Global Insights on Medical Laboratory Operations:
How World-Class Performers are Combining Dynamic Costing, Lean, and Quality Management Systems to Deliver More Value
<table>
<thead>
<tr>
<th>Pre-analytics</th>
<th>Analytics</th>
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</table>

- Money
- Time
- Quality
Non-production environment

Characteristics of cost efficient Labs

• Unique philosophy
• Clear focus on science, medicine and results that can be trusted
• Respect of standards, accreditation
• Qualified staff at all levels
• Proper use of technology
• Clear production concept
Non-production environment

Cost sensitive Pre-analytical issues

Most of problems are due to pre-analytical issues - quality of biomaterial, request or phlebotomy:

- Part of bio-material arriving to the labs might contain clots, hemolysis etc.
- Pre-analytical procedures are rarely respected - bio-material might arrive non-centrifuged, in non standard pre-analytics
- Basics such as labelling not respected - wrongly stucked barcodes, or not controlled by IT - unreadable barcodes
- Closing, counting and temperature conditions of transport boxes
- Tracing and custody during all pre-analytical steps
- Educate equip and re-educate your prescribers, collectors and phlebotomists about pre-analytics or nothing will be improved
Non-production environment

Unvalidated quality and procedures are expensive

- Not enough bio material means re-phlebotomy and reprocess for the same initial price

- Body liquids in non-conform transport pots can lead to cross contamination of other samples, become unacceptable for analytical stage and cause unnecessary logistics costs

- SST non gel separated tubes are acceptable for hospital labs, not for long logistics > 2hrs

- Transportation requirements such as UN3373 boxes and temperature control systems should be applied

- 80 is cheaper than 100, but 400 is definitely more expensive than 100

- 12 percent re-runs is far too high
Production environment

Gold standards of cost efficiency in Diagnostics

• Unique platform for each test cluster inside the lab or group of labs

• What can be done by a machine must be done by a machine

• All machine must be connected either to middle ware or to LIS

• Internal (per shift) and external (per reference interval) Quality Control

• Manual is not bad, provided it is accredited SOP

• Documentation of every process is a must and must be respected

• Unique qualification system for all staff as support for constant Quality of Production and Results that can be trusted

• Auto-validation as a standard, human validation for cases of interest
Production environment
Local vs Central distribution of production

- Centralize every assay which can be centralized, starting with routine
- Retro engineer your production concept to your expected Total time to results (TTR) and Volumes
- STAT is STAT, Routine is Routine
- Man vs Machine vs Time
- Constant arbitrage, no magic solution
- Golden rule is intelligent horizontal consolidation
- Multiple sites = multiple teams = multiple costs
Production environment

Data, reports and short-term production planning

- Data and «Data that can be trusted» are not equal
- Do not trust anybody more than data
- Extract data from systems, so people have little chance to manipulate. Trust data extraction to professionals.
- People hate automatic data collection, they cannot hide anymore
- Machines do not have one personality only- Use this to fit various production needs
- Design theoretical models, validate them and then make evidence based decisions
- Do not hesitate to regularly challenge your existing concept and verify simulations
Production environment

Problems of technological steps

- Track Vs. no track
- Evolution is a staircase, not a rocket
- Qualifications need to be adapted
- Systems need to be deployed and mastered
- Human process Vs. Machine process - «it is my job!»
- New systems are usually designed to reproduce old processes
- Tender documentation design and bias
- System ancillaries as important as system itself
- TCO more important than CPRR
- Hidden costs outside of CPRR
Production environment

Cost sensitivity of quality

- Perception Vs. reality
- Documentation and SOPs
- Standards, certification and accreditation, international or local must be respected, always cheaper on the long run
- Do not certify bad processes, clean them before. Do not be afraid to ask help from Vendors
- Be open – help to compare internally and externally
- Quality is reflection of qualifications and consistency of staff education
- Machine is rarely wrong unless Man taught it to be
- Auto-validation which can be trusted is a help, not a competition
Study case

- Worldwide Medical Diagnostics Laboratories with a workload of over 10,000 tubes a day face high indirect or hidden production-related costs that are not easily identifiable and attributable.

- Costs mostly depend on production platform, workflow, analyzers used and contractual obligations on Total Around Time (TAT).

