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编者按：2024浦江创新论坛——全球健康与发展论坛以“创新诊断产品赋能全球健康高质量发展”为主题，来自国际组织、政府部门、科研机构、企业等专家学者围绕全球健康发展需求、推动全球健康创新诊断产品的公平可及展开深入研讨，为全球健康高质量发展贡献上海力量。本期专报对全球健康与发展论坛嘉宾观点进行梳理，供参考。

Editor's note: With the theme of "High-quality Development of Global Health Empowered by Innovative Diagnostic Products", the 2024 Pujiang Innovation Forum - Global Health and Development Forum invited experts and scholars from international organizations, government departments, scientific research institutions, and enterprises, etc. to conduct in-depth discussions on global health and development needs and on promoting fair access to innovative diagnostic products for global health, contributing Shanghai's strength to the high-quality development of global health. This special report synthesizes the viewpoints of the guests at the Global Health and Development Forum for your information.

2024 浦江创新论坛专题简报之十三

Special Report 13 of the 2024 Pujiang Innovation Forum

创新诊断产品赋能全球健康高质量发展

High-quality Development of Global Health Empowered by Innovative Diagnostic Products

随着人工智能、基因测序、即时检测技术等前沿技术的飞速发展，全球健康创新产品的研发与应用迎来了前所未有的黄金时期，极大地增强了全球健康治理的效能。习近平总书记强调，在全球健康与发展的大背景下，我们有责任为人类的健康作出更大贡献。**与会嘉宾一致认为，全球健康危机日益严峻，对更加精准、简便、快捷且价格可负担的检测技术和工具的需求更加迫切，需要更加多元且精准的国际合作，实现人类健康水平的整体提升。**

With the rapid development of cutting-edge technologies such as artificial intelligence, gene sequencing, and instant testing technology, the research and development and application of innovative products for global health have ushered in an unprecedented golden period, greatly enhancing the effectiveness of global health governance. General Secretary Xi Jinping has emphasized that in the context of global health and development, we have the responsibility for making greater contributions to human health. **The guests present unanimously agreed that the global health crisis is becoming increasingly severe, and the demand for**

more accurate, simpler, faster and more affordable testing technologies and tools is becoming more urgent. More diverse and targeted international cooperation is needed to achieve the overall improvement of human health level.

一、全球创新诊断产品的研发与应用的最新进展

1. The latest progress in the research and application of global innovative diagnostic products

面对全球新发和再发传染病的持续挑战、健康不平等等问题，创新诊断产品的研发与应用，不仅能够提高疾病诊断的效率和精度，降低误诊率，还能够推动医疗资源的合理配置，为偏远地区和弱势群体带去更优质、更高效的医疗服务。

Faced with the continued challenges of emerging and re-emerging infectious diseases, health inequalities and other issues around the world, the research and development and application of innovative diagnostic products can not only improve the efficiency and accuracy of disease diagnosis and reduce the misdiagnosis rate, but also promote the rational allocation of medical resources and bring better and more efficient medical services to remote areas and vulnerable groups.

1、技术研发方面，人工智能技术的应用快速提升产品性能。上海交通大学医学院附属新华医院院长孙琨指出，基于云计算的人工智能听诊器诊断准确率高达 97%，极大提升了基层医生的听

诊能力。基于体音语言大模型的听诊器不仅可用于先天性心脏病筛查，还可用于儿童肺炎和肠炎等疾病的早期检测。**比尔及梅琳达·盖茨基金会北京代表处首席代表郑志杰**提到，AI 辅助阅读胸片技术大幅降低了传统胸片筛查对专业技术人员的依赖，节省了时间和经济成本，同时提升了诊断效率。**新加坡医疗诊断发展中心（DxD Hub）副首席执行官、首席技术官翁瑞芬**提到，数字化技术在多模态临床信息分析中的应用有效支持了临床决策，帮助医生更好地进行患者管理。**比尔及梅琳达·盖茨基金会 EDGE 高级项目官苏拉比·多西**强调，诊断工具的数字化发展应从基础层面深入了解用户需求，在数据收集和验证后，结合 AI 技术进一步优化诊断工具的效果和使用。

(1) In terms of technological research and development, the application of artificial intelligence technology rapidly improves product performance. Sun Kun, Director of Xinhua Hospital Affiliated to Shanghai Jiao Tong University School of Medicine, pointed out that the diagnostic accuracy of cloud-based artificial intelligence stethoscopes is as high as 97%, greatly improving the auscultation ability of community-level doctors. The stethoscope based on the large body sound language model can be used not only for congenital heart disease screening, but also for early detection of diseases such as childhood pneumonia and enteritis. **Zheng Zhijie, Chief Representative of the Beijing Office of the Bill & Melinda Gates Foundation,** mentioned that AI-assisted reading of chest

