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MAS™ Omni·CORE™ Controls, Ready-to-Use Tube Format

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Abstract

Background: The Thermo Fisher Scientific™ MAS™ Controls* are assayed controls to monitor assay performance within clinical laboratory settings. The user can compare observed results of controls with their expected ranges as a means of assuring consistent performance of both reagent and instrument.

The objective of developing MAS™ Ready-to-Use Tube Controls is to provide MAS™ controls in a new automation-friendly plastic tube format, as an alternative to the current glass vials. The MAS™ controls contained in the plastic tubes are intended to be used by core labs to be placed directly onto the analyzers, eliminating the need to aliquot into sample cups or other primary tubes.

This will help increase efficiency for labs, by allowing the analyzer to aspirate controls directly from the tube and allow for control storage in an on-board refrigeration unit shortly after use. Additionally, the plastic material will be advantageous to high throughput customers by offering a lower risk of breakage.

In this presentation we summarize the results of developing the first MAS product MAS™ Omni·CORE™ Ready-to-Use Tube Controls in the new configuration.

Methods: The performance was assessed for MAS™ Omni·CORE™ Ready-to-Use Tube Controls. The purpose of these studies is to verify material compatibility and acceptable product performance.

Study	Purpose
Torque and Leak	Determine application/removal torque for caps + observe for any liquid leakage
Cap Characterization	Quantify tube/cap ability to maintain gas overlay as well as prevent outgassing
In-Use (CO$_2$) Study	Determine CO$_2$ analyte in-use time-on-platform performance, in three scenarios: 1 – Capped 2-8˚C (TCA Plugs): For QuidelOrtho Vitros platform 2 – Un-Capped 2-8˚C: For platforms with onboard storage capabilities 3 – Un-Capped 25˚C: For platforms without onboard storage capabilities
Plastic Interaction	Determine potential interaction of claimed analytes with plastic (PET) material. Performed closed vial testing, up to 14 days in two scenarios: Plastic (PET) vs. current Glass (Fiolax)
Extractables / Leachables	Determine (if any) material leeched from plastic and/or rubber plug. Performed accelerated stress testing at 41˚C in three scenarios: 1 – The PET tube standalone 2 – The PET tube with cut up rubber plug in product 3 – Current Fiolax glass material as a baseline comparison
Light Transmission	Determine tube's ability to prevent photodegradation of light-sensitive analytes. Performed 15 days closed vial testing (under constant light exposure of 464 lux) in three scenarios: 1 – The PET tube standalone 2 – The PET tube covered with aluminum foil 3 – Current Fiolax glass material as a baseline comparison

Feasibility Results: The MAS™ Omni·CORE™ Ready-to-Use Control results demonstrated comparable performance as well as Fit/Form/Function criterion of select platforms.

Torque/Leak, Cap Characterization, and Plastic Interaction studies yielded passing results per protocol criterion. The In-Use (CO$_2$) study demonstrated acceptable "time-on-platform" performance of 9 hours in 2-8˚C (both with and without cap). The Extractables / Leachables study demonstrated passing results for most claimed analytes. Finally, all light-sensitive analytes yielded passing results during the light transmission study.

Conclusions: To conclude, the MAS™ Omni·CORE™ Ready-to-Use Controls contributes to the increased efficiency of core lab workflow by allowing the analyzer(s) to aspirate controls directly from the tube and allow for control storage in an on-board refrigeration unit shortly after use.

*The availability of product in each country depends on local regulatory marketing authorization status

Introduction

The objective of developing MAS™ Ready-to-Use Tube Controls is to provide MAS™ controls in a new automation-friendly plastic tube format, as an alternative to the current glass vials. The MAS™ controls contained in the plastic tubes are intended to be used by core labs to be placed directly onto the analyzers, eliminating the need to aliquot into sample cups or other primary tubes.

This helps to increase efficiency and maximize usage by allowing the analyzer to aspirate controls directly from the tube and allow for control storage in an on-board refrigeration unit shortly after use. Additionally, the plastic material will be advantageous to high throughput customers by offering a lower risk of breakage.

