



## 吉因加临床检测服务

学术、专业、值得信赖

服务临床，不止于临床 ·

泛癌种、全病程、多维度 ·

坚持创新，多重验证 ·

# 吉因加临床检测服务

学术、专业、值得信赖

吉因加临床检测服务围绕肿瘤诊疗切实需求,基于高通量测序技术和肿瘤基因大数据平台,提供专业全面的解决方案。

2017年,吉因加全线推出Onco系列泛癌种、全病程临床检测产品,从DNA、RNA、病毒和免疫等多个维度检测与肿瘤发生发展相关的1021个基因,为临床诊疗方案提供更为全面的辅助信息。在产品临床应用过程中,我们不断优化检测指标,并通过大数据对产品进行性能和临床的双重验证,使临床服务更加专业、高效、可靠。同时,我们创新性地将ctDNA检测应用于肿瘤早期,开发国内首个早期肿瘤专属检测产品OncoS,并引领行业将肿瘤检测从DNA层面扩展到RNA层面,推出OncoWESuper全外显子组和OncoFusion融合基因检测,让对抗肿瘤的战场更加清晰。

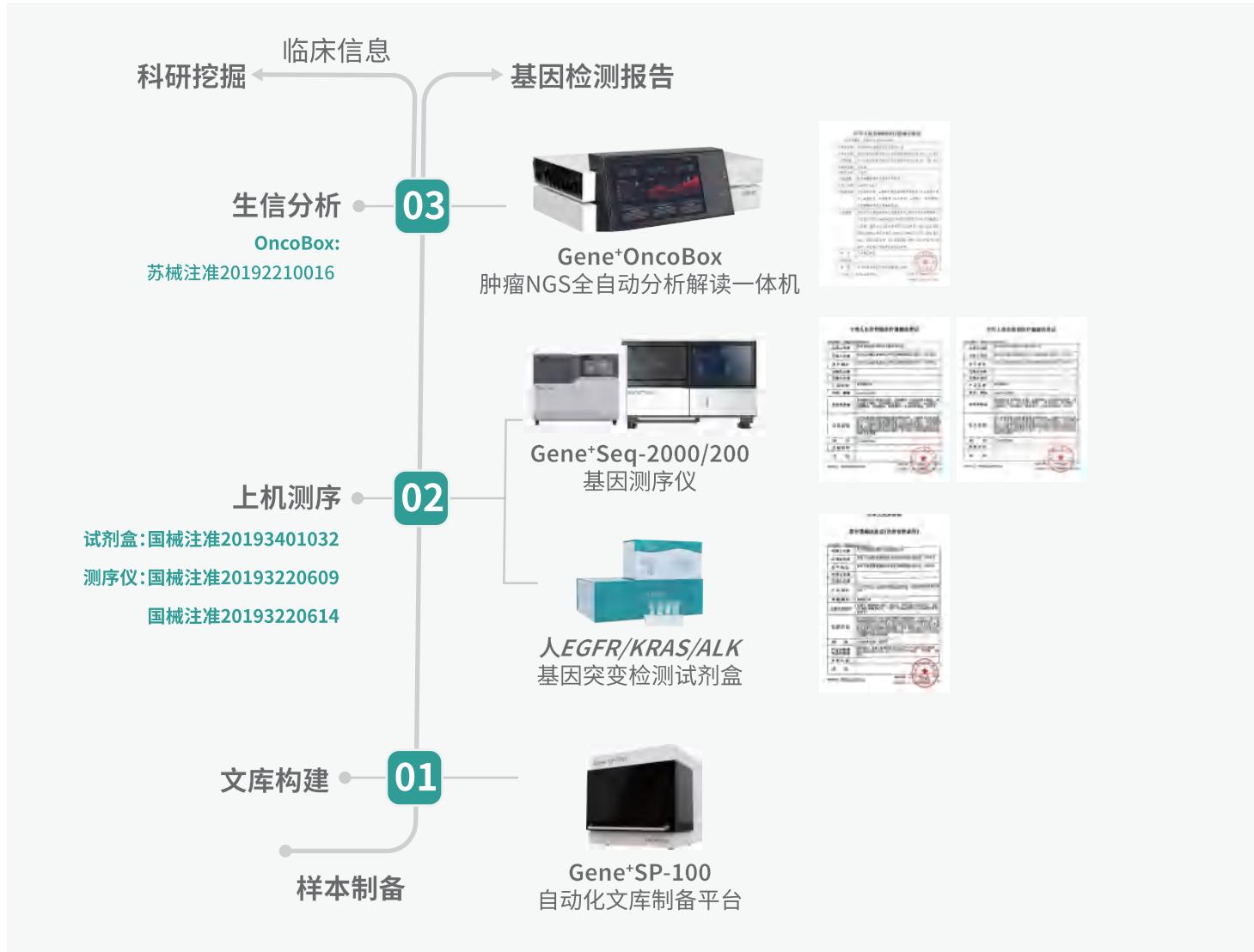
秉承学术、专业、值得信赖的服务信条,我们已为国内外400余家医院、药企及科研机构提供临床检测和新药研发检测服务;累积肿瘤医疗大数据14万余份;6项产品服务获得北京市新技术新产品(服务)证书;基于吉因加肿瘤大数据服务平台,与临床专家合作,产出90多项科研成果,在 *Nature, Clinical Cancer Research, Journal of Thoracic Oncology* 等国际权威学术期刊发表。

