilon A. Lancet Oncol. 2020;21(2):261-270. • Rozlytrek® (entrectinib). Package insert. Genentech USA, Inc. 2023.	Clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®CDx to detect ROS1 fusions in patients with NSCLC who may benefit from treatment with entrectinib was demonstrated in a **clinical bridging study** utilizing samples from ALKA-372-001, STARTRK-1 (NCT02097810), and STARTRK-2 (NCT02568267). See section 12.17 F1CDx Technical Information www.f1cdxlabel.com.

FoundationOne CDx: Evidence Portfolio

Cutaneous Melanoma and Breast Cancer

TUMOR TYPE	BIOMARKER(S) DETECTED	THERAPY	EVIDENCE	METHOD
Melanoma	*BRAF* V600E	BRAF Inhibitors approved by FDA*	• Boussemart, L. Oncologist. 2019:24(5):657-663. • BRAFTOVI. Prescribing information. Array Biopharma Inc; 2020. • MEKTOVI. Prescribing information. Array Biopharma Inc; 2020. • TAFINLAR. Prescribing information. Novartis Pharmaceuticals Corporation; 2021. • FDA-approved BRAF Inhibitors.	Clinical validity (concordance) of FoundationOne®CDx to detect BRAF alterations in patients with melanoma who may benefit from treatment with BRAF-directed therapies was demonstrated in a retrospective analysis against the cobas® 4800 BRAF V600 Mutation Test[a]. See section 12.6 F1CDx Technical Information www.f1cdxlabel.com.
	BRAF V600E and V600K	Mekinist® (trametinib) or BRAF/MEK Inhibitor Combinations approved by FDA*	• Boussemart, L. Oncologist. 2019:24(5):657-663. • MEKINIST. Prescribing information. Novartis Pharmaceuticals Corporation; 2021. • FDA-approved Combinations.	
	BRAF V600 mutation-positive	Tecentriq® (atezolizumab) in combination with Cotellic® (cobimetinib) and Zelboraf® (vemurafenib)	• Boussemart, L. Oncologist. 2019:24(5):657-663. • TECENTRIQ. Prescribing information. Genentech USA, Inc; 2021. • COTELLIC. Prescribing information. Genentech USA, Inc.; 2018. • ZELBORAF. Prescribing information. Genentech USA, Inc.; 2020.	Clinical validity (concordance) of FoundationOne®CDx to identify rare BRAF V600 mutations in patients with melanoma who may benefit from treatment with atezolizumab in combination with cobimetinib and vemurafenib was demonstrated in the IMspire150 trial (NCT02908672), and additional real-world data was provided from melanoma samples with rare variants. See section 12.6 F1CDx Technical Information at www.f1cdxlabel.com.
Breast Cancer	*ERBB2* (HER2) amplification	Herceptin® (trastuzumab), Kadcyla® (ado-trastuzumab-emtansine), or Perjeta® (pertuzumab)	• Herceptin® (trastuzumab). Package insert. Genentech USA, Inc. 2010. • Kadcyla® (ado-trastuzumab-emtansine). Package insert. Genentech USA, Inc. 2013. • Perjeta® (pertuzumab). Package insert. Genentech USA, Inc. 2012.	Clinical validity (concordance) of FoundationOne®CDx to detect ERBB2 (HER2) amplifications in patients with breast cancer who may benefit from treatment with trastuzumab, ado-trastuzumab-emtansine, or pertuzumab was demonstrated against HER2 FISH PharmDx1 Kit (Dako Denmark, A/S) in a retrospective analysis. See section 12.3 F1CDx Technical Information www.f1cdxlabel.com.
	PIK3CA, C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R, H1047L, H1047R, and H1047Y alterations	Piqray® (alpelisib)	• Andre F, et al. N Engl J Med. 2019; 380(20):1929–40. • Piqray® (alpelisib). Package insert. Novartis Pharmaceuticals Corporation. 2019.	Clinical validity (concordance) and clinical utility (clinical effectiveness) of F1CDx to detect PIK3CA alterations in patients with breast cancer who may benefit from treatment with alpelisib was demonstrated in a **clinical bridging study** using specimens from SOLAR-1 (NCT02437318). See section 12.10 of F1CDx Technical Information www.f1cdxlabel.com.
	AKT1 E17K; PIK3CA R88Q, N345K, C420R, E542K, E545A, E545D, E545Q, E545K, E545G, Q546E, Q546K, Q546R, Q546P, M1043V, M1043I, H1047Y, H1047R, H1047L, and G1049R; and *PTEN* alterations	Truqap™ (capivasertib) in combination with Faslodex® (fulvestrant)	• Turner, NC et al. CAPItello-291 Study Group. Capivasertib in Hormone Receptor-Positive Advanced Breast Cancer. N Engl J Med. 2023 Jun 1;388(22):2058-2070. doi: 10.1056/NEJMoa2214131. PMID: 37256976. • TRUQAP™ (capivasertib). Prescribing information. AstraZeneca 2023.	Clinical utility (clinical effectiveness) of FoundationOne®CDx to detect PIK3CA/AKT1/PTEN-altered tumors in patients with breast cancer who may benefit from treatment with capivasertib plus fulvestrant was directly demonstrated in the CAPItello-291 (NCT04305496) clinical trial, where **F1CDx was the clinical trial assay**. See F1CDx Technical Information www.f1cdx.label.com.

