

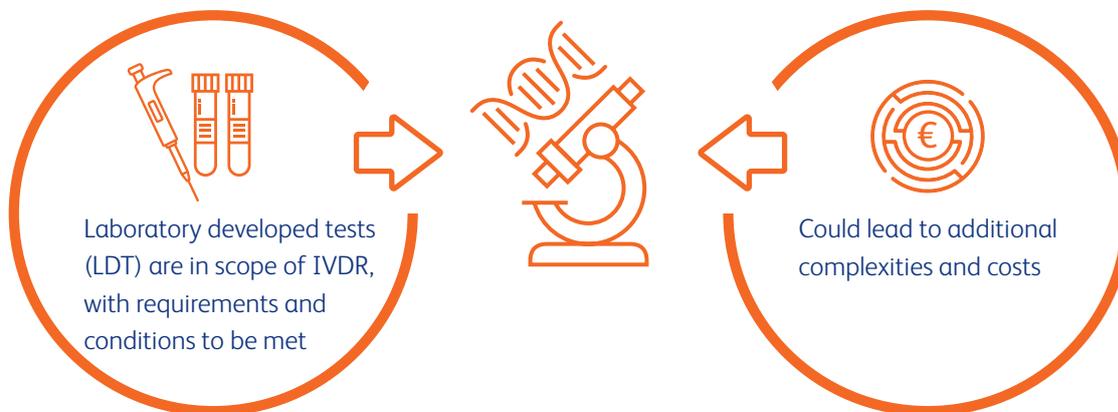
# Improve laboratory workflow:

BD OneFlow™ assays with  
BD FACSLyric™ Flow Cytometer

*In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) establishes a **new regulatory framework** for *in vitro* diagnostic medical devices and laboratory developed tests (LDTs).