2019年,吉因加国产自主品牌的测序仪、试剂盒、数据分析软件“三证齐全,全面合规”,将进一步带动院内肿瘤精准医疗全面开展,以其精准、灵活、实惠的优势服务更多患者,促进我国肿瘤精准诊疗水平不断提高。



## 全面合规,行业领先

2019年,在肿瘤基因检测领域,吉因加率先实现试剂、仪器和软件“三证齐全,全面合规”,配合吉因加自动化文库制备平台,为肿瘤NGS入院提供一体化解决方案。



## 惠及更多患者

国产高通量测序平台的全面获批,验证了国家大力发展战略品牌,打破医疗行业进口产品垄断的决心。国产高通量测序平台将极大降低基因检测的费用,促进基因检测技术下沉到基层,让更多的肿瘤患者受益于精准医疗。

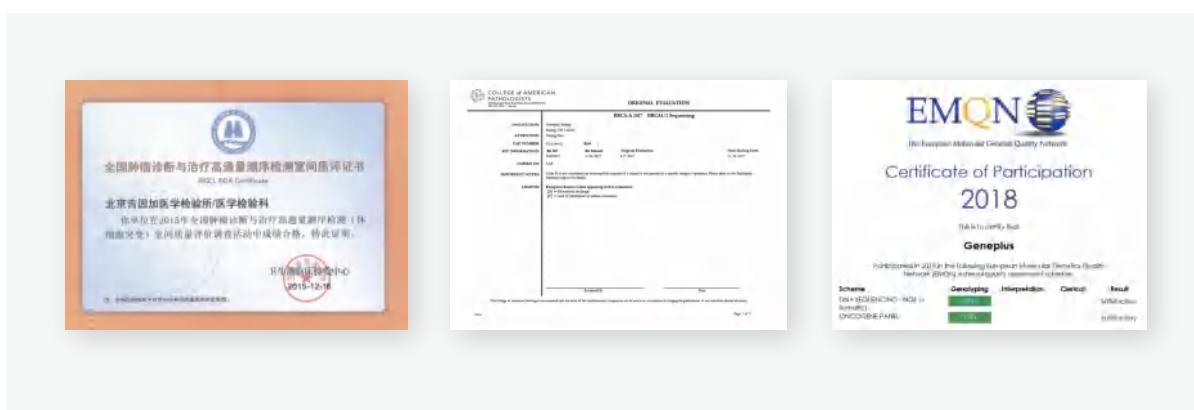
## 吉因加临床检验实验室

### 高质量、高标准的临床检验服务

吉因加临床检验实验室是卫健委批准成立的第三方独立医学检验实验室。实验室按照临床基因检测实验室最高标准搭建，已荣获国际权威医学实验室CAP认证、CLIA认证。自2015年，实验室连续4年高水平通过国家卫健委临检中心（NCCL）、美国病理学家协会（CAP）、欧洲分子基因诊断质量联盟（EMQN）等国内外权威机构的考核。2020年，实验室与CTONG中国胸部肿瘤协作组联合设立中心实验室，充分彰显了公司在精准检测、生信分析、专业解读方面的领先实力。

