Suppliers and GPOs

Device identification for traceability in the IVD-reagent supply chain

Dian Diagnostics Group Co., Ltd. (DIAN) is a China-based in-vitro diagnostics (IVD) company that primarily offers medical diagnostic outsourcing services. In China's IVD-reagent supply chains, there was no consolidated material coding standard. This caused a series of problems, such as information inconsistency between upstream and downstream enterprises, the lack of traceability in supply chain processes, human-input information that was prone to errors, and high costs with low efficiencies.

To address these issues, DIAN and the Zhejiang Institute of Standardization implemented an IVD-reagent solution based on GS1 standards. They labelled each IVD-reagent individual unit with a GS1 Global Trade Item Number® (GTIN®) and key attributes encoded in a GS1 DataMatrix barcode. They also linked upstream and downstream enterprise information to the GS1 identifiers, as well as upgraded healthcare providers' supply processing distribution (SPD) systems for compatibility with the GS1 standards.

DIAN has improved overall operating efficiency, reduced logistics information errors and maintained the traceability of IVD-reagents. GS1 standards have also eliminated the labourious work of applying non-standard proprietary codes in hospitals. Since DIAN is manually labelling the IVD-reagents, it is continuing its work to ensure that the labelling is eventually completed by IVD-reagent manufacturers.

By Zhenggang Wei, Lei Fang, Xiu Wang, Zhiqiang Zhao and Jin Shi

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Background

IVD-reagents—clinical test kits, quality control materials, calibration materials and more—are used for biological sample tests in the process of disease prevention, disease diagnosis, prognostic evaluation, health evaluation and genetic disease prediction. Initially, IVD-reagent logistics information often relied on handwritten notes and manual investigation, which was not efficient and error prone. Moreover, due to the lack of unique identification, when an issue occurred, DIAN could only estimate which IVD-reagent caused the issue by using the IVD-reagent's lot or batch number, thus, creating traceability errors in quality control.

With the emergence of automatic scanning information technologies, GS1 identifiers and barcodes are now applied to IVD-reagent secondary packages within the supply chain. In the US and Europe, major IVD-reagent manufacturers have already adopted GS1 standards for the unique identification of their products (e.g., Roche, Thermo Fisher, Sysmex, BioMérieux, and others). Yet, some manufacturers are applying GS1 barcodes only at the IVD-reagent's secondary level of packaging, which limits the granularity of tracing individual items.

In China, there is no consolidated material code regulation nor Chinese Unique Device Identification (UDI) regulation to necessitate the application of GS1 barcodes in the IVD-reagent supply chain, as yet. Different jurisdictions and supply chain participants are using their own way of material coding.

DIAN's third-party, independent clinical laboratories (ICL) provide diagnosis services to clients, and DIAN is the largest IVD reagent agency in China market. IVD-reagents are widely used in DIAN's core businesses, such as ICL tests, logistics processing in the supply chain, and precision medicine centre test projects.

The lack of a consolidated coding standard in IVD-reagent supply chain causes a series of problems. For example, the company must use a significant amount of labour to manually check and even generate logistics information in its processes. This manual work is very inefficient, error prone and can provide ambiguous information. Achieving traceability across the entire supply chain is also not possible. All of these problems significantly increase the company's operating costs and negatively impact quality control and customer satisfaction levels. With business becoming increasingly sophisticated coupled with growing volumes of products, the lack of a consolidated coding standard has impacted DIAN's growth.

To improve traceability, transparency, efficiency, information accuracy and data exchange in the IVD-reagent distribution process, DIAN and Zhejiang Institute of Standardization designed and implemented a GS1 standards-based IVD-reagent identification solution. The solution, used in DIAN's core business, also helps the company monitor adverse events and recall defective products, while eventually enhancing service quality and customer satisfaction.

Identify and label the minimum IVD-reagent unit pack with GS1 barcodes

When an IVD-reagent enters DIAN's warehouse, the warehouse operator labels the minimum unit pack with a unique GS1 GTIN, batch/lot number and expiration data, encoded in a GS1 DataMatrix barcode. This barcode is the key when DIAN traces the unit within the warehouse and in the supply chain. The IVD-reagent GS1 barcode structure is shown in Figure 1.

