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基于侧向层析的即时检测在临床中的研究进展

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【摘 要】侧向层析(lateral flow assay,LFA)作为即时检测(point-of-care testing,POCT)的核心技术,通过层压试纸条结构与多元检测原理,实现了病原体、肿瘤标志物及健康指标的快速检测,是当前即时检测最成功的技术之一。本综述系统阐述LFA的组成、检测原理及临床应用,并结合人工智能(artificial intelligence,AI)与全生命周期健康管理需求,探讨其智能化升级方向。当前该技术存在半定量判读主观性等问题,未来结合纳米材料、智能识别及云端管理,LFA将朝精准定量、多模态检测及智能化发展,助力分级诊疗,推动个性化精准医疗。随着医科与工科的融合,AI图像识别与深度学习技术的融入,使LFA从单纯结果判读可以考虑迈向"检测—建议"一体化,通过"纳米材料+智能算法+云端数据"的深度融合,成为基层医疗与精准医疗的关键纽带,助力实现"健康中国2030"的宏伟目标。

【关键词】即时检测;侧向层析;临床诊断;人工智能;全生命周期健康
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Research advances in the clinical application of lateral flow assay-based point-of-care testing

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【Abstract】Lateral flow assay (LFA), as the core technique of point-of-care testing (POCT), enables rapid detection of pathogens, tumor biomarkers, and health indicators through its laminated test strip structure and multiplex detection principles, making it one of the most successful instant diagnostic technologies to date. This review systematically elaborates on the components, detection principles, and clinical application of LFA and explores the directions for intelligent upgrade by integrating artificial intelligence (AI) and the demands of whole-lifecycle health management. Current challenges, such as subjective semi-quantitative interpretation, highlight the need for future advances in precise quantification of this technology, multimodal detection, and intelligent development through the integration of nanomaterials, smart recognition, and cloud management, thereby facilitating hierarchical diagnosis and treatment and promoting the development of individualized precision medicine. With the integration of medical and engineering fields, AI image recognition and deep learning techniques will help LFA evolve from simple interpretation of results into "detection-recommendation" integration and become a critical nexus between primary medical care and precision medicine through the deep integration of "nanomaterials+intelligent algorithms+cloud data", ultimately supporting the realization of the "Healthy China 2030" vision.

【Key words】point-of-care testing; lateral flow assay; clinical diagnosis; artificial intelligence; whole lifecycle health

即时检测(point-of-care testing,POCT)作为现代医疗体系的重要组成部分,正通过技术革新重塑诊疗模式,实现了"非专业人员操作[1]、采样现场即时分析、10~30 min反馈结果[2]"的即时化诊疗闭环。从医院临床旁的血糖监测[3]到社区慢性病(如高血压、糖尿病)的长期管理[4]再到传染病防控中人类免疫缺陷病毒(human immunodeficiency virus,HIV)、人乳头瘤病毒(human papilloma virus,HPV)的现场初筛[5],POCT以低成本、快速响应的特性,成为连接中心实验室与基层医疗的关键纽带,为临床医师咨询患者信息,制定医疗计划和后续随访提供更多的时间[6]。尤其在医疗资源匮乏的中低收入地区,依赖大型设备检测方法难以普及[7],便携式、经济实惠且用户友好的检测技术成为了研发的焦点[8]。

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作为POCT领域的核心技术，侧向层析技术（lateral flow assay，LFA）以“纳米探针标记＋毛细层析”的极简设计，在经济不发达地区疾病检测[9]、传染病应急筛查[10]、家庭健康自检[11]群体免疫情况的评估等场景中展现独特价值。其核心优势在于10~30 min完成定性/半定量检测，未来还可以通过与人工智能（artificial intelligence，AI）的深度融合，开启“检测－分析－建议”的智能化升级：智能手机搭载的AI图像识别算法可自动解析试纸条显色强度，结合云端医学知识库生成初步诊疗建议而全生命周期健康管理则是整合预防、筛查、诊断、治疗和康复的全程健康干预体系，该体系可以从时间维度、空间维度、主体维度等方面实现协同管理[12]。近年来在精准医学和数字健康技术推动下，世界卫生组织将其逐步发展为包含生物－心理－社会医学模式的综合健康管理范式。

值得关注的是，LFA正从单一疾病检测工具进化为全生命周期健康管理的核心载体，其应用场景正从传统疾病诊断向全生命周期健康管理拓展。全生命周期健康管理强调覆盖个体从孕前、儿童期、成年期到老年期的连续性健康监测需求，而LFA凭借其低成本、易操作和快速响应特性，恰好满足不同生命阶段的差异化需求，其可以在不同时期发挥不同作用，这一优势使其成为现代医疗体系中“早预防、早发现、早干预”的关键支点。

1 LFA的组成部分和检测靶标

1.1 组成部分

其结构由5部分协同构成，如图1所示，LFA核心部分－试纸条为层压结构[13]，样品垫对样品进行预处理，降低试纸条的非特异性吸附。结合垫主要搭载纳米探针-蛋白偶联物负载纳米探针标记的生物识别分子，可实现与靶标分子的特异性偶联；反应垫一般为以硝酸纤维素膜为基质，包被检测带（T带）和质控带（C带）。T带用于检测标本中是否有目的物；C带用于验证样本层析是否成功。

1.2 LFA的检测靶标及原理

根据靶标分子特性，LFA衍生出3种核心检测模式：双抗体夹心法和间接法（大分子检测）、竞争法（小分子检测）和适配体/规律间隔成簇短回文重复序列相关蛋白（clustered regularly interspaced short palindromic repeats-associated protein，CRISPR-Cas）系统耦合技术（核酸检测）。

1.2.1 大分子检测 LFA检测针对分子量≥5 kDa的蛋白质和激素，主要借助具有高特异性和灵敏度免疫分析法[14]，该方法基于抗原（Antigen，Ag）与抗体（Antibody，Ab）的反应，主要采用双位点识别：结合垫上的纳米探针-Ab1偶联物随样本迁移，若样本中存在靶标Ag，则形成“Ab1-Ag”复合物；当复合物流经T带时，被固定化的Ab2特异性捕获，形成“Ab2-Ag-Ab1-纳米探针”三元复合物，通过纳米探针的显色实现可视化检测。C带则通过捕获游离的Ab1-纳米探针复合物验证检测有效性。

以检测人绒毛膜促性腺激素（human chorionic gonadotropin，HCG）为例，液体样本如图2所示结合垫上的纳米探针-鼠源抗HCG抗体1与样本中的HCG结合，形成“Ab1-HCG”复合物，流经T带时被抗HCG抗体2捕获，形成“Ab2-HCG-Ab1-纳米探针”复合物，通过T线显色。C带验证检测有效性。HCG检测是早期妊娠诊断的金标准。LFA通过便携试纸条实现居家自检，为孕妇及时提供妊娠确认，助力早期孕期保健与计划生育决策。此外，异常妊娠的HCG水平异于正常妊娠，LFA的快速筛查可辅助临床早期识别异常，降低母婴健康风险。