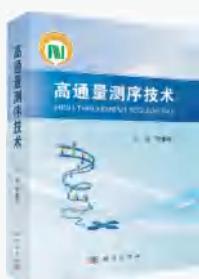


- 累计参加95次国内外室间质评及标准品项目，均高水准通过
- 53次NCCL组织的包括ctDNA、EGFR、BRCA、KRAS等检测在内的多项室间质评项目，全部满分通过
- 24次CAP-PT组织的包括实体瘤、生信分析、ctDNA、BRCA检测在内的多项室间质评项目，均高水平通过
- 9次EMQN组织的包括EGFR、ctDNA、BRCA检测在内的多项室间质评项目，均高水平通过
- 9次包括肿瘤组织、BRCA、EGFR、KRAS等基因标准品及TMB分析项检测，均取得良好的检测结果



## 推动行业标准建立

面对肿瘤基因检测缺乏统一行业标准的现实,吉因加利用自身在临床检测方面丰富的经验和过硬的技术,参与权威机构组织的多项行业标准建立工作,积极推进肿瘤基因检测进一步规范。



### 国内第一本 NGS规范化培训教材

国家卫健委中心李金明主任  
主编《高通量测序技术》

### 高通量测序技术临床规范化应用北京专家共识(第一版肿瘤部分)

北京大学肿瘤医院等。国家肿瘤学质控委员会、首都医科大学附属北京肿瘤医院  
血液肿瘤学组、血液病学组、肿瘤精准治疗组、肿瘤内科、放射治疗科、放疗质控组、化疗  
质控组、生物样本库管理与质控组等多学科专家共同协作完成。主编 李金明,  
Email: jinming@bjtumc.edu.cn  
基金项目: 医疗卫生管理与法规基金面上项目(T2013D0111)和首都医  
院基本科研项目(Q2W13)资助等。DOI:10.3969/j.issn.1006-2441.2015.01.004  
DOI:10.3969/j.issn.1006-2441.2015.01.004

