

SUCCESS IS IN THE EYE OF THE BEHOLDER: THE EFFECT OF TECHNICAL SPECIFICATIONS ON SUCCESS RATES

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Background

A stated goal of the National Institute of Justice (NIJ) Convicted Offender DNA Backlog Reduction Program (Outsourcing) program is to enter acceptable profiles into NDIS as soon as possible. To achieve this, it is desirable for the outsource laboratory to obtain a successful profile on the first attempt and to minimize repeat testing, reamplifications and reinjections. A high first pass success rate achieves the following: 1) decreased turnaround time; 2) decreased cost; 3) increased quality and 4) decreased data review for the States.

An often overlooked component of success rates are the technical specifications defined by the State. This includes 1) balance requirements; 2) RFU minimum and maximums and 3) reaction component and volume requirements. Typically, the requirements are based on the validation studies of the State, possibly with different platforms (e.g. 310 versus 3100), and not on the guidelines determined by the laboratory performing the work. The result is that the same sample generated from a laboratory will pass according to State A yet fail according to the guidelines of State B.

Methodology

To measure this effect in a systematic manner, 1021 oral swabs on Bode Buccal DNA Collectors were processed using validated procedures acceptable to the NIJ. The samples were extracted using DNA Release, quantified using BodeQuant LCN, an internally developed real-time quantification assay, normalized to 1ng/μL and amplified in a 6μL reaction volume using the Applied Biosystems Identifiler multiplex kit. The samples were electrophoresed on the Applied Biosystems 3100 Genetic Analyzer and injected at 3kV for 10 seconds. All samples were then analyzed under various State specifications, including differences in balance and RFU requirements. See **Table 1** for a listing of various technical specifications of State laboratories.

Results and Discussion

The impact can be dramatic. When analyzed under the laboratory's validated interpretation guidelines, success rates exceeded 90%. See **Table 2** for a summary of all conditions measured.

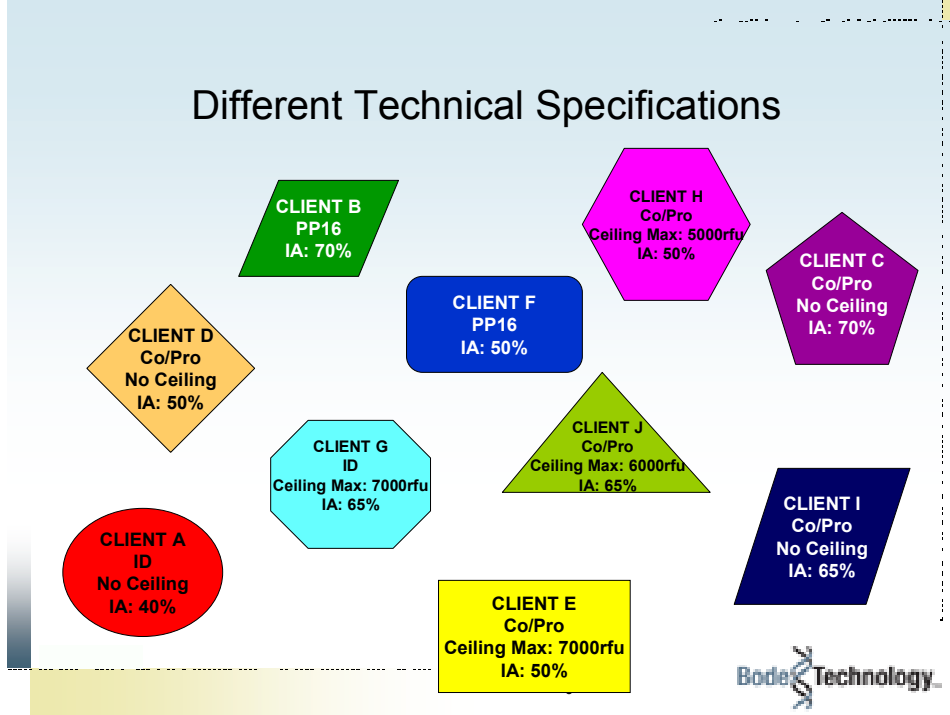
Impact of RFU Ceiling: Compared to samples analyzed without a ceiling, a 7000 RFU ceiling doubles the failure rate.