X-rays technology has significantly reduced the dependence of traditional chest X-ray screening on professional technicians, saved time and economic costs, and improved diagnostic efficiency. **Ruifen WENG, Deputy Chief Executive Officer & Chief Technology Officer of the Diagnostics Development Hub (DxD Hub) in Singapore**, mentioned that the application of digital technology in multimodal clinical information analysis effectively supports clinical decision-making and helps doctors better manage patients. **Sulaby Dorsey, Senior Program Officer for EDGE at the Bill & Melinda Gates Foundation,** emphasized that the digital development of diagnostic tools should deeply understand user needs at the foundational level, and take advantage of AI technology to further optimize the effectiveness and use of diagnostic tools after data collection and validation.

2、生产制造方面，推进本地化生产以降低成本、提升产品的可及性。细胞和分子平台中心（C-CAMP）首席执行官塔斯利马里夫·赛义德表示，印度诊断行业通过本地化生产大幅降低了试剂的生产成本，许多产品的价格已降至不到原来的 10%，使得中小型企业能够以较低的成本获取高质量试剂，大幅提升了诊断工具的可及性。**塞内加尔巴斯德研究所首席执行官阿马多·萨尔**指出，研究所通过 MADEBA 项目[1]推动非洲疫苗免疫自主能

[1] MADEBA 项目（Project MADIBA）是一个旨在提高非洲疫苗生产能力的重要合作项目。该项目由 Univercells 公司、Intact 和 KeyPlants 与塞内加尔政府及多个国际资助方合作，在达喀尔巴斯德研究所（Institut Pasteur de Dakar, IPD）建立一个疫苗生产设施。

[1]Project MADIBA is a major collaborative project aimed at increasing vaccine production capacity in Africa. Through collaboration between Univercells, Intact, and KeyPlants with the Senegalese government and multiple international

力的提升，并致力于诊断产品的本地化和工业化生产。这些举措显著增强了非洲在疫苗和诊断工具方面的自主供应能力。

(2) In terms of production and manufacturing, we should promote localized production to reduce costs and improve product accessibility.[2] **Taslimarif Saiyed, CEO of the Center for Cell and Molecular Platforms (C-CAMP)**, said that the India's diagnostic sector has significantly reduced the production cost of reagents through localized production, with many products now priced at less than 10% of their original levels. This has enabled small and medium-sized enterprises to obtain high-quality reagents at lower costs, greatly improving the accessibility of diagnostic tools. **Amadou A Sall, CEO of the Institut Pasteur de Dakar (IPD) in Senegal**, pointed out that the IPD is promoting the improvement of Africa's vaccine immunization autonomy through the MADEBA project and it is committed to localizing and industrializing diagnostic products. These initiatives significantly enhance Africa's ability to independently supply vaccines and diagnostic tools.

3、创新产品方面，性能大幅提升、灵敏度和便捷性显著增强。帕斯适宜卫生科技组织诊断部门负责人大卫·博伊尔指出，PCR 技术和基因组测序技术的突破为现代诊断工具的进步提供了有力支持，其性能提升不仅体现在检测精度上，还体现在减少

funders, the Project has established the vaccine production facilities at the Institut Pasteur de Dakar (IPD).

误诊率和加快处理速度方面。**予果生物首席执行官夏涵**阐述了该公司舌拭子诊断产品 TB Easy 的演变过程，从国际金标准到 Lamp 法及利福平耐药检测，再到 2023 年世卫组织提出的 TNGS 耐药检测方法，产品灵敏度和便捷性都得到了极大提升。**英科新创全球健康总监庄焱文**分享了该公司创新新产品 Cellcall，通过提升抗原分析性能，大幅增强了诊断的特异度和灵敏度，成为该领域产品诊断性能提升的又一里程碑。

(3) In terms of innovative products, significant improvement has been made in their performance, sensitivity and convenience. David Boyle, Head of the Diagnostic Department at the Program for Appropriate Technology in Health (PATH), pointed out that the breakthroughs in polymerase chain reaction (PCR) technique and genome sequencing technology have provided strong support for the advancement of modern diagnostic tools. The performance improvement of modern diagnostic tools is not only reflected in detection accuracy, but also in reducing the misdiagnosis rate and accelerating the processing speed. **Xia Han, CEO of HUGO BIOTECH**, explained the evolution of TB Easy (the Company's tongue swab diagnostic product). From the international standard to the loop-mediated isothermal amplification (LAMP) method and rifampicin resistance detection, and then to the tNGS drug resistance detection method proposed by the World Health Organization in 2023, the sensitivity

and convenience of the product have been greatly improved. **Zhuang Yanwen, Director of InTec Global Health,** shared the Company's innovative new product Cellcall. By improving antigen analysis performance, Cellcall has greatly enhanced the specificity and sensitivity of diagnosis, and become another milestone in the improvement of diagnostic performance of the product in this field.

