

The Little Book of Identification and Tracking for Diagnostics



Diagnostics:

a global industry dedicated to accurate, efficient, and innovative patient diagnosis

The global diagnostics market is growing at a rapid pace. It's constantly making innovative progress in the speed and accuracy with which diseases, infections, and conditions are detected. Results from diagnostic tests are critical in that they play a vital role in determining the types and availability of treatments.

Though there are many different disciplines, technologies, and focuses within diagnostics, one thing remains constant: the need for automatic identification.

Whether it's for tracking specimens, monitoring proprietary consumables or productizing reagents, the need for labels and RFID technology remains unchanged.

We're proud to provide tracking to some of the industry's leading diagnostic organizations, and you can be sure that as technology evolves, so will our solutions to help support it.

Diagnostics: all around the world

A global industry growing in terms of both size and complexity, diagnostics is comprised of several disciplines, each of which has specialized areas of focus.

27%
Immuno-Diagnostics:

- Immunoassays and immunochemistry techniques are focused on molecules through the utilization of antibodies and/or antigens
- Used to diagnose: HIV/AIDS virus, hepatitis C

16%
Blood Testing:

- Hematology focuses on the analysis of blood and its various components (red cells, white cells, platelets, vessels, bone marrow, etc.)
- Used to diagnose: leukemia, anemia

13%
Molecular Diagnostics:

- A variety of techniques that focus on DNA and RNA to map specific traits that may be more prominently associated with disease
- Used to diagnose: hereditary disorders like Cystic fibrosis

24%
Clinical Chemistry:

- A focus within clinical pathology that most often analyzes bodily fluids
- Used to diagnose: obesity-related diseases, thyroid-related diseases

15%
Tissue Diagnostics:

- Includes disciplines like immunohistochemistry, special staining, and digital pathology to analyze and diagnose tissue or biopsy samples
- Used to diagnose: cancers, auto-immune diseases

5%
Other IVD Techniques:

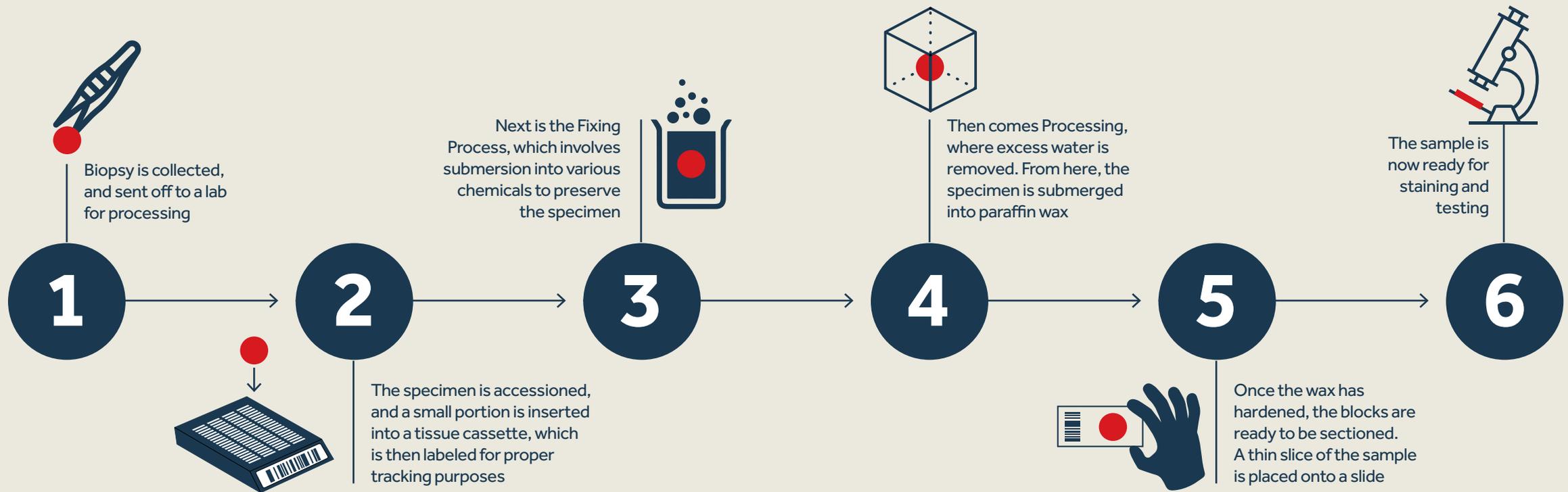
Ever evolving, there are many reasons why the global diagnostic industry is growing...