The IVD-reagent GS1 barcode structure

Required		Optional			
AI*	GTIN	AI	Batch/lot number	AI	Expiration date
01	N14	10	X20	17	N6

Figure 1: Each unit pack of IVD-reagent is labelled with this information encoded in a GS1 DataMatrix barcode.

Link upstream and downstream enterprise information to the GS1 barcode

When an IVD-reagent is delivered from storage, an operator scans the barcode, reviews the item, and binds the ODO (Outbound Delivery Order, including customer name, outbound date and order number) with the barcode in the system. Thus, DIAN links the upstream and downstream enterprise information with the GS1 barcode, and IVD-reagent traceability is established.

Upgrade hospitals' supply processing distribution (SPD) system to be compatible with the GS1 barcode

DIAN has shared the IVD-reagent GS1 identification structure and rules with hospital SPD software vendors that have upgraded their SPD software to be compatible with GS1 standards.

Hospitals can now utilise the same GS1 standards-based barcodes. When an IVD-reagent unit enters the hospital's storage area, hospital staff use a handheld wireless scanner to scan the GS1 barcode to collect the product information (shown in Figure 2).

Figure 2: The hospital staff scans the GS1 barcode to collect product information.

Since GS1 identifiers and barcodes are used to maintain traceability and are scalable, hospital staff can add more information based on use, such as stock inbound date, distributor's information, department information, and more. Since the end of Q1 2018, DIAN has deployed this solution to more than 60 hospitals.

Benefits

DIAN's GS1 standards solution improves the IVD-reagent supply chain by:

- ✓ **Ensuring the accuracy of IVD-reagent logistics information.** The data is collected by scanning the GS1 barcode instead of using manual input. Human-generated errors in this process have been dramatically reduced.

- ✓ **Improving the traceability in the IVD-reagent supply chain.** The IVD-reagent is labelled with a GS1 barcode at the single-use or unit-level of packaging. The upstream supplier information and downstream ODO (Outbound Delivery Order, including customer name, outbound date, order number) information is accessible via the identification information within this barcode, so all parties in the supply chain can easily query this information. When a quality issue occurs, DIAN can precisely locate the defective product and tell which IVD-reagent batch/lot the issue originated from. Parties in the entire supply chain can respond much quicker and with increased agility, and any logistics-induced medical negligence can be proactively managed.

- ✓ **Reducing the workload of labelling barcodes in hospitals.** Since the hospital SPD systems are compatible with GS1 standards, hospital staff can continue using GS1 barcodes in their work. When an IVD-reagent enters the hospital's warehouse, hospital staff only needs to use a handheld wireless scanner to scan GS1 barcodes, rather than printout a proprietary barcode and apply the label to the IVD-reagent again. As a result, hospital staff workload has been significantly reduced.

Conclusions

In summary, DIAN's GS1 standards solution increases access to accurate and complete logistics information in the IVD-reagent supply chain across participating entities, improves IVD-reagent product traceability and reduces hospital workload.

However, it should be noted that DIAN, as a distributor of IVD-reagents for its business trading segment, must still manually label a significant amount of IVD-reagents with GS1 barcodes when they are received into DIAN's warehouses for the following reasons:

- Manufacturers do not use identification barcodes.
- Identifiers and barcodes used by manufacturers are proprietary.
- Identifiers and barcodes do not provide enough information.

The resulting manual work is error prone. In addition, DIAN's GS1 barcodes can only trace back to DIAN's immediate upstream suppliers, and downstream traceability is compromised if the company's system is not compatible with GS1 standards.

Given this, a one-for-all material identification solution should begin with the IVD-reagent manufacturers. When a GS1 identifier is assigned and barcode applied on an IVD-reagent in production, before entering into circulation, true end-to-end traceability across the entire supply chain is possible. All entities that have participated in the process are able to trace every single IVD-reagent's status—whenever and wherever it may be, including manufacturers, suppliers, distributors, healthcare institutions, hospitals and even individual patients. Regulators can digitalise their monitoring systems to automate the supervisory process via the GS1 standard as well. The overall business scenario is illustrated in Figure 3.

Using GS1 standards in IVD-reagent distribution is gaining momentum. With ongoing adoption by key stakeholders, the overall IVD industry's distribution costs could be reduced while the service quality, security and customer satisfaction levels could increase.