1.2.2 小分子检测 针对小分子物质，因表位单一，采用竞争结合机制：结合垫上的纳米探针-Ab偶联物与样本中的游离靶标（小分子Ag）竞争结合T带上的固定化Ag。当样本中Ag浓度越高，结合垫上的Ab与Ag结合越充分，导致T带处可结合的Ab减少，条带显色强度与靶标浓度呈负相关，通过比色法或荧光定量实现浓度反推。

以小分子添加剂盐酸克伦特罗（clenbuterol，CLE）为例，如图3所示液体样本层析到结合垫，当样本中存在CLE时，会首先与结合垫上的纳米探针-鼠源抗CLE-Ab特异性结合，剩下多余的纳米探针-鼠源抗CLE-A会随着样品层析并与b与T带的Ag^{+}结合。样本中CLE浓度越高，T带显色越浅。CLE作为非法添加的“瘦肉精”，可引发人类心悸等中毒症状。LFA的现场快速检测能力，可应用于畜牧养殖、食品加工环节的实时筛查，保障公众饮食安全。

1.2.3 核酸检测 目前基于核酸适配体的LFA已广泛应用于疾病诊断研究[15]。通过“初级适配体-靶标-次级适配体”的夹心结构结合荧光纳米探针信号放大，可实现特定核酸靶标的高灵敏度检测。例如，在凝血酶（thrombin，THR）mRNA的检测中，实验测得的检测限（LOD）为0.046 pM[16]，但该灵敏度高度依赖于靶标核酸的特异性序列及适配体结合效率，不同核酸靶标需独立优化检测体系。

以凝血酶的检测为例，液体样本如图4所示方向层析到结合垫，使固化在结合垫上形成的THR-初级适配体-纳米探针复合物层析至T带，形成次级适配体-THR-初级适配体-纳米探针复合物，T带显色，C带验证其有效性。

LFA将CRISPR/Cas系统引入LFA，称为CRISPR/Cas9介导的侧向层析核酸试验，通过基因编辑特异性识别靶标核酸。

以检测新冠病毒RNA为例，将待测样本核酸提取后进行逆转录聚合酶链式反应（reverse transcription polymerase chain reaction，RT-PCR）并在反应中添加生物素修饰的引物，将扩增产物滴加在试纸条的样品垫上，样本如图5所示，

