HIGH THROUGHPUT PATERNITY TESTING: CHALLENGES AND ISSUES

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Challenges:

As a lab goes from a modest to a large caseload, things will begin to fall through the cracks. A crash in a lab process will have a larger impact on work flow and recovery will be harder. Inefficiencies will start to creep in and become a drain on existing resources. It becomes more difficult to identify and target the problem cases.

The Three Keys to Success:

1) Keep it simple. Automate all processes as much as possible. Strive to have ONE procedure only for each step of the process in your pipeline.
2) Automatically monitor the critical processes in the lab (cases in progress, average turn around time, various lab efficiency parameters, etc.). Set performance thresholds.
3) Be proactive rather than reactive. As soon as your system automatically notifies you of a decline in performance, CRUSH the problem. Don't wait to see if the problem will improve or go away on its own.

The Elements Involved:

1) Personnel
2) IT System
3) Technical Issues

Personnel

- Decide whether employees will be specialists or generalists. In general: Lab techs specialize, clerical/administrative folks are generalists.
- Have a VERY detailed job description for each position in the process. Hold people accountable for completing their tasks on time and properly by monitoring their performance.
- When an employee is falling behind, find out why and help put them back on track.

IT System

- Build an IT system that moves the data through the pipeline seamlessly. Avoid paper trails and human intervention as much as possible for the routine cases. Focus on identifying the difficult cases so your limited human resources can concentrate on those, while the routine work remains routine.
- Choose a relational database that can easily store, sort and tabulate large amounts of data.
- Design your system with the flexibility to accommodate new technologies in the lab.
- Design in automatic tracking of specimens, cases, performance thresholds, etc. Focus your efforts on problem specimens, cases, and processes.
- Find a way to quickly and reliably identify the rare, difficult cases from the common, straightforward ones.

Technical Issues:

- Carefully and thoroughly validate ALL lab processes, no matter how small, before going “live”
- Automatically check each case for: consistency of data between trios, possibility of M-C switch on all exclusions, CPI and RMNE requirements.
- Predict problems and program in the fixes before going “live”
- Avoid failures in the lab by developing REAL QA and QC programs, and actually obey them. Do not write manuals that collect dust between your AABB assessments.
<table>
<thead>
<tr>
<th>Steps in processing a case</th>
<th>Potential level of automation</th>
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<tbody>
<tr>
<td>Accession specimens</td>
<td>75% ??</td>
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<tr>
<td>Set up specimens for extr'n</td>
<td>virtually 100%</td>
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<tr>
<td>Extract DNA</td>
<td></td>
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<tr>
<td>Amplify/Digest</td>
<td>depends on platform</td>
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<tr>
<td>Electrophorese</td>
<td>perhaps 80% ??</td>
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<tr>
<td>Interpret Results</td>
<td>virtually 100%</td>
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<tr>
<td>Produce Report</td>
<td>variable; depends on the specific task</td>
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<tr>
<td>Client Services</td>
<td>varies</td>
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<td>Scheduling draws</td>
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