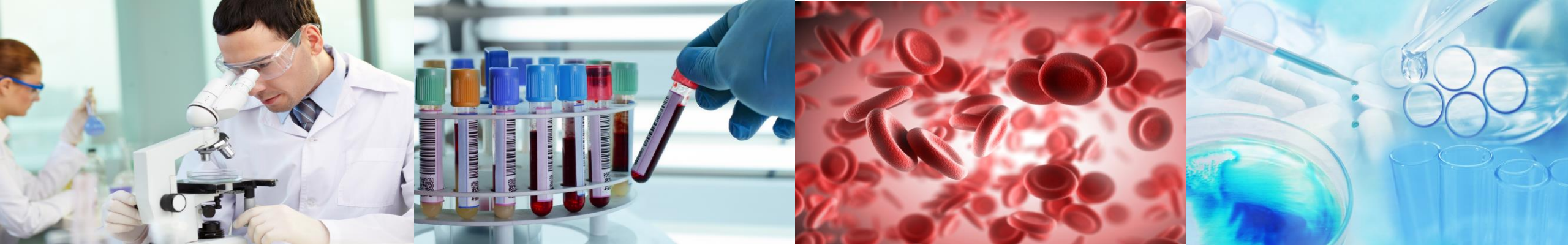


Clinical Diagnostic Solutions, Inc.

Training *Medonic M Series*



Clinical Diagnostic Solutions, Inc.

MODULE 1

General Overview

Instrument Components

➤ Analyzer

- Reagent probe connections
- Barcode reader connection
- Waste line
- Power Cord
- Power Switch location
- Printer Cable

➤ Printer

➤ Reagent Containers

- Reagent Probes
 - Yellow – Lytic
 - Red – Diluent

➤ Laboratory Information System (LIS) ***if applicable***

- Serial Port Connection

➤ Notes:

General Operation

- Analyzes whole blood to report CBCs (Complete **B**lood **C**ount)

- Blood samples introduced and mixed with 2 reagents.
- Automatically counts and sizes blood cells.

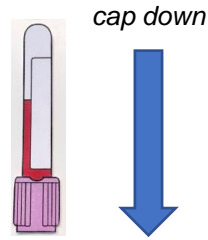
- What it reports

- Reports 16 parameters, including 3 part differential.
- Histogram for WBC, RBC and Platelets.

- Notes:

Ways to Introduce Sample

- Cap pierce (CP)
 - Insert tube cap down.



➤ Notes:

- Autoloader (AL/AS)

- Open Tube (OT/OV)
 - Ensure OT probe is free of residual diluent/sample by wiping with soft cloth.

- Micro pipette (MPA/MC)
 - See next slide.

Micro Pipette Mode (MPA/MC)

- Use proper sample collection technique.

- Run within 10 minutes of collection.

- Fill pipette end-to-end.

- Ensure no air bubbles are within pipette.

- Wipe outside of pipette without wicking sample.

- Notes:

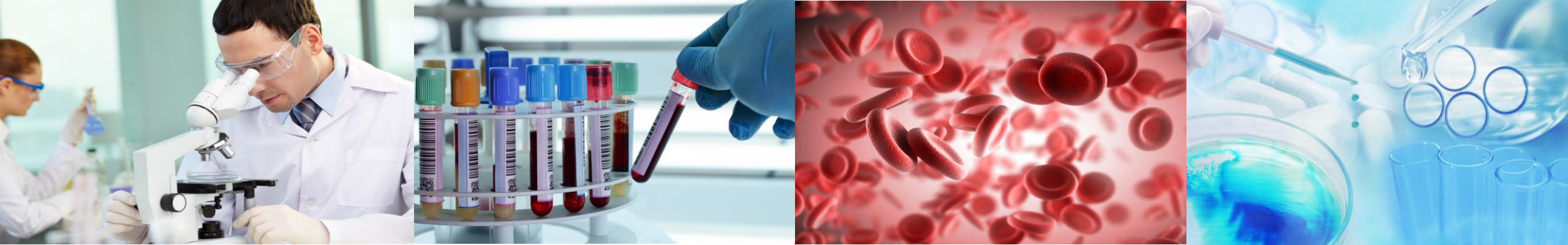
Module 1 - Q & A

1. What color is the reagent probe for the diluent reagent?
 - a. Red
 - b. Yellow
 - c. Blue

2. How do you introduce a sample in the OT mode?

3. The M Series uses 3 reagents.
 - a. TRUE
 - b. FALSE

4. How do you introduce a sample into the MPA/MC mode?



Clinical Diagnostic Solutions, Inc.