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FoundationOne CDx: Evidence Portfolio

Colorectal Cancer, Ovarian Cancer, Cholangiocarcinoma, Prostate Cancer

TUMOR TYPE	BIOMARKER(S) DETECTED	THERAPY	EVIDENCE	METHOD
Colorectal Cancer	*KRAS* wild-type (absence of mutations in codons 12 and 13)	Erbitux® (cetuximab)	• Erbitux® (cetuximab). Package insert. Bristol-Myers Squibb Company. 2012.	Clinical validity (concordance) of FoundationOne®CDx to detect *KRAS* alterations in patients with colorectal cancer who may not benefit from treatment with cetuximab or panitumumab was demonstrated against the therascreen® KRAS RGQ PCR Kit (QIAGEN) in a retrospective analysis. See section 12.5 of F1CDx Technical Information at www.f1cdxlabel.com.
	KRAS wild-type (absence of mutations in exons 2, 3, and 4) and *NRAS* wild type (absence of mutations in exons 2, 3, and 4)	Vectibix® (panitumumab)	• Vectibix® (panitumumab). Package insert. Amgen Inc. 2009.	Clinical validity (concordance) of FoundationOne®CDx to detect *KRAS/NRAS* alterations in patients with colorectal cancer who may benefit from treatment with Vectibix® (panitumumab) was demonstrated against the Praxis Extended RAS Panel (Praxis test) in a retrospective analysis. See section 12.7 of F1CDx Technical Information at www.ficdxlabel.com.
Ovarian Cancer	*BRCA1/2* alterations	Lynparza® (olaparib)	• Moore K. N Engl J Med. 2018 Dec 27;379(26):2495-2505. • Lynparza® (Olaparib). Package insert. AstraZeneca: 2020.	Clinical utility (clinical effectiveness) of FoundationOne®CDx to detect *BRCA1/2* alterations in patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who may benefit from treatment with Olaparib was directly demonstrated in in the SOLO-1 trial (NCT01844986) where **F1CDx was the clinical trial assay**. See section 12.9 F1CDx Technical Information www.f1cdxlabel.com.
Cholangiocarcinoma	*FGFR2* fusions and select rearrangements	Pemazyre® (pemigatinib)	• Abou-Alfa GK, et al. The Lancet Oncology. 2020; 21(5):671–84. • Pemazyre® (pemigatinib). Package insert. Incyte Corporation. 2022.	Clinical utility (clinical effectiveness) of FoundationOne® to detect *FGFR* gene fusions and select rearrangements in patients with cholangiocarcinoma who may benefit from treatment with pemigatinib was directly demonstrated in FIGHT-202 (NCT03656536) where **F1 was the clinical trial assay**. See section 12.11 of F1CDx Technical Information www.f1lcdxlabel.com.
Prostate Cancer	Homologous Recombination Repair (HRR) gene (*BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D* and *RAD54L*) alterations	Lynparza® (olaparib)	• de Bono J. N Engl J Med. 2020:382(22):2091-2102. • Lynparza® (Olaparib). Package insert. AstraZeneca: 2020.	Clinical utility (clinical effectiveness) of FoundationOne®CDx to detect HRR gene alterations in patients with prostate cancer who may benefit from treatment with Olaparib was directly demonstrated in the PROfound trial (NCT02987543) where **F1CDx was the clinical trial assay.** See section 12.13 of F1CDx Technical Information www.f1cdxlabel.com.
	BRCA1/2 alterations	AKEEGA™ (niraparib and abiraterone acetate)	• Chi KN. J Clin Oncol. 2023 Jun 20;41(18):3339-3351. • AKEEGA™ Package insert. Janssen:2023	Clinical utility (clinical effectiveness) of FoundationOne®CDx to detect *BRCA1/2* alterations in patients with prostate cancer who may benefit from treatment with niraparib plus abiraterone acetate was directly demonstrated in the MAGNITUDE trial (NCT03748641) where **F1CDx was the clinical trial assay**. See section 12.19 of F1CDx Technical Information www.f1cdxlabel.com.
	BRCA1/2 alterations	Lynparza® (olaparib) in combination with abiraterone	• Saad et al. Lancet Oncology. 2023; 24(10):1094-108. • Lynparza® (Olaparib). Package insert. AstraZeneca: 2020.	Clinical utility (clinical effectiveness) of FoundationOne®CDx to detect *BRCA1/2* alterations in patients with prostate cancer who may benefit from treatment with Olaparib plus abiraterone was directly demonstrated in PROpel (NCT03732820) where **F1CDx was the clinical trial assay**. See section 12.23 of F1CDx Technical Information www.f1lcdx.com.

