

The design engineer's guide to improved IVD fluid handling

How connector capabilities impact equipment productivity and reliability

Whether designing for immunoassay, clinical chemistry, hematology, molecular diagnostics or infectious disease applications, in vitro diagnostics (IVD) equipment manufacturers want components that help them deliver high-throughput, top performing products.

Efficient reagent and bulk fluid handling are critical to optimal performance, and connectors are a significant part of fluid management systems.

Connector technologies can contribute to better equipment design, improved ease of use for operators, and increased testing capacity.

Here are key factors to consider when selecting connectors for IVD systems to support user-friendly designs and outstanding equipment functionality.

MATERIAL COMPATIBILITY

In an effort to help avoid equipment leaks, contamination or corrosion, the components within IVD equipment, including connectors, must be compatible with the fluids they come into contact with, both during use and maintenance.

This includes cleaning solutions or other chemicals (for example bleach, hydrogen peroxide or isopropyl alcohol) that may be flushed through the fluid lines or wiped on the exterior. Though common in lab spaces, these chemicals must be considered when identifying compliant materials for IVD devices.

Applications involving stronger acids or solvents may require components to be



made of engineered polymers such as PEEK or PVDF to maintain compatibility.

Connectors are available in a range of materials to ensure that the couplings and their internal components work well with the fluids and chemicals in the flow path.

NON-SPILL CAPABILITIES

Connectors with integrated non-spill valves help avoid both air inclusion and spills upon disconnection.

These robust non-spill connection options also eliminate the need for clamps and secondary shutoff valves, streamlining equipment design and operation.

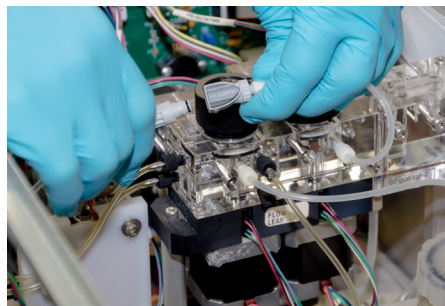


Figure 1: Non-spill connectors are designed to help eliminate spills and air inclusion in closed system.

ENHANCED FLUID TRACKING WITH RFID

Connectors help manage flow, and those with built-in radio frequency (RFID) capabilities also monitor the fluids used in IVD applications.

RFID-enabled couplings are capable of real-time reagent inventory monitoring, batch identification, brand and product protection, and expiration date tracking.

The data transfer capabilities of an RFID-enabled connector, for example, allow labs to track the amounts of reagents used on each piece of equipment to ensure sufficient reagent supplies to complete testing cycles. In addition, the couplings can confirm that the specified reagent is being used, helping reduce errors and equipment downtime.



Figure 2: The IdentiQuik® Series RFID-enabled connector's body (right) houses an RFID reader while the insert (left) contains an RFID tag, which together transfer useful data in IVD processes.

MULTI-LINE CONVENIENCE

IVD equipment often includes multiple lines that carry fluids and/or gases and use either pressure or vacuum forces to drive fluid through the instrument. Consolidating multiple fluid lines into a single connection can greatly improve serviceability and help reduce misconnection risk.

Multi-line connections on waste containers are particularly valuable in providing the necessary lines for supply, empty, and vacuum functions in a single interface.



Figure 3: Multiple fluid lines can be color-coded or even vary in material or tubing size to fit the application.

Hybrid couplers can accommodate fluid, pneumatic, and electrical lines, allowing connection in a single quick operation.

Flow cytometry, for example, uses large volumes of reagents in the diagnosis of health disorders, especially blood cancers. Hybrid couplings on the end of umbilical lines enable a single connection to deliver the reagents and test solutions from the containers to the test site.

Optional integrated sensors also allow hybrid connectors to signal when supply containers are running low and need replacement, or waste containers require emptying.

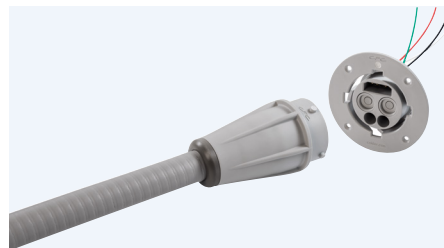


Figure 4: Hybrid connectors can consolidate fluid and electrical connections into one coupler.