### 行业权威NGS临床检验 和病理专家共识

《肿瘤基因突变高通量测序技术  
临床检测规范化应用北京专家共识》



### 共建中国人群 基因解读标准

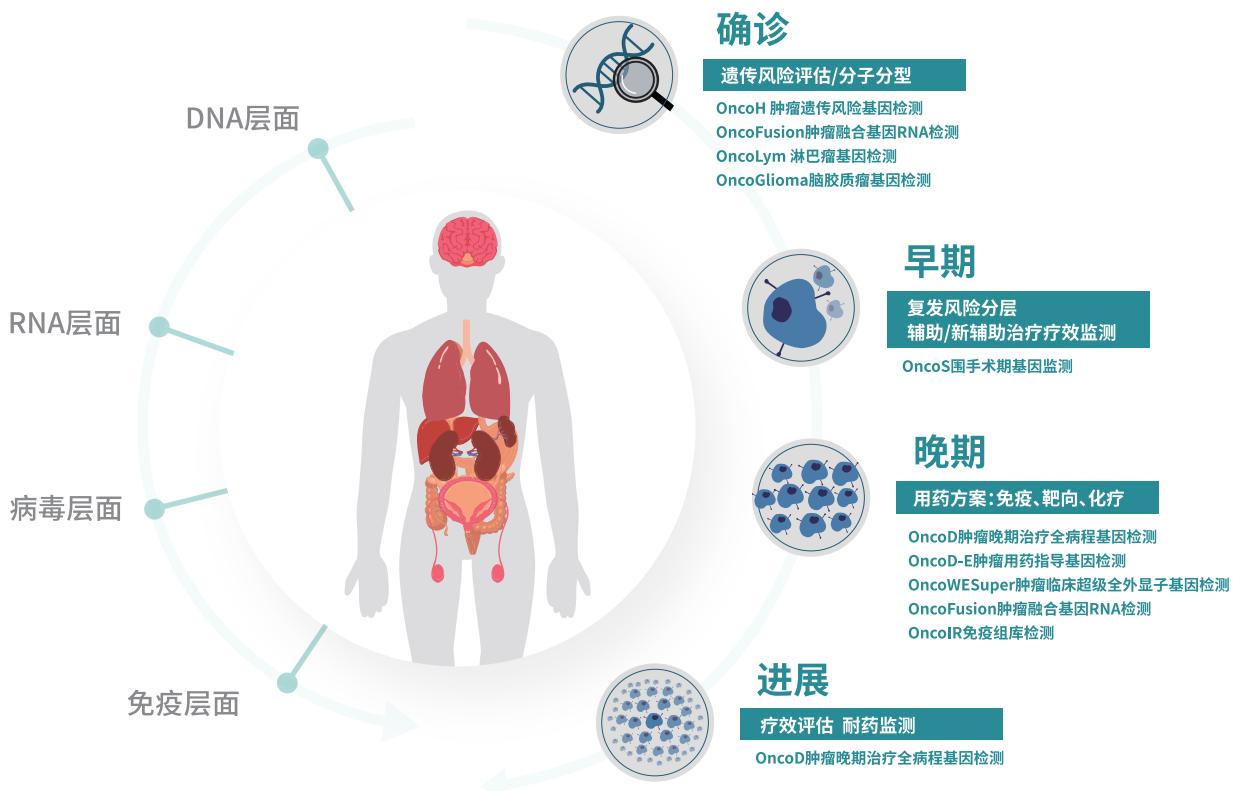
基于中国人群的  
BRCA基因突变参考数据库



### 首个肿瘤突变负荷 检测标准

中检院关于TMB注册检验  
国家标准品和参考说明书

### 全癌种、全病程、多维度



吉因加Onco系列泛癌种、全病程临床检测产品，围绕肿瘤临床诊疗切实需求，从DNA层面、RNA层面、病毒层面、免疫层面等多个维度全面解析肿瘤。40余款产品针对不同治疗阶段的诊疗需求，从疾病的确诊分型、遗传基因检测、围手术期复发风险及治疗方案制定、肿瘤晚期靶向、化疗及免疫治疗方案等需求助力临床进行精准决策；并结合独创指标，实现肿瘤耐药原因分析、疗效评估、疾病进展监测。产品可根据临床诊疗需求、应用科室、患者人群进行灵活组合，辅助临床医生快速找到最佳治疗方案。

## 创新引领, 让临床检测更精准



### 国内首个大Panel:

1021Panel覆盖 900+肿瘤发生发展相关基因、肿瘤遗传风险易感基因及病毒序列基因, 满足临床检测的同时, 快速积累肿瘤基因数据, 助力医生透过数据更深入地解析肿瘤, 推动临床转化。