Impact of Imbalance Ratio: Analyzing at a 60% balance requirement, compared to 40%, triples the failure rate.

For comparison purposes, the cost of an increased failure rate was calculated using a 10% failure rate and a 30% failure rate. Using conservative assumptions for cost per sample, productivity per analyst and average salary, the increased cost for a project consisting of 24,000 samples was measured to be \$93K (**see Table 3**). Without the hiring of additional staff to offset the increased failure rate, turnaround time increased by 28%. More than 7500 additional samples required analysis to develop the same 24,000 profiles.

In summary, high success rates can be achieved through the use of a laboratory's internally developed and validated interpretation guidelines. Due to differences in technical specifications, samples that would be considered 'successful' by the testing laboratory require reprocessing under restrictive State requirements. For the State, the result is 1) increased turnaround time; 2) increased cost; and 3) increased data review. In order to meet the objectives of the NIJ and to fully utilize the power of NDIS, participating laboratories must acknowledge the impact of these requirements on success rates and reexamine the current system for defining what constitutes a 'successful' profile.

Table 1. Technical Specifications



Note: IA- Imbalance

Table 2. Success Rates

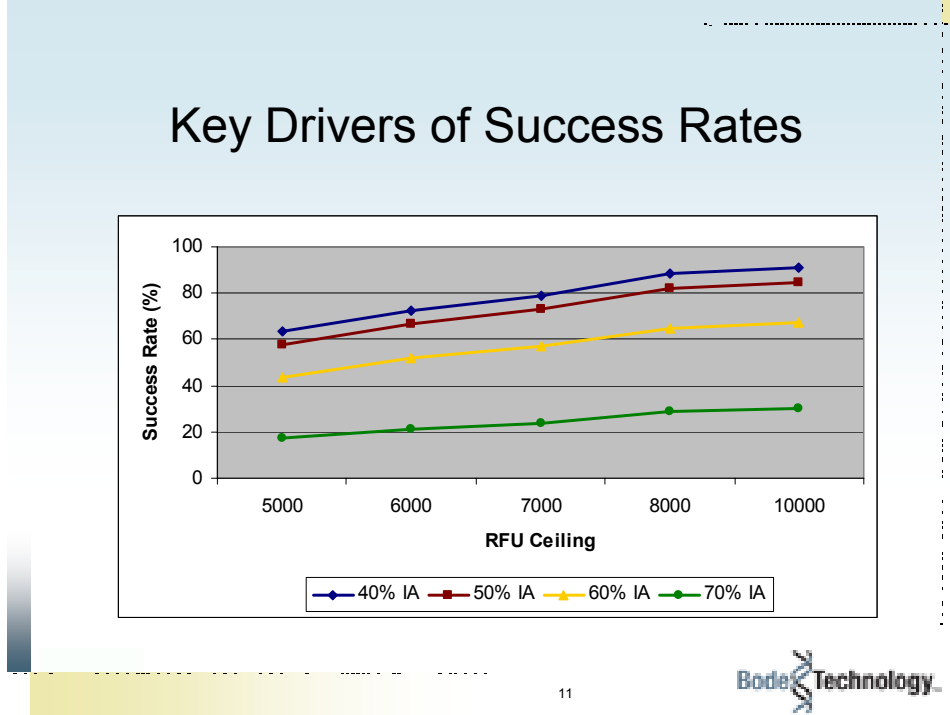


Table 3. Cost of Increased Failure Rate

Impact of Increased Failure Rate

Increased Cost

Example Project: 24,000 Samples

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|----------------------------------|----------------------------------|
| • Failure Rate = 10% | • Failure Rate = 30% |
| • 24000 Profiles = 26664 Samples | • 24000 Profiles = 34272 Samples |
| • Analysts = 2.0 | • Analysts = 2.0 |
| • Analyst Cost = \$130,000* | • Analyst Cost = \$166,833# |
| • Reagent Cost = \$199,980 | • Reagent Cost = \$257,040 |
| • Total Cost = \$329,980 | • Total Cost = \$423,873 |

• **Cost Increased \$93,893**

**Assume Salary \$50K plus 30% overhead
#3.4 additional months*