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HUMAN HEALTH | ENVIRONMENTAL HEALTH

Current Thinking on Future Product Development

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PerkinElmer as a Global Leader…

We are committed to protecting the health of expecting mothers, babies and families

INSTRUMENTATION REAGENTS INFORMATICS

✓*PerkinElmer has helped enable neonatal screening for more than 468 million babies*

✓*Every day 63 infants are given a healthy start in life - thanks to our products*

…*provides tools and services for proven cost effective care*

Current NBS MS Product Portfolio

NeoGram Kit (Derivitized):

- For AAAC analysis
- Methanol based extraction solution
- Acetonitrile based flow solvent and reconstitution solution
- Eight step protocol, evaporation
- Utilize MRM or Full Scan (NL,PS)
- FDA cleared

NeoBase Kit (Non-Derivitized):

- For AAAC & SUAC analysis
- Methanol based extraction & flow solvents
- Two step protocol, no evaporation required
- Utilize multiple reaction monitoring (MRMs)
- FDA cleared

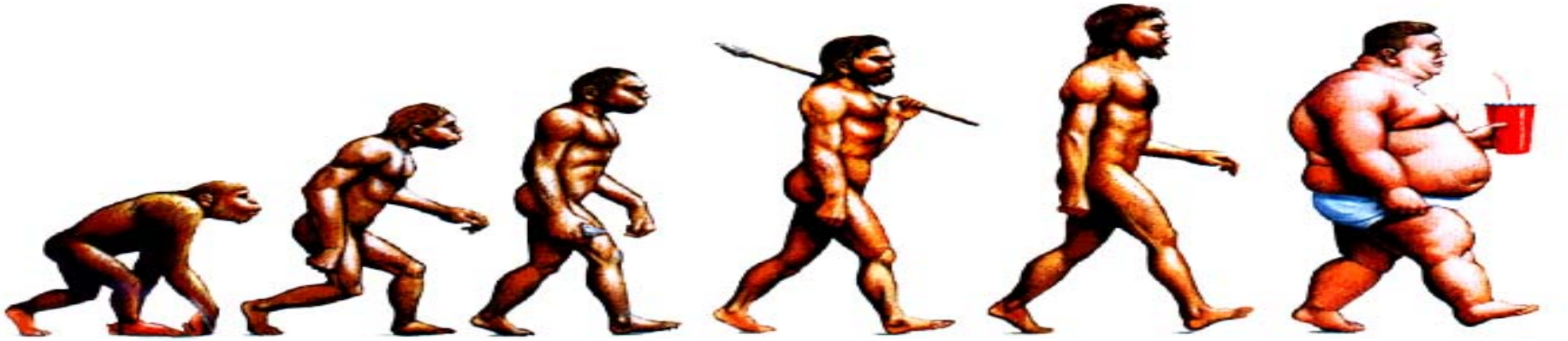
Adding Value to Future Testing

Current MSMS Solution:

- Limited to AA & AC
- Manual sample manipulation
- Analyte specific results
- Screening only

The Future?:

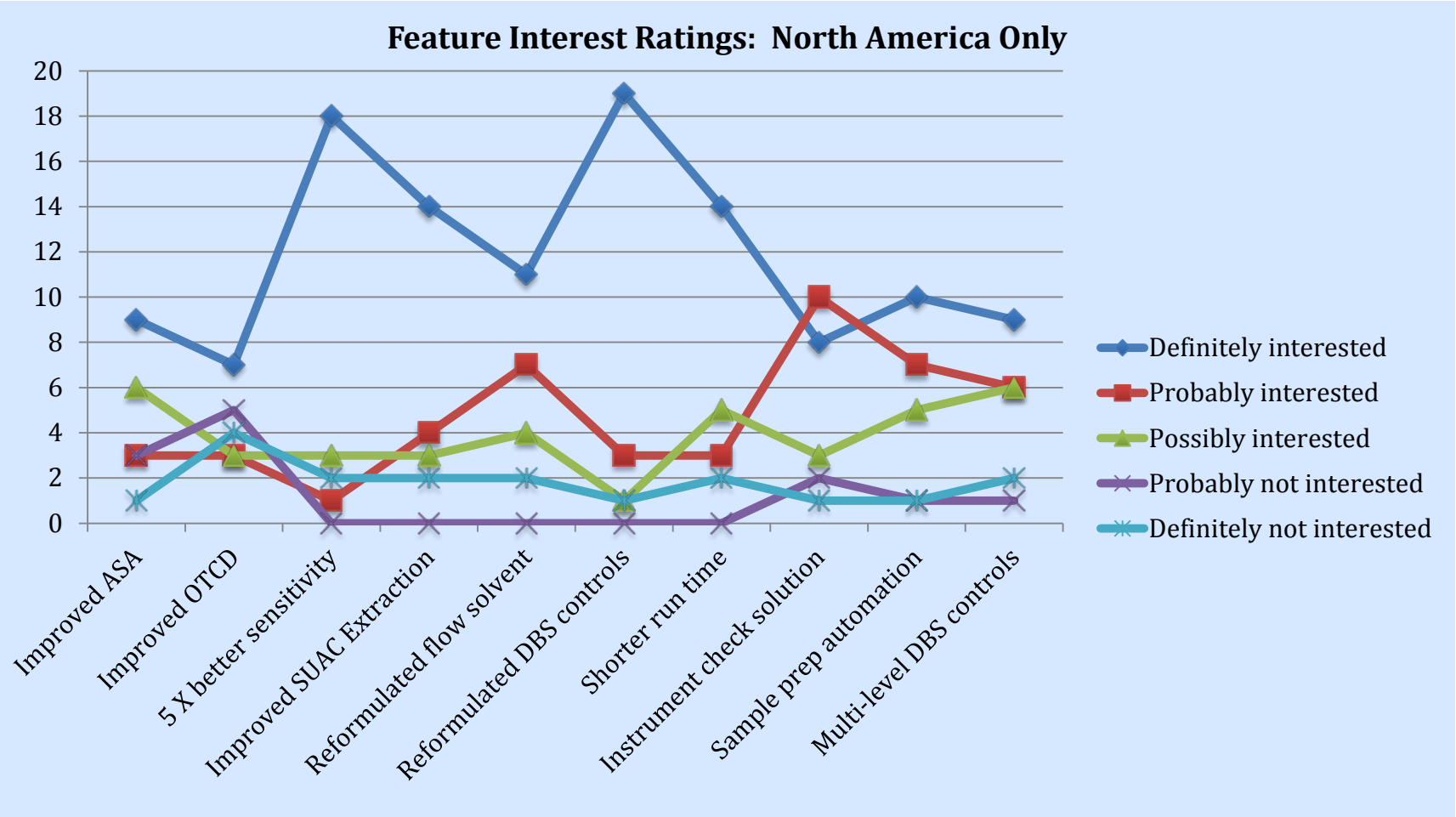
- New markers + enzyme activity
- Automation options
- Disorder logic & results profiling
- Screening & 2nd Tier Testing



Future AAAC Test Design Goals

- Expand disorder menu
  - Add X-ALD, OTC, ASA, ADA
- Improve performance
  - C0, C6
  - SUAC recovery
  - Shorter incubation/run times
  - Improved flow solvent
  - Cleaner samples / Instrument
- Re-align IS and DBS control levels
- Validate on next generation MSMS
- Sample preparation automation options

