



DESCRIPTION OF THE TEST-MATE ChE

The Test-mate ChE Cholinesterase Test System is intended for use in monitoring occupational exposure to pesticides. By routinely measuring the blood cholinesterase levels of individuals handling pesticides, workers may be protected from overexposure before becoming symptomatic. Additionally, pesticide handling safety programs may be assessed for effectiveness and compliance, leading to the improved long-term protection of the workers. Although cholinesterase testing may also be useful in diagnosing both succinylcholine sensitivity and liver dysfunction, the Test-mate ChE system is only intended for monitoring exposure to pesticides.

The Test-mate ChE is marketed as three distinct components:

- The Test-mate ChE Cholinesterase Test System (Model 400).
- The AChE Erythrocyte Cholinesterase Assay Kit (Model 460).
- The PChE Plasma Cholinesterase Assay Kit (Model 470).

The Test-mate ChE is a complete, self-contained and portable cholinesterase testing system. The system requires only 10 μ L for each blood test, which may be conveniently obtained from a fingerstick sample. The entire assay may be completed in under 4 minutes, facilitating the rapid evaluation of poisoning status. The small size (11" x 7" x 10") and weight (10 pounds) allows the unit to be easily transported between test sites.

The main component of the Test-mate ChE system is the photometric analyzer. The photometric analyzer is a compact (3½" x 5¾" x 2"), dedicated application, fixed wavelength absorption photometer, powered from either a 9 Volt battery or a power adapter. This instrument guides the operator in a step-by-step fashion through the assay procedure. The photometric analyzer measures absorbances during the assay procedure, calculates the final analyte concentrations, temperature compensates these concentrations using a built-in temperature sensor, and then displays the final test results. By switching the photometric analyzer between AChE mode and PChE mode, the operator can use either the AChE Erythrocyte Cholinesterase Assay Kit or the PChE Plasma Cholinesterase Assay Kit, respectively.

The Test-mate ChE Cholinesterase Test System (Model 400) includes the hard-shell storage case, photometric analyzer with battery, reagent tool, assay tube rack, one AChE Assay Kit to perform 96 erythrocyte cholinesterase test and a detailed instruction manual. This system is for use only with the AChE Assay Kit and the PChE Assay Kit and is not intended for use with any other assay or reagent kit.

The AChE Erythrocyte Cholinesterase Assay Kit (Model 460) contains all of the supplies necessary to perform 96 tests to determine the erythrocyte cholinesterase activity in whole blood. Erythrocyte cholinesterase testing is used to monitor exposure to organophosphate and carbamate pesticides. When used in AChE mode, the photometric analyzer measures and displays:

- AChE (erythrocyte cholinesterase) activity in U/mL (units per milliliter).
- AChE in %N (percentage normal) relative to 4.71 U/mL.
- Hgb (hemoglobin) in g/dL (grams per deciliter).
- Hgb in %N relative to 15.0 g/dL.
- Q (quotient) in U/g (units per gram).
- Q in %N relative to 31.4 U/g.

Q is a hemoglobin adjusted value of erythrocyte cholinesterase, which is computed by dividing the AChE result by the Hgb result. Q improves the assay precision by minimizing biological and sample variabilities.

The PChE Plasma Cholinesterase Assay Kit (Model 470) contains all of the supplies necessary to perform 96 tests to determine the plasma cholinesterase activity in whole blood. Plasma cholinesterase testing is used as an additional marker of pesticide exposure due to its greater sensitivity to certain pesticides and to its shorter half-life, which can be used to distinguish between chronic and acute poisoning. When used in PChE mode, the photometric analyzer measures and displays:

- PChE (plasma cholinesterase) activity in U/mL.
- PChE in %N relative to 2.55 U/mL.
- Hgb in g/dL.
- Hgb in %N relative to 15.0 g/dL.

Both the AChE Erythrocyte Cholinesterase Assay Kit and the PChE Plasma Cholinesterase Assay Kit include: assay buffer tubes, premeasured single-test reagents, blood sampling capillaries, sample capillary wipes, dropper bottle of distilled water, transfer pipettes, 9 Volt battery and a detailed package insert. These kits are for use only with the Test-mate ChE System and are not intended for use with any other testing equipment.