KFBIO & Intel End-to-end Digital Pathology Solution

As the leading manufacturer of digital pathology products, KFBIO has partnered with Intel in developing an end-to-end digital pathology solution for customers. **This white paper clarifies detailed KFBIO solutions in different aspects of digital pathology and gives 4 KFBIO digital pathology solution application cases in hospitals and labs for customers to learn.**

1 Situation and challenges of digital pathology

In the 21st century, electronic payment, face recognition and paperless office have become very common. It brings convenience and benefits to people's lives. As an important part of the digital economy, the development and application of digital health care alleviates the contradiction between the scarcity of medical resources and people's pursuit of high-quality medical services. On July 20, 2017, The State Council issued the "the Development Plan on the New Generation of Artificial Intelligence". It mentioned to vigorously support the development and application of "Medical big data+AI". In January 2018, to promote the construction process of smart hospitals, the National Health Commission issued the "Notice on the Issuance of the Action Plan for Further Improvement of Medical Services (2018-2020)". It mentioned that the proportion of "smart hospitals" increased from 6% to 14%. To further improve medical services and patients' medical experience, the National Health Commission proposed a graded evaluation standard system plan for hospital smart services for the first time. It leads the direction of hospital development and promotes the informationization of smart hospitals to a new level.

On March 18, 2009, the Office of the Ministry of Health issued "the Guidelines for the Construction and Management of Pathology Departments (Trial)". Chen Zhu, the Minister of Health, pointed out that pathology departments have become the weakness of medical services due to their shrinking technology and reduced service capacity. On September 8, 2015, "the Guiding Opinions of the General Office of the State Council on Promoting the Construction of Hierarchical Medical System (GBF (2015) No.70)" clearly put forward the concepts of remote pathology diagnosis, Internet health care and big data for the first time. Independent pathology diagnosis institutions are established to realize regional medical resource sharing and promote mutual recognition of diagnose results between medical institutions and independent pathology diagnosis institutions. On December 21, 2016, the National Health and Family Planning Commission issued a notice on the issuance of basic standards and management norms (trial) for pathology diagnostic centers (GWYF (2010) No. 65) for the first time. It elaborates the significance, property and management of pathology diagnostic centers. To avoid the use of antitumor drugs without indications, on December 22, 2020, National Health Commission, issued "the Administrative Measures on the Clinical Application of Antineoplastic Drugs (Trial) (GWYH [2020] No. 487)". It stipulated that antitumor drugs should

be prescribed only after the molecular or cytological pathology diagnosis, or gene target detection, etc. and the drugs are confirmed to be applicable to the patient. On June 4, 2021, the General Office of the State Council issued "the Opinions on Promoting the High-quality Development of Public Hospitals (GBF (2021) No. 18)". It mentioned that the development of clinical specialties should be improved: focusing on the development of clinical specialties such as tumor and pathology; promoting the development of diagnosis and treatment capacity. It pointed out that we should continuously improve the medical quality control system and standard system to improve the medical service level of public hospitals in different regions and levels; We should promote the construction of smart hospitals with the holistic "Trinity" of electronic medical records, smart services and smart management, and the standard hospital information management, and vigorously develop telemedicine and Internet diagnosis and treatment.

The above relevant policy documents not only accelerate the development of the pathology industry, but also point out the development direction: Promote the construction of remote pathology diagnosis and third-party pathology diagnosis institutions to solve the uneven distribution of pathology diagnosis resources; Give full play to the role of pathology diagnosis in tumor medication guidance; Promote the construction of pathology specialty to support the high-quality development of public hospitals.

Pathology diagnosis is the judge of disease diagnosis, the commander of disease treatment solution, and the bridge between basic medicine and clinical medicine. Pathology diagnosis lays the most reliable basis for clinical diagnosis, treatment, patient medication guidance and prognosis assessment. It is the most reliable method among the commonly recognized auxiliary diagnostic methods, also known as the "gold standard" of clinical diagnosis. Pathologists are titled as "doctors' doctors".

However, the current development of pathology automation, informatization and digitization is very weak and even backward. Its automated sample preprocessing technology and information management level is far behind that of the clinical lab. And digitization process is far behind that of radiology department. Weak automation, informatization, digitization and the scarcity of high-level pathology diagnosis resources in pathology department have severely restricted the improvement of hospital's diagnosis and treatment capacity.

The development of WSI digital scanning technology and the rapid development of Internet, 5G, AI, big data and other technologies brings the innovation of pathology diagnosis mode (Fig. 1). In the future, pathology will be a holistic "Quaternity" development ecology of digitization, informatization, intellectualization and network (Fig 2): Pathology slides will be transformed from traditional physical slides to digital slides; Pathology workflow will be

transformed from manual management to the paperless information management; Pathology diagnosis will be transformed from traditional light microscope diagnosis to AI-assisted pathology diagnosis. Moreover, considering the industrialization of digital pathology and the scarcity of pathology diagnostic resources, intensive, grid and integrated regional pathology and interconnected remote pathology diagnosis platform will provide patients with more accurate and convenient diagnostic services.

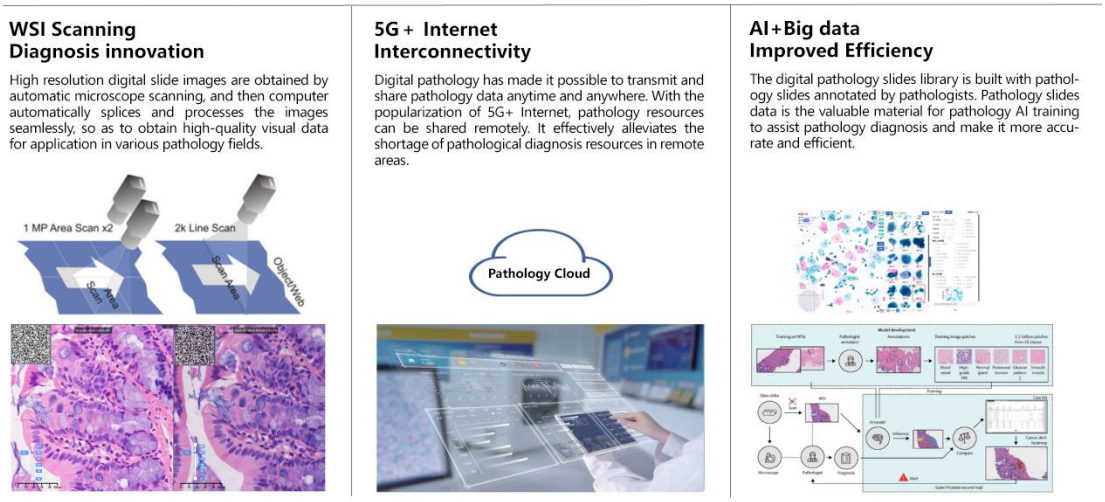


Fig. 1 Innovation of pathology diagnosis model

Fig. 2 Pathology development trend in the future

However, the development of the new pathology ecology in the future faces many challenges.

Challenge 1:

Low degree of automatic pathology slides production

Pathology slides are made by preprocessing operations on pathology samples including

sampling, dehydration, embedding, sectioning, staining and sealing. The preprocessing of pathology samples contains many steps. It's complex and cumbersome. Making a qualified pathology slide requires well-trained pathologists. Excessive manual operation affects the standardization of pathology slides and thus delays the development of digital pathology. Therefore, automation and standardization of pathological preprocessing lays the foundation of digital pathology.

Challenge 2:

Backward development of pathology informatization

At present, most hospital pathology departments use a simple graphic report system, which only supports sample registration and report issuance, and lacks the management of pathology sample laboratory processing workflow. The sample preprocessing information relies on manual recording on paper, which is inefficient and prone to errors. Once errors are made, it will lead to very serious medical accidents. The fine management of sample preprocessing is also the key to ensure the standardization of pathology workflow and the quality of pathology diagnosis. At present, only a few pathology departments in China have a whole workflow management system for pathology samples, and less than 20 science departments have been certified by CNAS or CAP. It is clear that the development of pathology informatization in China is lagging behind. Pathology digitization and informatization should be developed simultaneously.

