



# LEAN-SIX SIGMA APPLIED TO HbA1c TESTING: ORGANISATIONAL IMPACT OF THE D-100 SYSTEM



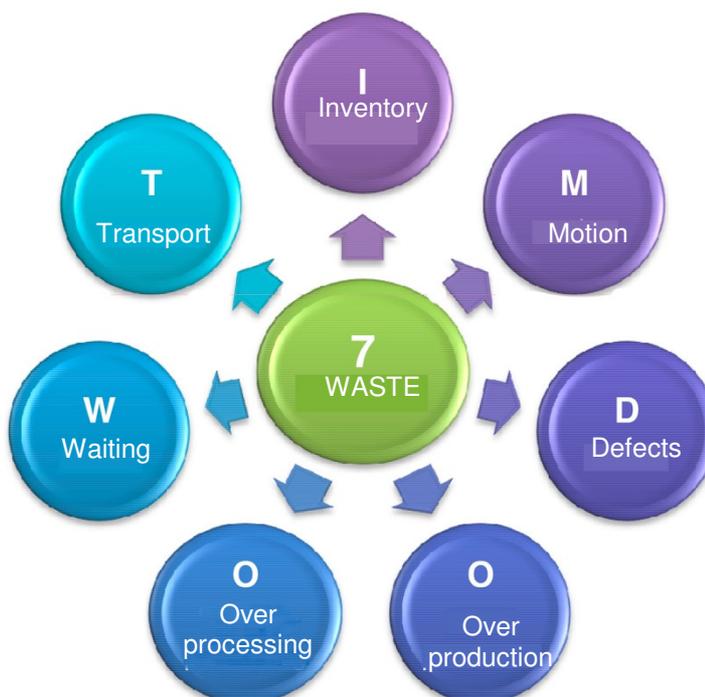
## Bio-Rad Laboratories

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### INTRODUCTION

The Lean-Six Sigma process, originally created for industrial production sites, is also applicable to laboratory activities. It helps to increase the efficiency, flexibility of production, decision-making processes (LEAN: eliminate waste "7 waste TIM WOOD") and also increase the reliability of the processes themselves. This is achieved by reducing variables, costs and increasing process yields (Six Sigma).



### PURPOSE of the experiment

To assess the organisational impact that the new Bio-Rad Laboratories D-100 system would have on the Department of Laboratory Medicine for HbA1c testing, using Lean-Six Sigma.

## MATERIALS AND METHODS

### 1. Instruments



D-100 Haemoglobin Testing System  
Bio-Rad Laboratories, Inc.



HA-8180V  
Menarini/ARKRAY  
ADAMS

### 2. Study of operational flows

- PRE-ANALYTICAL PHASE: current situation and simulation with the D-100 system.
- ANALYTICAL PHASE: comparison of 200 routine samples between the system in use and the D-100 system, and also simulating a "double routine" to assess the system in emergency cases.
- POST-ANALYTICAL PHASE: assessment of the "clinical risk", using the "Mission: Control™" software from Bio-Rad Laboratories.

## RESULTS

### PRE-ANALYTICAL PHASE

#### CURRENT SITUATION

The samples, in dedicated tubes, are separated by the pre-analytic instrumentation, and delivered to the technician who places them in the instrument racks

When placing the tubes into the racks, **the bar code must face the right way in order to be read.**

**The HA-8180V system will accommodate 5 racks of 10 samples at one time.**

#### SIMULATION WITH D-100

The samples, sorted at the pre-analytic station can be placed directly into the instrument racks

The samples do not require any manual orientation of the bar code labels in order to be read, because the D100 system finds them **automatically.**