MODULE 2

Daily Operation

Start-Up

1. Exit Standby

- Enter Operator ID (*optional*) or press [Cancel].
- System will prime and perform background count
 - Check that background count is acceptable.
 - Repeat if unacceptable
 - Press [New Sample] → select [Background] profile → press '1:1 Start' plate

2. Controls

- Scan barcode on vial before running.
- Run controls in each mode that samples will be analyzed.
- Check that results are within acceptable ranges.
- See details on next slide

➤ Notes:

Start-Up (Controls)

- Open vial stability – 14 days
- Run 3 levels everyday
- Remove controls from refrigerator and allow to come to room temperature for 30 minutes.
- Mix by manually rolling between hands and gentle inversion. (8x8x8x8)
- **Do not shake or place on mechanical mixer**
- If results acceptable:
 - Run patients
- If results unacceptable:
 - Check Open Vial Stability Date.
 - Re-mix and re-analyze.
 - Try a new vial of same level.
 - **If new vial out of range, call CDS for assistance or refer to user manual.**

➤ Notes:

Patients

➤ Running Patient Samples:

- Enter Operator ID *(optional)*
- Enter Patient ID *(optional)*
- Choose appropriate patient profile *(if applicable)*
- Run through one of the sampling modes (~~CP~~, ~~AL~~, OT, MPA/MC)
- Review results
 - Report acceptable results.
 - If a result is unacceptable, refer to your laboratory protocol.

➤ Notes:

End of Day Care

- No comprehensive shutdown procedure.
- Simply wipe OT probe with alcohol pad.

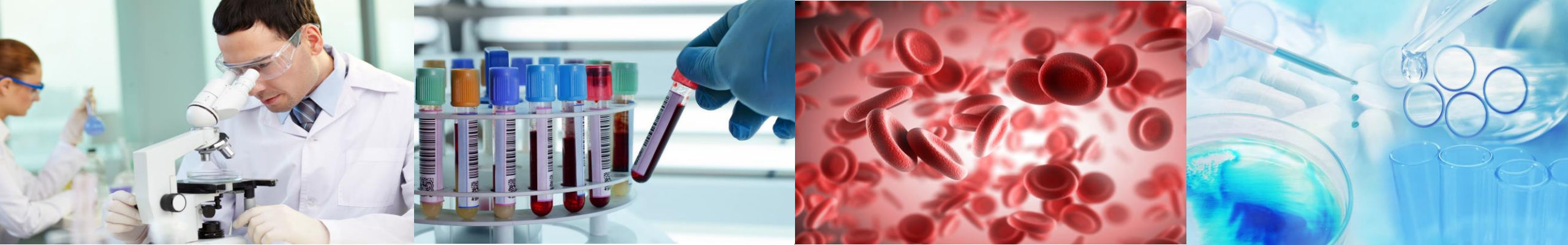
➤ Notes:

Module 2 - Q & A

1. If samples will be analyzed in the OT **and** MPA/MC mode, controls are required to be run in both modes.
 - a. True
 - b. False

2. What must be done prior to running controls? Mark all that apply.
 - a. Scan barcode on control tube
 - b. Run 2 backgrounds
 - c. Warm controls to room temperature (30 minutes)
 - d. Wipe the probe if running them in OT mode

3. What is the **first** thing that should be done if one of the control levels is out of range?
 - a. Run a new vial of control
 - b. Call CDS for assistance
 - c. Re-mix and Re-run control level
 - d. Run a background



Clinical Diagnostic Solutions, Inc.

MODULE 3

Special Procedures

Quality Control (QC)

➤ QC Setup

- Enter new controls using barcode scanner
 - Use Medonic M Series Sheet.
- Instructions for barcode scanning are printed on sheet.
- Keep assay and barcode sheets for your records.

➤ COLA/CLIA requirements

- Run controls everyday
- Save all backgrounds, controls, and LJ plots

➤ Notes:

CDS Quality Assurance Program (eCQAP)

- Benefits of enrollment
 - Peer group results.
 - Assists with identifying need for calibration.
 - Shows comparison to group means.

 - Interpretation of Report
 - Your results vs. Group Results.
 - SDI Graphs.
 - Message Flags.

 - Submit data by 6th of following month
 - Upload or Manually Enter data via Web Portal
- Notes:

Calibration

- Required every 6 months or if deemed necessary by CDS.

- Calibrate all modes in which patients are analyzed.
- Calibration must be verified by running all 3 levels of controls after procedure.
- For detailed procedure, see Section 7 of the User Manual.

- Notes:

*** Refer to Section 7 of the User Manual.*

Proficiency Testing

- Follow proficiency program instructions.
- System information messages for differential abnormalities indicate reviewable, not reportable results.
 - Follow your laboratory's protocol.
- Report requested CBC parameters and differential results.
 - Pay close attention when reporting differential results.
 - Some programs require differential percentages while others require absolute numbers.

➤ Notes:

Changing Reagents

- An indicator will let you know when there is approximately 15% reagent remaining in the container.
- To change reagents:
 - Press [Reagent Setup] from Main Menu
 - Select [Enter New Reagent]
 - Scan Barcode 1 and then Barcode 2 on reagent container
 - Select [Exit] to return to Main Menu
- NOTE: Same reagents can be scanned a maximum of 3 times.
- **NEVER** pour remaining contents of old reagents into new container of reagents
- Open stability – 90 days

➤ Notes:

*** Refer to Section 2 of the User Manual.*

Maintaining the Medonic M-Series

Follow instructions on Quick Reference Sheet and User Manual

➤ Notes:

- Monthly Maintenance
 - Run hypochlorite solution twice through pre-dilute probe.
 - **NOTE** – Pre-dilute mode has intentional delay...press and hold start plate.
 - Run diluent twice through pre-dilute probe.
 - Utilize built-in dispense function to dispense diluent.
 - Run clot prevention procedure once a month or more frequently if processing >1000 samples/month
 - Use Enzymatic Cleaner from cleaning kit.
- Semi-Annual Maintenance
 - Select:
 - ADVANCED→ Maintenance→ Cleaning
 - Follow instructions on screen.