FoundationOne CDx: Evidence Portfolio

Glioma, Solid Tumors

TUMOR TYPE	BIOMARKER(S) DETECTED	THERAPY	EVIDENCE	METHOD
Pediatric Low-Grade Glioma	*BRAF* V600 alterations and *BRAF* fusions	Ojemda™ (tovorafenib)	• Kilburn, L, et al. Nature Medicine. 2024 Jan;30:207-2017. • OJEMDA™ (tovorafenib). Package Insert. Day One Biopharmaceuticals, Inc.: 2024.	Clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®CDx to detect *BRAF* V600 mutations and *BRAF* fusions in glioma patient who may benefit from treatment with tovorafenib was demonstrated in a **clinical bridging study** in samples from the FIREFLY-1 (FF-1) clinical trial (NCT04775485). See section 12.24 F1CDx Technical Information www.f1cdxlabel.com.
Solid Tumors	MSI-High	Keytruda® (pembrolizumab)	• Marabelle A, et al. Lancet Oncol. 2020 Oct;21(10):1353-1365. • Dung LT. J Clin Oncol. 2020 Jan 1;38(1):11-19. • Keytruda® (pembrolizumab). Package insert. Merck & Co.: 2023.	Clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®CDx to detect MSI-H status in patients with solid tumors who may benefit from treatment with pembrolizumab was demonstrated in a **clinical bridging study** in samples KEYNOTE-158 Cohort K (NCT02628067) and KEYNOTE-164 (NCT02460198) . See section 12.16 F1CDx Technical Information www.f1cdxlabel.com.
	TMB ≥ 10 mutations per megabase	Keytruda® (pembrolizumab)	• Marabelle A, et al. Lancet Oncol. 2020 Oct;21(10):1353-1365. • Marcus L, et al. Clin Cancer Res. 2021 Sep 1;27(17):4685-4689. • Keytruda® (pembrolizumab). Package insert. Merck & Co.: 2023.	Clinical utility (clinical effectiveness) of FoundationOne®CDx to detect TMB-H (TMB ≥10 mutations per megabase) in patients with various previously treated unresectable or metastatic solid tumors who may benefit from treatment with pembrolizumab was directly demonstrated in KEYNOTE-158 (NCT02628067) where **F1CDx was used as the clinical trial assay**. See section 12.14 F1CDx Technical Information www.f1cdxlabel.com.
	NTRK1/2/3 fusions	Rozlytrek® (entrectinib)	• Doebele RC, et al. Lancet Oncol. 2020 Feb;21(2):271-282. • Rozlytrek® (entrectinib). Package insert. Genentech USA, Inc.: 2023.	Clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®CDx to detect *NTRK1/2/3* gene fusions in patients with solid tumors who may benefit from treatment with entrectinib was demonstrated in a **clinical bridging study** using samples from STARTRK-1 (NCT02097810) and STARTRK-2 (NCT02568267). See section 3.17 in F1CDx Technical Information www.f1cdxlabel.com.
		Vitrakvi® (larotrectinib)	• Drilon A. N Engl J Med. 2018;378(8):731–739. • Hong DS, et al. The Lancet Oncology. 2020; 21(4):531–40. • Vitrakvi® (larotrectinib). Package insert. Bayer HealthCare Pharmaceuticals Inc. 2021.	Clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®CDx to detect *NTRK1/2/3* gene fusions in patients with solid tumors who may benefit from treatment with larotrectinib was demonstrated in a **clinical bridging study** using samples from LOXO-TRK-14001 (NCT02122913), NAVIGATE (NCT02576431), and SCOUT (NCT02637687) and supplemental *NTRK* fusion negative samples. See section 12.15 F1CDx Technical Information www.f1cdxlabel.com.
	RET fusions	Retevmo® (selpercatinib)	• Subbiah V. The Lancet Oncology, Volume 23, Issue 10,1261-1273 • Duke ES. Clin Cancer Res. 2023 Sep 15;29(18):3573-3578. • Retevmo®(selpercatinib) Package insert	Clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®CDx to detect *RET* fusions in patients with solid tumors who may benefit from treatment with selpercatinib was demonstrated in a **clinical bridging study** using samples from LIBRETTO-001 (NCT01357128) and supplemental RET fusion negative samples. See section 12.20 F1CDx Technical Information www.f1cdxlabel.com.