### 独创时空异质性算法:

mTBI分子肿瘤负荷指数辅助临床提前识别疾病进展, mClone分子克隆锁定耐药原因。化零为整, 轻松实现肿瘤异质性评估和监测。



### ctDNA新应用:

OncoS系列产品挑战早期肿瘤液体活检技术难题, 关注肿瘤预后评估和治疗方案制定, 补充临床诊疗体系, 让围手术期治疗更加精细化。



### 免疫数字化:

OncolR免疫组库检测, 从免疫微环境和宿主状态等维度全面数字化评估机体免疫系统, 精准探寻免疫治疗获益人群。



### 肿瘤检测新高度

OncoWESuper系列产品通过WES和RNA-seq一次性获得100G测序数据, 从DNA和RNA两个层面, 让临床更精准, 让科研无缺憾。

OncoFusion产品基于NGS-RNA进行融合突变检测, 从RNA层面攻克融合突变, 让罕见突变无所遁形。

多重验证, 让产品应用更可靠



**性能验证:**

40余万肿瘤突变数据训练, 实现肿瘤检测区域全覆盖, 检测指标性能更灵敏

**临床验证:**

14万以上中国人群肿瘤数据临床验证,  
确保产品临床应用准确高效

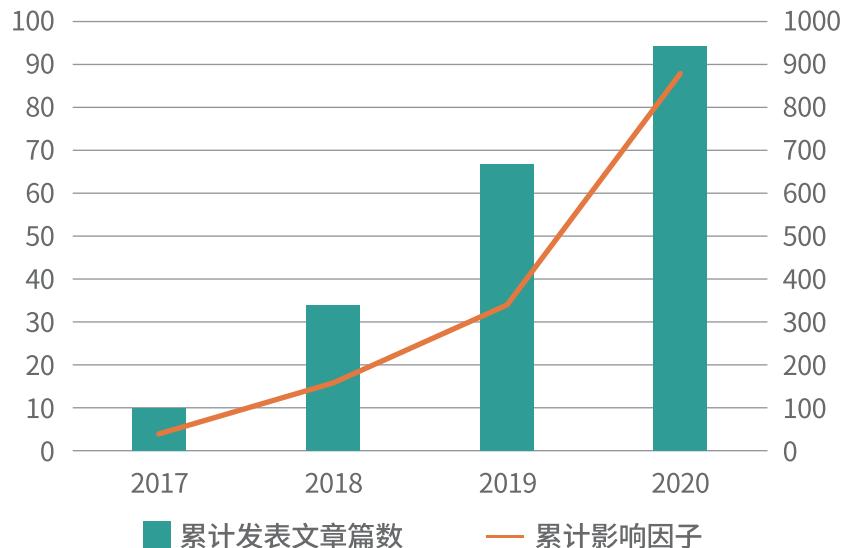
**同行评议:**

90多项学术成果权威期刊发表, 支撑每一项产品与技术精准可靠

吉因加致力于成为最值得信赖的肿瘤基因大数据服务平台, 我们始终践行双  
样本平行分析策略; 每一款产品和临床检测指标均经过万余份数据和千余例  
样本, 进行性能和临床的双重验证; 同时, 我们与临床专家合作, 产出近百篇  
高质量学术文章, 进一步支撑了产品和技术在临床应用的可靠性。

## 丰硕的学术成果

基于吉因加肿瘤基因大数据平台14万余份肿瘤基因大数据,临床专家与我们合作,截至2020年3月,已在国际权威学术期刊发表SCI论文90+篇,累计影响因子约930分。在ASCO、WCLC、ESMO、AACR等国际会议发表摘要157余篇。



## 高效的数据挖掘工具



### · V-USE医学数据分析系统

通过专业的MSL医学服务团队的协助,临床专家可利用V-USE进行患者管理,在线MDT案例交流、多中心项目合作等临床探索,用医疗大数据解锁新发现、新应用、新探索。

### · 吉云平台-云端信息分析工具

通过该平台,临床医生、药企和科研机构可免去数据管理、分发和分析的负担,通过自由组合的生信分析模块,进行基因频谱、免疫等方面的科研探索。



## 多中心临床研究项目

基于ctDNA临床诊疗的实用性,吉因加与临床专家合作启动了数项多中心临床项目,利用高标准的ctDNA检测分析平台和独特的分析技术,从分子层面探索克服肿瘤异质性的有效方法。



多中心临床项目围绕多个癌种建立了12条基线,展开300多项科研合作,累计样本14万余,产出大量研究成果,推动临床检测技术进步的同时,再次验证了吉因加全病程监测产品的可靠性。



## 大数据挖掘人才联合培养

针对肿瘤领域“临床+科研”的转化医学研究特点，吉因加与西安交通大学、北京协和医院、中国医学科学院肿瘤医院、中南大学湘雅医院等30几家单位的临床专家合作，启动研究生联合培养计划。通过双导师培养，提高临床医生在肿瘤基因组学领域的科研探索及临床问题解决能力。

