

Checklist for Selecting New Equipment/Assays

A. Determining Need

- Demand present
 - Clinician (improved treatment or change in clinical care) driven
 - Laboratory (improved cost, efficiency, safety, quality, or technology) driven
 - Regulation (clinical guideline or standard of practice) driven
 - Facility (increased profit, or customer satisfaction) driven
- Cost effective
 - Volume
 - Improved TAT
 - Improved throughput
 - Decreased manual hands-on time
- Compatible and/or adaptable with current LIS systems
 - LIS support
- Location
 - Space limitations

B. Research and Analysis

- Form a research team
- Establish timeline/goals
- Costs/reimbursement/billing codes
 - Cost of reagents, controls, calibrators, and validation materials
 - Cost of instrument including volume and service contracts
 - Cost of additional non-supplied reagents, materials
 - Cost of Tech-time

- Instrument availability and intended use
 - Physical needs (temperature, humidity, lighting)
 - Vendor service and support
 - List of other clients using the instrument
 - Visit lab and talk to techs running the test
 - Discuss failures and set-backs
 - Discuss successes and improvements
 - Type of assistance (free instrument with use of assay, free kits for validation, provide training, etc.)
- Assay availability
 - FDA approved/-cleared
 - Quantitative
 - Qualitative
 - Multiplex
 - Type of test
 - Single target vs. panel testing
- Assay requirements
 - Throughput
 - Batching
 - On demand as needed
 - Turn-around-time
 - Ease of use/test complexity
 - Accuracy
 - Reliability/precision
 - Sensitivity/specificity
 - Reagents needed

- Reagent shelf-life
- Packaging
- Disposables
- Additional supplies not-provided
- Waste produced and waste disposal
- Training
- Evaluation - compared to other methods
 - Literature reviews

(<http://www.ncbi.nlm.nih.gov/pubmed> is the main free search site. From this site you can go to the “PubMed Quick Start” site that offers a tutorial on searching PubMed:

http://www.ncbi.nlm.nih.gov/books/NBK3827/#pubmedhelp.PubMed_Quick_Start)

- Performance vs other methods
- Performance vs. reference standards

C. Making a Decision

- Create pros and cons table to implementing test
- Cost/benefit analysis
 - Cost assessment
 - Current costs (in-house, or reference) including collection, packaging, transport, QC and QA
 - Development/validation costs
 - Start-up costs (instrumentation)
 - Operating costs including disposables and reagents
 - Repeat testing and frequency of repeat testing
 - Justification (effects on downstream patient care including antibiotic usage, other diagnostic tests, and length of stay)
 - Reimbursements
- Balancing priorities – what is obvious isn’t always the right decision