- Increasing incidences
- Aging population
- Improved healthcare awareness
- High demand for accurate and cost-effective tests
- Demand for faster time to market

What do all of these disciplines have in common?

That's right – the need to track specimens and samples through a process. Whether it's a blood sample, saliva, or a tissue biopsy, managing patient-specific information through unique automatic identification is imperative to ensure an accurate diagnosis quickly makes its way back to the patient.

Tissue Processing: the journey of a biopsy



Some labs have direct mark technology to identify their cassettes, while others rely on barcode labels. Either way, ensuring accurate sample chain of custody is the most important goal.

Whether submerged for hours, or just wiped with a chemical agent, the barcodes on tissue cassettes need to withstand some harsh components:

- Xylene
- Paraffin Wax
- Ethanol
- Formaldehyde
- Saline

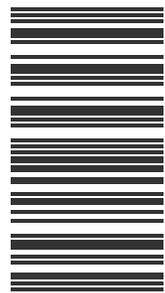
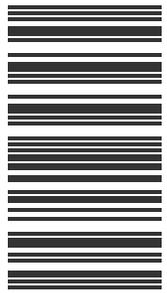
Maintaining chain of custody

Print-on-demand replicator systems allow labs to scan the barcode on the tissue cassette and print the corresponding slide label. This ensures proper chain of custody throughout the journey of a sample.

Histology Slide Labels: assisting in accurate and efficient diagnoses

The barcode enables each specimen to communicate at every stage in the automated process, ensuring the most important priorities are met:

- ✓ Quality
- ✓ Risk mitigation
- ✓ Lean processes
- ✓ Reduction in non-value added time
- ✓ Patient protection
- ✓ Efficiency and accuracy in diagnosis



While serving multiple purposes, the primary function of these small but dependable labels are to ensure each specimen maintains its original identity.

- Whether printed with a linear code, 2D, human readable, or a combination, the primary purpose of the histology slide label is to uniquely identify each specimen

- A barcode is often automatically scanned multiple times upon being loaded to the automated staining platform, and hence ensures proper workflow functionality
- Uniquely engineered to withstand conditions, these little labels hold up to H&E staining agents, special stains and other lab chemicals
- Functional beyond just identification, the construction, shape and slope of a slide label can also ensure the direction and flow of staining agent over the slide itself

Did you know...

CompuType ships over
135,000,000

uniquely engineered histology slide labels annually for usage in automated staining platforms

Slides are often stored for up to

10 Years

Automatic identification to support accurate, efficient diagnosis

Ensuring proper patient diagnosis is a discipline where precision and certainty are crucial. With Comptuype's proven automatic ID solutions, workflows are streamlined through improved data management and connectivity.



REAGENT MANUFACTURING



Print-on-demand systems
Automatic label applicators support cost-effective, reliable ID, branding, and packaging of reagents.



Color options
Enable at-a-glance product identification and differentiation.



READY Labware Services
Outsourcing of pre-labeled containers or for reagent kitting and packing



PATIENT



Sample collection
Sample is collected.



Labeled
Swab or tissue sample labeled with appropriate ID for tracking.

LAB

TEST PREPARATION

Labels engineered to withstand harsh environments. High heat, liquid nitrogen freezing, and chemical resistance. Variants to suit plates, tubes/vials, cassettes, and slides.

