Test Simplicity

The simplicity or complexity of IVD test systems can be described in various ways, some of which are listed below. Each feature is followed by characteristics typical of low, moderate and high complexity devices.

Knowledge

1. Test can be performed accurately by reading the directions or package insert.
2. Some previous academic instruction or knowledge of concepts required. Sometimes you need knowledge of antibody/antigen reactions.
3. Specialized technical knowledge required, e.g., microscopic characteristics of most organisms, using a standard curve, handling radioisotopes.

Training and Experience

1. Analyst may be self-taught or follow simple direction.
2. Some general training in technique is needed, but training may be in the procedure itself, e.g., identifying visual endpoints, specimen collection, gram stain.
3. Specialized training requires a longer time, and involves supervision and practice, e.g., recognize quantitative endpoint reaction, inoculating viruses, using a fluorescent microscope, constructing a standard curve, handling radioisotopes.

Reagents or Materials Preparation

1. Minimal or no preparation of reagents needed, e.g., adding 10 mLs and qs to 1 liter, or combining bottles. Materials are stable and require no special handling, e.g., refrigerator, freezer, or dark storage.
2. Some preparation and handling needed, e.g., reconstitute reagents immediately before use, store plates between 2-6° and protect from light and freezing.
3. Materials may be labile or require special preparation, e.g., gravimetric or volumetric measurements involved, or calculations are needed to prepare the correct concentration.

Characteristics of Operational Steps

1. Steps are automatically executed, e.g., pipetting, temperature monitoring, or timing steps, or they are easily controlled, e.g., dipping and reading a color.
2. Steps are not fully automated and may require some monitoring, timing, or the test involves a simple, clearly defined arithmetic calculation. Specimen requires a pretreatment.
3. Steps require close monitoring and control, e.g., precise specimen collection, preparation, temperature control, timing, pipetting, or extensive calculations. Examples: Constructing a manual standard curve, log or statistical calculations.

Calibration, Quality Control, or Proficiency Testing Materials

1. All materials are stable and readily available. PT has the potential for being available.
2. Either calibration, QC or PT materials are not stable or not available. (One is not available, others are.)
3. Materials are not labile or not available, e.g., bleeding time.

Troubleshooting and Maintenance

1. T&M are automatic, self-correcting, or involves clearly described procedures. Minimum judgment is required. Examples are test strip meters, or when simple procedures are involved, e.g., lamp or battery replacement.
2. Some judgment and intervention. Examples: There are multiple steps in the procedures but they are clearly described, large volume instruments with error messages and flow charts.
3. T&M are not automatic and requires decision making and direct intervention. Examples: gas chromatographs, or steps are technically complex, e.g., soaking and replacing membranes, changing tubing.

Interpretation and Judgment

1. Minimal I&J is needed, i.e., decision steps are clearly defined. Instrument gives direct print out of results.
2. Some I&J needed. Some independence needed to resolve problems. Examples: Recognizing hemolysis and knowing what tests it effects, Recognizing a color change or agglutination, estimating if # of WBCs on a slide is consistent with total WBC count. Recognizing that inconclusive results require additional testing.
3. Extensive I&J is required to perform pre-analytical, analytical, or post-analytical processes. Examples: When analyst performs extensive calculations or constructs a standard curve, correlating biochemical and microscopic characteristics to identify organisms, or needing to identify abnormal cells and relate them to possible hematologic disorders or parameters.