Coagulation Instrumentation: How to choose wisely!

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Disclosure

Relevant Financial Relationships

None

Off-Label Usage

None

Objectives:

- Identify instrumentation that works for your laboratory
- Enhance knowledge of validation protocols
- Analyze strategies for cost effective coagulation

Historical Perspective:

- Early 1900's slide tests looked at fibrin and clotting
- Blowing through capillary tubes counting seconds until clots
- Koagulometer (1912) measured temperature controlled clotting by use of a plunger
- Klinke (1931) added nephelometry measuring degrees of light
- Chandler (1958) used a "Chandler loop"
- 1970 (Watt) developed a coagulation timer that measured clot formation that interfered with a light beam .

Owen, CA., A History of Blood Coagulation, Mayo, 2001.

Our History:

- Tilt tubes
- Wire loops
- Fibrometers
- Optical Density
- Electromechanical
- Total Laboratory Automation

Instrumentation

Where do we begin?

Prepare: Project Management

- Develop a plan for evaluation and validation of instrument
- Identify key personnel
- Set-up a time line
- Identify workloads and break into measurable tasks

Phases of Selection Process:

- Preliminary planning: funding, space, utilization, staff
- Pre-budget evaluation-assess instrument capabilities, options and quotes
- Financial planning: lease reagent rental
- Post-budgeting: confirm capabilities and details, enter into an aggrement

Myers, J (2007) MLO.

Prepare: Choosing Instrumentation

- Know what works for your institution
- Do you want an open system?
- Do you want speed?
- Flexibility and adaptability?
- Ask questions, then ask more!

Prepare: Instrumentation

- Read, search company sites
- Decide which instrument suits your needs
- Look at similar sites that operate the instrument
- Bring the instrument on site

CAP Today: Jan 2007

- Overview of all instrumentation
- Most important question asked about patients related to coagulation:
  1. Are they bleeding?
  2. Are they going to clot?
  3. Are they okay?

Selection Criteria

- Test volume
- Test menu
- Size (foot print of instrument)
- Cost /Consumables
- Ease of use
- Current practice needs
- Multiple sites
- Proficiency surveys
- Required options
- "Nice to have" options
- Technical Support
- Future growth
- Experience/relation-ship with company

Test Volume

- What throughput is required
  - Run in batch or random access
  - TAT issues
- Routine assays performed 24 / 7
  - Run as needed
  - Evenings, nights, etc
- Routine testing plus specialty
  - Random access
  - 24 / 7 lab or less

Test Menu

- Routine testing
  - PT, APTT, Fibrinogen, D-Dimer
  - Heparin assays
- Specialty testing
  - Clot based
  - Chromogenic
  - Particle based (LIA)
  - ELISA
- Routine and Specialty

  -Can the instrument handle both together

Logistics:

- Will it be replacing an existing instrument, or will this be added to existing equipment?
- Will remodeling be necessary
  - Depth & length of counter vs depth of instrument and counter space required for computer, liquid containers, etc
  - Does instrument require a dedicated circuit
  - Take into account required work space as well as instrument foot print

Financial Perspective:

- Economic Useful Life (time the instrument will be used in the laboratory)
- Accounting useful life (amount of time instrument will be depreciated in the lab financial statement)
- Does your institution have a contract for a Preferred Provider

Financial:

- Evaluate current practice
- What additions/improvements would you like to make?
- Do you have a 5 or 10 year plan?
  - Will you be expanding test menu in future or increasing volume of testing?
  - Is there a plan for replacement of instrument(s) or process in place for upgrades?
- How will new instrument(s) fit in to plan?

Purchase Options

- Evaluation with option to purchase
  - Detailed contract with performance criteria spelled out specifically
  - Allows for “Test drive” beyond company demo and gives opportunity to see instrument in your workflow and surroundings
- Up-front purchase
- Reagent rental/leasing

Support Considerations

- Instrument Support/Access to trained technical company personnel
  - 24 hour "hot-line"
  - Response time to messages (do they follow up calls within 1 hour when instrument down)
  - Assist with validation
- Key operator training
  - On site training or training program slots with purchase
  - Comprehensive training for advanced applications or basic use of instrument

Current Practice

- Type of instrumentation in use
- Reagents in use
- Current in-house coagulation test menus
- Anticoagulants in use
- Type and volume of reference lab testing
- Costs of assays
- Single or duplicate testing
- Quality control programs in use
- Therapeutic ranges for anticoagulation
- Full, Half or Quarter volume testing in use.

The Players

- Beckman Coulter
- Dade Behring
- Diagnostica Stago
- Trinity Biotech/ Biomerieux
- Others

Dade/Behring

- Sysmex CA500,1500,6000,7000, BCS
- Optical Chromogenic, immunologic, agglutination of fixed platelets
- Robotic capabilities
- BCS- flexible for special tests, broad menu, Ristocetin Cofactor assay

Dade Behring

Instrument	Track Sampling	Bar coding	Operational Type	Closed sampling	Instrument dilutions	Stat testing	Chromogenic testing	Throughput tests/hour PT/APTT
BCS/XP	Y	Y	Random	Y	Y	Y	Y	380/325
CA 500		Y	Random	N	Y	Y	Y	50/33
CA 1500	Y	Y	Random	Y	Y	Y	Y	120/80
CA 7000	Y	Y	Random	Y	Y	Y	Y	280/480

Diagnostica Stago

- STA compact, STA-R Evolution, Start 4
- Electromechanical-viscosity based clot detection
- Clotting, chromogenic, immunologic assays