ANALYSIS VIA AUTOMATED PLATFORMS

Labels and RFID compliment the functionality of automated testing systems to ensure tight controls, precision, and efficiency.



FAST & ACCURATE RESULTS!

In part because barcodes, labels and RFID systems helped manage the data throughout the entire workflow



ANALYTICAL EQUIPMENT MANUFACTURING



Labels
Engineered labels for integration with and optimization of your automated platforms



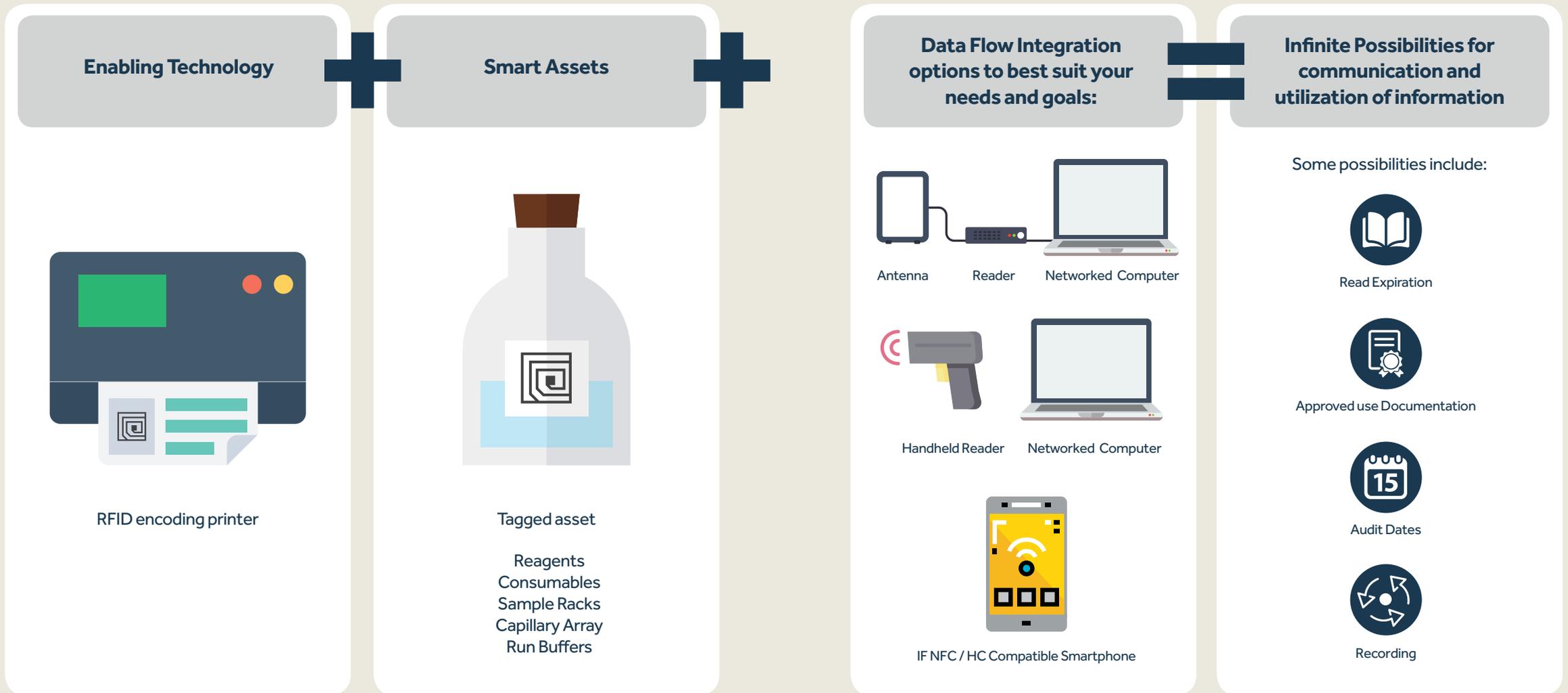
RFID
Labels enabled with read/write data capabilities. For the smart tracking and monitoring of proprietary reagents and consumables.



