Performance Characteristics:

Spectral Curves of the four color solutions are printed on the back of the Technical Data Sheet.

Procedural Notes:

1. Avoid using test tubes composed of materials that absorb at 340nm and/or 405 nm. The quality of the glassware used has a significant impact on the quality of test results. Type I glass is recommended

2. If your reader requires a tube too small to prepare this serial dilution, you may either substitute a smaller pipet OR make the dilutions in larger glassware and transfer them into smaller tubes for reading.

3. Bichromatic absorbance readings (primary minus differential readings) generally increase precision, since the element of variation that is caused by imperfections in disposable glass test tubes is removed from test results. Choose wavelength combinations given on the Technical Data Sheet.

4. Prepare the blank and serial dilutions using a larger pipet in the event that your instrument requires more than a 2ml minimum read volume.

5. Do not attempt to re-calibrate your instrument with Redi-check. Loss of calibration, linearity, or precision indicates service requirements.

6. Be sure the Lot No. on the Technical Data Sheet corresponds to Lot No. on the Redi-Check Solutions used.

Symbols Glossary:

Symbol	Standard Title and Number	Title of Symbol	Symbol reference #	Explanatory Text
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Manufacturer	5.1.1	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
EC REP	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Authorized representative in the European Community	5.1.2	Indicates the Authorized representative in the European Community.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Use-by-date	5.1.4	Indicates the date after which the medical device is not to be used.
LOT	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Batch code	5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.
REF	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Catalog number	5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	Consult instruction for use	5.4.3	Indicates the need for the user to consult the instructions for use.
IVD	ISO 15223-1: Medical Devices – Symbols to be used with medical device labels, labeling, and information to be supplied	*In vitro* diagnostic medical device	5.5.1	Indicates a medical device that is intended to be used as an *in vitro* diagnostic medical device.
Rx Only	Guidance for Industry and FDA on Alternative to Certain Prescription Device Labeling Requirements	Rx Only	N/A	Caution: Federal law prohibits dispensing without prescription.

Limitations:

1. Work within your instrument specifications. Check your instrument manual for the specified linearity range. Only points that are within this range should be plotted on the Linearity Plot. Check that the absorbance value given on the Technical Data Sheet for the Calibration Reference Tube is within and specified absorbance range of your instrument.

2. Acceptance criterial for absorbance calibration are given for filter photomets with 10nm half bandpass or better. Data are also based upon a reference instrument with a 1cm path length. If your absorbance calibration is out of range, check your instrument instruction manual to determine the need for a path length adjustment factor.

References:

A Guided Tour of Certified Food Dyes, Warner- Jenkinson, Co, 2526 Baldwin St., St. Louis, MO 63178

Selected Methods of Clinical Chemistry, AACC, Vol. 10, pp 25-28, 1982.

Rand, R. N., Practical Spectrophotometric Standards, Clin Chem, Vol. 15, no. 9, pp 839-863, 1969.

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REDI-CHECK® PHOTOMETER Q.A.

FOR IN VITRO DIAGNOSTIC USE

Intended Use:

Redi-Check is a photometer check set useful in verifying absorbance calibration, precision, and linearity on a routine basis.

Description:

Redi-Check contains this instruction sheet, calibration records, linearity plots, repeatability charts, a technical data sheet, 4 colored solutions, and 2 dilution buffers . Absorbance values are pre-determined using a reference spectrophotometer with a 1cm pathlength, and a +/-2nm typical half bandpass. The calibration of this reference instrument is routinely verified and traceable to NIST. The following instructions describe how to dilute and use the color solutions in this kit to assess photometer performance at 340, 380, 405, 415, 490-492, 505, 545-550, and 600nm. The charts provided in this kit are designed to replace calculations with easy-to-visualize, built-in, acceptance criteria.

Reagents and Materials:

Buffer A: Cat. no. 3010, 60 ml, weak Sulfuric Acid preserved with Sodium Azide.

Buffer B: Cat. no. 3011, 120 ml, weak Sulfuric Acid preserved with Sodium Azide.

Yellow Solution: Cat. no. 3001, 30 ml, Potassium Dichromate in Buffer A.

Blue Solution: Cat. no. 3002, 30 ml, Chromic Perchlorate in Buffer B.

Orange Solution: Cat. no. 3003, 30 ml, FD&C Red Dye#40 and Yellow Dye#5 in Buffer B.

Red Solution: Cat. no. 3004, 30 ml, Cobalt Sulfate Hydrate in Buffer B.