文章名称（联合培养实习生在国际学术会议上发表摘要）	会议名称
Analysis of Circulating Tumor DNA to Monitor Metastatic Breast Cancer Patients Treated with First-Line Chemotherapy (CAMELLIA study).	ASCO
KLF4 p.A472D Mutation, an Acquired Resistant Mutation to Cetuximab in Colorectal Cancer.	ASCO
Pathogenic Germline Mutation Profile in Chinese Lung Cancers and Related Driver Mutation Pattern.	ASCO
Tumor and Microenvironment Evolution during Chemotherapy Combine with Bevacizumab in Colorectal Cancer Liver Metastasis	ASCO
A Novel Non-invasive Biomarker Based on Peripheral PD-1posi CD8 T Cell Receptor Repertoire Correlated with Clinical Outcomes to Immunotherapy in Non-Small Cell Lung Cancer.	ASCO
Clinical and Genomic Features of Chinese Lung Cancer Patients with Germline Mutations	WCLC
The Sharing of T Cell Clones in Peripheral CD8+PD-1+ T Cells with TILs Is a Novel Biomarker Predicting the Efficacy of Anti-PD-L1 Therapy	WCLC
A Novel Non-Invasive Biomarker Based on Peripheral PD-1+CD8+T Cell Receptor Repertoire Predicts Clinical Outcomes of Immunotherapy in NSCLC	WCLC
The Co-Occurring Genomic Landscape of ERBB2 Exon 20 Insertion in NSCLC and the Potential Indicator of Response to Afatinib	WCLC

临床+科研

双导师培养

40+临床研究生

来自全国30+医院/高校

多项学术成果

## 搭建国际学术合作的桥梁

吉因加与美国MD安德森癌症中心、美国杜克大学、美国俄亥俄州立大学，美国华盛顿大学等建立了长期合作关系，在肿瘤基因组学、肿瘤进化与异质性、肿瘤早期检测、肿瘤遗传风险、肿瘤免疫治疗、肿瘤基因大数据等领域，搭建国内专家和国外科研机构合作的桥梁，为开展国际合作研究建立通道，并已在国际权威期刊发表多项研究成果。



## 共建精准医疗生态圈

吉因加与肿瘤精准医疗各领域引领者建立了紧密合作关系,通过多方社会资源的合作,共建肿瘤精准医疗生态圈,推动肿瘤基因检测技术进一步发展,提升中国基因检测整体能力和水平,加速我国个体化医疗落地惠民。



## 吉因加发表文章列表

文章名称 (临床数据挖掘类)	期刊
Dendritic cell/cytokine-induced killer cell immunotherapy combined with S-1 in patients with advanced pancreatic cancer: A prospective study	Clinical Cancer Research
HIF2A germline-mutation-induced polycythemia in a patient with VHL-associated renal-cell carcinoma	Cancer Biology & Therapy
Carney complex with PRKAR1A gene mutation: A case report and literature review	Medicine (Baltimore)
A novel germline ARMC5 mutation in a patient with bilateral macronodular adrenal hyperplasia: a case report	BMC Medical Genetics
A novel BRCA2 mutation in prostate cancer sensitive to combined radiotherapy and androgen deprivation therapy	Cancer Biology & Therapy
Identifying circulating tumor DNA mutation profiles in metastatic breast cancer patients with multilane resistance	EBioMedicine
Novel genotype-phenotype correlations in five Chinese families with Von Hippel-Lindau disease	Endocrine Connections
A retrospective case study of sunitinib treatment in three patients with Von Hippel-Lindau disease	Cancer Biology & Therapy
Giant bilateral adrenal myelolipomas in two Chinese families with congenital adrenal hyperplasia	Endocrine Connections
Next generation sequencing reveals a novel ALK G1128A mutation resistant to crizotinib in an ALK-Rearranged NSCLC patient	Lung Cancer
Autologous dendritic cell-cytokine induced killer cell immunotherapy combined with S-1 plus cisplatin in patients with advanced gastric cancer: a prospective study	Clinical Cancer Research
SRBD1-ALK, a novel ALK fusion gene identified in an adenocarcinoma patient by next-generation sequencing	Journal of Thoracic Oncology
EGFR L718Q mutation occurs without T790M mutation in a lung adenocarcinoma patient with acquired resistance to osimertinib	Journal of Translational Medicine
Identification of germline mismatch repair gene mutations in lung cancer patients with paired tumor-normal next generation sequencing: a retrospective study	Frontiers in Oncology
Genetic analysis of a hereditary medullary thyroid carcinoma case with normal preoperative serum calcitonin levels	Pathology Research and Practice
Identification of the aRAF V600E mutation in a patient with sclerosing pneumocytoma: A case report	Lung Cancer
Different responses to anti-programmed cell death protein 1 (PD-1) immunotherapy in a patient with Lynch syndrome and metachronous urothelial and colon cancer: A case report.	Oncology Letters
Identification of a novel RBPMS-ROS1 fusion in an adolescent patient with microsatellite-instable advanced lung adenocarcinoma sensitive to crizotinib: a case Report	Clinical Lung Cancer
Identification of driver genes related to high tumor mutation burden in hepatocellular carcinoma using next-generation sequencing: implications for immunotherapy	Oncology Letters
Coexistence of a novel PRKCB-ALK, EML4-ALK double-fusion in a lung adenocarcinoma patient and response to crizotinib	Journal of Thoracic Oncology