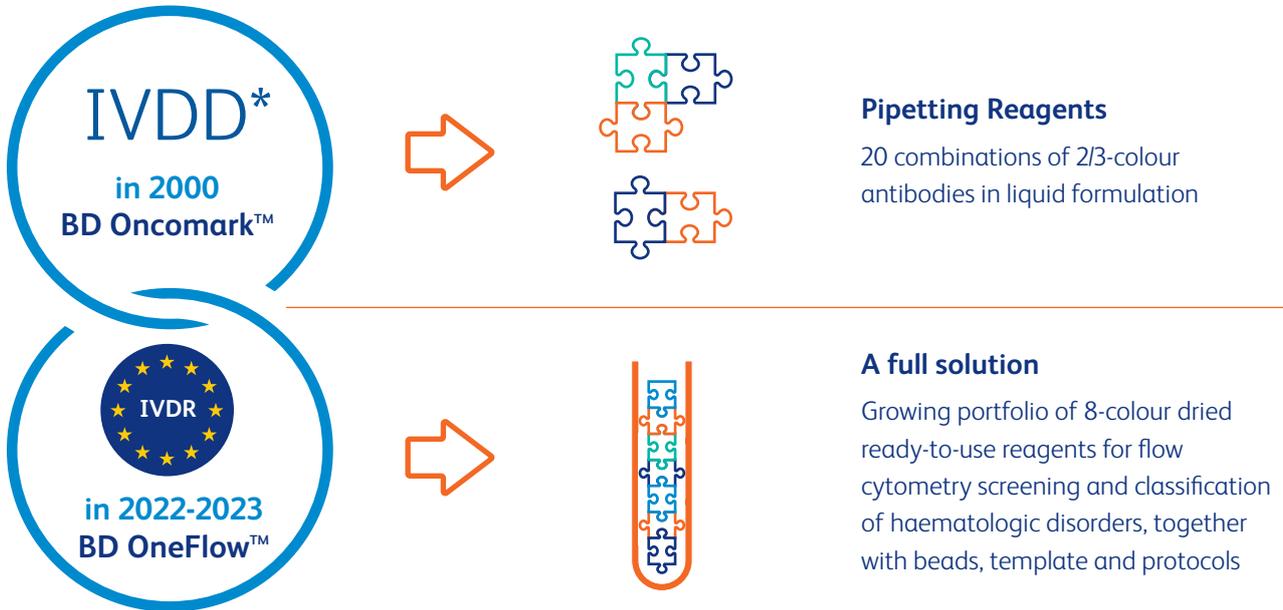
## Impact on Diagnostic Laboratories



**BD OneFlow™ Haematological testing** is standardised and (EU) 2017/746 (IVDR) compliant

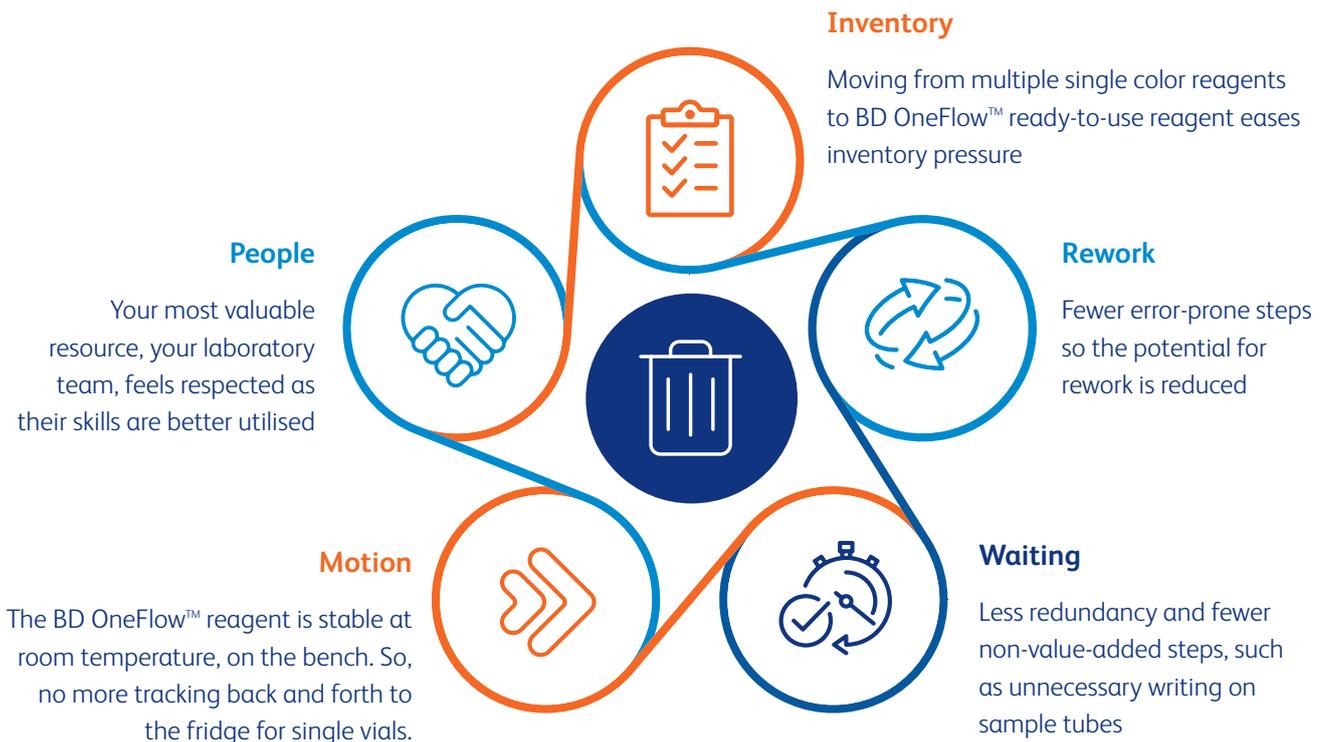


# BD has a history of helping your laboratory evolve and remain doing so by providing *IVDR compliant reagents*



\*European In Vitro Diagnostic Medical Device Directive 98/79/EC (IVDD)

## Standardisation and automation with BD OneFlow™ reduces *Wastes*

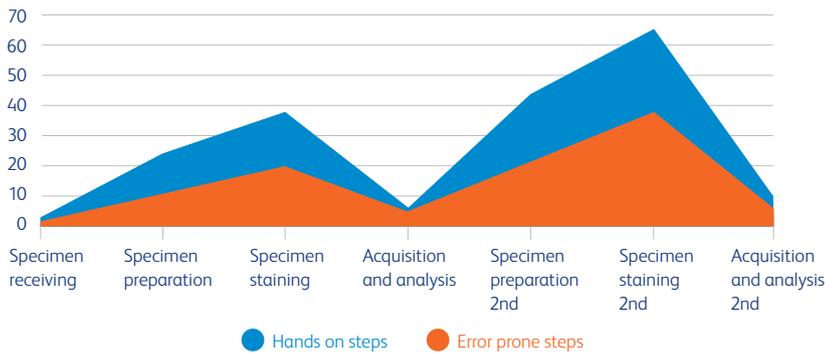


# Comparison of 3 different workflows when considering as condition of interest a Chronic Lymphocytic Leukemia. The results are shown below.

## Scenarios

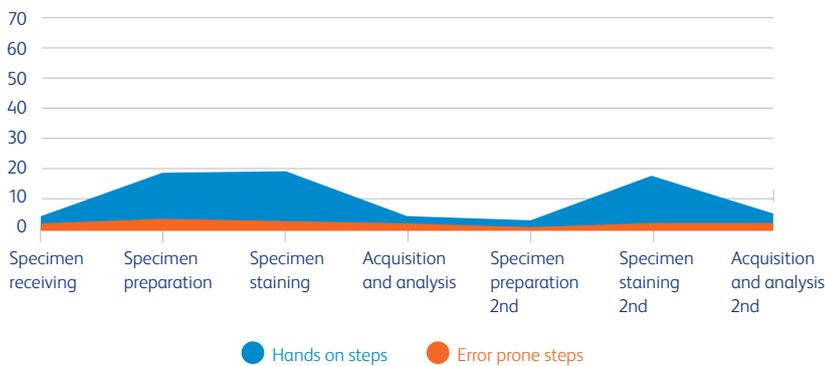
### 3-color cocktails + drop in on BD FACSCanto™ II Flow Cytometer