4、场景应用方面，从传染病扩展至公共卫生风险监测，应用场景日益广泛。中国疾病预防控制中心副主任施小明指出，污水流行病学检测技术不仅应用于传染病的监测，还扩展至化学品、耐药基因、毒品等领域，是公共卫生风险监测的重要工具。目前全球已有多个国家大规模实施污水监测，用于疫情监测和跨国人口流动的风险评估。**印度尼西亚结核病防控工作组博士加鲁·布迪·勒克索诺·阿迪**强调，从高负担疾病（如结核病）的诊断到基层医疗机构的使用，创新诊断工具在全球范围，尤其是中低收入国家的广泛应用展现了其高度适应性，在欠发达国家基层医疗系统中取得了显著成效。

4. In terms of scenario applications, the application scenarios have expanded from infectious diseases to public health risk monitoring, and are becoming increasingly broad. Shi Xiaoming, Deputy Director of the Chinese Center for Disease Control and Prevention, pointed out that the wastewater-based epidemiology (WBE) detection technology is not only applied to the monitoring of infectious diseases, but also

extended to fields such as chemicals, drug resistance genes, and drugs, and is an important tool for public health risk monitoring. At present, many countries around the world have implemented large-scale wastewater surveillance for epidemic monitoring and risk assessment of transnational population movements. **Dr. Jaru Budi Luxono Adi of the Tuberculosis Prevention and Control Working Group in Indonesia** stressed that, from the diagnosis of high-burden diseases (such as tuberculosis) to the use of primary medical institutions, the wide applications of innovative diagnostic tools in the world, especially in low- and middle-income countries, have demonstrated their high adaptability, and achieved remarkable results in the primary medical system of underdeveloped countries.

二、创新诊断产品面临的全球挑战

2. Global challenges faced by innovative diagnostic products

一方面，诊断产品研发的资金投入持续不足。结核病、疟疾等顽固传染病持续挑战现有技术的检测能力，不断涌现的新型传染病又需要技术的创新突破，这些都使得诊断产品研发方面需要投入大量资金。**郑志杰**指出，据世界卫生组织估算，尽管 70%的医疗决策依赖于诊断结果，但全球医疗预算中仅有 3%-5%用于诊断领域。**翁瑞芬**提到，风险投资往往更关注药品开发，而诊断产品研发的资金投入严重不足。**United Al-Saqer Group**

（UASG）医疗保健和生命科学执行董事马尔·纳吉姆指出，非洲、中东、南美和亚洲国家在过去主要依赖发达国家的诊断技术，本地化的诊断技术研发投入严重不足。**比尔及梅琳达•盖茨基金会中西非区域代表巴哈蒂·恩戈恩戈**强调，缺乏投资导致针对被忽视疾病（Neglected Diseases）的产品创新研发受阻。

On the one hand, the funding for the research and development of diagnostic products remains insufficient. Stubborn infectious diseases such as tuberculosis and malaria persistently challenge the detection capabilities of existing technologies, and the emergence of new infectious diseases requires innovative technological breakthroughs, all of which require a large amount of capital to be invested in the research and development of diagnostic products. **Zheng Zhijie** pointed out that according to the World Health Organization's estimation, although 70% of medical decisions rely on diagnostic results, only 3% -5% of the global medical budget is used in the diagnostic field. **Ruifen WENG** mentioned that venture capital investment usually focuses more on drug development, while funding for diagnostic product research and development is seriously insufficient. **Omar Najim, Executive Director of Healthcare and Life Sciences at United Al Saqer Group (UASG)**, pointed out that in the past, African, Middle Eastern, South American, and Asian countries mainly relied on diagnostic technologies from developed countries, while there was a

serious lack of investment in localized diagnostic technology research and development. **Bahati Ngongo, Representative of the Bill & Melinda Gates Foundation for West and Central Africa,** emphasized that the lack of investment has hindered product innovation and R&D for neglected diseases.