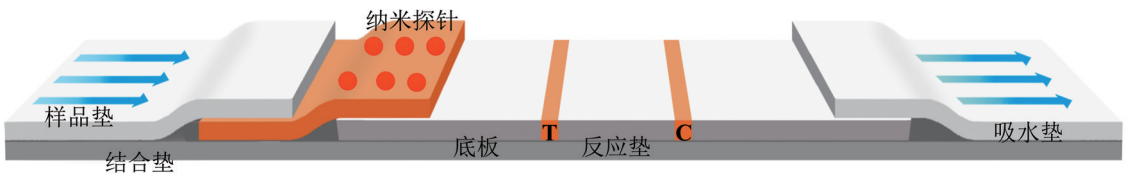


图1 LFA试纸条的典型结构

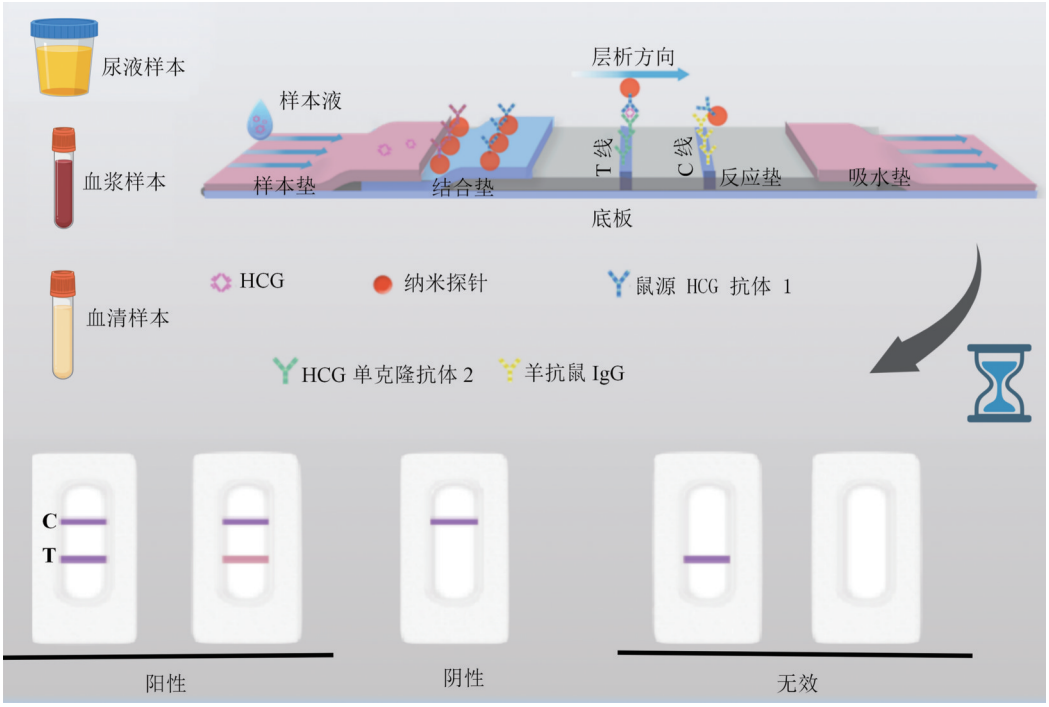


图2 双抗体夹心法HCG试纸条样本来源、内部结构、反应原理及结果读取示意图

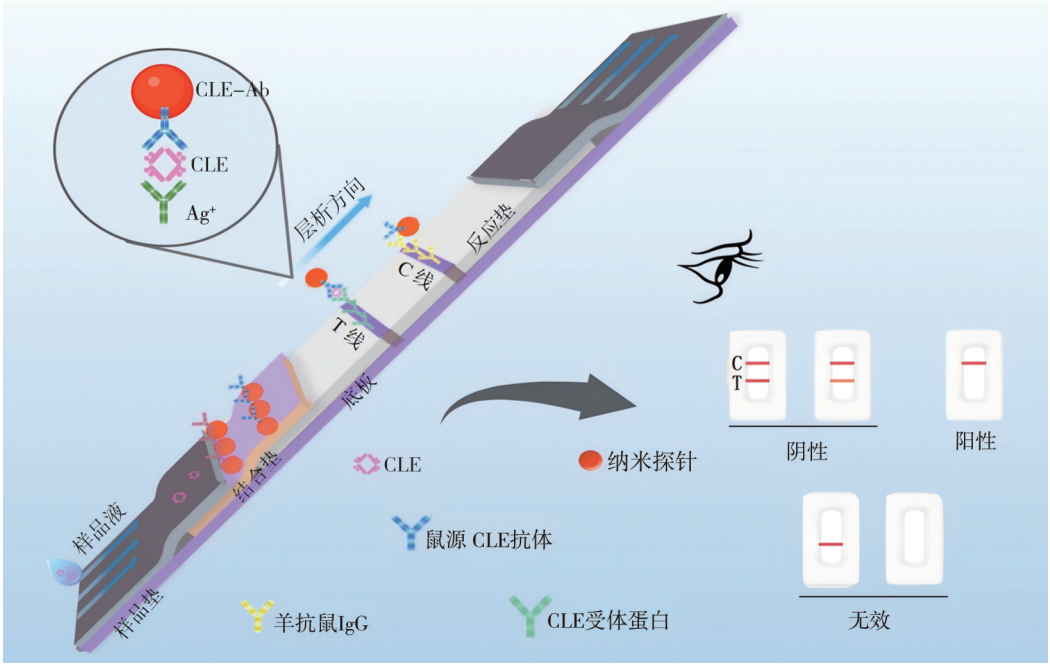


图3 竞争法CLE试纸条内部结构、反应原理及结果读取示意图

结合RT-PCR扩增与CRISPR/Cas9-单导向RNA(single guide RNA,sgRNA)复合物,解决传统抗体检测的窗口期漏检问题[86]。

适配体与CRISPR技术为LFA核酸检测带来临床突破:在肿瘤领域,适配体可用于监测嵌合抗原受体T细胞免疫疗法(chimeric antigen receptor T-Cell immunotherapy,CAR-T)转基因效率,CRISPR-LFA更将基因编辑疗效评估时间大大缩短,推动个体化治疗,实现基层医疗普惠。

2 LFA技术在临床诊断中的应用

在临床检测应用中,LFA针对细菌与病毒感染性疾病展现出广泛的适用性,其检测靶标覆盖多种病原体,如表1所示,样本类型涵盖临床常见生物样本,广泛适用于血液、血清、血浆、尿液、唾液、鼻咽拭子、粪便等临床常见生物样本,满足不同感染性疾病的检测需求,为感染性疾病的快速诊断提供了多元化解决方案。

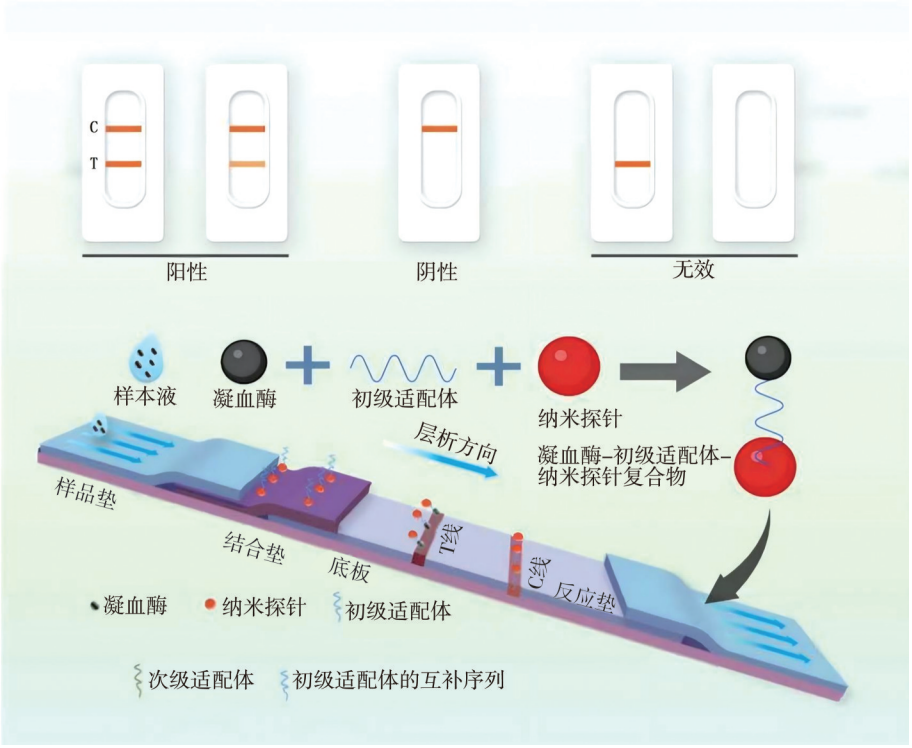


图4　凝血酶核酸检测试纸条内部结构、反应原理及结果读取示意图

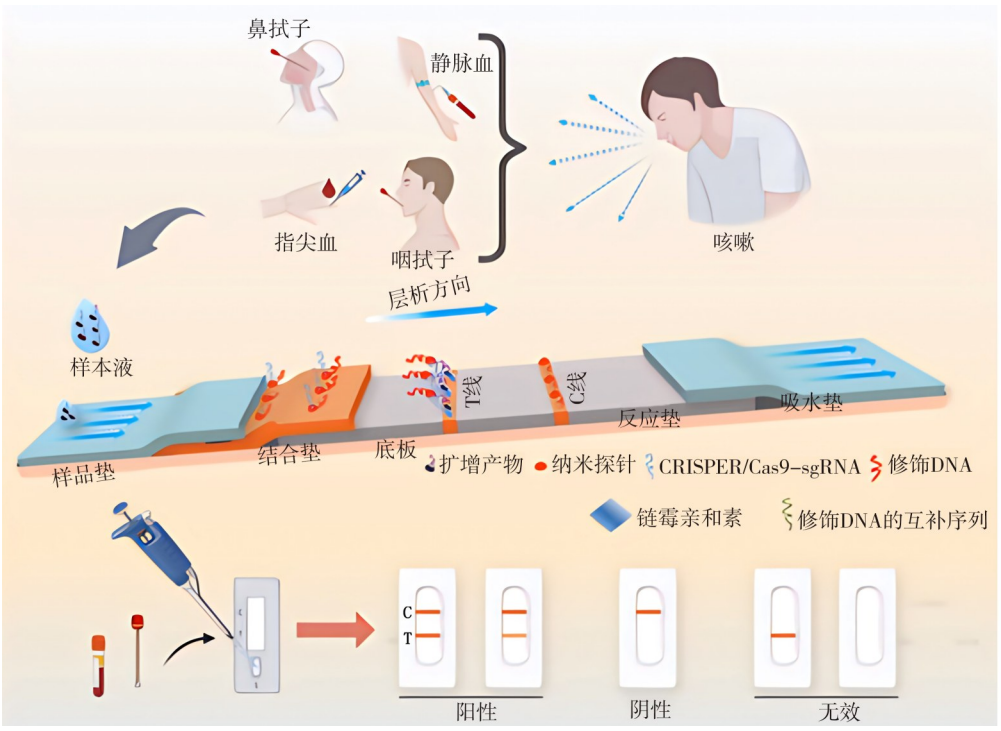


图5　新冠病毒RNA CRISPR/Cas9样本来源、检测试纸条内部结构、反应原理及结果读取示意图

2.1　传染性疾病检测

在新冠疫情中，采用CRISPR/Cas9介导的侧向层析核酸检测，利用CRISPR/Cas9介导的三线侧流检测法与多重反转录-重组聚合酶扩增相结合，阴性预测一致率100%，阳性预测一致率为97.14%，从基因层面进行层析检测，大大提高了试纸条的性能[87]，有效解决了传统抗体检测的窗口期漏检问题，缓解了传染病防控压力[88]。LFA在选取中和抗体用于评估疫苗接种水平中发挥重要作用[89-90]。