CAUTION: The salts and buffers used with this check set may be harmful if ingested, and will irritate eyes and skin. Use appropriate precaution when handling, and rinse exposed areas thoroughly with water.
WARNING: Contains Sodium Azide which may react with lead and copper plumbing to form explosive metal oxides. Flush with a large volume of water to prevent Azide build-up.

Solutions remain stable until expiration date shown on the label when stored at room temperature (18-26ºC) and protected from light.Do not use reagents after the expiration date printed on the bottles.

Materials required but Not Provided:
2 ml pipet with accuracy of better than ±2%
Glass test tubes appropriate for your instrument (See Procedural Notes 1 & 2.)
Caps or laboratory film to cover tubes

Procedure:

A. Preparation of serial dilutions:

1. Be sure that color solutions and buffers are at room temperature and mixed well before use. Turn on your instrument and let it warm up according to its instruction manual.

2. Read all instructions and Procedural Notes before making your first serial dilution to determine which solutions are best for your application.

3. Select the desired color solution(s) and appropriate dilution buffer(s) according to the following table:

TABLE

the primary filter you are checking: (nm)	the color solution to dilute:	the appropriate dilution buffer to use:
340, 380	Yellow	A
405, 415*, 545-550, & 600	Blue	B
415*, 450	Orange	B
490-492, 505	Red	B

* 415 nm may be tested using either Blue or Orange

4. Select 4 good quality test tubes for each color to be diluted. You will need one additional tube for the blank. It is important that all of the tubes are of the same size and composition. (See Procedural Notes 1 & 2.)

5. Put 2 ml of Buffer A into one tube and label it "Blank". This same tube will be used to blank the photometer at all wavelengths

FOR EACH COLOR NEEDED:

6. Label four test tubes as "Conc"., "1:2"," 1:4", and "1:8".

7. Pipet 2.0 ml of appropriate buffer (A or B, see TABLE) into tubes labeled 1:2, 1:4, and 1:8, but not into the tube labeled Conc.

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8. Using the same pipet and tip rinse the pipet in the concentrated color solution by aspirating and dispensing into the solution three times. Accurately pipet 2.0 ml of concentrated color solution into the Conc. tube. Then add another 2.0 ml of the concentrated color solution to the 1:2 tube.

9. Cap, or cover with laboratory film, the 1:2 tube and mix well by inverting several times.

10. Using the same pipet and tip, rinse the pipet three times in 1:2 tube and accurately transfer 2.0 ml of 1:2 to the 1:4 tube. Cap and mix the 1:4 tube.

11. Using the same pipet and tip, rinse the pipet three times in 1:4 tube and accurately transfer 2.0 ml of 1:4 to the 1:8 tube. Cap and mix well.

12. Cover all tubes to prevent evaporation or accidental spills. Wipe all finger prints from the tubes before reading.

B. Data Collection:

1. Referring to the Technical Data sheet, select the desired primary filter (and differential filter, if available). See Procedural Note 3.

2. Set up your instrument for concentration calculation based upon a single standard. Blank the instrument. Use the 1:4 tube as the standard with an assigned concentration value of "50."

3. Read each tube of the serial dilution at least twice.

4. Refer to the Technical Data sheet to identify the Calibration Reference tube. If your instrument print out from the previous step indicates the absorbance values as well as concentrations, move on to Step 6.

5. Read the absorbance of the Calibration Reference tube against the Blank, at the wavelength(s) selected in step 1 above.

6. Repeat Steps 1-5 at each wavelength to be tested. Refer to the Technical Data sheet for appropriate filter selections and to identify Calibration Reference tubes.

7. Repeatability may be checked at any wavelength(s) listed in the TABLE. Blank the instrument and re-read the absorbance of the blank tube five times.