**You can load up to 10 racks of 10 samples in the D-100 system at one time.**

2 MANUAL STEPS REMOVED  
RESETTING AFTER FAILURE TO READ THE BAR CODE

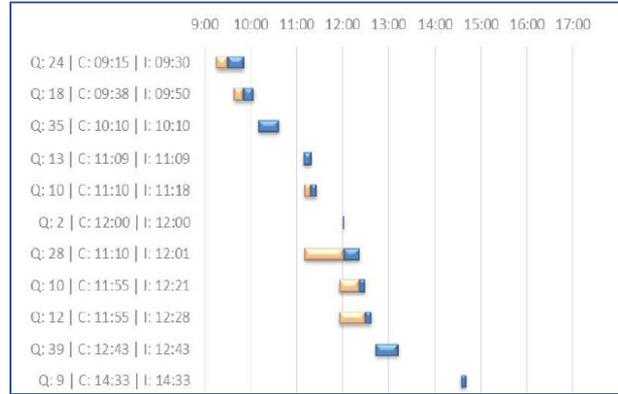
# ANALYTICAL PHASE

## CURRENT SITUATION



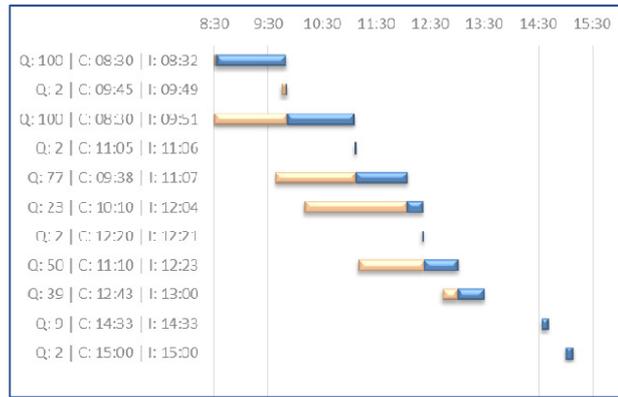
Waiting time  
Analysis time

## SIMULATION WITH D-100



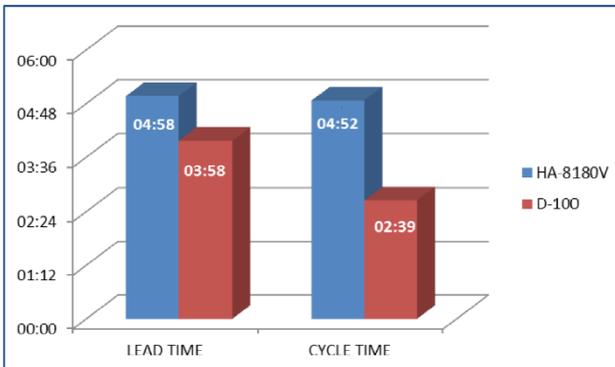
Waiting time  
Analysis time

### What if the routine involved 400 samples?



WAITING TIMES ARE SIGNIFICANTLY REDUCED WITH THE D-100 SYSTEM, EVEN WITH A DOUBLE ROUTINE

## LEAD TIME VS CYCLE TIME



Lead Time: time calculated between the arrival of the sample and the production of the result.  
Cycle Time: machine time.

REDUCTION IN LEAD TIME is BETWEEN 20 AND 36%, AND CYCLE TIME BETWEEN 45 and 48%, ALLOWING WORK WITH A SINGLE SYSTEM AND A SINGLE TECHNICIAN, EVEN WITH A DOUBLE ROUTINE

# POST ANALYTICAL PHASE

## 1. Audit trail

Each sample can be traced, at any time, to the batches of reagents and the calibrators used for the HbA1c analysis.

**More Details:**

Sample  
Internal injection number: DT6B122116-64

Note

Advisor Rules  
Advisor Rule Set Name:  
Last Edited: 14-Feb-2017 14:50:19 View Rules

Method  
Method Type: FastA1C  
Method Version: 0.3  
Method Revision: 8 More Parameters...

