

Evaluating and Selecting Coagulation Analyzers

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Disclosure

Relevant Financial Relationships

None

Off-Label Usage

None

Objectives

- ◆ Discuss specific selection criteria for coagulation instrumentation.
- ◆ Identify individual laboratory considerations that may impact the decision process.
- ◆ Compare the available coagulation instrumentation and their features.
- ◆ Discuss the components of coagulation instrumentation evaluation.

Historical Perspective:

- ◆ Early 1900's slide tests observing fibrin and clotting
- ◆ Koagulometer (1912) measured temperature controlled clotting by use of a plunger
- ◆ Kugelmass (1923) added nephelometry
- ◆ Nygaard (1939) developed a photo-electric coagulometer
- ◆ Chandler (1958) used a "Chandler loop"
- ◆ 1970 (Watt) photo-optical measurement

Owen, CA., *A History of Blood Coagulation*, Mayo Foundation for Medical Education and Research, 2001.



Phases of Selection Process:

- ◆ Preliminary planning
- ◆ Pre-budget evaluation
- ◆ Financial planning
- ◆ Post-budgeting

Myers, J. Primer for selecting lab equipment. MLO, Jan 2007.

Selection Criteria

- ◆ Test menu/volume
- ◆ Instrument physical characteristics
- ◆ Current/future practice needs
- ◆ Ease of use
- ◆ Support considerations
- ◆ Group practice considerations
- ◆ Financial considerations

Test Menu

- ◆ Routine testing
- ◆ Specialty testing
- ◆ Routine and Specialty

Test Volume

- ◆ What throughput is required
- ◆ Large volume of routine tests, low volume specialty testing or both equal

Batch vs. Random Testing Considerations

- ◆ Is there a concern for carryover in system when random testing?
- ◆ Does random testing affect efficiency?

Size



Size/Physical Characteristics of Instrument

- ◆ Will it be replacing an existing instrument, or will this be added to existing equipment?
- ◆ Will remodeling be necessary?

Current practice/Future

- ◆ Evaluate current practice
- ◆ Additions/improvements?
- ◆ 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?

Current Practice Needs

- ◆ Type of instrumentation & reagents
- ◆ Current test menu & volume
- ◆ Current costs of assays
- ◆ Single/duplicate testing
- ◆ QC & therapeutic ranges for anticoagulant monitoring
- ◆ Full, half or quarter volume samples

What will enhance productivity?

- ◆ Better turn around time
- ◆ Efficient reagent handling
- ◆ Efficient throughput
- ◆ LIS interface

Enhanced Productivity

- ◆ Minimal maintenance
- ◆ Ease of viewing results
- ◆ Sample considerations

Support Considerations

- ◆ Instrument Support/Access to trained technical company personnel



- ◆ Key operator training

Group Practice Considerations

- ◆ Does the vendor offer instruments for varying needs
- ◆ Will it be necessary to calibrate instruments across a practice?

The Players

- ◆ Beckman Coulter
- ◆ Dade Behring
- ◆ Diagnostica Stago
- ◆ Trinity Biotech/ Biomerieux
- ◆ Helena

CAP Today: Jan 2007

- ◆ Survey of coagulation instrumentation
 - FDA-cleared tests
 - Supported methodologies
 - Features
 - Unique advantages

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 (Cap piercing)	Instrument dilutions	Stat testing	Chromogenic testing	Throughput tests/hour PT/PT,APTT
ACL Advance/2000	N	Y (samples, not reagents)	Random	N	Y	Y	Y	240/180
ACL ELITE	N	Y	Modified Random	N	Y	N	Y	175/125
ACL TOP	Y	Y	Continuous Random	Y	Y	Y	Y	360/165
ACL Classic	N	Y (samples, not reagents)	Random	N	Y	N	Y	175/110

Dade/Behring

- ◆ Sysmex CA500, 1500, 6000, 7000, BCS
- ◆ Optical, Chromogenic, immunologic, agglutination of fixed platelets
- ◆ Robotic capabilities
- ◆ BCS- Ristocetin Cofactor assay

Dade Behring

Instrument	Track Sampling	Bar coding	Operational Type	Closed sampling (Cap piercing)	Instrument dilutions	Stat testing	Chromogenic testing	Throughput tests/hour PT/PT,APTT
BCSXP	N	Y	Random	N	Y	Y	Y	380/325
CA 500	N	N	Random	N	Y	Y	Y	54/43
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 (cap piercing)	Instrument dilutions	Stat testing	Chromogenic testing	Throughput tests/hour PTT,APTT
STA R Evolution	Y	Y	Random	Y	Y	Y	Y	300/150
STA compact	N	Y	Random	Y	Y	Y	Y	150/75
START 4	N	N	Batch	N	N	N	N	Varies

Trinity Biotech

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

Trinity Biotech acquired BioMerieux Instruments

- ◆ Coag-A-Mate XM & MTX, MDAII
- ◆ Photo-optical clot detection, chromogenic, immunologic assays

Trinity BioTech

Instrument	Track Sampling	Bar coding	Operational Type	Closed sampling (cap piercing)	Instrument dilutions	Stat testing	Chromogenic testing	Throughput tests/hour PTT,APTT
MDA II	N	Y	Random	Y	Y	Y	Y	180/180
Destiny Optical	N	Y (samples, reagent in develop)	Random	N	Y	Y	Y	110/60
AMAX Destiny Plus	N	Y (samples, reagent in develop)	Random	N	Y	Y	Y	180/90
Coag-A-Mate MTXIII	N	Y (samples, reagent in develop)	Random	N	Y	Y	Y	90/60
Coag-A-Mate XM	N	N	Discrete	N	N	Y	N	200/50

Helena

- ◆ Thor (support), Cascade series, Packs 4
- ◆ Clot based assays only or aggregation and chromogenic assays (Packs 4)
- ◆ Clot detection optical, turbidimetric

Others

Instrument	Vendor	Access	Barcode	Stat	Patient Dilutions	Chromogenic	#samples per hour PT/PT,APTT
CD2000	American Labor	Batch	N	N	N	N	User defined
CoaLab	American Labor	Batch	Y (samples, not reagents)	N	Y	N	140
Thrombo Screen 200	Thermo Scientific	Batch	N	N	N	N	120/Varies
Thrombo Screen 400	Thermo Scientific		N	N	N	Y	120/Varies
Thrombo Screen 1000	Thermo Scientific	Batch/random access	Y (samples, not reagents)	Y	Y	N	100/50
Cascade M-4	Helena	Random	N	N	N	N	140/80
Cascade M	Helena	Batch	N	N	N	N	120/60

\$ Purchase Options \$

- ◆ Evaluation with option to purchase
 - Detailed contract--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

References (current users)

- ◆ 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?

Confused?



In a nut shell...

- ◆ Test menu/volume
- ◆ Reagents
- ◆ Software/Quality Control
- ◆ Enhance productivity
- ◆ Service/technical support
- ◆ References
- ◆ Evaluation

Summary

- ◆ Evaluate current practice
- ◆ Determine current and future needs
- ◆ Evaluate instruments/company for desired features
- ◆ Network with current users and company technical representatives
- ◆ Determine components of evaluation/purchase agreement

Avoiding “Buyers Remorse”

- ◆ Do your homework
- ◆ Ask for references
- ◆ Do a “trial run” with the instrument in your laboratory before purchase, if possible
- ◆ Carefully validate instrument to know its limitations and potential
- ◆ Develop relationships with technical specialists at company