- And yet..., decisions on which platform to choose are still made based on:
  - reagent costs
  - final discount
  - Immediate availability of machines
  - Bundles

- The major part of the operation costs, which directly depends on the chosen platform, is usually not fully taken into consideration.
Holistic & Methodological Approach

Cross departmental joint effort:

<table>
<thead>
<tr>
<th>How can we achieve that?</th>
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<tbody>
<tr>
<td>Initiate &amp; validate theoretical model</td>
</tr>
<tr>
<td>Repeated data validation (small and large scale)</td>
</tr>
<tr>
<td>Multi-parameter monitoring, full platform assessment possibility</td>
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<tr>
<td>Repeat of critical measures (Quarter, 6 months)</td>
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<tr>
<td>TCO perfect SMART management tool</td>
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<td>Enables dynamic follow-up of all relevant cost components</td>
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<tr>
<td>Data re-validation through follow-up study</td>
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Methods

- Main Laboratory routine operation of Immunoassays & Clinical Chemistry alternating on a monthly basis, between instrumentation of its main providers Abbott and Roche.

- Fully identify and attribute direct and indirect costs
Results

Overall Absolute Values of Costs for Immunoassays with % variances

<table>
<thead>
<tr>
<th>Starting Point - Cost of Production</th>
<th>Second step - Cost of Production plus variable direct costs</th>
<th>Third step - Costs including variable indirect costs</th>
<th>Forth step - Total Costs, including INDIRECT fixed costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>17 % Higher</td>
<td>56 % Lower</td>
<td>36 % Lower</td>
<td>33 % Lower</td>
</tr>
</tbody>
</table>

Roche - Blue bar
Abbott - Grey bar

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Results

Overall Absolute Values of Costs for Clinical Chemistry with % variances
Conclusions

Retrospective analysis suggests, that this novel methodological approach is more advantageous compared to the conventional procurement approach since it is:

- An efficient tool to put focus on EBITDA without losing focus on quality, complexity and time

- TCO enables practice of “evidence based” management and technology procurement decisions

- TCO empowers the Lab specialists to participate fully in procurement decisions with a holistic approach

- TCO enables labs to create economic dashboards for each catalog object, machine and production center facilitating future resource allocation and budgeting exercises
2nd Study case

- Private Laboratory Seoul, Korea.

- TCO based Main Laboratory routine operation of Immunoassays & Clinical Chemistry switch to alternative supplier.
2\textsuperscript{nd} Study case

- Looking for additional profitability improvement:


- Top management coaching (owner, CEO, COO, production director, medical director, etc.)

- Full laboratory assessment (production, pre-analytics, logistics, IT)

- 45 concrete tangible recommendations for efficiency improvement and creation of a 1 year roadmap to increase EBITDA substantially

- Full “Lab efficiency toolbox” Workshop
2\textsuperscript{nd} Study case

- Private Laboratory Seoul, Korea.

- TCO based Main Laboratory routine operation of Immunoassays & Clinical Chemistry switch to alternative supplier.
2nd Study case

- Tube distribution philosophy reengineering
- Improvements of workflows
- Implementation of golden rules in pre-analytics
- Overheads reduction
- Machine-readable blanks
- Personal training and coaching
- Process mapping for top 40 tests
2\textsuperscript{nd} Study case

- Preliminary results – October 2017 – EBITDA + 22%

<table>
<thead>
<tr>
<th>Technology</th>
<th>EBITDA</th>
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<tbody>
<tr>
<td>Technology A</td>
<td>7%</td>
</tr>
<tr>
<td>Technology B</td>
<td>17%</td>
</tr>
<tr>
<td>Post assessment</td>
<td>29%</td>
</tr>
</tbody>
</table>
3rd Study case

**Australia** (hospitals and laboratories, government structure)

- Training for top management of the network
- Full assessment of 6 laboratories (production, pre-analytics, logistics, IT, BI)
- Recommendations for efficiency improvement
- Full “Lab efficiency toolbox” Workshop
- Internal and external benchmarking of production sites against other laboratories
3<sup>rd</sup> Study case

- Unique system of internal and external benchmarking of production sites against other laboratories.

- Fully describe lab activity, weak points and bottlenecks
3rd Study case

- Worldwide lab to lab benchmark.
- Evidence based assessments history

<table>
<thead>
<tr>
<th>LAB Benchmarking</th>
<th>Value</th>
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<tbody>
<tr>
<td>EUROPEAN LAB B</td>
<td>122</td>
</tr>
<tr>
<td>EUROPEAN LAB A</td>
<td>113</td>
</tr>
<tr>
<td>ASIAN LAB A</td>
<td>44</td>
</tr>
<tr>
<td>LAB E</td>
<td>22</td>
</tr>
<tr>
<td>LAB D</td>
<td>50</td>
</tr>
<tr>
<td>LAB C</td>
<td>53</td>
</tr>
<tr>
<td>LAB B</td>
<td>62</td>
</tr>
<tr>
<td>LAB A</td>
<td>49</td>
</tr>
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</table>
3rd Study case

- Full assessment reports and the list recommendations for efficiency improvement and creation of a 3 year roadmap to increase EBITDA substantially

- Planned annual intermediate reassessments to see the progress

- Top management consulting and coaching program for 2 years
Thank You!

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