Calibration  
Date/Time: 13-Feb-2017 16:29:26

Consumables

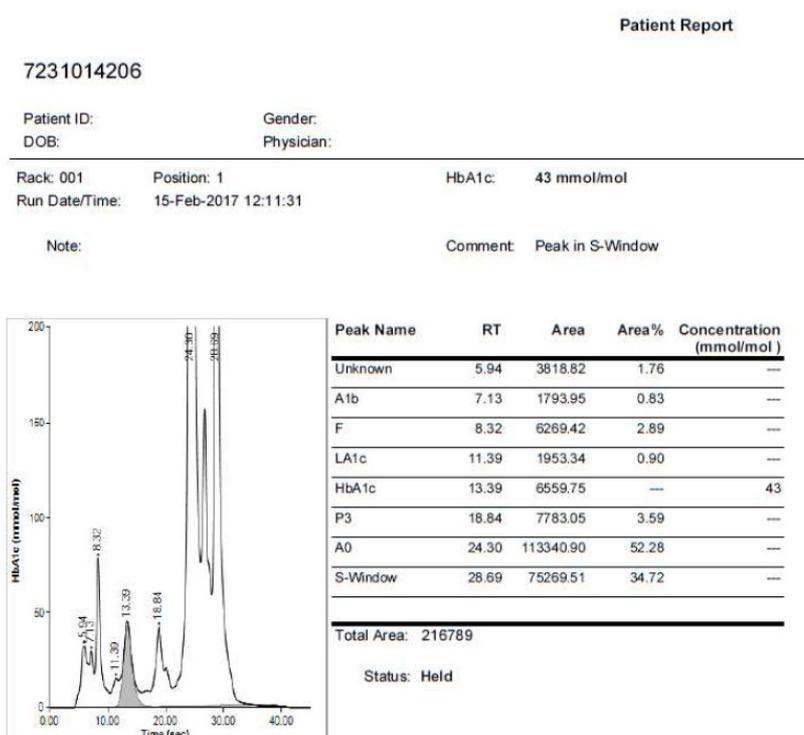
Name	L/N	S/N
Buffer A	64060717	
Buffer B	64076192	
Wash	64060711	
Prefilter	31036AR	118927
Cartridge	31037AC	105027

Comment last modified by  
User:  
Date/Time:

Sample Held  
User:  
Date/Time:

Sample ID entered by  
User:  
Date/Time:

Close



## 2. Clinical risk: Mission Control™

In line with international standard UNI EN ISO15189 and U.S. guidelines CLSI EP23-A, the quality of the services provided has become the main objective of laboratory activities. The risk of reporting an incorrect clinical result can cause harm to the patient, depending on several quality systems criteria adopted by the laboratory.

Mission:Control™ is a software package designed to manage clinical risk. It allows the performance of the analytical methods and equipment in use to be assessed, based on quality control (QC) results. Analysis of the QC data enables the laboratory to assess the current risk of reporting incorrect patient results, to quantify a possible risk reduction (based on instrumental performance). Selection of appropriate rules and frequency of application minimise the probability of reporting incorrect results.

Based on the work flows proposed, risk simulations have been carried out, enabling measurement of the capacity of the QC system to:

- identify clinical errors (**E(QCE)** - Expected number of QC Events to detect the error)
- estimate clinical risk levels by calculating the number of incorrect results already reported (**E(NUF)** - Expected Number of Unreliable results Final)
- estimate clinical risk levels by calculating the number of incorrect results not reported (**E(NUC)** - Expected Number of Unreliable results Correctable)

## CONCLUSIONS



**REDUCED MANUAL WORK BY THE OPERATOR  
DAILY AND ROUTINE MAINTENANCE MINIMISED**



**REDUCED WAITING TIMES FOR SAMPLE ANALYSIS**



**IMPROVED PRODUCTIVITY AND REDUCED REPORTING TIME**



**REDUCED VOLUMES OF WASTE AND DISPOSAL COSTS**

The D-100 Hemoglobin Testing System, generally emits a very low daily quantity of waste (less than 1 litre for the routine of 200 samples), thus optimising overall disposal costs.



**COMPLETE TRACEABILITY**

Reagents and calibrators are automatically recognised by the system, traced in the software and stored in the archive. Also, calibration curves are stored in such a way that for each sample performed it is always possible to trace, even after a long period of time, the batch of reagents and the calibration curve used.



**REDUCED ANALYTICAL RISK**

The D-100 Hemoglobin Testing System is **reliable**, with a clinical risk calculated, based on the checks performed, **practically zero** with  $E(Nuf) < 1$  and  $E(Nuc) < 1$ .

The analytical performance of the D-100 Hemoglobin Testing System associated with Mission Control would allow the laboratory to streamline quality control management resources for glycated hemoglobin testing.

*We would like to thank Dr Maria Rosa Bergami (Lab Optimisation Services Expert) for her collaboration*