Materials

| MAS Product Description	Kit Size	Proposed Shelf Life (-15 - -25ºC)	Proposed Open Vial Stability (2-8ºC)	Proposed Closed Vial Stability (2-8ºC)
Thermo Scientific™ MAS™ Omni·CORE™ QTROL™ Level 1 (B40000510)	6 X 4 mL	36 months	30 days (15 days for Bilirubin)	60 days (30 days for Bilirubin)
Thermo Scientific™ MAS™ Omni·CORE™ QTROL™ Level 2 (B40000511)	6 X 4 mL	36 months	30 days (15 days for Bilirubin)	60 days (30 days for Bilirubin)
Thermo Scientific™ MAS™ Omni·CORE™ QTROL™ Level 3 (B40000512)	6 X 4 mL	36 months	30 days (15 days for Bilirubin)	60 days (30 days for Bilirubin)

Table 1. MAS™ Omni·CORE™ QTROL™ Controls
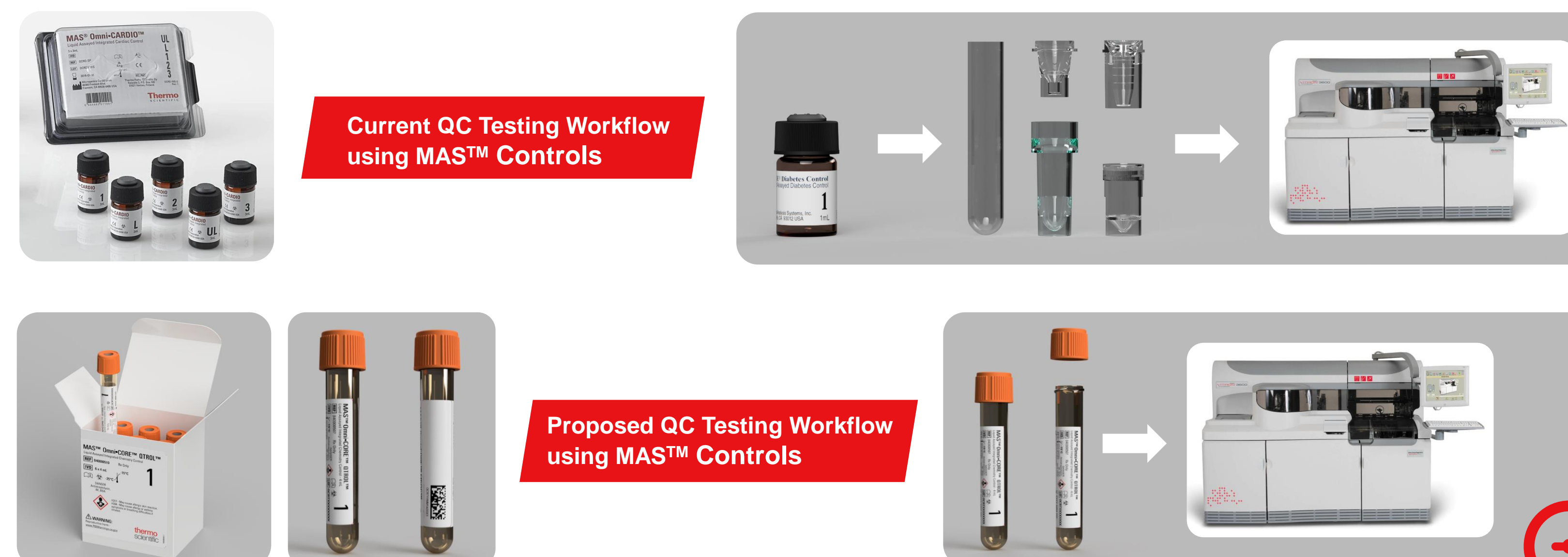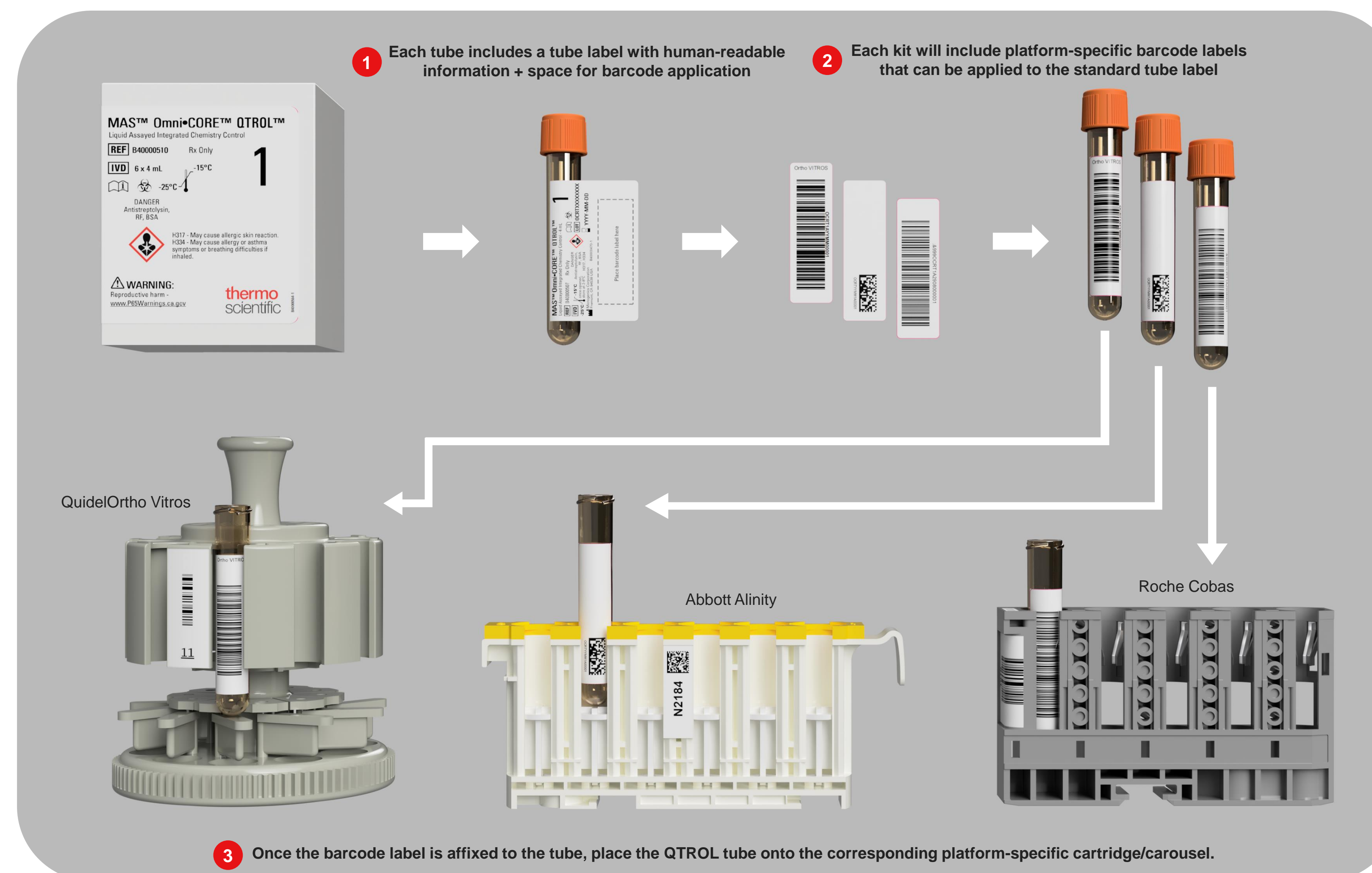

Figure 1. MAS™ Control Workflow Comparison

Figure 2. MAS™ QTROL™ Control Label Application Schema

Results

Study	Results
Torque and Leak	Passing results per protocol criteria
Cap Characterization	Passing results per protocol criteria
In-Use (CO$_2$) Study	1 – Capped 2-8˚C (TCA Plugs): 9 hours CO$_2$ Stability 2 – Un-Capped 2-8˚C: 9 hours CO$_2$ Stability
Plastic Interaction	Passing results for both PET plastic and Fiolax glass
Extractables / Leachables	Passing results for most claimed analytes
Light Transmission	Passing results for all sensitive analytes.

Table 2. MAS™ Omni·CORE™ QTROL™ Control Initial Study Results

Conclusions

- The MAS™ Omni·CORE™ Ready-to-Use Tube Controls meets the requirements of the initial study criterion when used and stored properly.

- The MAS™ Omni·CORE™ Ready-to-Use Controls contributes to the increased efficiency of core lab workflow by allowing the analyzer(s) to aspirate controls directly from the tube and allow for control storage in an on-board refrigeration unit shortly after use.

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Trademarks

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