文章名称 (联合培养实习生参与文章)	期刊
ctDNA dynamics: a novel indicator to track resistance in metastatic breast cancer treated with anti-HER2 therapy	Oncotarget
Landscape of somatic mutations in different subtypes of advanced breast cancer with circulating tumor DNA analysis	Scientific Reports
Association of tumor protein p53 and ataxia-telangiectasia mutated comutation with response to immune checkpoint inhibitors and mortality in patients with non-small cell lung cancer	JAMA Network Open
TCR repertoire diversity of peripheral PD-1+CD8+ T cells predicts clinical outcomes after immunotherapy in patients with non-small cell lung cancer	Cancer Immunology Research

## 吉因加发表文章列表

文章名称 (检测标准类)	期刊
Quality control of next-generation sequencing-based in vitro diagnostic test for onco-relevant mutations using multiplex reference materials in plasma	Journal of Cancer
A reference system for BRCA mutation detection based on next-generation sequencing in the Chinese population	Journal of Molecular Diagnostics
《高通量测序技术临床规范化应用北京专家共识》(第一版肿瘤部分)	中华医学杂志
文章名称 (技术验证类)	期刊
Technical validation of a next-generation sequencing assay for detecting clinically relevant levels of breast cancer-related single-nucleotide variants and copy number variants using simulated cell-free DNA	Journal of Molecular Diagnostics
The feasibility of using mutation detection in ctDNA to assess tumor dynamics	International Journal of Cancer
Detection of rare mutations in ctDNA using next generation sequencing	J Vis Exp
SOAPnuke: a MapReduce acceleration-supported software for integrated quality control and pre-processing of high-throughput sequencing data	GigaScience
Simultaneous VENTANA IHC and RT-PCR testing of ALK status in Chinese non-small cell lung cancer patients and response to crizotinib	Journal of Translational Medicine
Characteristics and prognostic significance of profiling the peripheral blood T-cell receptor repertoire in patients with advanced lung cancer	International Journal of Cancer
Circulating tumor DNA analyses predict progressive disease and indicate trastuzumab-resistant mechanism in advanced gastric cancer	EBioMedicine
Preferable background filtering for next-generation sequencing analysis in non-small cell lung cancer: pericarcinomatous tissues or peripheral blood lymphocytes?	Cancer Communications
Assessing tumor heterogeneity using ctDNA to predict and monitor therapeutic response in metastatic breast cancer	International Journal of Cancer
Co-mutational assessment of circulating tumour DNA (ctDNA) during osimertinib treatment for T790M mutant lung cancer	Journal of Cellular and Molecular Medicine
Cost-effectiveness analysis of pembrolizumab versus chemotherapy as first-line treatment in locally advanced or metastatic non-small cell lung cancer with PD-L1 tumor proportion score 1% or greater	Lung Cancer
文章名称 (产品应用类)	期刊
Application of circulating tumor DNA as a non-invasive tool for monitoring the progression of colorectal cancer	PLOS One
ctDNA dynamics: a novel indicator to track resistance in metastatic breast cancer treated with anti-HER2 therapy	Oncotarget
Mutational profiling of non-small-cell lung cancer resistant to osimertinib using next-generation sequencing in Chinese patients	BioMed Research International
Detection and differential diagnosis of cancer relapse using circulating tumor DNA profiling in a patient with synchronous breast and rectal cancer	Cancer Biology & Therapy
Germline SDHB and SDHD mutations in pheochromocytoma and paraganglioma patients	Endocrine Connections
Clinical factors associated with circulating tumor DNA (ctDNA) in primary breast cancer	Molecular Oncology
The correlations of tumor mutational burden among single-region tissue, multi-region tissues and blood in non-small cell lung cancer	Journal for Immunotherapy of Cancer
The diagnostic and prognostic usage of circulating tumor DNA in operable hepatocellular carcinoma	American Journal of Translational Research