此外，在虫媒传染病（如登革热、疟疾）领域，LFA在资源匮乏地区实现现场病原体抗原或特异性抗体检测，辅助判断地域流行态势。对于血源及性传播疾病（如HIV、乙肝），基于抗体/抗原的双检测策略可在基层医疗机构提供初步诊

表1 LFA针对感染性疾病的广泛适用性

疾病类型	靶标	样本类型	样品检测一致性	检测时间	引用
细菌感染相关	幽门螺杆菌	粪便	75%	30 min	[17]
	鼻疽伯克霍尔德菌	血液、尿液、其他体液	70%	15 min	[18]
	念珠菌	咽拭子	89.8%	30 min	[19]
	肺孢子菌肺炎	血清	100%	10 min	[20]
	肺炎球菌性肺炎	胸膜积液	92.6%	10 min	[21]
	布鲁氏菌病	血清、血浆、全血	100%	3 min	[22-23]
	梅毒螺旋杆菌	血清	97%	15 min	[24]
	李斯特菌	唾液	98%	30 min	[25]
	隐球菌	脑脊液、血清	98.9%	10 min	[26]
	进行性播散性组织胞浆菌病	血清	90%	1 h	[27]
	脓毒病	血清	99.4%	15 min	[28]
	过敏性支气管肺曲霉病	血清	83%	45 min	[29-30]
病毒感染相关	埃博拉病毒	全血、血浆	85.7%	15 min	[31-32]
	SARS-CoV-2	血清、血液、唾液	89%	10 min	[33-39]
	单纯疱疹病毒2型	血浆、血清	96.7%	10 min	[40]
寄生虫感染相关	HIV-1、HIV-2	血液、血清	100%	10 min	[41-42]
	诺如病毒	粪便	87.7%	10 min	[43]
	登革病毒	血液	98.92%	25 min	[44-45]
	基孔肯雅病毒	血清	92%	15~20 min	[46]
	Influenza A/B	鼻咽拭子	84.4%	10 min	[47]
	恶性疟原虫感染	全血	100%	20 min	[48]
	丝虫病	血清	89.7%	15 min	[49-50]
	恙虫	血清	100%	15 min	[51]
	弓形虫病	血清	89.7%	20 min	[52]
	脑管圆线虫病	血清	93.9%	15 min	[53]
	恰加斯病	血清	100%	15 min	[54]
	内脏利什曼病	血清	98.4%	15 min	[55]
	片型吸虫病	血清	100%	15 min	[56]
癌症检测	胃癌	血浆	95.88%	25 min	[57]
	子宫颈癌	尿液	96%	30 min	[58]
	卵巢癌	血清	88.88%	30 min	[59]
	膀胱癌	尿液	98.9%	15 min	[60]
	前列腺癌	尿液	100%	10 min	[61]
	胰腺癌	血清	60%	15 min	[62]
其他疾病标志物	急性高血糖和糖尿病	血清	93.2%	15 min	[63-64]
	系统性红斑狼疮	血清	100%	5 min	[65]
	糖尿病视网膜病变	尿液	90%	15 min	[66]
	Alpha型地中海贫血症	全血	63.06%	3 min	[67]
	肾损伤	尿液	90%	5 min	[68]
	心脏标志物	血清、指尖血	100%	1.5 min	[69-71]
	C反应蛋白	血清	100%	3 min	[72]
健康监测	叶酸	血清	97.8%	40 min	[73]
	荷尔蒙	唾液、尿液、血清	90%	10 min	[74-79]
	铁蛋白	血清	100%	10 min	[80]
	肌红蛋白	血清	100%	10 min	[81]
治疗药物监测	α-1-抗胰蛋白酶	血清	96.8%	15~30 min	[82]
	替诺福韦	尿液	98%	15 min	[83-84]
毒品检测	大麻、鸦片	唾液	92%、100%	15 min	[85]

断，缩短窗口期风险。疫苗可预防疾病（如麻疹、风疹）则通过抗体LFA评估人群免疫水平。该技术凭借操作简易（15~30 min出结果）、无需设备及低成本优势，显著提升基层和突发疫情现场的检测可及性。以上实现了全血、唾液等多样本类型的快速初筛，为大规模人群筛查提供了“随到随检”的便捷方案。

2.2 肿瘤的检测与筛查

肿瘤作为严重危害人类健康的重大疾病，其防治工作已成为全球公共卫生领域的核心挑战。医学研究表明，实施规范的早期筛查和精准诊疗方案，能够有效提升患者生存质量并显著改善临床预后，但是传统的病理、影像学检查等手段无法满足自检和普筛需求，限制了肿瘤的早诊早治[91]。随着

肿瘤标志物的发现以及临床应用，LFA与其结合后所开发的产品，可以应用于家庭自检和早期肿瘤筛查，提升了肿瘤的检出效率，并对患者的预后监测提供了一种经济方便的评估手段[92]。

针对蛋白类标志物，如前列腺特异性抗原（prostate-specific antigen，PSA）用于前列腺癌、甲胎蛋白（alpha fetoprotein，AFP）用于肝癌、糖类抗原（carbohydrate antigen 125，CA125）用于卵巢癌，LFA可提供快速初筛，适用于基层医疗机构或高危人群的定期监测，其操作便捷性（15~30 min出结果）显著提升了筛查可及性。对于核酸类标志物（如循环肿瘤DNA、microRNA），新兴的LFA平台通过整合等温扩增技术实现现场化检测，为肿瘤早期分子异常提供线索，但其灵敏度仍需持续优化。此外，部分LFA可检测外泌体相关标志物或异常糖基化蛋白，辅助判断肿瘤发生风险。

2.3 健康标志物的检测

LFA在针对健康标志物的自检方面也有良好的表现。例如传统叶酸水平检测需4~8 h且有场地要求。Rey EG等[73]开发的LFA通过荧光竞争法将检测时间缩短至40 min，灵敏度达93%，LFA对叶酸浓度的诊断适用于孕前女性、老年人等高危人群的叶酸水平筛查，为公共卫生干预提供实时数据支持。

LFA的快速优势有效减少了就诊次数，避免转诊和医疗费用的浪费[93]，在糖尿病、心血管疾病等慢性病管理中，LFA的低成本与易操作性优势显著。例如Byzova NA等[69]提出了一种联合LFA，它结合了传统的硝化纤维素膜，与微孢子打印一起用于构建用于联合检测的相邻微流控“轨迹”，可联合检测人血液中的心脏和炎症标记物，有高重复性（8%~15%变异系数），较普通试纸条10 min得出检测结果，此类技术突破也增加了LFA技术在更多疾病检测中的可能性及准确性。