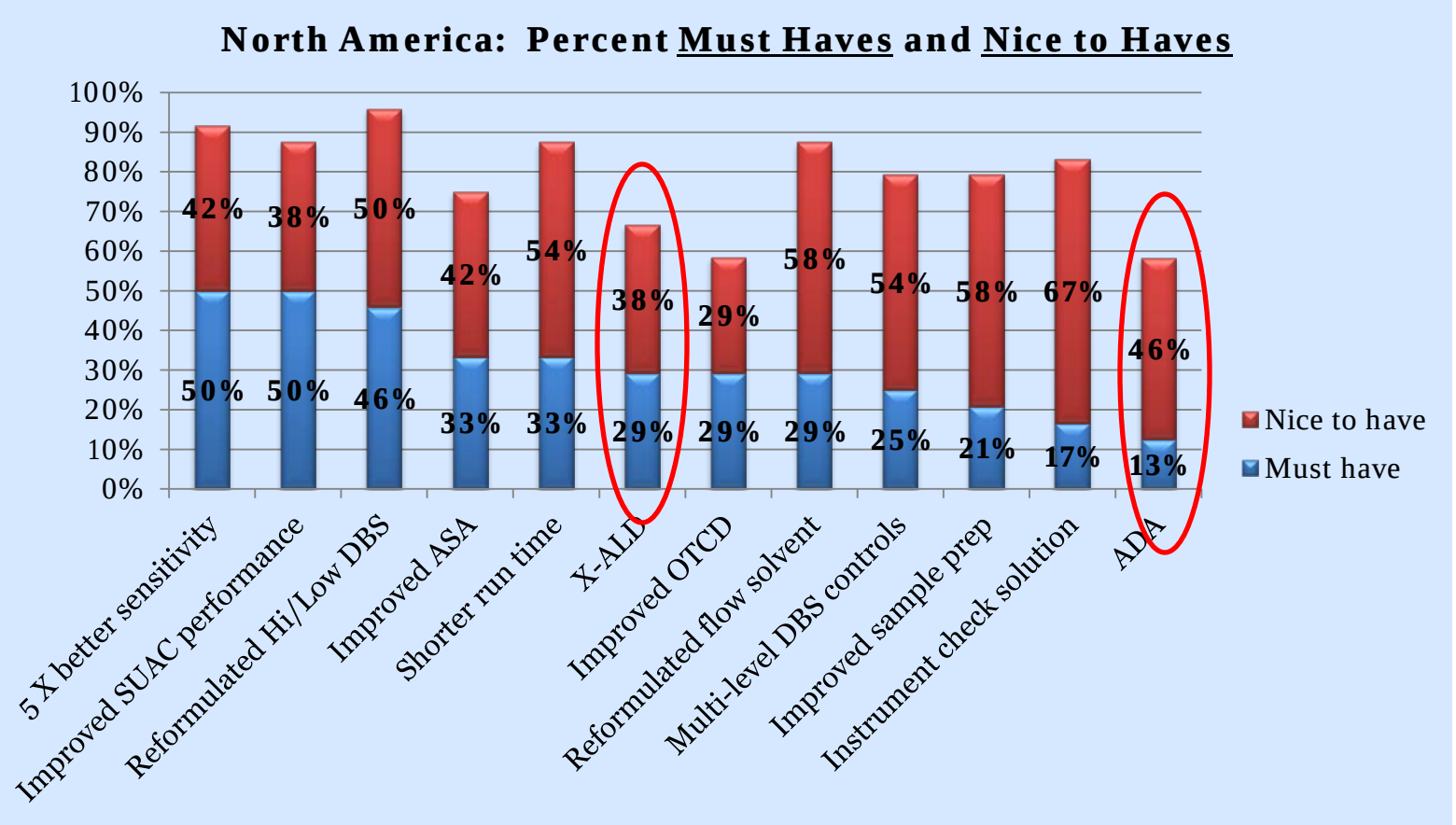
Customer Survey Results



Interest-rating by new feature, out of a total of 24 N.A. survey respondents

Information presented represents product development inputs

Customer Survey Results

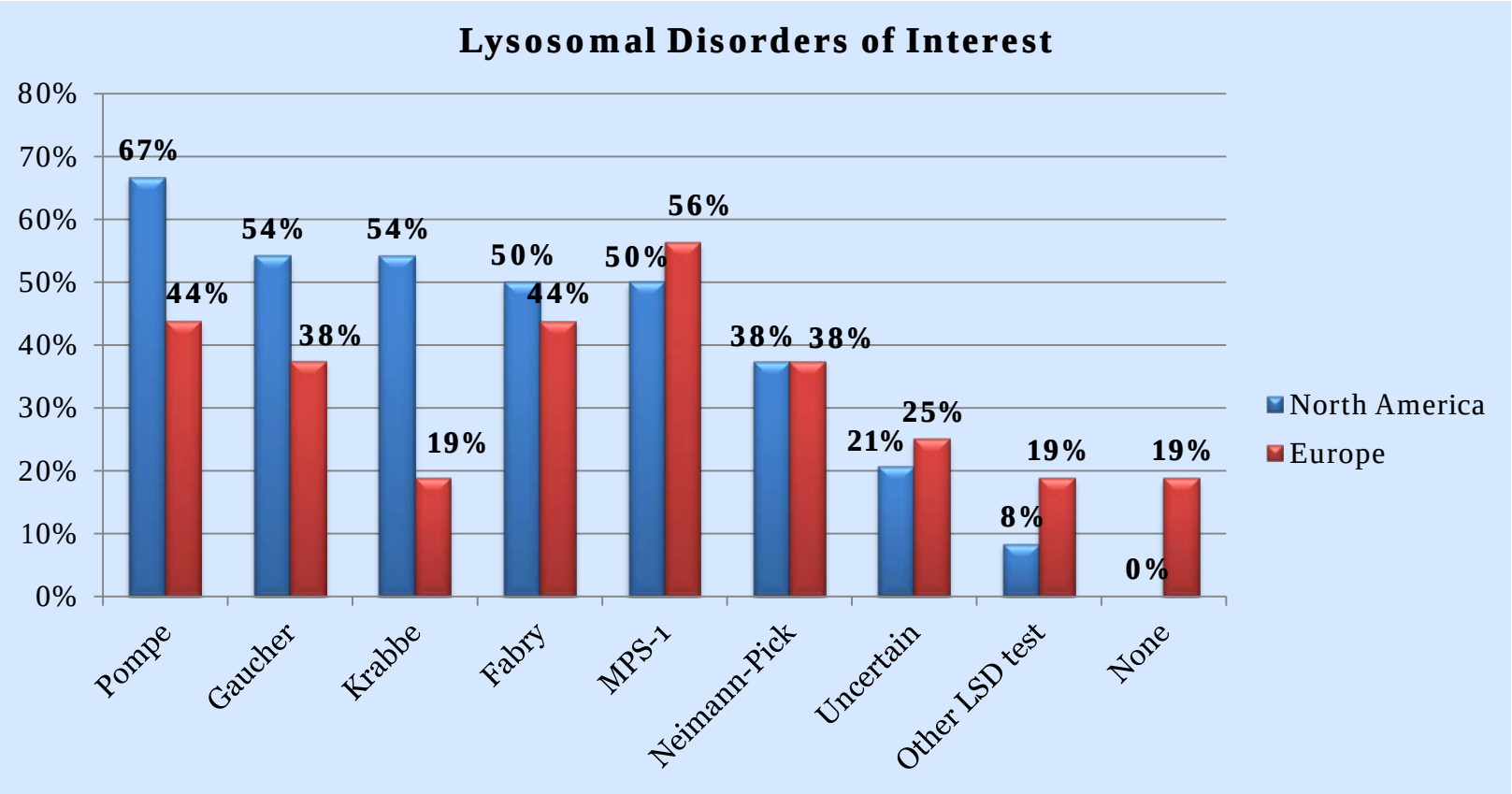


Percent of N.A. respondents for whom each feature is a must have vs nice to have

Most features are must haves for at least 25% of respondents

ADA is a must have for only 13% (3 of 24 respondents)

Customer Survey Results



Respondents asked which lysosomal disorders they might be asked to test for in the next 2-3 years

The only statistically significant difference between North America and Europe was for Krabbe, which was less likely to be required in Europe

Future LSD Test Design Goals

- Test for Fabry, Gaucher, Krabbe, Niemann-Pick A/B, Pompe and MPS I
- Test for all from a single DBS punch with a NBS compatible workflow & throughput
  - Direct injection ESI, no LC column
- High dynamic range (blood/blank ratio) to minimize false positives
- Utilize same equipment used for AAAC
- Provide components to verify instrument and method performance
