Technology White Paper

Cap Inspection Provides Critical Information for Lab Automation

Improving Clinical Test Data Using a Cap Inspection System

MICROSCAN®

Cap Inspection Provides Critical Information for Lab Automation

Cost containment in the healthcare system has placed clinical laboratories under constant pressure to improve efficiency while addressing patient care and safety concerns. As part of the design process, today's instrument manufacturers seek to ensure that automation errors do not occur. A cap inspection system is one solution to improve error prevention processes. By inspecting test tubes and caps to collect detailed information such as diameter, cap color, and cap type, instrument manufacturers no longer need to engineer for the worst case scenario. This white paper focuses on the importance of cap inspection in lab automation and outlines the capabilities of a cap inspection system. Topics of this paper include:

- *Present Challenges Facing Clinical Laboratories*
- *Why Perform Cap Inspection?*
- *Cap Inspection System Capabilities*
- *Imaging Technology Advancements*

Microscan Systems, Inc.

Present Challenges Facing Clinical Laboratories

Each day, large independent labs handle and process several types of test tubes. The test tubes vary in shape, length, and diameter; their caps vary in size, shape, and functionality. Most importantly, however, the tubes contain different additives.

Vacuum test tubes commonly used for blood collection have color-coded caps indicating substance(s) that may have been added to pre-treat the blood or preserve it for processing. There are 14 cap colors in total, each color representing a specific additive or none at all

(see Figure 1).[1] For example, lavender caps indicate that the tube contains EDTA as an anticoagulant commonly used in hematology. The additives in each tube are designed to optimize the results for specific tests and should not be intermixed. Consequently, the color of each cap must be accurately identified to achieve a successful outcome.

Why Perform Cap Inspection?

Studies have shown that a significant majority of all laboratory "errors" are caused during the pre-analytical phase.[2] Test tube handling prior to the analytical process can directly affect the outcome of a test.

While clinical labs already use bar codes to automate the identification of test tubes and reagents, much of the preliminary sortation of multiple sized tubes is still performed by hand. Cap inspection advances the tube identification process by enabling diagnostic instruments to further prevent automation mishaps caused by sortation errors. Megapixel imaging technology can provide valuable tube and cap information before laboratory testing is performed.

By applying data about each test tube and cap, lab automation instruments can:

COLOR	DESCRIPTION	ADDITIVE	TEST TYPE
	Royal Blue	No additive, glass stopper	Drug levels, toxicology screens and trace elements
	Red	No additive	Type & screen, cryoglobulins and CH_{50}
	Light Blue	3.2% Sodium citrate	PT, PTT,TCT, CMV buffy coat, Factor Activity, Fill 100%
	Gold Top	Gel & clot activator	Chemistry, endocrine, and serology tests
	Green	Sodium heparin	Ammonia, lactate, HLA typing
	Tan	Sodium heparin	Lead levels
	Yellow	ACD solution	DNA studies, HIV cultures
	Pink	(K_2) EDTA	Blood Type & Screen, Compatibility Study, Direct Coombs

COLOR	DESCRIPTION	ADDITIVE	TEST TYPE
	Pearl	Plasma separating gel, (K_2) EDTA	HIV viral load
	Lavender	(K_2) EDTA	CBC/diff/retic/sed rate, FK506, cyclosporin, platelet ab, coombs, flow cytometry
	Grey/Red (Tiger top)	No anticoagulant	Chemistry and viral antibody testing
	Brown	Sodium heparin	Cytogenetic testing
	Black	Sodium citrate	Sed rates (ESR)
	Grey	Potassium oxalate with sodium fluoride	Glucose testing

Figure 1: *Color coded blood collection test tube caps*

Automate handling and sorting of test tubes of different sizes by identifying color and providing diameter measurements. Increasing instrument intelligence can also help automate complex sortation applications. For example, in order to automate 80 percent of a large, international reference lab's test volume, the automation system may need to sort more than 1,000 different tests each day.[3] The data provided by cap inspection makes this automation challenge much easier.

Prevent pipette crashes by determining if the de-capping operation is successful or, if closed container sampling is implemented, whether a given cap type can be pierced.

Streamline the fluid aspiration process. Test tube and cap data makes it easier and faster to perform the calculations needed to determine the distance the probe/pipette must travel after the liquid is detected.

Reduce carry-over by providing lab instruments with the data needed to calculate the precise distance to extend the probes. By minimizing excess exposure of the probe to the serum, labs can reduce the amount of liquid waste generated by washing the probes after each aspiration.

Cap Inspection System Capabilities

To perform cap inspection, an imager measures each test tube and cap and matches the dimensions to test tube profiles stored in a tube and cap database. Once the imager finds an exact match, it sends the tube and cap data, along with the decoded symbol data, to the instrument. A well-engineered imager can collect the following data:

Linear and 2D Symbol Data: The imager can read and decode both long linear and high-density 2D symbols such as Data Matrix.