2.4 全生命周期覆盖

LFA凭借便携、快速的特性，覆盖从新生儿到老年人的全生命周期健康管理。对于儿童，LFA可以快速检测流感病毒、肺炎球菌，指导儿科急诊用药；孕妇产检，检测HCG评估胎儿健康；老年慢性病管理：居家监测血糖、血脂、心肌标志物，结合AI算法预警病情波动。

3 LFA未来的发展方向及应用前景

侧向层析技术是生物检测领域的重要手段，如图6所示呈现了其多样化应用。该技术以快速、便捷为优势，在临床诊断、疾病预防监控等场景中发挥关键作用，为医疗健康领域提供高效检测方案，推动精准医疗发展，为守护人类健康贡献力量，其未来的发展方向和应用前景非常广阔。

3.1 医工融合驱动下的技术革新与智能化升级

近年来随着医工学科交汇和发展，新兴材料、装置、技术的出现也给LFA带来了更旺盛的生命力。各种定量分析仪的应用和智能手机摄像功能的开发不仅突破了主观判断带来误差的瓶颈，同时在一定程度上也实现了分析物的定量检测[94]。与其他检测技术，如与PCR的联合应用增加了LFA检测灵敏度，检测对象也不再局限，可以达到核酸层面，使快速检测结果更加准确[95]。随着5G互联技术的应用和智能大数据发展，适合临床初筛检测的LFA也可以提供大量的数据，结合云端分析，可以更好地为医疗人员因地制宜地选择治疗措施和制定防控方案等提供参考，也有利于进行流行病学调查[96-97]。

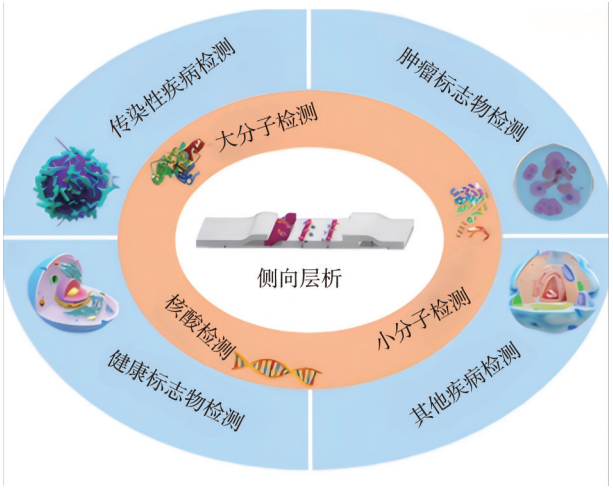


图6 侧向层析适用于多样化领域应用检测

3.2 AI深度赋能下的智能化诊疗与全生命周期健康管理

人工智能正推动LFA向“智能诊疗终端”跃迁，以将“检测-图像识别-云端分析-智能建议”整合成闭环为方向：通过智能手机搭载的AI图像识别算法解析试纸条信号[98]，结合多光源校准技术显著降低主观判读误差，实现从肉眼判读向精准量化的跨越[99]。检测数据经5G传输至云端后，提供肿瘤标志物定量结果，同时与DeepSeek等AI模型相结合提供初步诊疗建议—从血糖异常的饮食指导等基础建议，到血压临界值的疾病进展预警，再到糖尿病药物剂量定制等干预方案，形成个性化诊疗路径。在全生命周期应用中，AI-LFA从新生儿病毒快速筛查、孕期异位妊娠风险预测，到老年慢性病的智能监测与管理，形成“从摇篮到暮年”的健康守护体系，实现从疾病筛查到健康维护的全场景覆盖。

4 结 语

LFA技术凭借操作简单、出结果快、成本低的优势，在医疗检测领域占据重要地位。近年来，通过整合CRISPR基因编辑技术，LFA实现了超高灵敏度的核酸检测；结合AI图像识别算法，大幅提高了结果判读的准确性；新型纳米材料的应用则让多指标同时检测成为可能。这些创新让LFA不再只是简单的检测工具，而是升级为智能化的健康管理平台。特别是在基层医疗和家庭自检场景中，LFA展现出了独特价值。未来，随着技术的持续优化，LFA有望让高质量医疗检测服务更加普及，真正实现“家门口就能做专业检查”的愿景。

参 考 文 献

[1] Goble JA, Rocafort PT. Point-of-care testing. J Pharm Pract. 2017, 30(2): 229-237.

[2] Ferreira CES, Guerra JCC, Slhessarenko N, et al. Point-of-care testing: general aspects[J]. Clin Lab, 2018, 64(1): 1-9.

[3] Sunstrum FN, Khan JU, Li NW, et al. Wearable textile sensors for continuous glucose monitoring[J]. Biosens Bioelectron, 2025, 273: 117133.

[4] Durrington C, Battersby C, Holt L, et al. NT-proBNP and BNP testing in pulmonary arterial hypertension: point-of-care and remote monitoring[J]. Respirology, 2025.

[5] Xie YP, Yu Y, Huang SW, et al. A streamlined POCT solution for rapid infectious disease detection[J]. Sci Rep, 2025, 15(1): 13739.

[6] Florkowski C, Don-Wauchope A, Gimenez N, et al. Point-of-care testing (POCT) and evidence-based laboratory medicine (EBLM) - does it leverage any advantage in clinical decision making?[J]. Crit Rev Clin Lab Sci, 2017, 54(7/8): 471-494.

[7] Campbell VR, Carson MS, Lao A, et al. Point-of-need diagnostics for foodborne pathogen screening[J]. SLAS Technol, 2021, 26(1): 55-79.

[8] Chen CX, Liang JH, Hu HZ, et al. Research progress in methods for detecting neutralizing antibodies against SARS-CoV-2[J]. Anal Biochem, 2023, 673: 115199.

[9] Bian L, Li ZY, He A, et al. Ultrabright nanoparticle-labeled lateral flow immunoassay for detection of anti-SARS-CoV-2 neutralizing antibodies in human serum[J]. Biomaterials, 2022, 288: 121694.

[10] Sotnikov DV, Byzova NA, Zherdev AV, et al. Comparison of three lateral flow immunoassay formats for the detection of antibodies against the SARS-CoV-2 antigen[J]. Biosensors (Basel), 2023, 13(7): 750.

[11] Wang LJ, Wu ML, Ma JJ, et al. Development of a point-of-care test based on selenium nanoparticles for heart-type fatty acid-binding proteins in human plasma and blood[J]. Int J Nanomedicine, 2022, 17: 1273-1284.

[12] 尚少梅, 王 翠, 侯罗娅. 全生命周期健康概念演变及应用[J]. 中国实用护理杂志, 2021, 37(25): 1921-1925.
Shang SM, Wang C, Hou LY, Evolution and application of the concept of life cycle health[J]. abbreviated as J. Adv. Res, 2021, 37(25): 1921-1925.

[13] Bahadır EB, Sezgintürk MK. Lateral flow assays: Principles, designs and labels[J]. Trac Trends Anal Chem, 2016, 82: 286-306.