DIAGNOSIS & TREATMENT

RFID Label Systems: The Basics

RFID simply means the use of radio waves to provide automatic identification. Depending on your needs and goals, there are virtually limitless possibilities to what you can utilize RFID for.



RFID: Improving Processes and Information Flow in Diagnostics

How is RFID being utilized in global diagnostics? The possibilities are limited only by the imagination of innovative healthcare professionals. The communication of Smart data in real time opens up possibilities for improved information sharing that were never before possible...



Authentication:

When utilizing reagents or consumables in conjunction with automated instruments, it's important to ensure that unauthorized reagents are not used in an instrument for which they are not intended. RFID can be used to verify approved reagents, or utilized to 'kill' or disable a chip when tampering or an unauthorized reagent is detected.

Predictive Maintenance:

Diagnostic instruments typically require preventive maintenance visits by technicians and occasionally need spare parts, firmware upgrades and software modifications.

RFID can be used as an important component in a predictive maintenance program, alerting operators of the need to refill consumables or to perform other tasks necessary to optimize system throughput and reduce downtime.



Quality Control:

RFID transponders can include a 'read' capability that is valuable for quality control purposes, as it is possible to write information to the IC chip at various points during the life of the item. For specimen tracking, it is possible to record the date and time that various operations occurred, or record conditions such as weight, environmental parameters or cycle times. RFID can be used to identify when process variables are outside of expected limits and also to alert operators when downtime may be imminent if corrective action isn't taken.

Automated Data Logging:

A new technology employing RFID is low cost data logging, using passive or 'battery-assisted' sensors to provide laboratory technicians with a means of recording data history on the RFID chip, updating the information at regular intervals. This capability is most valuable in situations where the quality of a specimen is determined, to a large degree, by stable environmental conditions during storage and processing. RFID can act as the memory of the sample and record variables that fall outside specific parameters.



Specimen Tracking:

While laboratory information systems can easily accommodate the processes managed within the lab with their LIMS platforms, specimen tracking can be complicated when processes are shared between multiple facilities. In these cases, it is beneficial to use RFID as a strategy for managing incoming specimens at the accessioning phase. A shipping door, for example, could be fitted with RFID readers capable of determining the contents of shipped specimens without having to open the package.



RFID: Tracking Reagents and Consumables in Closed Loop Analytical Equipment

Reagents used in diagnostic instrumentation often represent a significant source of customer value. Not only are many reagents and consumables specialized, but some are even proprietary and designed specifically for use in a single platform or instrument.

Utilization of RFID technology helps ensure the proper connectivity and communication of reagents and consumables to their associated platforms:

Expiration Date:

RFID tags can be encoded to include the expiration date of the reagent or consumable. Data associated to this can even be tied back to a centralized inventory management package for automated consumable reordering based on usage. As the expiration date can be stored on each separate container of reagent, manufacturers can ensure accurate testing based on whether the unit is within the set expiration date parameters.

Remaining Life:

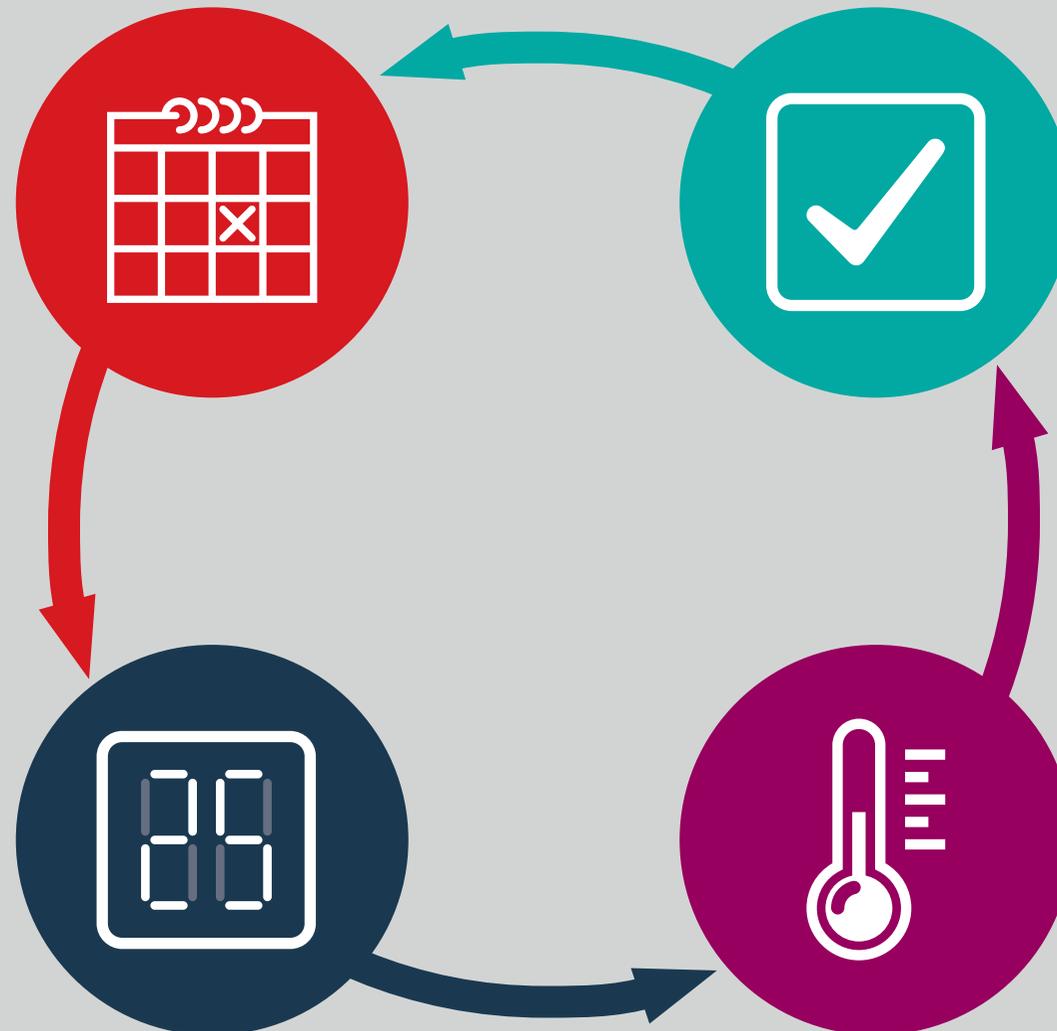
RFID can store incrementing variable data related to useful life and/or number of remaining tests associated to a specific reagent. For example, if reagent volume allows for 100 tests, the tag itself can increment a 'tests performed' variable and display the number of tests remaining on the interface of the equipment or associated monitor. This ensures every test is accurate and utilizes the proper amount of reagent to perform the task at hand.

Verifying Authenticity:

RFID can be used to verify OEM authenticity of a reagent or consumable. Through reading an encrypted string of data and decrypting through the device software, equipment manufacturers can guarantee that only approved reagents and consumables are being utilized in the equipment.

Sensed Data:

In situations where, for example, reagents are temperature sensitive, RFID tags can be coupled with sensors to ensure the reagent was never out of the designated temperature range. Incorporating a 'kill code' enables the reagent to provide an error alert and prevent the compromised reagent pack from being utilized.