Challenge 3:

Resolution and speed of digital slide scanning cannot meet the clinical needs

Pathology diagnosis is based on the observation of cell morphology, biomarker expression and gene fragment expression to determine the diagnosis and treatment plan.

The thickness of routine pathology tissue slides is about 2-5 um while the pathology diagnosis requires the actual physical size as small as 0.5 um. According to this standard, the numerical aperture (N.A.) of the microscopic objective lens needs to be above 0.75, but in this way the depth of field of the objective lens with high optical resolution is less than 1um. Therefore, precise motion control is required to achieve precise focusing and real-time depth-of-field tracking during imaging, so as to clearly image cells with height differences under the microscopic. In addition, the clear imaging of cell mass requires the use of multi-layer scanning fusion technology to achieve.

Digitization of multiplex fluorescent sides staining is commonly used in pathological research and personalized cancer therapy. Due to the WSI (whole slide imaging) imaging of discrete fluorescent probe point signals, the physical position accuracy of the motion platform is required to realize the panoramic stitching of adjacent fields of view without correlated image information.

In addition to the above basic requirements of imaging accuracy, to meet the needs of daily diagnosis, the time and stability of digitally scanning are also important. The scanning time of one slide using the traditional scanner obviously exceeds 10 minutes. It cannot meet the needs to scan large number of slides. Especially for the intraoperative frozen sections, the whole worklflow from specimen registration to report issuance should be completed within 30 minutes. The preprocessing workflow of the specimen takes about 15 minutes, and the time for expert's diagnosis is only 5 to 10 minutes. Generally, about 3-5 slides need intraoperative diagnosis, and digital scanning is required to be completed within 5 minutes, that is, each slide should be completed within 1 minute on average.

Challenge 4:

Lack of unified standard for appplication of digital pathology

Besides the impact of sample preprocessing on data standardization and normalization, there is also no unified standards for image formats, image quality evaluation, data storage, digital workflow, image transmission methods, big data use, and image analysis requirements in digital pathology around the world. The lack of data standardization also poses challenge to the application of digital pathology. The key to accelerating the application of digital pathology is to standardize the evaluation of images from multiple levels such as image contrast, resolution, color reproduction, distortion rate, saturation, and defocus. Standardized and high-quality digital slide images guarantee the accuracy of pathology remote diagnosis, especially intraoperative frozen section diagnosis. It also lays the basis for the application of AI pathology.

Challenge 5:

High cost of digital pathology storage

A digital pathology slide is about 1GB, or even larger. And one pathology department often generates petabytes of digital slide images every year. Therefore, pathology digital storage solutions also need to be highly reliable, cost-effective, easy to expand and maintain, and can meet the

needs of rapid access to daily diagnosis. If a large hospital have 5000 digital slides per day, and the size of each 20x magnification digital slide image is 0.5GB, the daily data volume could reach 2.5TB. The cumulative storage capacity should be 0.75PB if 300 days are calculated in a year, and considering redundancy, the annual storage capacity is about 1PB. In the development of digital pathology, hospital faces great budget pressure on the petabytes of medical data.

Challenge 6:

Limited application of AI pathology

As the AI pathology industry booms across the world, numerous milestones marked in this field: In March 2019, AI-assisted cancer platform developed by Paige.AI (an American digital pathology company) was awarded the title of "breakthrough device" from FDA; In November 6, 2019, Proscia's Concentriq Dx solution passed the EU's CE certification; In September 2021, Paige.AI received FDA approval for in vitro diagnosis (IVD) with FullFocus™ Digital Pathology Reader. There are also many new pathology AI products in China, mainly for cervical cytology, immunohistochemistry PD-L1, thyroid histology, etc. The challenges in the above-mentioned industrialization achievements are as follows: 1) The standardization of pathology data is low, which makes it difficult to obtain a high-performance AI model; 2) How to improve the training efficiency of pathology AI models and reduce R&D costs; 3) Generalization ability of AI application on different clinical data prediction; 4) The pathology data is large and how to guarantee the analysis speed.

To cope with the above challenges and improve the pathology diagnosis level, based on the rich experience of providing services to the pathology departments of thousands of hospitals, KFBIO has cooperated with Intel to launch the end-to-end digital pathology solution. It includes the standardization of pathology sample preprocessing, pathology information management system, KF-PRO series digital pathology slides scanner, digital pathology storage solution, remote consultation platform and AI pathology for medical institutions, physical examination institutions, scientific research institutions, ICL, CRO, pharmaceutical factories, insurance and government.

2 KFBIO End-to-end digital pathology solution

Taking the pathology digitization as the starting point, the pathology informatization as the cornerstone, and the application of AI pathology as the engine, KFBIO has realized the end-to-end digital pathology solution for pathology department, regional pathology center, medical alliance and ICL. It includes standardized slide production, whole workflow sample tracking, online slide reading, AI-assisted diagnosis and pathology information management.

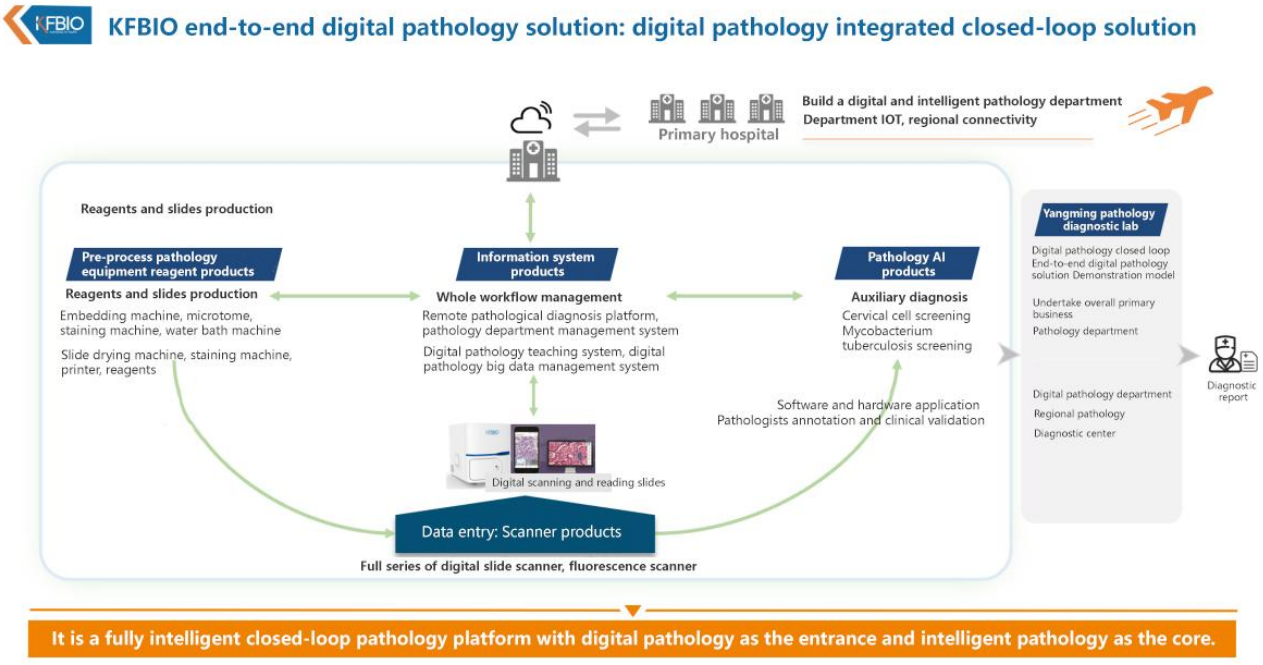


Fig.3 KFBIO End-to-end digital pathology solution

KFBIO pathology sample preprocessing solution

To improve the standardization of pathology sample preprocessing and making slides, to provide support for the development of pathology digitization, KFBIO launched two sets of sample preprocessing standardization technology platforms, histology and cytology (Fig. 4).