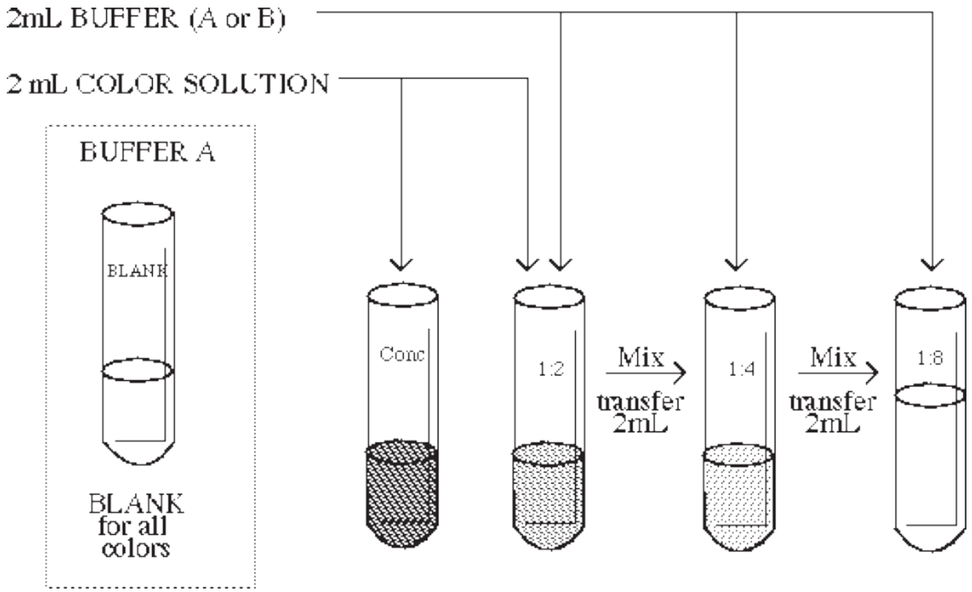
8. 8. Then read the 1:2 tube (of the corresponding color, see TABLE) five times.

Data Handling:

A. Calibration Record:

THE FIRST USE OF REDI-CHECK

1. Fill in the instrument serial number, filters, and other information on the Calibration Records provided.



2. Place a mark representing the average absorbance of the Calibration Reference tube in the first column for each filter tested.

3. Draw a permanent horizontal line (through all 6 month columns) 0.045 absorbance units above your mark. Draw another similar line 0.045 absorbance units below your mark. Date and initial each record.

SUBSEQUENT USES OF REDI-CHECK

4. For each filter tested, place a mark corresponding to the average absorbance of the Calibration Reference tube in the next month column. Date and initial each record.

B. Linearity Plot:

1. Fill in the instrument serial number, filters, and other information on each Linearity Plot for each filter in use.

2. Average the concentration readings for each dilution tube and plot against the expected values (25, 50, 100, 200). Note any points that do not fall within the designated area. Date and initial each record.

C. Repeatability:

1. Record the filter selection(s) and the five Blank absorbance readings on the lines provided on the Repeatability Chart. Find the average of the five and write it on the line marked 'Ave. Blank'.

Record the five repeat readings of the 1:2 tube on the lines provided. Calculate and record the average absorbance readings on the line marked 'Ave. Abs.' If a differential filter was used, calculate the range of ±3% of the average absorbance. If a differential filter was NOT used, calculate the range of ±6% of the average absorbance. Date and initial each record.

Interpretation of Results:

A. Calibration:

1. The initial absorbance of each Calibration Reference tube should be within the acceptable range printed on the Technical Data sheet. This indicates acceptable calibra- tion, within ±10% of the reference value for bichromatic readings, and within ±15% for monochromatic readings. These ranges incorporate the expected variation contrib- uted by the serial dilution, vessel, instrument-to-instru-
ment variation, and handling.

2. Subsequent absorbance readings of the Calibration Reference tube should be between the lines drawn across the Clibration Record. See Data Handling Step A-3. This indicates stable absorbance calibration. The acceptable range of ±0.045 absorbance units incorporates the expected variation contributed by the serial dilution, and handling.

3. Absorbance readings outside the acceptable ranges may indicate that your instrument requires service. Check all of the Procedural Notes and repeat the serial dilutions for verification before requesting service. Save the data from both tests, since this information will be requested by the service technician.

B. Linearity Plot:

1. Averaged concentration values should be within the designated area of each chart. This indicates acceptable linearity. The ±10% range incorporates expected varia- tion contributed by the serial dilution, instrument-to-instrument variation, and handling.

2. Loss of linearity above 1.5 absorbance units is the most important indicator of stray light caused by aging filters.

3. Concentration readings outside the acceptable ranges may indicate that your instrument requires service. Check all of the Procedural Notes and repeat the serial dilutions for verification before requesting service. Save the data from both tests, since this information will be requested by the service technician.

C. Repeatability:

1. If a differential filter was used, each of the Blank absorbance readings should be within ±0.005 absorbance units of the average. This variation should be increased to ±0.010 absorbance units for non-differential filter pho- tometers.

2. The 1:2 tube should have a variation of less than ±3% from the average absorbance observed. (6% for non-differential filter photometers)

2. Absorbance readings outside these acceptance criteria may indicate that your instrument requires service. Review all of the Procedural Notes and be sure that all tubes are of good quality, clean, and free of scratches. Check that the color solution is not cloudy, and assure good tube fit. Then, repeat the readings for verification before requesting service. Save the data, since this information will be requested by the service technician.

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