More than just a pretty package: adding color to diagnostic labeling strategies



Company identification, logos, and product information on reagent containers, packaging, and kits

Color is finding its way onto labels in all corners of diagnostics, and it's adding more value than just being eye-catching:



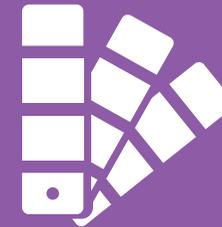
Color coding of labware or reagents, so users know when to use it, or to what specific process it belongs

Abc

Extended content labels to separate the information on a label using color fonts or color 'tabs'

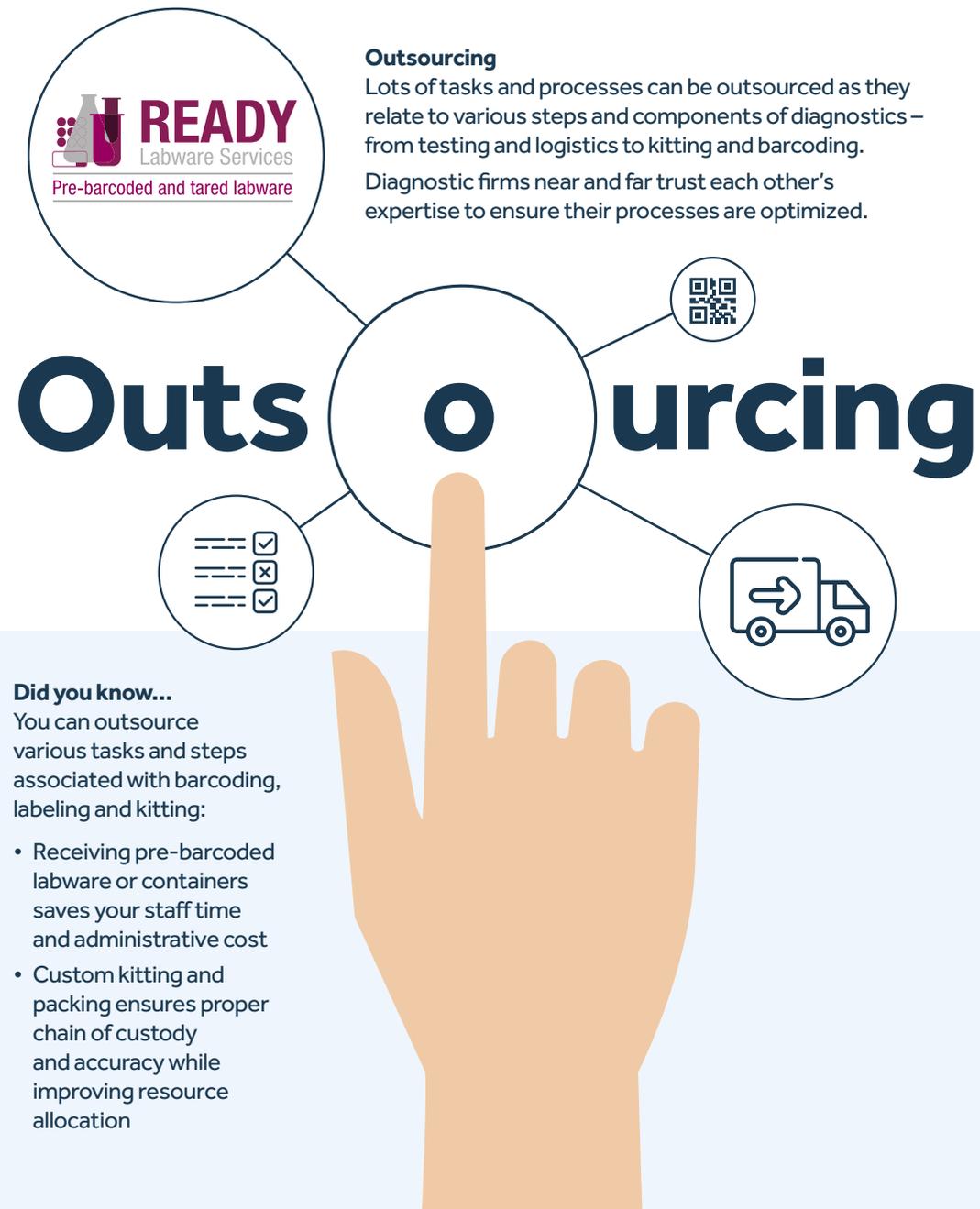


Warning and hazard communication, GHS Compliance



Color matching and coding with other containers or instructions for collection kits