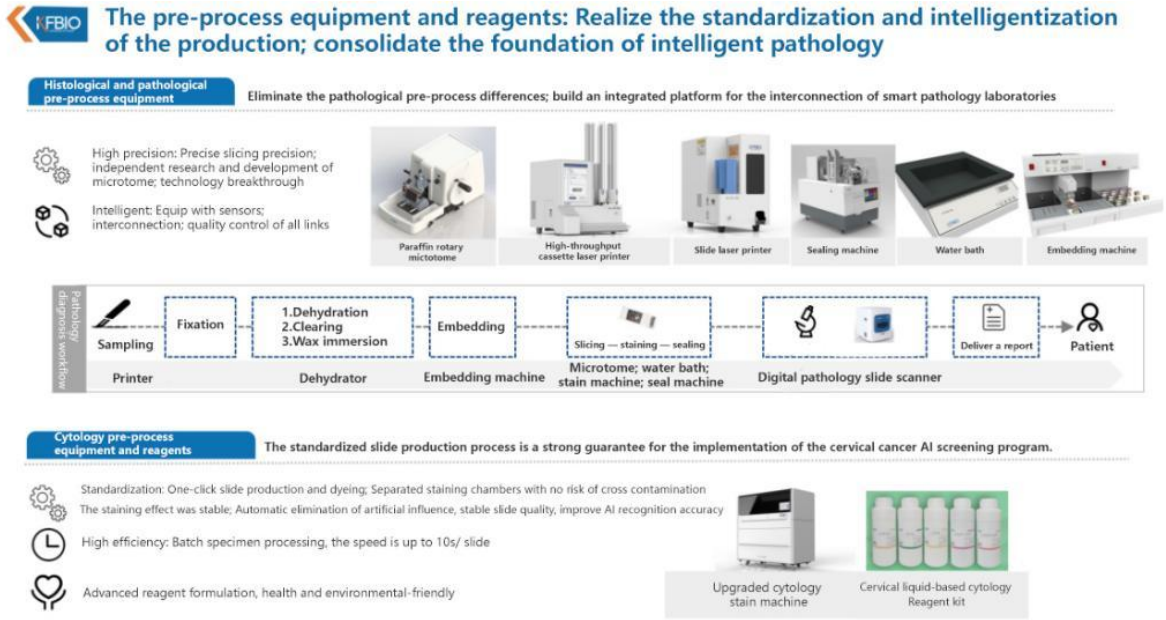


Fig.4 Pathology sample preprocessing solution

KFBIO pathology information management solution

Based on the B/S architecture, KFBIO developed the Pathology Information Management System (PIMS) (Fig. 5). It helps realize cross-hospital and multi-center business management. PIMS is connected with the sample preprocessing hardware to realize the whole workflow tracking management of pathology samples. At the same time, developed based on ISO15189 quality system standard, PIMS can automatically count the business volume and analyze the quality control data, truly and effectively record the quality of pathology work, and clarify the direction to solve the problems. In addition, PIMS connects to the pathology remote consultation platform, AI-assisted diagnosis platform, etc., and integrates a number of services into an end-to-end platform for the convenience of users. Therefore, KFBIO pathology information management solution, based on digital pathology and AI technology, can effectively enhance the working efficiency of the pathology department, save labor and property consumption, standardize the workflow, effectively enhance the management and quality control level and furthermore, help the pathology laboratory pass the ISO15189 and CNAS certification.

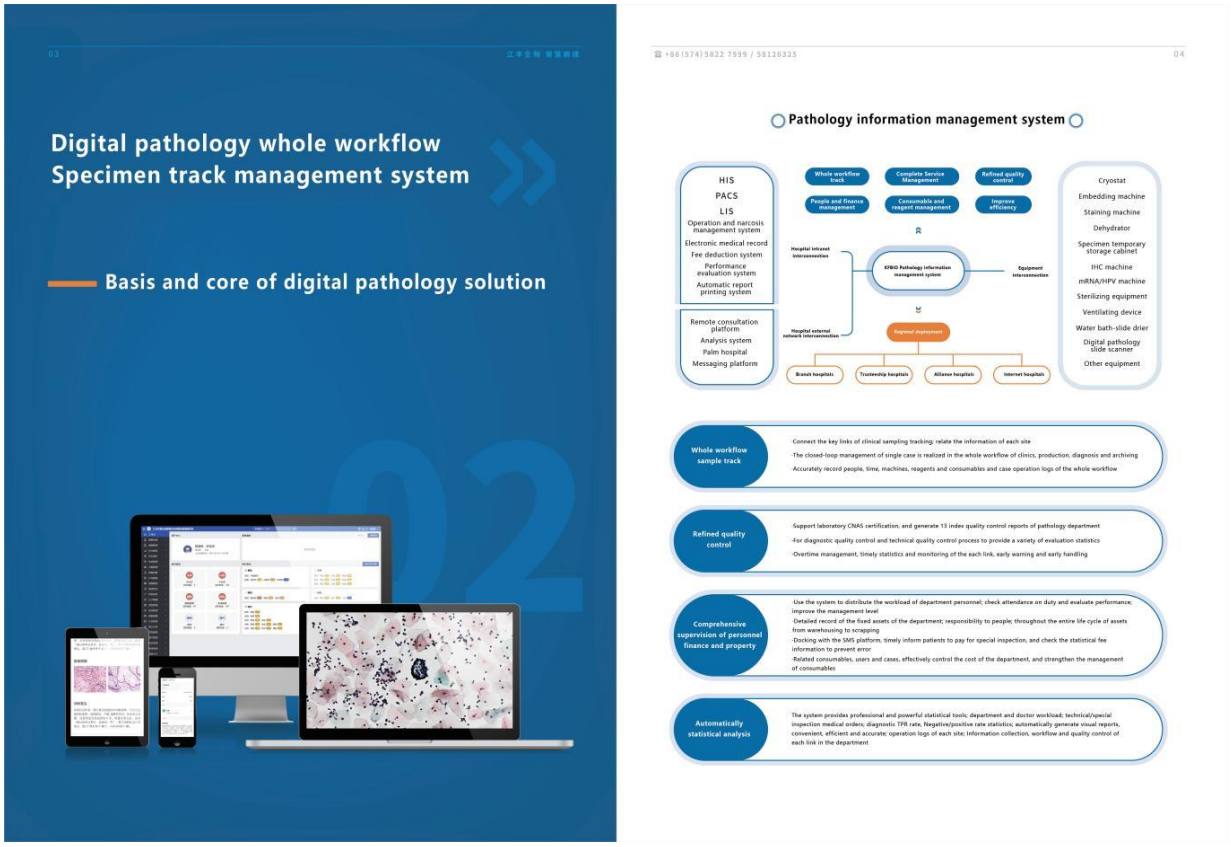


Fig. 5 KFBIO Pathology Information Management System (PIMS)

KFBIO digital pathology scanner solution

To improve scanning resolution and speed, KFBIO adopts line scanning technology, high-speed and stable motion linear magnetic motor and high-precision 50nm grating positioning system to ensure high-speed and clear imaging within 25s. The scanner adopts the world's top camera and objective lens, and its imaging quality is in a leading position in the world, which has been widely used for pathology remote consultation in China. At the same time, KFBIO also carries out research cooperation projects with Nanjing University of Science and Technology, to build the intelligent computing imaging laboratory and reconstructs ideal images with ultra-high resolution through multiple coherent low-resolution optical images, leading the development of new digital scanning technology.