Diagnostica Stago

Instrument	Track Sample	Bar coding	Operational Type	Closed sampling	Instrument dilutions	Stat testing	Chromogenic testing	Throughput tests/hour PT/APTT
STA R Evolution	Y	Y	Random	Y	Y	Y	Y	300/150
STA	N	Y	Random	N	Y	Y	Y	150/75
STA compact	N	Y	Random	N	Y	Y	Y	150/75
START 4	N	N	Batch	N	N	N	N	Varies

IL/Beckman Coulter

- ACL, ACL Elite, ACL Advance, TOP
- Optical or nephelometric clot detection, chromogenic testing, immunologic assays

Beckman Coulter/IL

Instrument	Track Sampling	Bar coding	Operational Type	Closed sampling	Instrument dilutions	Stat testing	Chromogenic testing	Throughput tests/hour PT/APTT
ACL Advance/ 2000	N	Y	Random	N	Y	Y	Y	240/180
ACL ELITE	N	N	Modified Random	N	Y	N	N	110/80
ACL TOPS	Y	Y	Random	Y	Y	N	N	360/165
ACL Classic	N	Y	Random	N	Y	N	Y	175/115
ACL 9000		Y	Random	N	Y	Y	Y	175/110

Trinity BioTech

Instrument	Track Sampling	Bar coding	Operational Type	Closed sampling	Instrument dilutions	Stat testing	Chromogenic testing	Throughput tests/hour PT/APTT
MDA II	N	Y	Random	Y	Y	Y	Y	180/180
Destiny Optical	N	Y	Random	Y	Y	Y	Y	110/60
AMAX Destiny Plus	N	Y	Random	Y	Y	Y	Y	180/90
XC1	N/A	N/A	Semi-automatic	N/a	N/a	N/a	N	48/10

Trinity Biotech

- Amax 200,400 & Destiny series
- Clotting, chromogenic, immunologic
- Mechanical & optical detection clot
- Quarter volume testing

Others:

Instrument	Vendor	Access	Barcode	Stat	Patient Dilutions	Chromogenic	#samples
CD2000	American Labor	Batch	N	N	N	N	User defined
Coat/Lab	American Labor	Batch	Y	N	Y	N	140
Thrombo Screen 200	Thermo Scientific	Batch	N	N	N	N	120
Thrombo Screen 400	Thermo Scientific	Batch	N	N	N	Y	120
Cascade M/1991	Helena	Batch	N	N	N	N	120/50
Cascade M/4	Helena	Random	N	N	N	N	140/80

What will increase productivity?

- Cap piercing option
- TAT
- Adding stat samples
- Replacing reagents
- Reagent on-board stability
- Real time throughput
- Interfacing with LIS
- Viewing results
- Routine maintenance
- Real time monitoring of reagent volumes and stability

What are things do you need to know?

- Can it read reagent bar codes? If not, can it make bar codes?
- Does it display an inventory of reagents on board? Can I add/access reagents while the instrument is running?
- What is the dead volume of samples?
- Do I need adaptors for micro samples?
- Is there an automatic re-run or reflex capability?
- LIS interface? Bi-directional capability?

More stuff?

- What are all the methodologies defined?
- Are all reagents kept cool?
- Can reagents be stirred?
- Can the instrument support other vendors applications?
- Can I run a standard curve while samples are being processed?

Confused?

What to do?

- Talk to techs, not just sales people, talk to technical specialists
- DO NOT PURCHASE AN INSTRUMENT WITHOUT HANDS ON EXPERIENCE OR A SITE VISIT-SIMILAR TO YOUR INSTITUTION
- Find out minimum volumes, protocols, adaptations, available kits
- If you will be part of a QAP program

Evaluation System:

- Best case is getting your hands into the instrument
- If you can, have technologists evaluate and grade the instrument for several parameters
- May give you insight to things you might not have considered

Evaluation Form: MLO- 2/2001 "Selecting Instrumentation"

Circle: 0-4 (0=poor, 4=excellent)

Instrument: Size	0 1 2 3 4	Comments:
Screen Display	0 1 2 3 4	Comments:
Ease of use	0 1 2 3 4	Comments:
Loading Sample	0 1 2 3 4	Comments:
Reagents: ID	0 1 2 3 4	Comments:
Volume	0 1 2 3 4	Comments:
Testing: TAT	0 1 2 3 4	Comments:
Reflex	0 1 2 3 4	Comments:

Advantages of using a form:

- Enables objective assessment of instruments
- Each technologist can give a numerical rating to specific functions
- What may not seem important to you, may be to the techs that run the instrument
- You will have measurable data

Call people

- Will the vendors supply you with a list of people that you can contact?
- How is the vendors' reputation?
- Is the consumable-product cost estimation accurate?
- What about training programs both off site and on site?

Questions for site visit:

- How is service?
- Is it reliable?
- Does it perform as manufacturer states as to accuracy and specificity?
- What assays does user perform?
- Is it easy to use?
- Is the cost per test what you hoped?

In a nut shell...

- Work flow analysis
- Reagents
- Quality Control
- Software
- Instrument flexibility
- Service
- Technical support
- References from company

Outcome: Prepare or Perish!

- Invest time in determining instrument that is a fit for your laboratory
- Evaluate how it performs in comparison to your gold standard
- Analyze how technologists can adapt to this new testing environment

Avoiding "Buyers Remorse"

- Do your homework
- Ask for references
- Do a "trial run" as an instrument evaluation before purchase if possible
- Carefully validate instrument to know its limitations and potential
- Develop relationships with technical specialists at company—they can be great resources for troubleshooting and setting up new methods

Conclusion:

- Choose wisely
- Never let an instrument run you, you run the instrument
- Make a commitment to ensure the best results
- This investment will be cost effective in the long run