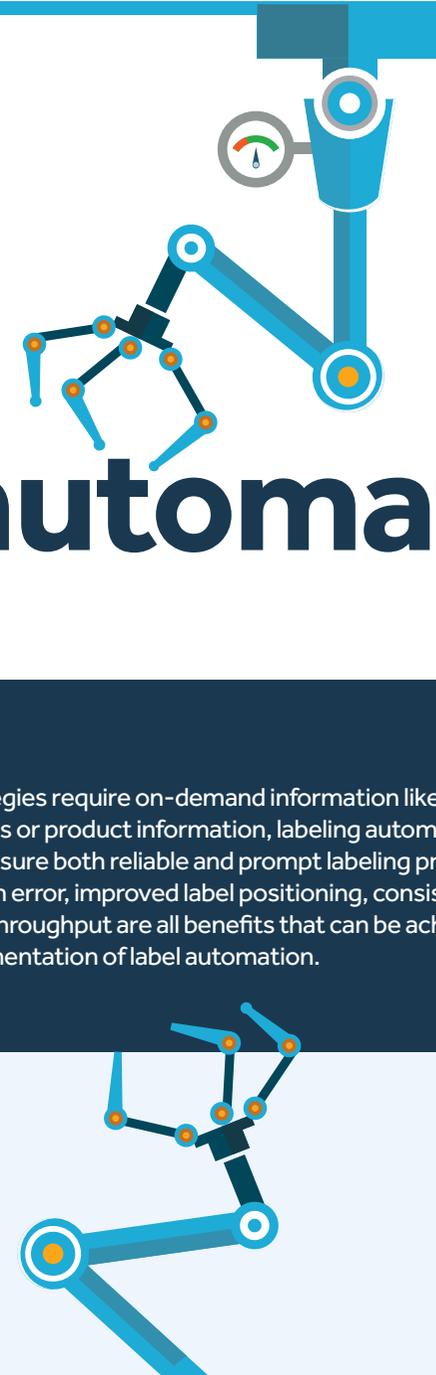
Doing more with limited resources:



and automation

Automation

If labeling strategies require on-demand information like date and time stamps or product information, labeling automation can be utilized to ensure both reliable and prompt labeling processes. Reduced human error, improved label positioning, consistency and increased throughput are all benefits that can be achieved through implementation of label automation.



As the global healthcare industry continues to grow, so too will the sophistication of techniques, the level of automation, and the processes associated with diagnostics.

The future is bright, and is all about achieving ever faster and ever more efficient diagnosis.

Key areas that will see major developments over the coming months and years include:

The future of diagnostics

Automation:

The industry will be ever striving to provide the quickest diagnosis possible. Through the use of automation that can perform multiple tests simultaneously, the speed to diagnosis will improve.

Self-Testing/ Point-of-Care Testing:

The popularity of point-of-care tests will continue to rise, as there is no quicker way to get a result than using an on-demand test.

Minimally Invasive Techniques:

Utilizing minimally invasive procedures to perform tests and obtain smaller sample sizes will continue to help reduce patients' recovery time.

Personalized Treatments:

Precision in achieving an accurate diagnosis, based on an individual's unique make-up, will continue to improve and expand in the diagnostics market, as the pharma industry and diagnostics industry work closer together than ever before.

Awareness of Healthcare:

Increased education and government-driven programs are helping to spread awareness of disease and associated healthcare treatments across the globe. Increased government spend on healthcare around the world will continue to support the growth of this industry.