COLOR CODING AND KEYING

In a fast-paced lab environment, the use of color-coded or physically keyed connectors can help operators accurately connect the corresponding fluid lines.

Accidentally connecting an incorrect line can require extensive washing and flushing of supply lines if, for example, a biohazardous waste line was inadvertently connected to a reagent line leading to test vessels.

Color-coded or keyed connectors are especially useful in large, automated immunoassay instruments where multiple reagent supply lines are co-located with rinse and waste lines.

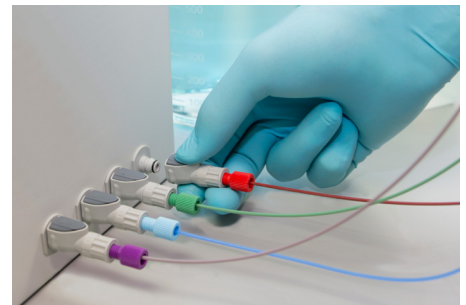


Figure 5: Quick disconnect couplings can be color coded or physically keyed to support correct connections.

RELY ON FLUID MANAGEMENT EXPERTS

Companies that specialize in fluid management are an excellent resource to achieve the performance goals of IVD equipment.

Engineer-to-engineer collaboration early in the design process can flag common issues, provide pathways for improving fluid designs, and help identify components that match specific instrument needs.

Innovative fluid handling components such as RFID-enabled or hybrid fluid connectors allow equipment manufacturers to maximize instrument performance, helping make IVD testing faster and easier for labs and operators.

For design engineers, it is useful to remember that highly reliable, productive and advanced IVD equipment depends in large part on efficient, effective fluid handling—and connectors are critical components in fluid management systems.

ABOUT RFID

Radio frequency identification (RFID) technology is available in today's fluid connectors, helping move data in addition to fluids, and monitoring the type and status of consumable fluids within an IVD instrument.

HOW IT WORKS

Data is stored on an RFID tag embedded in the "insert" half of the coupling and an RFID reader is housed in the "body" half of the coupling. When the coupling insert and body are brought within a few centimeters of each other, the reader detects the tag, reads it, and send the tag data to the control unit running the system.

IVD APPLICATIONS

RFID technology can store and/or transfer important information such as:

- **Product data:** date of manufacture, batch/serial number, date/time of installation, number of uses remaining, etc.
- **Auto-calibration parameters:** e.g., identification of media and expiration date
- **Process controls:** e.g., number of tests completed, notification of test completion
- **Security:** Reader and RFID tags can mutually authenticate the connection before sharing data, helping protect the transfer

BENEFITS IN IVD

As a part of IVD instrumentation, electronic data capture and automatic documentation capabilities are faster and more efficient than manual processes and can:

- **Flag connection errors in multiple-port systems.** The RFID reader "reads" the tag, telling the control unit what is being connected to the instrument port. If a misconnection is attempted, the control unit can display an error message, trigger an alarm, or shut down the instrument until the error is corrected.
- **Support the correct operational settings.** After reading the tag's identification data, the control unit can automatically set testing parameters such product characteristics, cycle counts and operating time to match the requirements for the connected media.
- **Enforce reagent shelf life.** The controller can track usage of a tagged consumable, helping avoid the use of potentially outdated media.
- **Validate connected media.** RFID tags can be programmed to only connect with a specific reader, helping ensure that authorized media is connected before the system will continue with the next step.
- **Monitor media consumption.** RFID-enabled couplings can also be used to monitor the amount of reagent used for each test. If a container is close to empty, the control unit will let the operator know that additional reagents are needed before a test can be started.

ABOUT CPC

IVD instrument manufacturers around the world rely on CPC's quick disconnect couplings and fittings to quickly connect and disconnect tubing used on a wide variety of instruments. We offer a wide range of sizes, materials, configurations and capabilities, including non-spill and RFID-enabled options. Our hybrid connectors also simplify instrument connections by transferring electrical signals, liquid and air in one easy step. For more information, visit cpcworldwide.com/IVD.



We Inspire Confidence at Every Point of Connection