[14] Brand RM, Pitlor D, Metter EJ, et al. rxCOV is a quantitative metric for assessing immunoassay analyte fidelity[J]. Sci Rep, 2023, 13(1): 88.

[15] Wang T, Chen LM, Chikkanna A, et al. Development of nucleic acid aptamer-based lateral flow assays: A robust platform for cost-effective point-of-care diagnosis[J]. Theranostics, 2021, 11(11): 5174-5196.

[16] Shu HW, Mei H, Gu JX, et al. A novel three-dimensional DNA nanostructure used for thrombin detection[J]. Anal Methods, 2017, 9(35): 5115-5120.

[17] Han YJ, Dai W, Meng FS, et al. Diagnosis of *Helicobacter pylori* infection in the elderly using an immunochromatographic assay-based stool antigen test[J]. Microbiologyopen, 2020, 9(9): e1102.

[18] Choi JY, Hii KC, Bailey ES, et al. *Burkholderia pseudomallei* detection among hospitalized patients, Sarawak[J]. Am J Trop Med Hyg, 2020, 102(2): 388-391.

[19] Matsui H, Higashide M, Hanaki H. Evaluation of a rapid immunochromatographic test for the detection of *Candida* species from oropharyngeal samples[J]. J Microbiol Methods, 2020, 179: 106090.

[20] Tomás AL, de Almeida MP, Cardoso F, et al. Development of a gold nanoparticle-based lateral-flow immunoassay for *Pneumocystis* pneumonia serological diagnosis at point-of-care[J]. Front Microbiol, 2019, 10: 2917.

[21] Romero Herrero D, Soler-Palacin P, Burgos Cibrian J, et al. Detection of streptococcus pneumoniae antigen in pleural fluid: usefulness of an immunofluorescence-based lateral flow assay for the diagnosis of pneumococcal pneumonia[J]. Diagn Microbiol Infect Dis, 2020, 98(4): 115-162.

[22] Zhu MS, Zhang J, Cao JJ, et al. Ultrasensitive dual-color rapid lateral flow immunoassay *via* gold nanoparticles with two different morphologies for the serodiagnosis of human brucellosis[J]. Anal Bioanal Chem, 2019, 411(30): 8033-8042.

[23] Lu JH, Wu Z, Liu BC, et al. A time-resolved fluorescence lateral flow immunoassay for rapid and quantitative serodiagnosis of *Brucella* infection in humans[J]. J Pharm Biomed Anal, 2021, 200: 114071.

[24] Yang D, Ma JZ, Zhang QL, et al. Polyelectrolyte-coated gold magnetic nanoparticles for immunoassay development: toward point of care diagnostics for syphilis screening[J]. Anal Chem, 2013, 85(14): 6688-6695.

[25] Fogaça MBT, Bhunia AK, Lopes-Luz L, et al. Antibody- and nucleic acid-based lateral flow immunoassay for *Listeria monocytogenes* detection[J]. Anal Bioanal Chem, 2021, 413(16): 4161-4180.

[26] Liu Y, Kang M, Wu SY, et al. Evaluation of a *Cryptococcus* capsular polysaccharide detection FungiXpert LFA (lateral flow assay) for the rapid diagnosis of Cryptococcosis[J]. Med Mycol, 2022, 60(4): myac020.

[27] Cáceres DH, Gómez BL, Tobón AM, et al. Evaluation of a *Histoplasma* antigen lateral flow assay for the rapid diagnosis of progressive disseminated histoplasmosis in Colombian patients with AIDS[J]. Mycoses, 2020, 63(2): 139-144.

[28] Huang DZ, Ying HJ, Jiang DN, et al. Rapid and sensitive detection of interleukin-6 in serum *via* time-resolved lateral flow immunoassay[J]. Anal Biochem, 2020, 588: 113468.

[29] Mercier T, Dunbar A, de Kort E, et al. Lateral flow assays for diagnosing invasive pulmonary aspergillosis in adult hematology patients: A comparative multicenter study[J]. Med Mycol, 2020, 58(4): 444-452.

[30] Hunter ES, Page ID, Richardson MD, et al. Evaluation of the LDBio *Aspergillus* ICT lateral flow assay for serodiagnosis of allergic bronchopulmonary aspergillosis[J]. PLoS One, 2020, 15(9): e0238855.

[31] Couturier C, Wada A, Louis K, et al. Characterization and analytical validation of a new antigenic rapid diagnostic test for Ebola virus disease detection[J]. PLoS Negl Trop Dis, 2020, 14(1): e0007965.

[32] Wonderly B, Jones S, Gatton ML, et al. Comparative performance of four rapid Ebola antigen-detection lateral flow immunoassays during the 2014-2016 Ebola epidemic in West Africa[J]. PLoS One, 2019, 14(3): e0212113.

[33] Wen T, Huang C, Shi FJ, et al. Development of a lateral flow immunoassay strip for rapid detection of IgG antibody against SARS-CoV-2 virus[J]. Analyst, 2020, 145(15): 5345-5352.

[34] Chen ZH, Zhang ZG, Zhai XM, et al. Rapid and sensitive detection of anti-SARS-CoV-2 IgG, using lanthanide-doped nanoparticles-based lateral flow immunoassay[J]. Anal Chem, 2020, 92(10): 7226-7231.

[35] Yu S, Nimse SB, Kim J, et al. Development of a lateral flow strip membrane assay for rapid and sensitive detection of the SARS-CoV-2 [J]. Anal Chem, 2020, 92(20): 14139-14144.

[36] Peng T, Sui ZW, Huang ZH, et al. Point-of-care test system for

detection of immunoglobulin-G and-M against nucleocapsid protein and spike glycoprotein of SARS-CoV-2[J]. Sens Actuators B Chem, 2021,331:129415.

[37] Kim HY, Lee JH, Kim MJ, et al. Development of a SARS-CoV-2-specific biosensor for antigen detection using scFv-Fc fusion proteins [J]. Biosens Bioelectron,2021,175:112868.

[38] Roda A, Cavalera S, Di Nardo F, et al. Dual lateral flow optical/chemiluminescence immunosensors for the rapid detection of salivary and serum IgA in patients with COVID-19 disease[J]. Biosens Bioelectron,2021,172:112765.

[39] Cavalera S, Colitti B, Rosati S, et al. A multi-target lateral flow immunoassay enabling the specific and sensitive detection of total antibodies to SARS COV-2[J]. Talanta,2021,223(Pt 1):121737.

[40] Goux HJ, Raja B, Kourentzi K, et al. Evaluation of a nanophosphor lateral-flow assay for self-testing for herpes simplex virus type 2 seropositivity[J]. PLoS One,2019,14(12):e0225365.

[41] Cavalera S, Di Nardo F, Forte L, et al. Switching from multiplex to multimodal colorimetric lateral flow immunosensor[J]. Sensors,2020,20(22):6609.

[42] Martiskainen I, Juntunen E, Salminen T, et al. Double-antigen lateral flow immunoassay for the detection of anti-HIV-1 and-2 antibodies using upconverting nanoparticle reporters[J]. Sensors (Basel), 2021,21(2):330.