另一方面，诊断产品的可及性和分配的公平性亟待提升。阿马多·萨尔提到，自 1927 年发现黄热病毒以来，许多新的危险病原不断被发现，全球亟需推出更公平、更可持续的诊断产品，特别是在非洲等资源有限的地区。非洲 99%的疫苗产品依赖进口，诊断和医疗设备试剂仅有 5%为本地生产，外部依存度非常高。郑志杰表示，尽管已有许多有效的检测技术和产品，全球范围内的公平获取仍然是一个难题。**帕斯适宜卫生科技组织诊断部门负责人大卫·博伊尔**指出，全球近 50%的人口无法获得诊断工具，尤其是在中低收入国家，只有 19%的患者能够享受最基本的诊断服务。**孙锟**提到，先天性心脏病是儿童死亡的重要原因之一，许多低收入国家的早期筛查与诊断能力不足，导致漏诊风险增大。

On the other hand, the accessibility and distributional fairness of diagnostic products need to be improved urgently. Amadou A Sall mentioned that since the discovery of yellow fever virus in 1927, many new dangerous pathogens have been constantly discovered, and there is an urgent need globally to introduce more equitable and sustainable diagnostic products, especially in resource-limited regions such as Africa. In Africa, 99% of vaccine

products rely on imports, while only 5% of diagnostic and medical equipment reagents are locally produced, resulting in a high degree of external dependence. **Zheng Zhijie** said that despite the existence of many effective detection technologies and products, fair access on a global scale remains a challenge. **David Boyle, Head of the Diagnostic Department at the Program for Appropriate Technology in Health (PATH)**, pointed out that nearly 50% of the global population lacks access to diagnostic tools, especially in low - and middle-income countries where only 19% of patients can enjoy the most basic diagnostic services. **Sun Kun** mentioned that congenital heart disease is one of the important causes of child mortality, and many low-income countries have insufficient early screening and diagnostic capabilities, leading to an increased risk of missed diagnosis.

三、相关建议

3. Relevant suggestions

一是通过数据资源共享降低研发成本，打造全链条研发服务体系。塔斯利马里夫·赛义德指出，通过搭建数字化市场平台，将政府、企业和供应商汇聚一处，利用已有的资源来建设基础设施和知识系统，能够极大提升诊断行业的生态系统。**巴哈蒂·恩戈恩戈**表示，在临床研究中，使用数字化系统共享研究数据可以将研发成本降低 40-60%。他还强调，数字化平台在技术共享和

提高成本效益方面具有重要作用，能够推动全球健康创新产品的研发和应用。**翁瑞芬**提到，新加坡诊断发展中心（DxD Hub）为诊断公司提供从生产到监管、质量控制、临床验证等全链条的孵化和技术支持服务。这种全方位的支持体系能够加速研发商业化进程，提升整体行业效率。

The first is to reduce R&D costs through data resource sharing and create a full chain R&D service system. Taslimarif Saiyed pointed out that we should bring together governments, enterprises and suppliers by establishing the digital market platform, and we should utilize existing resources to build infrastructure and knowledge systems, which can greatly enhance the ecosystem of the diagnostic sector. **Bahati Ngongo** said that in clinical research, using digital systems to share research data can reduce R&D costs by 40-60%.He also stressed that digital platforms play an important role in technology sharing and improving cost-effectiveness, and can promote the research and development and application of innovative products for global health. **Ruifen WENG** mentioned that the Diagnostics Development Hub (DxD Hub) in Singapore provides incubation and technical support services for diagnostic companies throughout the entire chain, from production to regulation, quality control, clinical validation, and more.Such comprehensive support system can accelerate the commercialization process of research and development, and improve overall industry efficiency.

二是通过国际合作打造生产制造能力，提升创新产品的可及性。大卫·博伊尔提到，合作伙伴间的资源和技术共享，不仅能够大幅降低开发成本，还能加速产品的上市。帕斯组织也在帮助中国企业开拓海外市场，提供高质量、可负担的体外诊断产品。**阿马多·萨尔**指出，在盖茨基金会、非洲发展银行、法国和英国政府等国际机构的支持下，研究所成功建立了诊断工具的生产能力，特别是在疫情应对和传染病防控方面取得了显著成果。**巴哈蒂·恩戈恩戈**表示，中非合作在技术转移、低成本制造和分子诊断领域具有巨大潜力。未来的合作机会包括利用 mRNA、单抗和人工智能技术实现低成本制造，并通过临床网络进一步降低成本、提高效率。

The second is to build up production and manufacturing capabilities through international cooperation and improve the accessibility of innovative products. David Boyle mentioned that resources and technology sharing among partners can not only significantly reduce development costs, but also accelerate product launch. The PATH organization is also helping Chinese companies to explore overseas markets and provide high-quality and affordable in vitro diagnostic products. **Amadou A Sall** pointed out that with the support of international institutions such as the Bill & Melinda Gates Foundation, the African Development Bank, and the governments of France and the United Kingdom, the IPD has successfully built up the capacity for manufacturing diagnostic tools.

In particular, it has achieved significant results in epidemic response and infectious disease prevention and control. **Bahati Ngongo** said that China-Africa cooperation has enormous potential in the fields of technology transfer, low-cost manufacturing, and molecular diagnostics. Future collaboration opportunities include leveraging mRNA, monoclonal antibodies and artificial intelligence technologies to achieve low-cost manufacturing, and further reducing costs and improving efficiency through clinical networks.

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