Specimen stained with 3x 8-color user defined assay panels comprising each of a 3-color cocktail + 5 single color reagents as drop in\*\*



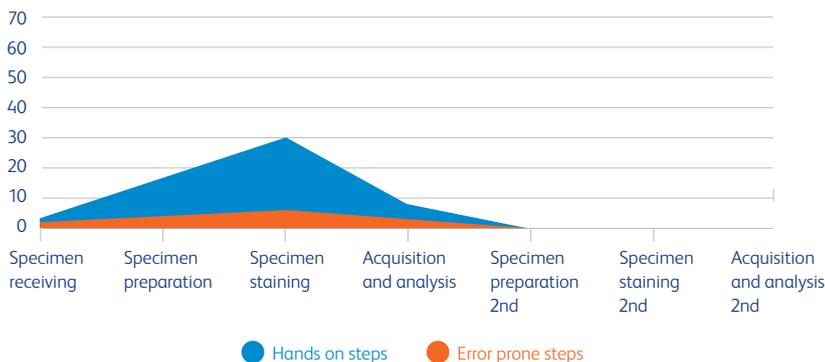
### BD OneFlow™ on BD FACSLyric™ Flow Cytometer\*

Specimen stained with BD OneFlow™ LST and BD OneFlow™ B-CLPD T1 reagents in two sequential steps\*\*



### BD OneFlow™ on BD FACSLyric™ Flow Cytometer - One Step

Specimen stained with BD OneFlow™ LST and BD OneFlow™ B-CLPD T1 reagents in one parallel step\*\*



**BD OneFlow™ assay on BD FACSLyric™ Flow Cytometer improves laboratory workflow and efficiency:**

#### BD OneFlow™ Reagent

**69%**  
Fewer hands-on steps during specimen preparation and staining

Reduced redundancy and potential for reworking

#### BD FACSLyric™ Flow Cytometer:

Automation reduces potential for analytical error

**84%**  
Fewer error prone steps

**88-92%**  
Fewer critical error prone steps

Reduction in number of process steps along the workflow

\* Results between BD FACSCanto™ II and BD FACSLyric™ Flow Cytometers were comparable as improvements in steps are attributed mainly to BD Oneflow™ reagents

\*\* See back page for reagents used in this case study

**\*\* Reagents compared:**

Three (3) 8-color user defined assay panels were designed for the comparison with two (2) BD OneFlow™ ready to use panels (BD OneFlow™ LST and BD OneFlow™ B-CLPD T1) ; each user defined assay panel was designed as a combination of one ready-to-use 3-color cocktail and additional 5 single color reagents.

This workflow has been foreseen as a 2 step staining: the specimen would be stained first with the user defined assay panel 1 and subsequently, in case of further investigation needed, with user defined assay panel 2 and 3 in parallel.

**VS**

**BD OneFlow™ LST:**

CD8 FITC/Lambda FITC/CD56 PE/kappa PE/CD5 PerCP-Cy5.5/ CD19 PE-Cy7/TGRgd PE-CY7/CD3 APC/CD38 APC-H7/ CD4 BD Horizon™ V450/CD20 BD Horizon™ V450/CD45 BD Horizon™ V500-C

**BD OneFlow™ B-CLPD T1:**

CD23 FITC/CD10 PE/CD79b PerCP-Cy5.5/CD19 PE-CY7/CD200 APC/CD43 APC-H7 / CD20 BD Horizon™ V450/CD45 BD Horizon™ V500-C

Two workflows have been foreseen as a possible processing approach : in one workflow, the specimen would be stained first with the BD OneFlow™ LST and subsequently, for further investigation, with BD OneFlow™ B-CLPD T1 (sequential staining). In the second workflow, the same specimen would be stained at the same time with BD OneFlow™ LST and with BD OneFlow™ B-CLPD T1 (parallel staining).

BD Flow Cytometers are Class 1 Laser Products

 BD FACSLyric™ Flow Cytometer with the BD FACSuite™ Clinical and BD FACSuite™ applications and BD FACSCanto™ II are in vitro diagnostic medical devices bearing a CE mark.

 BD OneFlow™ LST and BD OneFlow™ B-CLPD T1 are in vitro diagnostic medical devices bearing a CE mark and are CE certified by BSI Group The Netherlands B.V. (Notified Body Number = 2797).

CE-IVD BD FACSCanto™ II and BD Oncomark™ reagents are no longer for sale.

BD Europe, Terre Bonne Park - A4, Route de Crassier 17, 1262 Eysins, Switzerland.

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