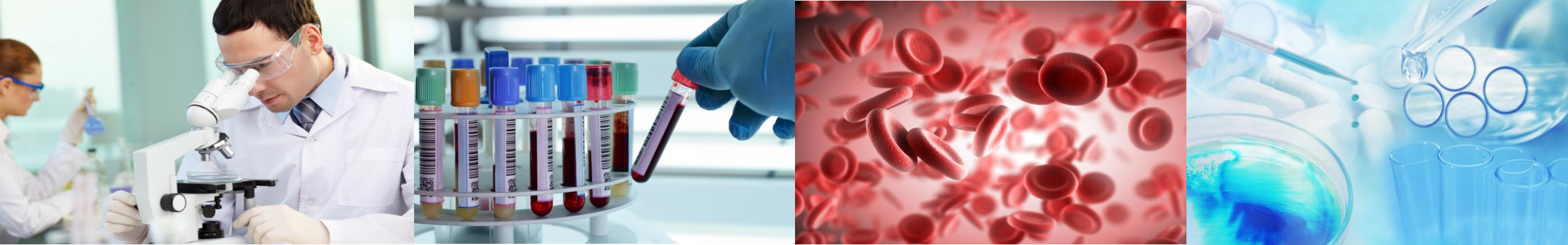
*** Refer to Section 8 of the User Manual.*

Module 3 - Q & A

1. When new control lot arrives, how are assay values entered into the system?
 - a. Through the OT mode
 - b. Scanning barcodes
 - c. Manually typing in values
 - d. No need to enter values

2. You **must** calibrate _____ times a year.
 - a. 12
 - b. 4
 - c. 2
 - d. 1

3. Which analysis profile should proficiency samples be run in?
 - a. Patient
 - b. Control
 - c. Background



Clinical Diagnostic Solutions, Inc.

MODULE 4

Troubleshooting

System Alert Messages

- Out of range indicators
 - Outside normal range
 - H = High
 - L = Low
 - Check all abnormal results for alert limits
- Out of Linear range
 - AL = the result is above linear range
 - BL = the result is below linear range
- Out of displayed range
 - ##### = count is too high or too low to measure.
- System information messages
 - System **information indicator** is highlighted if message is present

➤ Notes:

**** Refer to Section 9 of the User Manual.**

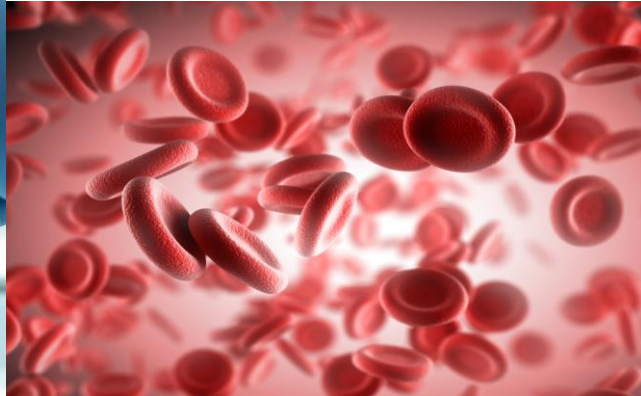
Basic Troubleshooting

- User Manual
 - Contains troubleshooting flowcharts for common issues.
 - Good resource for easy resolution of simple problems.
 - Information Messages – Section 9
 - Troubleshooting – Section 12
 - Troubleshooting flowcharts – Appendix A

- Clots
 - Clot prevention.
 - Call for assistance.

- Control problems
 - Re-mix and Re-analyze.
 - Try new vial.
 - Call for assistance.

- Notes:



Clinical Diagnostic Solutions, Inc.

CDS Technical Support Team

Call (954) 791-1773



M-portant Information

- Reagents
 - Expire 90 days from opening
- Controls
 - Scan in M Series Barcodes
 - 14 day open vial stability, 110 day closed vial stability
- Barcode scanning – controls, calibrators, reagents, patients (*if applicable*)
- Daily operation
 - Background → Controls → Patients
- Proficiency Samples
 - Run as instructed by selected program.
 - Report all results and document flags.
- QC Review
 - Keep daily results.
 - Follow QC flowchart (p/n 204141) to ensure CLIA/COLA requirements are met.
 - Keep all QC data – **never** delete control data
- Calibration (at least twice a year)
 - Scan in M Series Barcodes
 - Calibrate the modes in which patient samples are analyzed
- Maintenance - Daily, Monthly and Semi-Annual