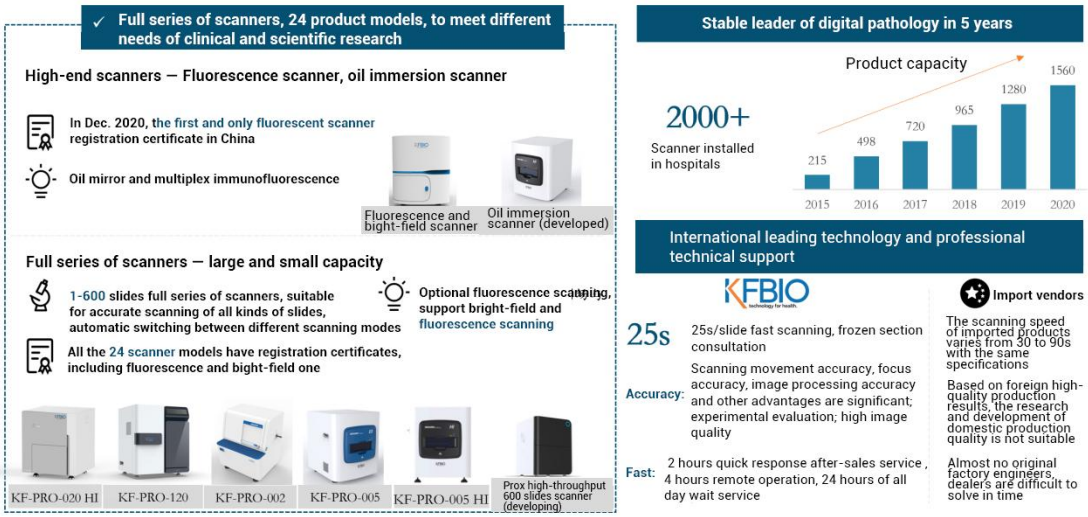


Fig. 6 KFBIO Series digital pathology slide scanners

Fig. 6 *shows KFBIO series digital pathology slide scanners. It includes high-speed scanner for frozen section diagnosis, multiplex fluorescence scanner for clinic and scientific research, low-throughput scanner for remote diagnosis in primary hospitals, middle-throughput scanner (40 slides and 120 slides) for daily use in pathology labs and hospitals, high-throughput scanner (400 slides) for digital pathology and AI-assisted cervical cancer screening (KF-PRO-400-HI). The scanning imaging system of KF-PRO-400-HI has been comprehensively optimized and upgraded including its motion accuracy control, color calibration algorithm, illumination evaluation method, etc. In addition, to ensure the reliability of AI algorithm, KF-PRO-400-HI has further been optimized in its color, brightness and contrast. The scanned images are more suitable for AI training and application, and the AI-assisted diagnosis results are more accurate and reliable.*

KFBIO digital slide standardization solution

To face the challenge of digital pathology slide standardization, KFBIO implements the end-to-end digital pathology solution with following measures: 1) Compatible with different digital pathology slide formats; 2) Different parameters to eliminate scanning errors caused by raw materials, habits and reagents; 3) Intelligent evaluation on the integrity, resolution and image noise of the scanning images, and the slides that do not meet the diagnostic requirements are scanned again, so as to form relatively standardized digital pathology slides; In addition, KFBIO also actively works with partners to promote promote the development of the pathology industry

KFBIO Digital pathology dedicated storage solution

For the digital pathology storage challenges, KFBIO has cooperated with Huawei, H3C and other leading information management manufacturers to launch digital pathology storage solution. The solution is as follows:

- ✓ Huawei unique secondary compression algorithm reduces storage cost by 20%-30%;
- ✓ Blu-ray storage medium: 30-year Blu-ray storage TCO is only 47% of distributed storage, 51% of cloud storage;
- ✓ Separation of storage and computation: The computation and storage are expanded independently on demand to avoid the waste of resources and reduce the cost by 40%;
- ✓ Hot, warm and cold data classification: optimize the cost based on the data life cycle, support fast access and 30-year archiving;
- ✓ Elastic expansion: meet the demand of 100PB level data growth in the future.
- ✓ In addition, the installation of Intel's Optane™ enables rapid access to pathology hot data, and the Optane™ SSD can be extended for pathology warm data storage.

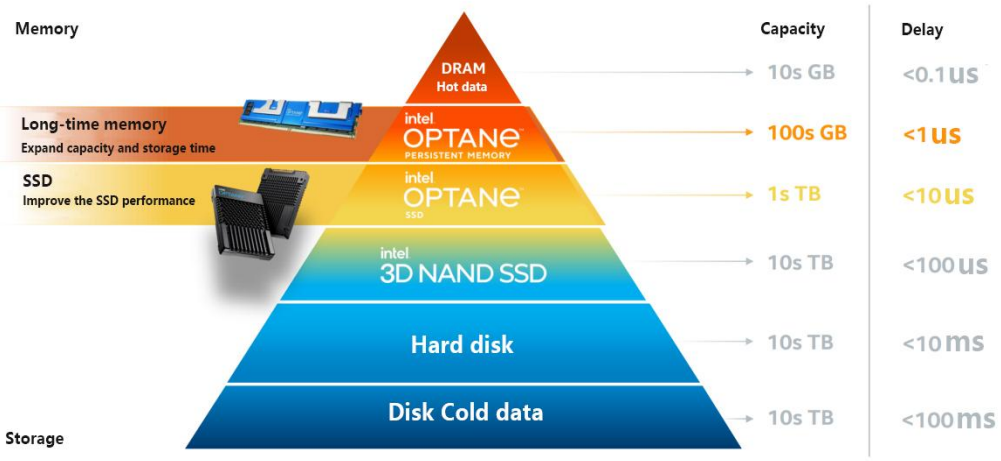


Fig. 7 Intel®'s Optane™ products

KFBIO pathology AI optimization solution

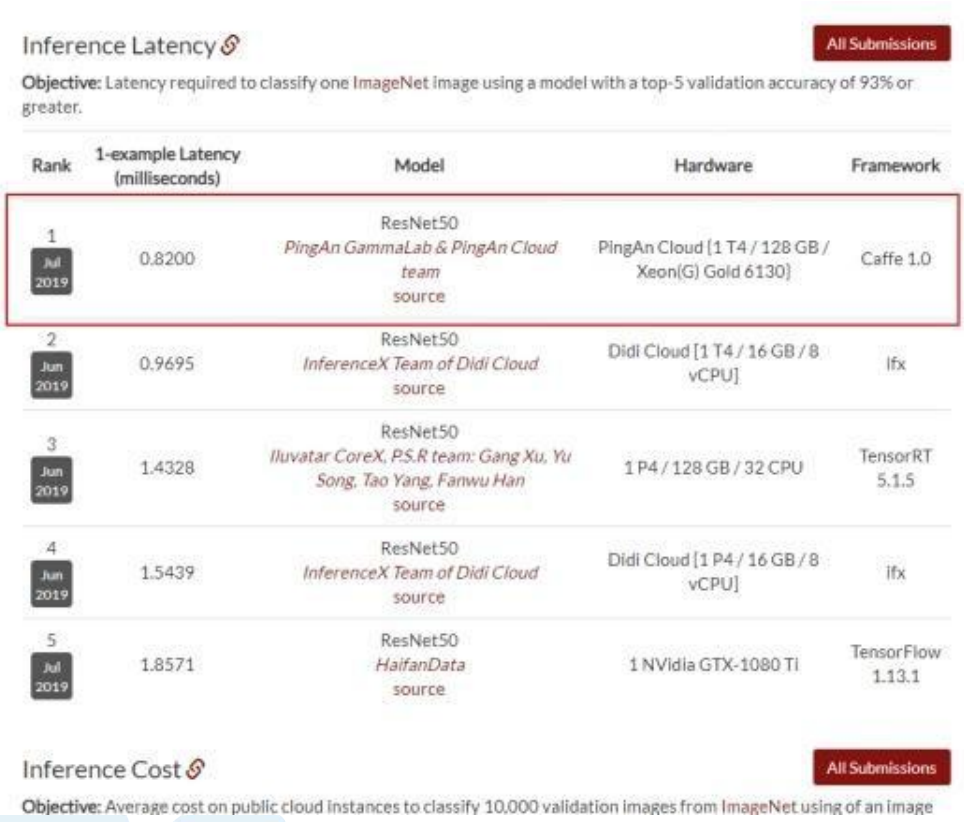
In order to optimize the AI application performance, KFBIO and Intel set up a Joint Laboratory of Pathology Artificial Intelligence. Intel AI core algorithm team provides professional technical support in algorithm improvement, hardware development and other aspects.