## 吉因加发表文章列表

文章名称 (科研产出类)	期刊
Whole-exome sequencing predicted cancer epitope trees of 23 early cervical cancers in Chinese women	Cancer Medicine
Landscape of somatic mutations in different subtypes of advanced breast cancer with circulating tumor DNA analysis	Scientific Reports
Clonal characteristics of paired infiltrating and circulating B lymphocyte repertoire in patients with primary biliary cholangitis	Liver International
TP53 mutations predict for poor survival in ALK rearrangement lung adenocarcinoma patients treated with crizotinib	Journal of Thoracic Disease
Comprehensive molecular characterization of young Chinese patients with lung adenocarcinoma identified a distinctive genetic profile	The Oncologist
Circulating tumor DNA analysis depicts subclonal architecture and genomic evolution of small cell lung cancer	Nature Communications
Landscape of somatic mutations in gastric cancer assessed using next-generation sequencing analysis	Oncology letters
Plasma PIK3CA ctDNA specific mutation detected by next generation sequencing is associated with clinical outcome in advanced breast cancer	American Journal of Cancer Research
Osimertinib quantitative and gene variation analyses in cerebrospinal fluid and plasma of non-small cell lung cancer patient with leptomeningeal metastases	Current Cancer Drug Targets
Anti-PD-1 antibody SHR-1210 combined with apatinib for advanced hepatocellular carcinoma, gastric or esophagogastric junction cancer: An open-label, dose escalation and expansion study	Clinical Cancer Research
Comprehensive genomic variation profiling of cervical intraepithelial neoplasia and cervical cancer identifies potential targets for cervical cancer early warning	Journal of Medical Genetics
Local mutational diversity drives intratumoral immune heterogeneity in non-small cell lung cancer	Nature Communications
Clinical and genetic risk factors for Fulvestrant treatment in post-menopause ER-positive advanced breast cancer patients	Journal of Translational Medicine
Intratumor heterogeneity comparison among different subtypes of non-small-cell lung cancer through multi-region tissue and matched ctDNA sequencing	Molecular Cancer
Clinical characteristics and genetic analysis of gene mutations in a Chinese pedigree with Peutz - Jeghers syndrome	Clinical Case Reports
Prevalence of recurrent oncogenic fusion in mismatch repair-deficient colorectal carcinoma with hypermethylated MLH1 and wild-type BRAF and KRAS	Modern Pathology
Clonal architectures predict clinical outcome in clear cell renal cell carcinoma	Nature Communications
A single-arm, phase II study of apatinib in refractory metastatic colorectal cancer	The Oncologist
Genotyping of circulating tumor DNA reveals the clinically-actionable mutation landscape of advanced colorectal cancer	Molecular Cancer Therapeutics
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Genomic analysis of primary and recurrent gliomas reveals clinical outcome related molecular features	Scientific Reports
TCR repertoire diversity of peripheral PD-1+CD8+ T cells predicts clinical outcomes after immunotherapy in patients with non-small cell lung cancer	Cancer Immunology Research
Next-generation sequencing based mutation profiling reveals heterogeneity of clinical response and resistance to osimertinib	Lung Cancer
The role of genomic subtyping by sequencing tumor or cell-free DNA in pulmonary large-cell neuroendocrine carcinoma	Clinical Cancer Research

统计截止至2019年底



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