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FULLY AUTOMATED SYSTEM FOR PKU/GAL/MSUD/BIO USING 384 WELL MICROPLATES.

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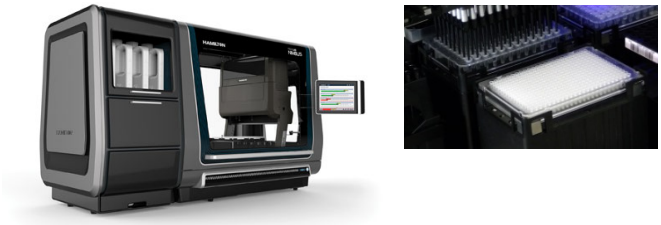
Newborn screening labs are undergoing an increasing set of revolutionary changes when one considers the emergence of new technologies, parameters and solutions. We present in this study the development of fully automated systems for these aforementioned newborn screening labs by utilizing 384 well microplates for the quantification of phenylalanine, total galactose, Leucine/isoleucine, and analysis of enzymatic activity for Biotinidase. This work is part of a continuous innovation program to offer the most appropriate solutions to every newborn screening lab's needs. More sustainable processes help to increase lab productivity by using efficient solutions with reduced physical space, less sample usage, less consumables, reagents and water.



384 well microplates function to maximize sample integrity and use, improve equipment productivity with 75% less sample used, and reduce operational steps in the equipment.

After an initial evaluation of the analytical performance of these NeoLISA kits using both 96 and 384 well microplates (presented at X Congreso Latinoamericano de Errores Inatos del Metabolismo, Santiago, Chile - 2015) this study evaluated approximately 5,000 samples from a routine newborn screening lab using 384 well microplates in a fully automated system. An automated DBS puncher (2.1mm) was used to prepare 384 well microplates. Automation was configured using Nimbus (Hamilton Inc.) and Synergy HT (Biotek Instruments, Inc.), as well as the NeoLISA kits for Phenylketonuria, Galactosemia, Maple Syrup Urine Disease, and Biotinidase Deficiency (Intercientifica).

The full system can run 8 plates of 384 wells in a single routine, auto -adjusting the times for a better and safer performance. The assay protocols were preloaded and the user selected the desired assay routine before loading the appropriate reagents, utilizing the barcode system in the unique/specific spots inside of the equipment. The startup time before the run initiated took approximately 15 minutes.

The results demonstrate the gains obtained by the lab when compared with the gains obtained with equipment that utilized the 96 well microplate format. In short, we have increased the processing capacity with both the same equipment and physical space. The protocol's time was reduced an average of 3 hours while still running the same number of samples. More robust movements during the process reduced the number of steps in 75 %, consumables were reduced in 80 %, use of transfer/filtering microplates were eliminated. Sample size was reduced from 3.00mm to 2.1mm, generating significantly less liquid hazardous waste overall. Additionally, reduction of consumables produced with plastic (reagent volumes - 40%, tips - 50% and microplates - 75%) resulted in a considerable improvement in sustainability.

Performance Caracteristics and Observations using 384 well microplates and the fully automated system :		
Capacity	8 x 384 microplates (3072)	Microplates can be divided for more than one assay.
Consumables	- Tips (unique size) - 384 well microplates	- All reagents are included - Do not require wash / rinse reag / service kit
Daily set up	~ 15 minutes	Load/unload reagents
Run time	~1-4 hours	- PKU/GAL/MSUD ~1 hour - BIO ~4 hours
Reagent Prep	~5 minutes	- Add water (liophilized reagents only) - BIO all reagents ready for use.
Automation	No intervation required after system is started	- Continuos sample and reagent loading - Include Remote / online access support

The results of this study are revolutionary for any labs searching for fully automated systems with high throughput and open platforms, permitting more control and independence overall. Sample usage, in particular, is an important issue when considering the implementation of new parameters in newborn screening programs. In this study we presented an alternative from the 96 well microplate that demonstrates more productivity and less sample usage, utilizing a high throughput platform integration (puncher, liquid handling, microplate reading, and enzymatic colorimetric method) to quantify phenylalanine, total galactose, Leucine/Isoleucine/Valine and analysis of Biotinidase activity.

The next steps involve the integration of the analysis of G6PD activity. These results are considered to be a prototype integration named Nimbus NeoLISA 384. This innovative model shows revolutionary potential to bring continuous improvement to both newborn screening labs and programs geared towards the screening of PKU, GAL, MSUD and Biotinidase.

This project is part of a continuos development program
Simple and revolutionary solutions for sustanable newborn screening labs