KFBIO pathology AI model training adopts Intel® architecture processor platform, and the platform server has a large memory (usually several TB or even tens of TB). The BatchSize can be easily set to more than 100 when training the pathology AI model. It helps speed up the

training process. At the same time, the innovative micro-architecture of Intel® Xeon® scalable processors also helps accelerate the model training.The multi-node Xeon server can further improve the model training efficiency and linearly reduce the training time, thus reducing the R&D cost.

KFBIO pathology AI forms a standard database by labeling a large quantity of digital pathology slides from different sources. The large database is used to train, test and verify the performance of AI, and improve the generalization performance.

Intel Caffe algorithm system and Intel Xon6/8 series processors are also adopted to reduce the reasoning time of each pathology slide less than 1 minute. In the 2018 AI Competition, Intel Caffe won the top three in reasoning speed, and won the top two in reasoning overhead, outpacing all competitors, including Google TPUV2 and Nvidia GPUV100 (Figure 8).



Inference Latency

All Submissions

Objective: Latency required to classify one ImageNet image using a model with a top-5 validation accuracy of 93% or greater.

Rank	1-example Latency (milliseconds)	Model	Hardware	Framework
1 Jul 2019	0.8200	ResNet50 *PingAn GammaLab & PingAn Cloud team* source	PingAn Cloud [1 T4 / 128 GB / Xeon(G) Gold 6130]	Caffe 1.0
2 Jun 2019	0.9695	ResNet50 *InferenceX Team of Didi Cloud* source	Didi Cloud [1 T4 / 16 GB / 8 vCPU]	Ifx
3 Jun 2019	1.4328	ResNet50 *Iluvatar CoreX, P.S.R team: Gang Xu, Yu Song, Tao Yang, Fanwu Han* source	1 P4 / 128 GB / 32 CPU	TensorRT 5.1.5
4 Jun 2019	1.5439	ResNet50 *InferenceX Team of Didi Cloud* source	Didi Cloud [1 P4 / 16 GB / 8 vCPU]	Ifx
5 Jul 2019	1.8571	ResNet50 *HaifanData* source	1 NVidia GTX-1080 Ti	TensorFlow 1.13.1

Inference Cost

All Submissions

Objective: Average cost on public cloud instances to classify 10,000 validation images from ImageNet using of an image

Fig. 8 Arithmetic speed of DAWNBench Caffe 1.0

3 KFBIO Digital pathology solution application cases

Case 1:

Digital pathology solution for pathology department in Henan Provincial People's Hospital

KFBIO digital pathology solution for pathology department is based on the digital scanners. It takes pathology information management system (PIMS) as the business management platform, integrate pathology remote consultation platform and artificial intelligence pathology to achieve the following objectives:

- Standardize the pathology workflow; improve the information management level of the department; help the department's quality system certification;
- Improve the efficiency of slide circulation in the department; reduce slide loss and damage; build a pathology slide database; assist teaching and scientific research;
- Reduce simple and repetitive work and improve department efficiency; Help accurate diagnosis and boost precision medicine;
- Remote guidance and communication of difficult cases and frozen section diagnosis;

To achieve the above objectives, KFBIO partners with Huawei, H3C and other information manufacturers. KFBIO digital pathology solution has the following features:

- Cost-effective digital pathology storage solution; provide security for digital pathology application;
- 4K/8K high-definition digital pathology slide image display guarantees the image quality for digital pathology diagnosis;
- The high-definition online consultation room makes remote teaching, diagnosis and daily teaching easier and more convenient.

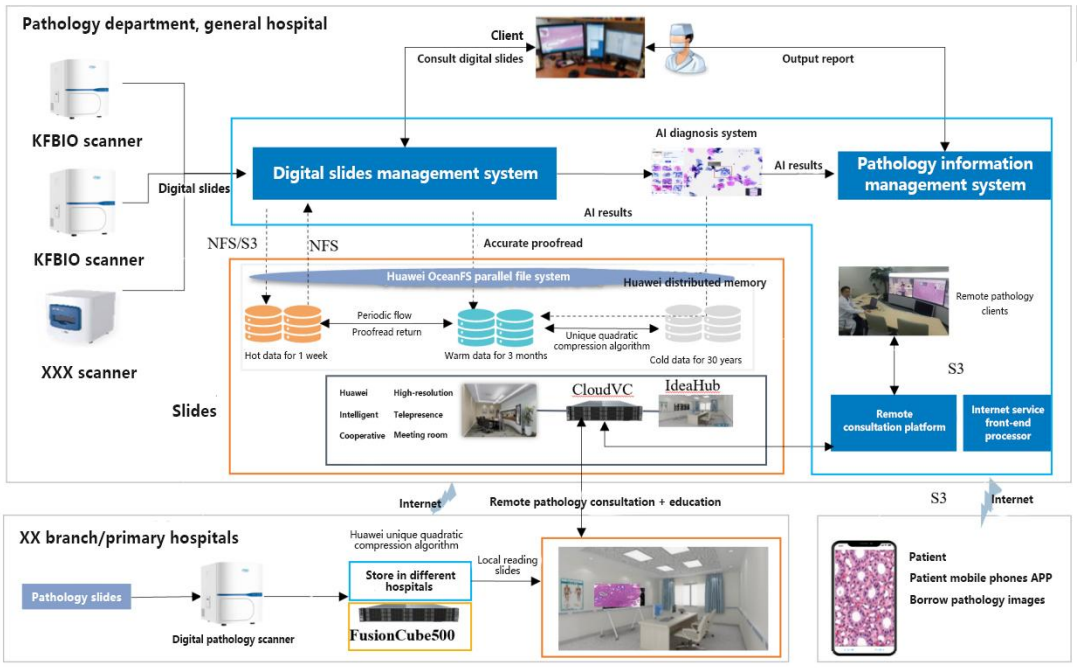


Fig. 8 Full-digital pathology department construction solution

The Henan Provincial People's Hospital pathology department integrates medical treatment, teaching and scientific research functions. It's one of the most powerful pathology departments in Henan Province, and undertakes the important work of the telepathology consultation in Henan Province. In May 2018, the department was recognized by China National Accreditation Committee for Conformity Assessment (CNAS). It's the first one in Henan province and the fifth one in China to get this qualification in the pathology department. Henan Provincial People's Hospital pathology department has realized whole workflow digitization. Besides basic diagnosis functions, the pathology information management system (PIMS) also supports whole workflow sample track, refined quality control and supervision of personnel and property of the pathology department. The system is seamlessly connected with various systems of the hospital intranet and the Internet to transmit patient data for pathology diagnosis and improves the communication efficiency between pathology and clinic department. The whole workflow of sample tracking is realized by scanning the QR code of sample and slide. It links with the cassette laser printer and slide laser printer. The above intelligent hardware can accurately and quickly record the information of operators, equipment, reagents and consumables used, time and other information in all links. These accurate information records lays the basis for later data statistics, quality control, error correction, cost control. It's also an important improvement different from traditional information systems.

Henan Provincial People's Hospital pathology department is carrying out the whole digitization of the pathology department. The department has been equipped with four KF-PRO-400 (digital pathology 400 slides scanner) and one KF-PRO-005 (digital pathology 5 slides scanner with bright-field & fluorescence in one machine). The daily work of digital slide scanning has been carried out. At the same time, the PIMS integrates slide reading software and AI pathology to support the department's daily diagnosis. To guarantee the stable operation of daily digital diagnosis in the pathology department, it is necessary to carry out grading management and effective storage of thousands of digital slides every day.

The digital pathology solution for pathology department provided by KFBIO for Henan Provincial People's Hospital includes:

- **Digital slide management system:** Integrate with scanner, storage system and pathology information system. Scanned slides can be uploaded to the server and automatically linked to patient information. Doctors check cases and relevant digital slides can be displayed;
- **Digital slide graded storage system:** To archive the big slide data more economically, the system adopts three data storage modes: hot, warm and cold;
- **AI diagnosis system:** It provides complete functions from annotation to algorithm training and model prediction. The AI results are automatically input to the PIMS;
- **Cross-hospital data application support:** To meet needs of comprehensive management of its branch hospitals, the system provides online services to enable cross-hospital digital slide reading, and supports different terminal applications such as PC and mobile phone.

