**Health problem addressed**

Immunoassay analyzers test patient samples for a variety of substances, including antiarrhythmic, antibiotic, anticonvulsant, or cardiac glycoside drug concentration determination; infectious diseases; allergy testing; cardiac markers; endocrine hormone testing; and protein, viral, or bacterial toxin determinations.

**Product description**

Laboratory analyzers used to identify and quantify specific substances, typically using an antibody (e.g., immunoglobulin) as a reagent to detect the substance (i.e., antigen, hapten) of interest. These analyzers typically include an autosampler, a reagent dispenser, a washer, and a detection system. Configuration and levels of sophistication, as well as available testing options, vary greatly.

**Principles of operation**

Labeled molecules are added to patient specimens and passed through a light of a particular wavelength. If the labeled molecules bind to the molecules in the patient specimen, the bound molecules will emit light. This indicates a positive result that can then be quantified. The light signals are captured by a detector and analyzed by the system’s computer. Models may use an enzyme-substrate system, a fluorescent substance (either a natural substance or a dye), or an acridinium ester or luminol.

**Operating steps**

The operator loads sample cells into the analyzer; reagents are already stored in the instrument. Typically, a bar-code scanner will read the test orders off the label on each test tube. The analyzer will perform the required test(s), and the results can be displayed on-screen, printed out, stored in the analyzer’s internal memory, and/or transferred to a computer.

**Reported problems**

Operators should be aware of the risk of exposure to potentially infectious bloodborne pathogens during testing procedures and should use universal precautions, including wearing gloves, face shields or masks, and gowns.

**Use and maintenance**

**User(s):** Laboratory technician

**Maintenance:** Laboratory technician; biomedical or clinical engineer

**Training:** Initial training by manufacturer and manuals

**Environment of use**

**Settings of use:** Clinical laboratory

**Requirements:** Adequate benchtop or floor space, water supply, line power, biohazard disposal

**Product specifications**

- Approx. dimensions (mm): 600 x 750 x 1,000
- Approx. weight (kg): 10-60
- Consumables: Reagents (cartridges, test strips, etc.), reaction cuvettes
- Price range (USD): 4,278 - 339,000
- Typical product life time (years): 5-7
- Shelf life (consumables): Reagents: 1-2 years

**Types and variations**

Enzyme, fluorescence, or chemiluminescence methodolgies; some models can be interfaced to an automated chemistry analyzer to decrease operator intervention and possibly improve workflow.