Tube Absence or Presence: The imager can provide the instrument with the status of the test tube's position in relationship to the automation process. If the tube is present, the instrument can proceed with the next step. If it is absent, it can send an alert message to the host.

Cap Absence or Presence: By identifying the presence or absence of a cap, the imager helps determine whether the pipetter can proceed. It can also identify test tubes missed by an automated de-capper.

Cap Type/Diameter: By measuring the cap's diameter, the imager helps the instrument determine if the cap can be pierced. This data also provides the de-capper with valuable feedback. Additional information about the cap, such as the color and shape, enable the instrument to identify it from a library of up to one hundred different cap types.

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Tube Height: Providing data on the location of the top of the test tube, combined with data on the cap, allows the system to identify the height of the tube and whether a tube is properly seated in the carrier.

Imaging Technology Advancements

Cap identification is already being performed today. However, most solutions available for instrument engineers are very complex, some requiring up to 10 sensors. To simplify instrument design and total cost of ownership, Microscan has combined megapixel imaging technology with world-class algorithms to develop an alternative, single component solution: the EZ Match imager.

Over the last four years, most array imagers have read at VGA resolution (640 x 480) with 307,200 pixels. This has forced instrument designers to choose between resolution and field of view. The introduction of miniature megapixel imagers with SXGA resolution (1280 x 1024) and higher offers an array of more than 1,000,000 pixels, delivering a much larger field of view without sacrificing resolution. (See Figure 2.) This large field of view enables the EZ Match to read bar-coded test tubes, or to read combinations of linear and 2D symbols while capturing the height of the test tube and its cap for inspection.

A large field of view provides design engineers with additional advantages, as it directly affects the amount of space required for performing test tube inspection. The field of view is the total dimensional space required by the imager to capture the data from an object at a specified distance. Smaller fields of view have the advantage of less physical space required between the imager and the object. The EZ Match is capable of capturing an entire test tube within the space of one inch between the imager and the tube.

Additional considerations include the capabilities of the imaging technology itself. Multi-sensor solutions typically only provide height information, subsequently requiring all the test tubes to

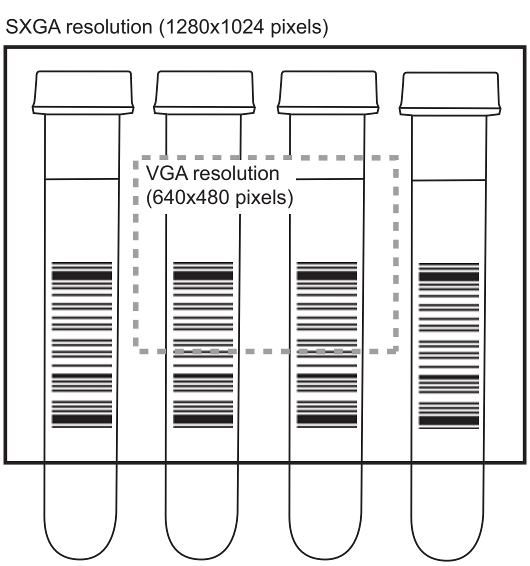

Figure 2: *SXGA versus VGA imager resolution*

be properly seated. An improperly seated test tube without a cap may be mistaken for a test tube with a cap. In contrast, the EZ Match uses shape information to determine cap absence or presence, and will return the correct absence/presence acknowledgement whether or not the tube is properly seated.

Conclusion

Cap inspection is a value-added subsystem in diagnostic instruments that extends the reach of lab automation. By providing instruments with additional data about each test tube and cap, cap inspection systems make it easier to automate even the most complex sortation applications while preventing many potential automation errors. Design engineers can now take advantage of all the benefits of cap inspection by integrating a single component: Microscan's EZ Match imager.

[1]"Evacuated Blood Collection Tube Guide" McLendon Clinical Laboratories

[1]"Blood Collection Tubes" Brigham & Women's Hospital Clinical Pathology & Laboratories

[2]Pierangelo Bonini, Mario Plebani, Ferruccio Ceriotti, and Francesca Ruboli "Errors in Laboratory Medicine", American Association for Clinical Chemistry, Inc. 48: 691-698, 2002.

[3]Charles D. Hawker, Susan B. Garr, Leslie T. Hamilton, John R. Penrose, Edward R. Ashwood, and Ronald L. Weiss "Automated Transport and Sorting System in a Large Reference Laboratory: Part 1. Evaluation of Needs and Alternatives and Development of a Plan", American Association for Clinical Chemistry, Inc. 48: 1751-1760, 2002.

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