FoundationOne Liquid CDx

15+ FDA-approved companion diagnostic indications, 1 group indication

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FoundationOne Liquid CDx: Evidence Portfolio

Non-Small Cell Lung Cancer (NSCLC)

TUMOR TYPE	BIOMARKER(S) DETECTED	THERAPY	EVIDENCE	METHOD
Non-Small Cell Lung Cancer (NSCLC)	*ALK* rearrangements	ALECENSA® (alectinib)	• Dziadziuszko R. J Thorac Oncol. July 24, 2021. • Peters S. N Engl J Med. 2017:377(9):829-838. • Camidge DR. Journal of Thoracic Oncology 14.7 (2019): 1233-1243. • Alecensa® (alectinib). Genentech USA, Inc.; 2021.	Clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®Liquid CDx to detect ALK rearrangements in patients with NSCLC who may benefit from treatment with alectinib was demonstrated in a **clinical bridging study** using samples from Cohort A of BFAST (NCTNCT03178552) See section 10.1 F1LCDx Technical Information at www.f1lcdxlabel.com.
	EGFR exon 19 deletions and *EGFR* exon 21 L858R substitution	EGFR Tyrosine Kinase Inhibitors (TKI) approved by FDA	• Lee CK. J Natl Cancer Inst. 2017:109(6):djw279. • Yi L. Int J Cancer. 2019:145(1):284-294. • Husain H, et al. JCO Precision Oncology no. 6 (2022) e2200261. • Schwartzberg LS, et al. Journal of Clinical Oncology 40, no. 16_suppl (June 01, 2022) e18778-e18778. • FDA-approved EGFR TKIs.	Clinical validity (concordance) of FoundationOne® Liquid CDx to detect EGFR exon 19 deletions and EGFR exon 21 L858R substitutions in patients with NSCLC who may benefit from treatment with EGFR TKI's approved by the FDA was demonstrated against cobas® *EGFR* Mutation Test v2 in a retrospective analysis. See section 10.2 F1LCDx Technical Information at www.f1lcdxlabel.com.
	MET single nucleotide variants (SNVs) and indels that lead to *MET* exon 14 skipping	TABRECTA® (capmatinib)	• Wolf, J. N Engl J Med. 2020:383(10):944-957. • Tabrecta® (capmatinib). Package insert. Novartis Pharmaceuticals Corporation; 2020.	Clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®Liquid CDx to detect *MET* SNVs and indels that lead to *MET* exon 14 skipping in patients with NSCLC who may benefit from treatment with capmatinib was demonstrated in a **clinical bridging study** using samples from GEOMETRY mono-1 (NCT02414139). See section 10.6 F1LCDx Technical Information at www.f1lcdxlabel.com.
	ROS1 fusions**	ROZLYTREK® (entrectinib)	• Drilon A, *Lancet Oncol*. 2020;21(2):261-270. • Dziadziuszko R, et al. Mol Oncol. 2022 May; 16(10):2000-2014. • Rozlytrek® (entrectinib). Package insert. Genentech USA, Inc.: 2023.	Clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®Liquid CDx to detect *ROS1* fusions in patients with NSCLC who may benefit from treatment with entrectinib was demonstrated in a **clinical bridging study** using samples from STARTRK-2 (NCT02568267). See section 10.7 F1LCDx Technical Information at www.f1lcdxlabel.com.
	BRAF V600E	Braftovi® (encorafenib) in combination with Mektovi® (binimetinib)	• Riely et al. J Clin Oncol. 2023 Jul 20;41(21):3700-3711. • BRAFTOVI. Prescribing Information. Array Biopharma Inc. 2023.	The clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®Liquid CDx to detect *BRAF* V600E alterations in patients with NSCLC who may benefit from treatment with encorafenib +binimetib was demonstrated in a clinical bridging study using samples from PHAROS(ARRAY-818-202; NCT03915951). See section 10.10 F1LCDx Technical Information at www.f1lcdxlabel.com.