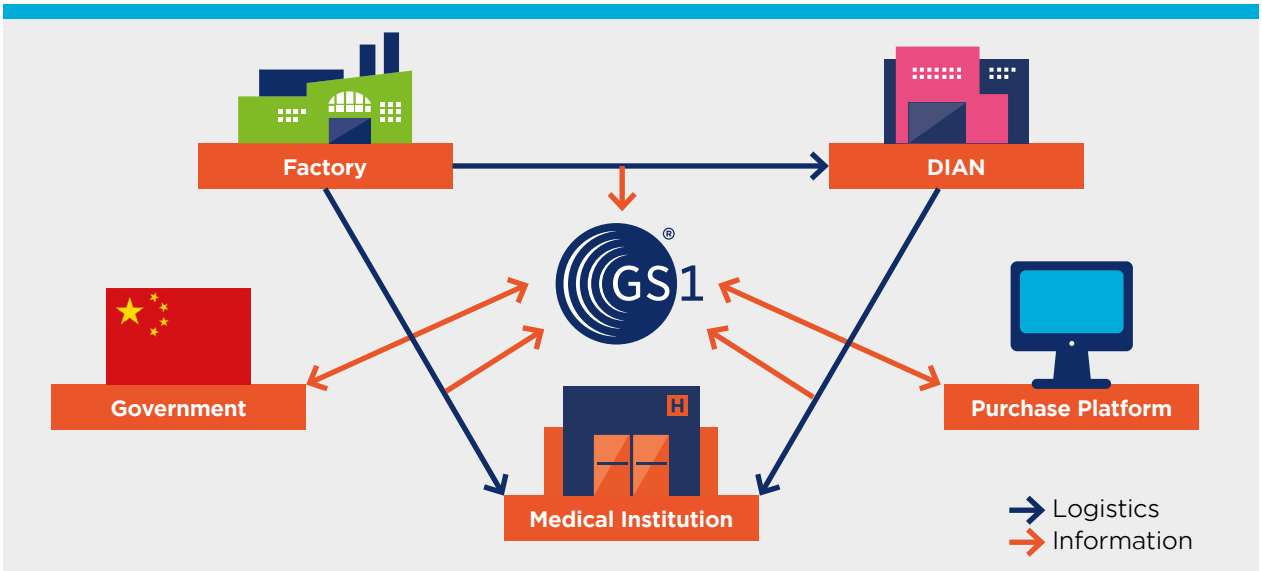

Figure 3: The overall business scenario when GS1 barcodes are applied to the entire IVD-reagent supply chain.

About the Authors

Zhenggang Wei *(David Wei) is the Vice President and Chief Information Officer (CIO) at DIAN. He has 20 years of consultancy and IT services practice in strategy, planning and digital technologies.*

Lei Fang *is the Warehouse Management System Project Manager. He has 10 years of experience in business analysis and IT solutions in the supply chain and logistics.*

Xiu Wang *is IT PMO at DIAN. She is experienced in IT project management assistance and coordination.*

Zhiqiang Zhao *is Chairman of Zhejiang Logistics Information Technology Standardization Technical Committee . He is engaged in the research and promotion of coding management, policy and automatic identification technology, especially in the field of coding internationalization and supply chain management.*

Jin Shi *is Member of Zhejiang Logistics Information Technology Standardization Technical Committee. He is engaged in the research and promotion of coding and automatic identification technology, especially in the field of pharmaceutical product coding and supply chain logistics management.*

About the Companies

Dian Diagnostics Group Co., Ltd.*, formerly Zhejiang Dian Diagnostics Co. Ltd., a listed company in China Shenzhen Stock Exchange, is a China-based in-vitro diagnostics company principally engaged in the provision of medical diagnosis outsourcing service. The company operates through two main segments: service industry segment and business trading segment. The service Industry segment is primarily involved in the fields, including diagnosis services, diagnostic equipment distribution, cold chain logistics and physical health examinations, among others.*

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Zhejiang Logistics Information Technology Standardization Technical Committee *provides the services of promoting, managing and supervising automatic identification technology in the entire Zhejiang province. In recent years, its prominent achievements have been accomplished in standardization of logistics information, electronic commerce and Smart Cities.*