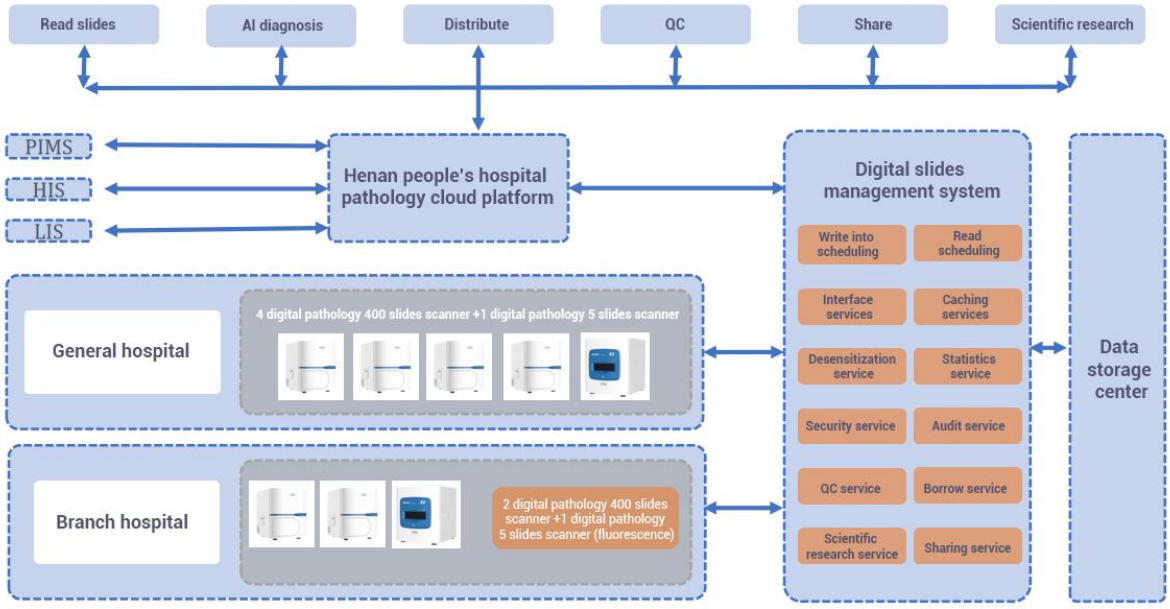


Fig. 10 Digital pathology solution for pathology department in Henan Provincial People's Hospital

See the table below for the list of software and hardware configuration

	Hardware	Software
Storage server	4-node Processor: 2* Intel® Xeon® Silver 4214R(2.4GHz/12-Core/16.5MB/100W) Cascade lake Processor (with radiator) Memory: 16*16GB DDR4 RDIMM Memory Hard disk: 2*600GB 10K RPM SAS Hard disk unit, 36*14TB 7.2K RPM SATA Hard disk unit, 1*1.6TB SSD NVMe Hard disk unit RAID: support RAID0, 1, 5, 6, 10, 50, 60, 2GB cache, supercapacitor Network interface: 2*GE, 4*10GE (light module included)	CentOS7.6 Application Clusters
Application server	Processor: 2* Intel® Xeon® Gold 6240(2.6GHz/18-Core/24.75MB/150W) Cascade lake Processor(with radiator) Memory: 2*32GB DDR4 RDIMM Memory Hard disk: 4*SSD-1920GB-SATA 6Gb/s-Read intensive RAID: support RAID0,1,10 Network interface: 2*GE,2*10GE (light module included)	CentOS7.6
GPU server	2*intel Bronze 3206R(eight-core 1.90G) Memory: 4*32GDDR4-3200MHZ Hard disk: 2*480G Read intensive SSD Hard disk+2*4TBSAS Hard disk Network interface: 10GB network card+5720 dual port gigabit network card Graphics card: 4*Nvidia RTX A4000	Ubuntu20.04

Case 2:

Cervical Cancer AI Screening Solution for Xuzhou Maternal and Child Health Care Hospital

KFBIO AI-assisted cervical cancer screening solution (Fig. 11) covers pathology products covering liquid-based cell reagents and consumables, staining, digital pathology scanners, AI-assisted diagnosis, and third-party diagnostic services. AI cervical cancer screening information management system unified the method, standard, process, quality control, management, so as to improve the standardization, quality and coverage of cervical screening. In this way, the targeted screening population can be managed in a refined way, the financial expenditure can be reduced, the incidence and mortality of cervical cancer can be decreased, and the comprehensive health management service can be provided for women's health.

- **Liquid-based cytology equipment and consumables:** The quality is guaranteed with lower cost compared with other consumables; Equip with AI-specific stain solution and has better AI analysis performance;
- **Digital scanning and analysis system (KF-TCT):** Leader of digital scanning equipment manufacturer in China, customized design for cytology scanning to provide clear images for AI analysis; multi-layer fusion scanning provides clear scanning images of clustered cells and improves the TPR of glandular lesion cells; provide different throughput scanners including 5/20/40/120/400 slides models to meet different needs; unattended operation, the scanning success rate reaches 99.8%; support large-scale screening application scenarios; WSI scanning guarantees no missed field of view thus reducing the omission diagnostic rate; based on millions of training data, KFBIO & Intel Joint Laboratory of Artificial Intelligence has self-developed the AI cervical cytology algorithms, leading the pathology AI.

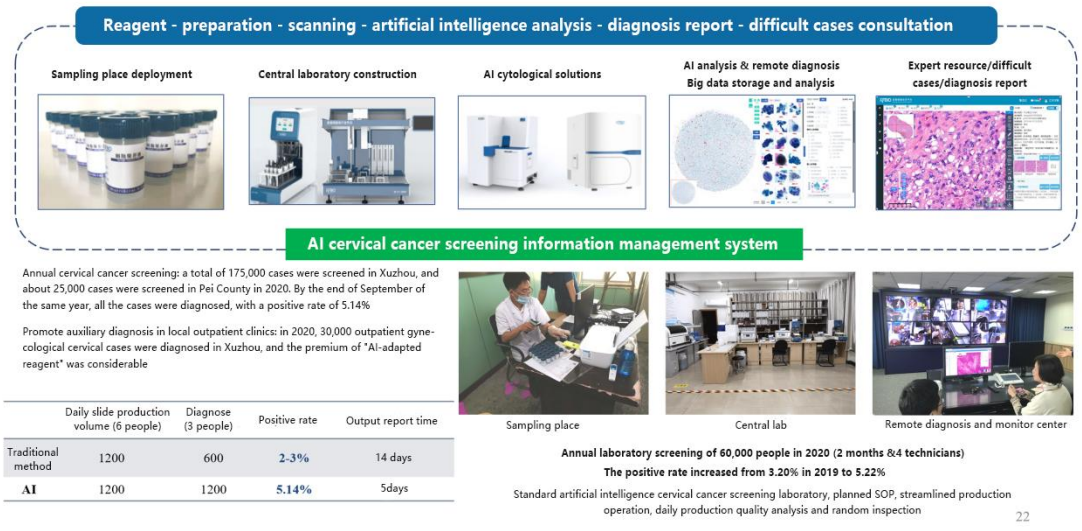


Fig. 11 KFBIO AI-assisted cervical cancer screening end-to-end solution

Xuzhou has a population of more than 8.8 million. Due to outsourcing, difficulty in unifying quality control and information traceability, the TPR of cervical cancer screening in rural areas has been difficult to meet the requirements, and no effective information management mechanism has been established. After in-depth investigation and rigorous demonstration, Xuzhou Maternal and Child Health Care Hospital, under the guidance of China Maternal and Child Health Care Association, with the technical support of KFBIO, established the "Xuzhou Maternal and Child Health Care Hospital Artificial Intelligence Cervical Cancer Prevention Center". KFBIO AI-assisted cervical cancer screening solution has helped screen more than 25000 cases in Pei County, and the positive rate has increased from 2-3% to more than 5%. At the same time, the whole workflow sample tracking, digital diagnosis and online real-time quality control of all screening cases have been realized. In addition, the normalization mechanism of cervical cancer screening and prevention has been effectively established and integrates with other medical information systems.