FoundationOne Liquid CDx: Evidence Portfolio

Prostate Cancer, Breast Cancer, Colorectal Cancer and Solid Tumors

TUMOR TYPE	BIOMARKER(S) DETECTED	THERAPY	EVIDENCE	METHOD
Prostate Cancer	*BRCA1*, *BRCA2*, *ATM* alterations	LYNPARZA® (olaparib)	• de Bono J. N Engl J Med. 2020:382(22):2091-2102. • Lynparza® (Olaparib). Package insert. AstraZeneca: 2020.	Clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®Liquid CDx to detect *BRCA1,BRCA2,ATM* alterations in patients with prostate cancer who may benefit from treatment with Olaparib was demonstrated in a **clinical bridging study** using samples from cohort A of the PROfound trial (NCT02987543). See section 10.3 F1LCDx Technical Information www.f1lcdxlabel.com.
	BRCA1/2 alterations	AKEEGA® (niraparib + abiraterone acetate)	• Chi et al. J Clin Oncol. 2023 Jun 20;41(18):3339-3351. • AKEEGA®(niraparib + abiraterone acetate). Prescribing Information. Janssen 2023.	Clinical validity (concordance) and clinical utility(clinical effectiveness) of FoundationOne®Liquid CDx to detect BRCA1/2 alterations in patients with prostate cancer who may benefit from treatment with niraparib + abiraterone acetate was demonstrated in a **clinical bridging study** in samples from cohort 1 of MAGNITUDE (NCT03748641). See section 10.11 F1LCDx Technical Information www.f1lcdx.com.
	BRCA1/2 alterations	RUBRACA® (rucaparib)	• Abida W. J Clin Oncol. 2020:38(32):3763-3772. • RUBRACA® (rucaparib) prescribing information.	Clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®Liquid CDx to detect BRCA1/2 alterations in patients with prostate cancer who may benefit from treatment with rucaparib was demonstrated in a **clinical bridging study** using samples from TRITON2 (NCT0952534). See section 10.4 F1LCDx Technical Information www.f1lcdxlabel.com.
	BRCA1/2 alterations	Lynparza® (olaparib) in combination with abiraterone	• Saad et al. Lancet Oncology. 2023; 24(10):1094-108. • Lynparza®(Olaparib). Package insert. AstraZeneca: 2020.	Clinical utility (clinical effectiveness) of FoundationOne®Liquid CDx to detect BRCA1/2 alterations in patients with prostate cancer who may benefit from treatment with Olaparib in combination with abiraterone was directly demonstrated in PROpel (NCT03732820) where **F1LCDx was used as a clinical trial assay**. See section 10.12 F1LCDx Technical Information www.f1lcdxlabel.com.
Breast Cancer	*PIK3CA* mutations C420R, E542K, E545A, E545D [1635G>T only], E545G, E545K, Q546E, Q546R; and H1047L, H1047R, and H1047Y	PIQRAY® (alpelisib)	• André F. N Engl J Med. 2019:380(20): 1929-1940. • Woodhouse R. *PLoS One*. 2020;15(9):e0237802. • PIQRAY® (alpelisib) Prescribing Information. Novartis.2019.	Clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®Liquid CDx to detect *PIK3CA* mutations in patients with breast cancer who may benefit from treatment with alpelisib was demonstrated in a **clinical bridging study** using samples from SOLAR-1 (NCT02437318). See section 10.5 F1LCDx Technical Information www.f1lcdxlabel.com.
	PIK3CA alterations	Itovebi™ (inavolisib) in combination with palbociclib and fulvestrant	• Juric et al. J Clin Oncol. 2024;42(16): 1003-1003. • Itovebi™ (inavolisib). Prescribing Information. Genentech. 2024.	Clinical utility (clinical effectiveness) of FoundationOne®Liquid CDx to detect PIK3CA alterations in patients with breast cancer who may benefit from treatment with inavolisib in combination with palbociclib and fulvestrant was directly demonstrated in INAVO120 (NCT04191499) where **F1LCDx was used as the clinical trial assay**. See section 10.13 F1LCDx Technical Information www.f1lcdxlabel.com.
Solid Tumors	*NTRK1/2/3* fusions*	ROZLYTREK® (entrectinib)	• Dziadziuszko R, et al. Mol Oncol. 2022 May; 16(10):2000-2014. • Doebele RC, et al. Lancet Oncol. 2020 Feb;21(2):271-282. • Rozlytrek® (entrectinib). Package insert. Genentech USA, Inc.: 2023.).	Clinical validity (concordance) and clinical utility (clinical effectiveness) of FoundationOne®CDx to detect *NTRK 1/2/3* fusions in patients with solid tumors who may benefit from treatment with entrectinib was demonstrated in a **clinical bridging study** using samples from STARTRK-2 (NCT02568267). See section 10.8 F1LCDx Technical Information www.f1lcdxlabel.com.
Colorectal Cancer (CRC)	*BRAF* V600E	BRAFTOVI® (encorafenib) in combination with cetuximab	• Kopetz S, et al. *N Engl J Med*. 2019;381(17):1632-1643. • BRAFTOVI® (encorafenib) Prescribing Information. Pfizer. 2018.	Clinical validity (concordance) and clnical utility(clinical effectiveness) of FoundationOne®Liquid CDx to detect *BRAF* V600Ein patients with CRC who may benefit from treatment with encorafenib in combination with cetuximab was demonstrated in a **clinical bridging study using** samples from BEACON (NCT02928224). See section 10.10 F1LCDx Technical Information www.f1lcdxlabel.com.

