

System Verify™

REF 4384240

INTENDED USE

The System Verify is a colorimetric dye test intended to assist in determining the accuracy and precision of the diluters and photometers within an automated microplate analyzer.

BACKGROUND

When evaluating patient sera using any automated system, it is imperative that the instrument in question be capable of precisely delivering various reagents. Additionally, the instrument should be periodically evaluated to ensure the photometer reads with a high degree of accuracy. Such instruments should be evaluated for these parameters at the manufacturer's designated intervals. Periodic testing with the System Verify will aid in verifying the reliability of obtained results. Additionally, System Verify testing may be performed as a means of trouble-shooting questionable performance.

PRINCIPLE

The Trinity Biotech System Verify contains a ready-to-use 10x dye reagent, pre-formulated standards, and a dye reagent diluent. When the instrument in question prepares multiple wells of the recommended dilutions, the variance in optical density between the wells is an indicator of the instrument's pipetting capabilities. The instrument should be programmed to repeatedly combine 50µl of the dye solution with 500µl of the dye diluent in a predilution tube. One hundred µl of the predilution is dispensed into separate empty wells of a blank microtiter plate. The optical densities (OD) of the wells are then measured at 450nm (with reference set to 600-650nm), and interpreted relative to the standard curve generated. For all replicate wells, a mean, standard deviation, and percent coefficient of variation (CV) can be calculated. The results should be within the parameters defined under Expected Values of the package insert.

KIT COMPONENTS

- 10x Dye Solution: One bottle containing 60mL of a colored dye in an aqueous solution.
- Dye Diluent: One bottle containing 500mL of a colorless diluent.
- Blank Plates: Four, 96-well blank ELISA plates for collecting and measuring the OD of the dilutions.
- Dye Standards: Two sets of four standard solutions representing 0.00, 0.25, 0.50, and 1.0 arbitrary units.
- Package Insert providing instructions.

PRECAUTIONS

- For laboratory use only.
- The dye solutions and the diluent contain Sodium Azide at a concentration of < 0.1% as a preservative.

Keep the bottom of the microtiter plate clean and free from spots and/or fingerprints which could alter optical densities and elevate CVs.

ADDITIONAL MATERIALS REQUIRED BUT NOT PROVIDED

- 12 X 55mm specimen tubes.
- Reagent containers for the diluent.
- Standard cups.

STORAGE CONDITIONS

- Store the unopened kit at room temperature (20-25°C).
- Do not re-use reagents. Discard leftover reagents in accordance with your facility's requirements for chemical reagent disposal.

PROCEDURE

- Remove the kit components from the packaging.
- Prepare a 1:11 dilution by combining 500µl of the Dye Diluent with 50µl of the 10x Dye Solution into each of 20 sample tubes.
- Pipette 100µl of each standard into the first well of a blank microplate, starting with the "0" Standard. Standards should be added in duplicate.
- Pipette 100µl of each of the prediluted samples into the remaining wells.
- Select 450nm wavelength (with reference set to 600-650nm) and measure the optical density (OD) of each well.

INTERPRETATION OF RESULTS

The analyzer will interpret each of the 20 replicate dilutions relative to the standard curve by linear regression. Each plate will be interpreted individually. Following the interpretation, a mean result, standard deviation, and absorbance percent coefficient of variation should be calculated for each of the three plates.

EXPECTED VALUES


- R-squared should be ≥ 0.96
- Intercept should be ≤ 0.10 .
- The calculated CV% for all sample absorbances should be $\leq 5\%$.
- The OD value for each standard should fall within the ranges determined (see reverse side).

System Verify™ Standard OD Ranges


Standard	OD Ranges
1	< 0.050
2	0.200 to 0.300
3	0.400 to 0.600
4	0.800 to 1.200

ORDERING INFORMATION


KIT		System Verify
Catalog No.	Item	Quantity
4384240	System Verify	1 Kit




Manufactured




High Pos or Positive Control




Authorized Representative




Low Pos or Cut-Off Control




Consult accompanying documents




Negative Control




Product Number




Calibrator




Lot




Coefficient Factor




Use by




Range




Caution, consult accompanying documents




Standard




Store at 2-8°C




For In Vitro Diagnostic use




Store at 2-30°C



X or Hazard



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