- Designed and manufactured according to FDA, CE-IVD requirements
- Target end user price of $6.00/ test ($USD) for all six disorders (reagents only)
- Be able to use the same method and workflow to switch between LSDs and AAACs
- Capability to bring additional LSD tests to market in the future

Information presented represents product development inputs

NeoBase™ MSMS Data Suite

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Neobase Data Suite – Current Features
✓ User defined cutoffs per analyte
✓ Default Disorder Groupings available
✓ Disorder Group editor for end-users
✓ User defined simple ratios
✓ Split-view grid for easier review of MS data
✓ Basic Disorder Logic algorithms
✓ Quality Control module
✓ Cutoff Analyzer module
✓ Automated Data Export options

Possible Future Enhancements
➢ LSD Enzyme Activity Support
➢ Improved interaction with R4S database upload
➢ R4S result download /report import
➢ Advanced Data Review tools to help with Borderline / Positive disorder determinations

Workflow Options – Future Possibilities

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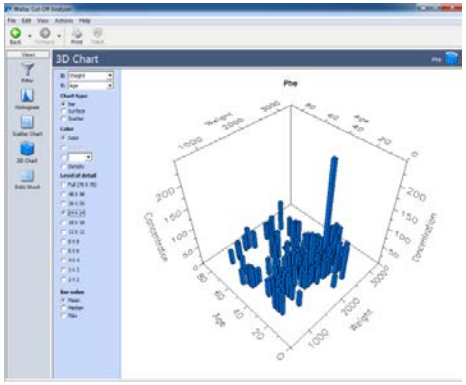
1. Import result file from MSMS in to Data Suite.