FOUNDATION MEDICINE®

FoundationOne®CDx is a qualitative next-generation sequencing based in vitro diagnostic test for advanced cancer patients with solid tumors and is for prescription use only. The test analyzes 324 genes as well as genomic signatures including microsatellite instability (MSI) and tumor mutational burden (TMB) and is a companion diagnostic to identify patients who may benefit from treatment with specific therapies in accordance with the approved therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. Some patients may require a biopsy. For the complete label, including companion diagnostic indications and important risk information, please visit www.F1CDxLabel.com.

FoundationOne®Liquid CDx is for prescription use only and is a qualitative next-generation sequencing based in vitro diagnostic test for advanced cancer patients with solid tumors. The test analyzes 324 genes utilizing circulating cell-free DNA and is FDA-approved to report short variants in 311 genes and as a companion diagnostic to identify patients who may benefit from treatment with specific therapies (listed in Table 1 of the Intended Use) in accordance with the approved therapeutic product labeling. Additional genomic findings may be reported and are not prescriptive or conclusive for labeled use of any specific therapeutic product. Use of the test does not guarantee a patient will be matched to a treatment. A negative result does not rule out the presence of an alteration. When considering eligibility for ROZLYTREK® based on the detection of NTRK1/2/3 and ROS1 fusions, or for TEPMETKO® based on the detection of MET SNVs and indels that lead to MET exon 14 skipping, testing using plasma specimens is only appropriate for patients for whom tumor tissue is not available for testing. Patients who are negative for other companion diagnostic mutations should be reflexed to tumor tissue testing and mutation status confirmed using an FDA-approved tumor tissue test, if feasible. For the complete label, including companion diagnostic indications and complete risk information, please visit www.F1LCDxLabel.com.

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