Mergers and Acquisitions:

As the lines continue to blur between pharmaceutical, biopharmaceutical, and diagnostics, companies will experience growth through strategies involving mergers and acquisitions. Doing so will enable organizations to be involved in both the diagnosis and the treatment of a given ailment.

Outsourcing:

Teaming up with laboratories that are taking on a more expanded role, diagnostic organizations now have the opportunity to dedicate more resources to diagnostic development. In addition, the increased demand for private laboratories in the industry will help in boosting the growth of diagnostics.

Identified strengths

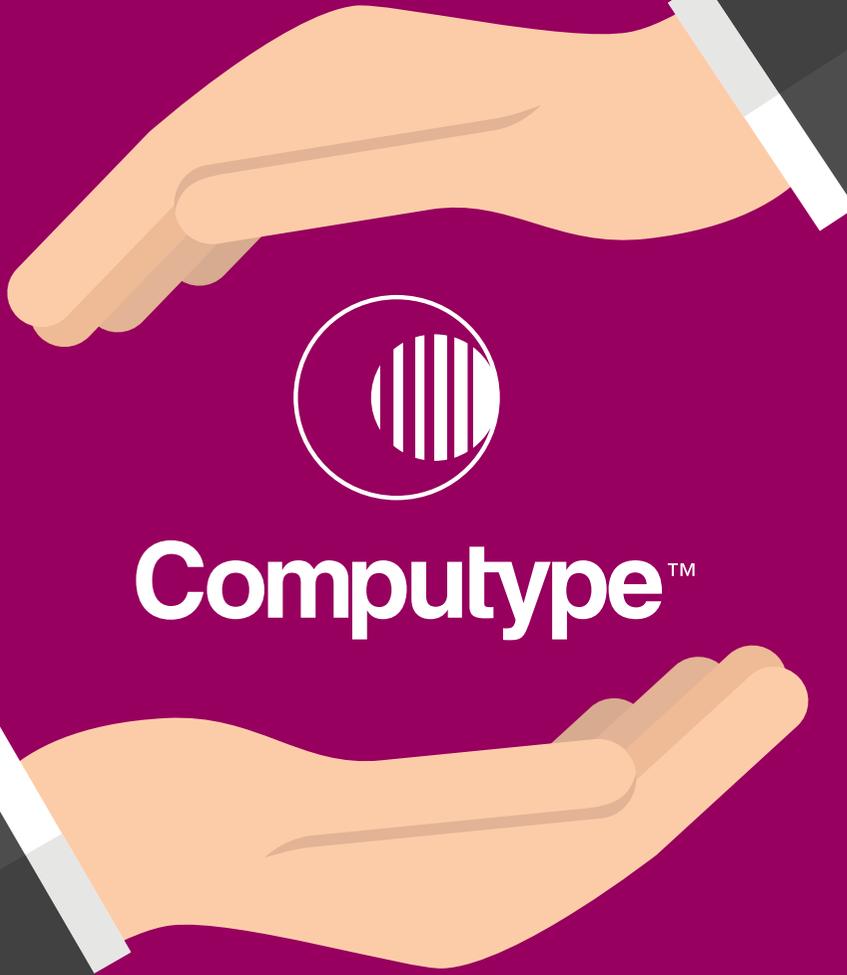
As the demand grows for greater accuracy and increased speed in diagnostics, so too does the need for reliable, automatic identification.

This is where we come in. We are recognized for our strengths in tracking specimens, monitoring proprietary consumables and productizing reagents, we can provide the RFID – and the labels – that you require.

But perhaps more importantly, we also provide a very strong level of service. We consult with you about your exact requirements, your immediate requirements and future goals and then devise a solution tailored to your precise needs. No compromises, no cut corners: a combination of consultation and technology that has seen us provide automatic identification systems to some of the industry's leading diagnostics organizations.

Strengths we feel certain you will identify with.

To find out more, please contact us at contactus@computype.com or visit www.computype.com



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