Xuzhou Maternal and Child Health Care Hospital Cervical Cancer AI Screening System has three layers of architecture: screening solution, central laboratory and remote diagnosis. It has the following functions:

- Screening solution: Due to the limited conditions of screening sites, stable collection environment cannot be provided. The system provides a complete package plan, including the NUC entry host, ID card reader, label printing and other full sets of equipment; complete the entry of one case within 30 seconds;
- Screening laboratory: After the slide is produced, the scanner scans and uploads the slides to the server automatically.
- Storage server: Structured digital slide storage function is provided to directly upload the slides to the storage server.
- AI diagnosis platform: AI diagnosis, manual diagnosis and review functions are provided.

See the table below for the list of software and hardware configuration

	Hardware	Software
Screening Solution	NUC Panther Canyon host computer	Win10
Storage Server	4-node: Processor: Intel® Xeon® Silver 5218 CPU @2.3GHZ Memory：32G System disk: SSD 480G Buffer disk: Intel S4610 48GB Object data disk：SATA 14TB*12 RAID: LS13008 Dual 10-gigabit NIC	CentOS7.6
Application Server	Processor: 2*Intel® Xeon® Silver 4210R Memory: 2*32GB DDR4 RDIMM Memory Hard Disk: 12T SAS*3 RAID: support RAID0,1,10 Network interface: 2*10GE (light module included)	CentOS7.6
GPU Server	2*intel Bronze3206R (eight-core 1.90G) Memory: 4*32GDDR4-3200MHZ Hard Disk: 2*480G Read intensive SSD Hard disk +2*4TBSAS Hard disk Network interface: 10GB network card+5720 dual port gigabit network card Graphics card: 4*Nvidia RTX A4000	Ubuntu20.04

Case 3:

Solution for Henan remote pathology consultation platform in the First Affiliated Hospital of Zhengzhou University

Through the network, KFBIO's digital pathology remote consultation platform can realize the data transmission between the experts, cooperative medical institutions and patients in different regions to view the slides at the same time. It also has the functions of browsing, editing and management of digital slides, and has many advantages including frozen section real-time diagnosis, real-time consultation, quality control, data monitoring and management, remote real-time sampling guidance, three-level diagnosis and review mechanism, customized HIS interface, MDT multidisciplinary consultation, graded diagnosis and treatment architecture, synchronous remote audio and video, and multi-expert signature, support terminals including PC, tablet, and mobile phone. The independent external network access does not interfere with the original information system of the hospital, encrypts user data, and ensures the security and privacy of customers; comprehensively record data requests, operation records, system maintenance and upgrade, system operation and other information; standardize filtering, merging and warning processing, thus realizing system log audit.

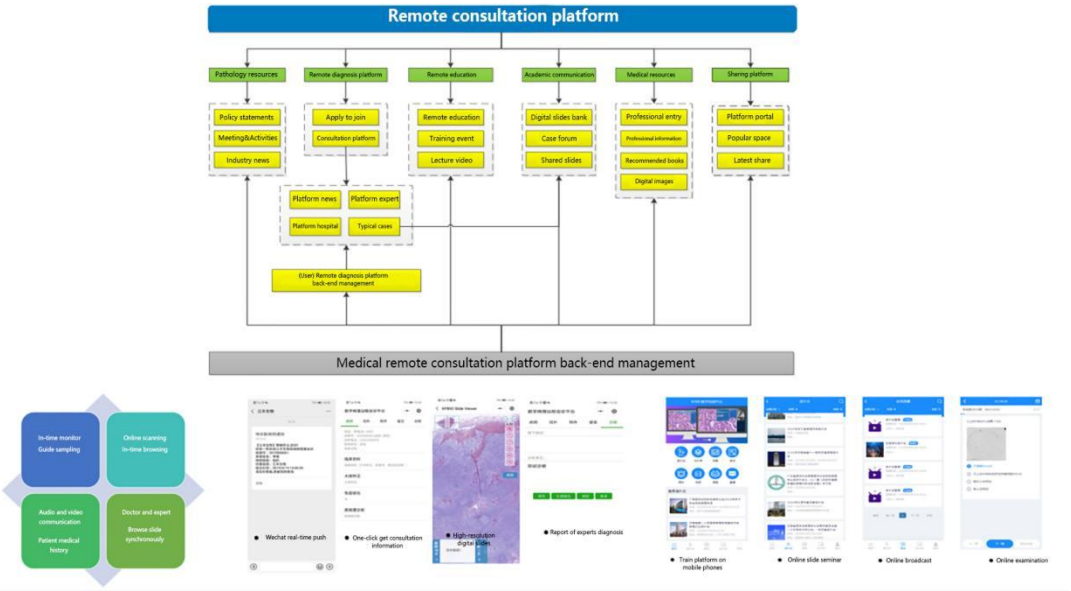


Fig. 12 KFBIO's digital pathology remote consultation solution

Henan Telemedicine Center, formerly known as Henan Remote Consultation Center, was renamed after approval of Health Department of Henan Province in December 2010. It's one of the earliest telemedicine centers established in China. In 2016, the center set up a remote consultation platform for pathology specialty. Taking the First Affiliated Hospital of Zhengzhou University as the center and 19 municipal hospitals as the sub-centers, telepathology services covers 249 medical institutions in China to provide remote pathological

consultation, quality control and education services for patients and medical institutions nationwide. As an excellent digital pathology solution supplier, KFBIO has provided digital pathology scanning system, remote consultation software, system integration services, leading the overall implementation, training, operation and maintenance of the project.

KFBIO has equipped cooperative hospitals and county telemedicine sub-centers with digital pathology scanners and workstations. KFBIO helps to debug the system and devices, organizes telemedicine and digital pathology diagnosis professionals to provide free training on digital pathology equipment and system, and continuously improves the academic and technical level of pathology technicians in primary hospitals, provides telepathology diagnosis guidance, establishes the cooperation mechanism, builds a regular telepathology service model, carries out the diagnosis of difficult cases for the primary hospitals, and continuously improves the pathology diagnosis ability of primary hospitals. KFBIO, in the process of platform construction and development, has fully considered the demands of data storage, network, audio and video connection, information security, business tracking and frozen section real-time consultation, covers the business function of hospital pathology departments, thus effectively improves the regional pathology level, promote the implementation of graded diagnosis and treatment. At present, the platform has more than 12,000 difficult cases per year. All of them are provided in the form of public welfare. It's an important part of the medical welfare project in Henan Province.

The system includes the central service module and application terminal module.

- **Application server**: Manage routine business; preserve all record requests; demonstrate the operation details through the time line browsing history;
- **Database server**: Realize linear expansion capability of service processing by means of sub-table and partition to ensure that the system response remains efficient as the amount of data increases.
- **Terminal computer**: Require a fixed IP address and a network of more than 10M and support intraoperative rapid frozen sections.

See the table below for the list of software and hardware configuration:

Server (Application server, Database server):

#	Configuration	Description
1	Operating system	Windows Servers 2008 r2 x64 Chinese version, Windows Servers 2012 x64 Chinese version, compatible with advanced versions
2	CPU	4-core 8-thread above
3	Memory	16G above
4	System disk	100G
5	Network bandwidth	50M

Application terminal configuration:

#	Configuration	Description
1	IP	Requires a fixed IP
2	Bandwidth	10M above
3	Port	Open the 8001 rapid video reading port
4	Interface	Interface with pathology information system

Case 4:

Regional pathology construction solution for Ningbo Diagnostic Pathology Center

As a public welfare self-funded institution directly afflicted to Ningbo Municipal Health and Family Planning Commission, Ningbo Diagnostic Pathology Diagnosis Center (Ningbo Pathology Center of Shanghai Cancer Hospital) was formed by the pathology departments of six municipal hospitals in Ningbo. It's the first regional clinical pathology diagnosis center in China. Since its establishment in 2011, the Center has been working for nearly a decade.