2. Data Suite will apply disorder logic based on customer established rules and cutoffs.

3. Data Suite provides options to export samples to R4S for further review. R4S data is imported back to Data Suite. Tools integrated to help finalize determination.

4. Further review may take place using the QC module and the Cutoff Analyzer applications. Results are Accepted.



5. Browser based system imports Data Suite results, allows for Patient Data Entry, and generates translated Patient Report. Additional searches and dashboard information is available.

DS database

Other LIMS

Export File

Information presented represents product development inputs

2nd Tier Testing Future Design Goals

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1st Tier Test	2nd Tier Test	Target Analytes
CAH	Steroid profile	• Cortisol • Androstenedione • 17 Hydroxy-Progesterone
MSUD	Allisoleucine & branched chain amino acids	• Leucine • Isoleucine • Alloisoleucine • Valine
C3- Disorders	Methylmalonic aciduria & propionic acidemia	• Methylmalonic acid • 3-OH propionic acid • Methylcitrate
IEM of Propionate	Methionine & cobalamin metabolism	• Homocysteine • Methylmalonic Acid • 2-Methylcitric Acid
Urea Cycle Defects	Ornithine Transcarbamylase deficiency	• Glutamine • Orotic acid

To reduce false positive rate, parent anxiety and $00Ks / year in confirmatory testing*

* Based upon presentation: Improving newborn screening MSMS based 2nd tier testing, D. Matern, Mayo, 2008

Customer Survey Results

Importance of FDA/CE-IVD Approved Kit	North America	Europe
Required to implement testing	38%	50%
Would prefer to have, but not required	50%	50%
Does not matter, we can implement testing ourselves	4%	0%
Uncertain	8%	0%

Impact of Proposed FDA LDT Guidance*

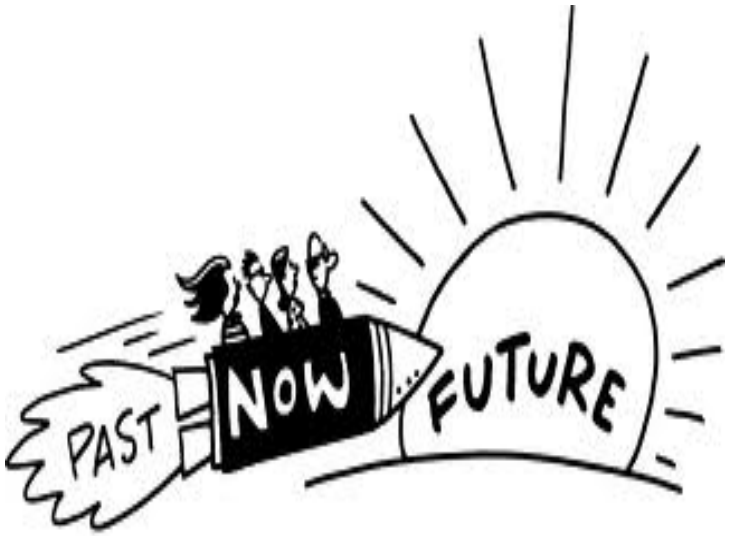
- Within first six months after FDA guidance is implemented, LDT users with existing tests must:
  - Notify FDA of the LDTs provided
  - Begin adverse event reporting for the LDTs
- Premarket submissions (510k or PMA) are required for LDTs:
  - Submit within years 1 to 5 post FDA guidance implementation for high risk LDTs,
  - Submit within years 5 to 9 post FDA guidance implementation for moderate risk LDTs
  - Compliant with FDA Quality System Regulations
    - By time the PMA is submitted or by time the 510k is cleared

Impact that NBS screening labs using LDTs could spend a lot of time and resources to comply with the new guidelines

*Based upon interpretation of October 3, 2014 FDA Draft Guidelines for Actively Regulating LDTs

Summary

- We are committed to protecting the health of expecting mothers & babies
- Our future focus includes:
  - New markers + enzyme activity assays
  - Faster, cleaner assays
  - Workflow automation options
  - Advanced data analysis & results profiling
  - Screening & 2nd Tier Testing



- We will continue to invest in new assays & technology to provide the most efficient and comprehensive FDA cleared NBS solutions available