[43] Xu M, Lu FF, Lyu CN, et al. Broad-range and effective detection of human noroviruses by colloidal gold immunochromatographic assay based on the shell domain of the major capsid protein[J]. BMC Microbiol,2021,21(1):22.

[44] Xiong YF, Luo YS, Li H, et al. Rapid visual detection of dengue virus by combining reverse transcription recombinase-aided amplification with lateral-flow dipstick assay[J]. Int J Infect Dis, 2020, 95:406-412.

[45] Martinez-Liu C, Machain-Williams C, Martinez-Acuña N, et al. Development of a rapid gold nanoparticle-based lateral flow immunoassay for the detection of dengue virus[J]. Biosensors,2022,12(7):495.

[46] Suzuki K, Huits R, Phadungsombat J, et al. Promising application of monoclonal antibody against chikungunya virus E1-antigen across genotypes in immunochromatographic rapid diagnostic tests. Virol J. 2020,17(1):90.

[47] Yoo SJ, Shim HS, Yoon S, et al. Evaluation of high-throughput digital lateral flow immunoassays for the detection of influenza A/B viruses from clinical swab samples[J]. J Med Virol, 2020, 92(8): 1040-1046.

[48] Salminen T, Mehdi F, Rohila D, et al. Ultrasensitive and robust point-of-care immunoassay for the detection of *Plasmodium falciparum* malaria[J]. Anal Chem,2020,92(24):15766-15772.

[49] Boonroumkaew P, Sadaow L, Sanpool O, et al. Effectiveness of Strongyloides Recombinant IgG Immunoreactive Antigen in Detecting IgG and IgG4 Subclass Antibodies for Diagnosis of Human Strongyloidiasis Using Rapid Immunochromatographic Tests. Diagnostics (Basel). 2020,10(9):615.

[50] Sadaow L, Sanpool O, Rodpai R, et al. Development of immunochromatographic device as a point-of-care tool for serodiagnosis of human strongyloidiasis cases[J]. Eur J Clin Microbiol Infect Dis, 2020, 39(3):465-470.

[51] Lee SH, Hwang J, Kim K, et al. Quantitative serodiagnosis of scrub typhus using surface-enhanced Raman scattering-based lateral flow assay platforms[J]. Anal Chem,2019,91(19):12275-12282.

[52] Ybañez RHD, Nishikawa Y. Serological detection of T. gondii infection in humans using an immunochromatographic assay based on dense granule protein 7[J]. Parasitol Int,2020,76:102089.

[53] Somboonpatarakun C, Intapan PM, Sadaow L, et al. Development of an immunochromatographic device to detect antibodies for rapid diagnosis of human angiostrongyliasis[J]. Parasitology, 2020, 147(2):194-198.

[54] Silva ED, Silva ÂAO, Santos EF, et al. Development of a new lateral flow assay based on IBMP-8.1 and IBMP-8.4 chimeric antigens to diagnose chagas disease[J]. Biomed Res Int,2020,2020:1803515.

[55] Anfossi L, Di Nardo F, Profiti M, et al. A versatile and sensitive lateral flow immunoassay for the rapid diagnosis of visceral leishmaniasis[J]. Anal Bioanal Chem,2018,410(17):4123-4134.

[56] Sadaow L, Yamasaki H, Morishima Y, et al. Effectiveness of *Fasciola gigantica* excretory-secretory and recombinant cathepsin L antigens for rapid diagnosis of human fascioliasis using immunochromatographic devices[J]. Parasitol Res,2020,119(11):3691-3698.

[57] Jiang WC, Sun GW, Zhang YQ, et al. Simultaneous determination of gastric cancer biomarkers pepsinogen PGI/PGII using element tagged immunoassay coupled with inductively coupled plasma mass spectrometry detection[J]. J Clin Lab Anal,2020,34(7):e23287.

[58] Oliveira CM, Musselwhite LW, de Paula Pantano N, et al. Detection of HPV E6 oncoprotein from urine *via* a novel immunochromatographic assay[J]. PLoS One,2020,15(4):e0232105.

[59] Bayoumy S, Hyytiä H, Leivo J, et al. Glycovariant-based lateral flow immunoassay to detect ovarian cancer-associated serum CA125[J]. Commun Biol,2020,3(1):460.

[60] Lei QF, Zhao LL, Ye SX, et al. Rapid and quantitative detection of urinary Cyfra21-1 using fluorescent nanosphere-based immunochromatographic test strip for diagnosis and prognostic monitoring of bladder cancer[J]. Artif Cells Nanomed Biotechnol,2019,47(1):4266-4272.

[61] Di Nardo F, Occhipinti S, Gontero P, et al. Detection of urinary prostate specific antigen by a lateral flow biosensor predicting repeat prostate biopsy outcome[J]. Sens Actuat B Chem,2020,325:128812.

[62] Jiao X, Peng T, Liang ZW, et al. Lateral flow immunoassay based on time-resolved fluorescence microspheres for rapid and quantitative screening CA199 in human serum[J]. Int J Mol Sci,2022,23(17):9991.

[63] Ki H, Jang H, Oh J, et al. Simultaneous detection of serum glucose and glycated albumin on a paper-based sensor for acute hyperglycemia and diabetes mellitus[J]. Anal Chem, 2020, 92(17): 11530-11534.

[64] Ki H, Oh J, Han GR, et al. Glycation ratio determination through simultaneous detection of human serum albumin and glycated albumin on an advanced lateral flow immunoassay sensor[J]. Lab Chip, 2020, 20(4):844-851.

[65] Sun YH, Li Z, Liang W, et al. A novel immunochromatographic strips assay for rapid and simple detection of systemic lupus erythematosus[J]. Sci Rep,2020,10(1):14178.

[66] Hainsworth DP, Gangula A, Ghoshdastidar S, et al. Diabetic retinopathy screening using a gold nanoparticle-based paper strip assay for the at-home detection of the urinary biomarker 8-hydroxy-2′-deoxyguanosine[J]. Am J Ophthalmol,2020,213:306-319.

[67] Nelson AC, Motum PI, Emeto TI. Evaluation of an immunochromatographic test for alpha thalassaemia screening in a multi-ethnic population[J]. Int J Lab Hematol,2019,41(3):397-403.

[68] Choi ES, Al Faruque H, Kim JH, et al. Immunochromatographic assay to detect α-tubulin in urine for the diagnosis of kidney injury[J]. J Clin Lab Anal, 2020, 34(1): e23015.

[69] Byzova NA, Vengerov YY, Voloshchuk SG, et al. Development of a lateral flow highway: ultra-rapid multitracking immunosensor for cardiac markers[J]. Sensors (Basel), 2019, 19(24): 5494.

[70] Navarro C, Fishlock SJ, Steele DN, et al. A point-of-care measurement of NT-proBNP for heart failure patients[J]. IEEE Access, 2020, 8: 138973-138983.