In 2021, the KFBIO whole workflow pathology information management system was introduced to the Center. The Center realized the whole workflow specimen tracking including surgery, registration, distribution, production and diagnosis in multiple hospitals. Firstly, the hardware access and sample bar code scanning of each work link through the information management system greatly reduce the error of manual input. And at the same time, the tracking and control of the whole workflow is digitized. It improves the business refinement level, and makes the quality control of the laboratory more intelligent and accurate. Secondly, the Center has also integrated application modules including digital slides scanning system, remote consultation platform and AI-assisted diagnosis system to realize seamless digital slides online reading, remote consultation and AI-assisted diagnosis on the same platform, thus achieving safer and more efficient diagnosis, finer pathology quality control, higher management level of the center. And, based on the actual needs, the Center has completed the integration with various information systems of cooperative hospitals to realize the interaction of clinical information and pathology information, standardize the work flow of pathology departments, improve the operation efficiency of pathology system, and finally improve the management ability of pathology department and diagnostic quality. Besides, the Center has also built a digital pathology data center, equipped with 5 digital pathology 400 slides scanners (high-throughput), 15 digital pathology 5 slides scanners (low-throughput) and 200T storage service capacity. It meets the needs of remote pathology consultation, archive storage, education and scientific research. The digital pathology information also provides a huge amount of data resources for the Center and related enterprises to jointly carry out AI-assisted diagnosis research.

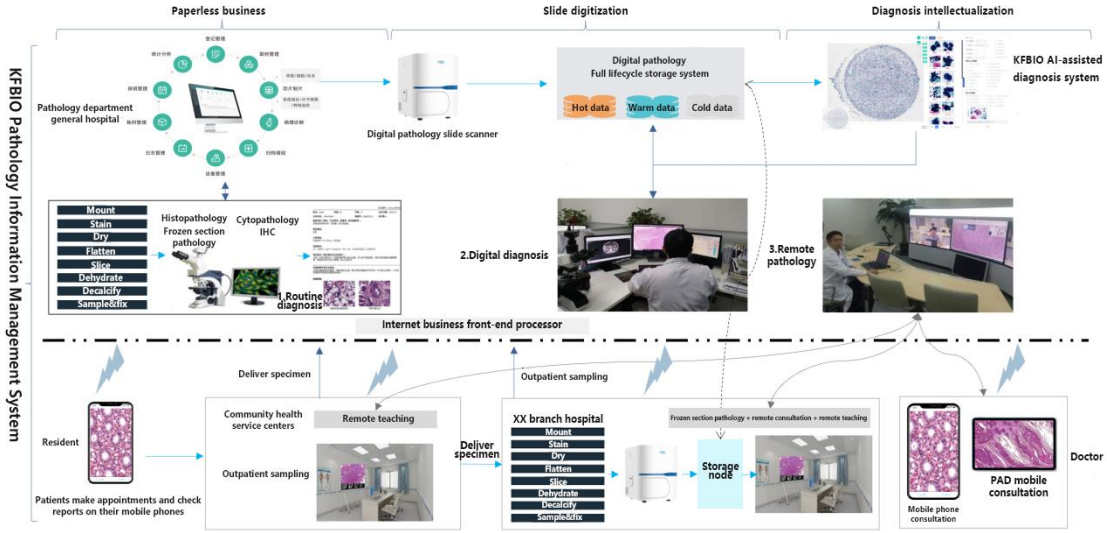


Fig. 13 KFBIO's regional end-to-end pathology cloud platform construction solution

The system includes the front-end processor service module and back-end application service module.

- Front-end processor: To ensure the safety and reliability of hospital data, all application servers are transferred through the front-end processor to ensure the minimal development of hospital data and services. The deployment of the front-end processor includes hospital front-end processor, third-party diagnostic center front-end processor and third-party business service front-end processor. The following functions are realized:

A. Hospital front-end processor: Application form data management, case management, digital slides remote consultation service management, etc

B. Third-party diagnostic center front-end processor: Responsible for connecting with the third-party diagnostic center system and completing the digitization of other hospitals' diagnosis request;

C. Third-party business service front-end processor: Provide report notification service by SMS, WeChat, and third-party services.

- Proxy server: Data forwarding and load balancing;
- Application server: Routine business processing; preserve all record requests; demonstrate the operation details through the time line browsing history;
- Database server: Realize linear expansion capability of service processing by means of sub-table and partition to ensure that the system response remains efficient as the amount of data increase

See the table below for the list of software and hardware configuration:

	Hardware	Software
Front-end processor	CPU: 1 Pentinum N6000	CentOS7.6 front-end processor service
Application server	CPU: 2 Xeon Silvcer Memory: 128G DDR4 Storage: 12 4T SSD hard disk Network: 4 10-gigabit optical ports	CentOS7.6 application cluster
Database server	CPU: 2 Xeon Silvcer Memory: 128G DDR4 Storage: 8 4T SSD hard disk Network: 4 10-gigabit optical ports	CentOS7.6 MySQL Primary/secondary database

4 Future Prospect

Digital pathology standardization

With the development of automatic and intelligent pathology preprocessing equipment, it is believed that in the near future, digital pathology will be standardized just like image data. It will bring great convenience for the application of digital pathology.

Application of end-to-end digital pathology

The fully digitization of pathology department will deeply integrate AI tools into various links, such as sampling analysis, section process analysis, slide quality analysis, equipment operation analysis, natural semantic analysis, intelligent initial screening, auxiliary image analysis, AI diagnosis, intelligent data analysis, intelligent error correction, etc., to reshape the department management process, diagnosis process, quality control process through AI. It's the general trend of the digital pathology future.

Digital pathology boosts precise diagnosis and treatment

With the application of immunohistochemistry and molecular pathology, and the discovery of more biomarkers, pathology diagnosis, as the gold standard for tumor diagnosis, classification, medication guidance and prognosis judgment, will play a more important role in precision diagnosis and treatment.

Appendix: KFBIO Digital Pathology Solution Product List

Name	Product	Model
Full digitization of pathology department solution	Pathology Information System	K-PIMS
	Ventilation hoods	TFG-II
	Pathology sampling workbench	QCT-II
	Gross sampling camera system	KF-Studio
	Microscopic camera and interface	K-MCam
	Automatic speech recognition entry system of sampling	KF-VI-2001
	Technical rugged tablet	MT75
	Paraffin block storage cabinet	B-L
	Bar-code scannerspecial for embedding	KF-EREC-001
	Cassette batch identification system	KF-ARC-001
	Cassette laser printer	KF-LSP-150E
	Paraffin embedding machine	KF-EMH-100
	Slide laser printer	KF-LEP-006
	Paraffin rotary microtome	KF-SLP-200
	Water bath-slide drier	KF-DW-100
	Slide storage cabinet	B-B
	Sample freezer	B-F
	Digital pathology scanning system	KF-PRO-005、KF-PRO-020 KF-PRO-040、KF-PRO-120 KF-PRO-400
	Fluorescence pathology scanner upgrade 3FL	Upgrade
	Fluorescence pathology scanner upgrade 6FL	Upgrade

	Digital slide storage system	/		
	AI analysis platform	K-AI		
End-to-end cervical cancer screening solution	Liquid-based cytology reagent	/		
	Sedimentary cytology staining machine	KF-CT-3000Y		
	Cytology scanning analysis system	KF-TCT-400、KF-TCT-120 KF-TCT-40、KF-TCT-20		
	AI cervical cancer screening management system	/		
	Ningbo Yangming medical diagnostic Laboratory	Diagnostic service		
	Customized deign for laboratory	/		
	Related equipment, consumables such as bar-code scanner, slide laser printer	KF-LEP-006		
Remote Pathology Consultation Platform	Pathology consultation platform - integral module	K-DIAG		
	Pathology consultation platform - application site	/		
	Digital pathology cloud platform portal	K-Portal		
	Audio/video online conference system	K-Meeting		
	Pathology education and training system	K-Edu		
	Quality control system	K-Qua		
	AI analysis platform	K-AI		
	Digital pathology scanning system	KF-PRO-005 KF-PRO-20		

Regional pathology diagnosis center	See the above	


KFBIO & Intel End-to-end
Digital Pathology Solution
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