[71] Lee KW, Kim KR, Chun HJ, et al. Time-resolved fluorescence resonance energy transfer-based lateral flow immunoassay using a raspberry-type europium particle and a single membrane for the detection of cardiac troponin I[J]. Biosens Bioelectron, 2020, 163: 112284.

[72] Kong DY, Heo NS, Kang JW, et al. Nanoceria-based lateral flow immunoassay for hydrogen peroxide-free colorimetric biosensing for C-reactive protein[J]. Anal Bioanal Chem, 2022, 414(10): 3257-3265.

[73] Rey EG, Finkelstein JL, Erickson D. Fluorescence lateral flow competitive protein binding assay for the assessment of serum folate concentrations[J]. PLoS One, 2019, 14(6): e0217403.

[74] Di Nardo F, Cavalera S, Baggiani C, et al. Direct vs mediated coupling of antibodies to gold nanoparticles: the case of salivary Cortisol detection by lateral flow immunoassay[J]. ACS Appl Mater Interfaces, 2019, 11(36): 32758-32768.

[75] Thakur R, Akram F, Rastogi V, et al. Development of smartphone-based lateral flow device for the quantification of LH and E3G hormones[J]. IEEE Sens J, 2020, 20(23): 14491-14500.

[76] Zangheri M, Mirasoli M, Guardigli M, et al. Chemiluminescence-based biosensor for monitoring astronauts' health status during space missions: Results from the International Space Station[J]. Biosens Bioelectron, 2019, 129: 260-268.

[77] Yang HY, He QY, Chen YS, et al. Platinum nanoflowers with peroxidase-like property in a dual immunoassay for dehydroepiandrosterone[J]. Mikrochim Acta, 2020, 187(11): 592.

[78] Yang HY, He QY, Pan JK, et al. A Pt-Ir nanocube amplified lateral flow immunoassay for dehydroepiandrosterone[J]. Analyst, 2021, 146(8): 2726-2733.

[79] Znoyko SL, Orlov AV, Bragina VA, et al. Nanomagnetic lateral flow assay for high-precision quantification of diagnostically relevant concentrations of serum TSH[J]. Talanta, 2020, 216: 120961.

[80] He QY, Yang HY, Pan JK, et al. Lateral flow immunosensor for ferritin based on dual signal-amplified strategy by rhodium nanoparticles[J]. ACS Appl Bio Mater, 2020, 3(12): 8849-8856.

[81] Zhu JM, Zou NL, Mao HJ, et al. Evaluation of a modified lateral flow immunoassay for detection of high-sensitivity cardiac troponin I and myoglobin[J]. Biosens Bioelectron, 2013, 42: 522-525.

[82] Greulich T, Rodríguez-Frias F, Belmonte I, et al. Real world evaluation of a novel lateral flow assay (AlphaKit® QuickScreen) for the detection of alpha-1-antitrypsin deficiency[J]. Respir Res, 2018, 19(1): 151.

[83] Gandhi M, Wang G, King R, et al. Development and validation of the first point-of-care assay to objectively monitor adherence to HIV treatment and prevention in real-time in routine settings. AIDS. 2020, 34(2): 255-260.

[84] Cavalera S, Agulló C, Mercader JV, et al. Monoclonal antibodies with subnanomolar affinity to tenofovir for monitoring adherence to antiretroviral therapies: from hapten synthesis to prototype development[J]. J Mater Chem B, 2020, 8(45): 10439-10449.

[85] Jehanli A, Brannan S, Moore L, et al. Blind trials of an onsite saliva drug test for marijuana and opiates[J]. J Forensic Sci, 2001, 46(5): 1214-1220.

[86] Montagud-Martínez R, Márquez-Costa R, Ruiz R, et al. Virus detection by CRISPR-Cas9-mediated strand displacement in a lateral flow assay[J]. ACS Appl Bio Mater, 2025, 8(5): 4221-4229.

[87] Xiong EH, Jiang L, Tian T, et al. Simultaneous dual-gene diagnosis of SARS-CoV-2 based on CRISPR/Cas9-mediated lateral flow assay [J]. Angew Chem Int Ed, 2021, 60(10): 5307-5315.

[88] Kostoulas P, Eusebi P, Hartnack S. Diagnostic Accuracy Estimates for COVID-19 Real-Time Polymerase Chain Reaction and Lateral Flow Immunoassay Tests With Bayesian Latent-Class Models. Am J Epidemiol. 2021, 190(8): 1689-1695.

[89] Peng T, Jiao X, Liang ZW, et al. Lateral flow immunoassay coupled with copper enhancement for rapid and sensitive SARS-CoV-2 nucleocapsid protein detection[J]. Biosensors (Basel), 2021, 12(1): 13.

[90] Ahmadi A, Mirzaeizadeh Z, Omidfar K. Simultaneous detection of SARS-CoV-2 IgG/IgM antibodies, using gold nanoparticles-based lateral flow immunoassay[J]. Monoclon Antib Immunodiagn Immunother, 2021, 40(5): 210-218.

[91] Farrell JJ, van Rijnsoever M, Elsaleh H. Early detection markers in pancreas cancer[J]. Cancer Biomark, 2005, 1(2/3): 157-175.

[92] Laraib U, Sargazi S, Rahdar A, et al. Nanotechnology-based approaches for effective detection of tumor markers: A comprehensive state-of-the-art review[J]. Int J Biol Macromol, 2022, 195: 356-383.

[93] Pai NP, Vadnais C, Denkinger C, et al. Point-of-care testing for infectious diseases: diversity, complexity, and barriers in low- and middle-income countries[J]. PLoS Med, 2012, 9(9): e1001306.

[94] Guo LL, Wu XL, Cui G, et al. Colloidal gold immunochromatographic assay for rapid detection of carbadox and cyadox in chicken breast[J]. ACS Omega, 2020, 5(3): 1422-1429.

[95] Boguszewska K, Szewczuk M, Urbaniak S, et al. Review: immunoassays in DNA damage and instability detection[J]. Cell Mol Life Sci, 2019, 76(23): 4689-4704.

[96] Yang JC, Wang K, Xu H, et al. Detection platforms for point-of-care testing based on colorimetric, luminescent and magnetic assays: A review[J]. Talanta, 2019, 202: 96-110.

[97] Qu Z, Wang K, Alfranca G, et al. A plasmonic thermal sensing based portable device for lateral flow assay detection and quantification [J]. Nanoscale Res Lett, 2020, 15(1): 10.

[98] Lamprou E, Kokkinis A, Kalligosfyri PM, et al. Harnessing machine vision and image processing in multicolor lateral flow assays for cutting-edge liquid biopsy applications[J]. Sens Actuat B Chem, 2025, 437: 137729.

[99] 冯馨锐，吴韦铷，张晓丽，等. 人工智能辅助血细胞形态学检查的机遇与挑战[J]. 现代检验医学杂志, 2025, 40(1): 189-195.
Feng XR, Wu WR, Zhang XL, et al. Opportunities and challenges of artificial intelligence assisted blood cell morphology examination[J]. J Mod Lab Med, 2025, 40(1): 189-195.

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