Quality assurance activities at LabRobot

- For better products and satisfied customers

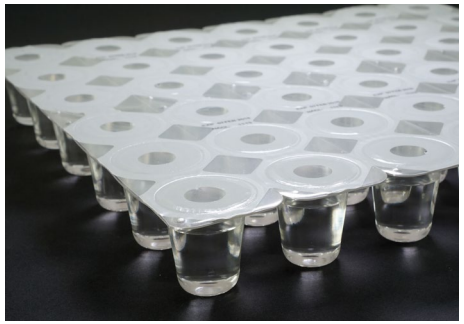
Jimmy Kjellén, Quality Manager

Quality Assurance at LabRobot

DISTRIBUTOR MEETING 2019



Dilucup System

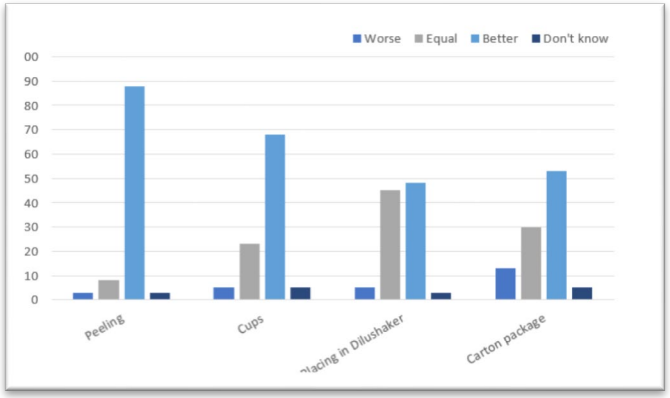


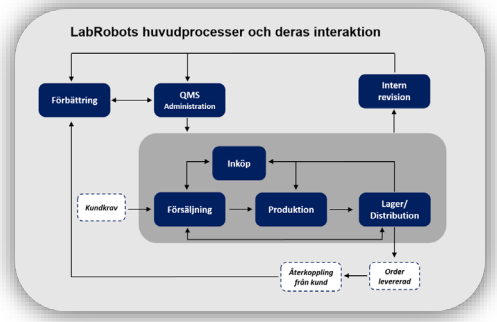




ISO 9001:2015





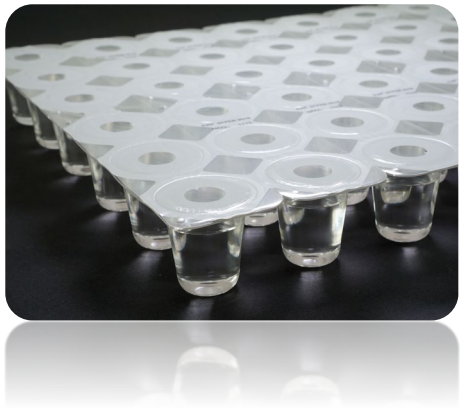


Quality Control of Dilucup™ ELEGANCE

PHYSICAL/CHEMICAL EVALUATION OK? ☑

MICROBIOLOGICAL EVALUATION OK? ☑

Issue certificate and release batch →





LabRobot

QUALITY CERTIFICATE

BATCH: 1608
PRODUCT: DILUCUP® ELEGANCE – MRD 9.0 mL
ARTICLE: 40DEMRD6
EXPIRY DATE: 20-APR-2021

Dilucup ELEGANCE

The expiry date is 20 months from production date when Dilucups are kept in the sealed aluminium package at +2°C to +25°C.
Once the aluminium package is opened Dilucups must be kept dry at +2°C to +8°C and be used within 3 months.

Medium formula
Buffered solution containing
NaCl 0.85%, Peptone 0.1% and de-ionized water (according to EN ISO 6887-1:2017).

pH
Adjusted to 7.0 ± 0.2 at 25°C (according to EN ISO 6887-1:2017).

Sterilization
E-Beam dose: >25 kGy.
Sterility control shows < 1 CFU/mL after radiation.

Volume control
Target volume is 9.0 mL.
Density at 20°C: 1.004 which means that 9.0 mL= 9.04 g.
Accepted deviation < ± 2% (according to EN ISO 6887-1:2017).
Minimum measured deviation: -0.05 %
Maximum measured deviation: 0.75 %.

Productivity
Verified with E. coli strain WDCM 00012 and S. aureus strain WDCM 00034 (according to EN ISO 11133:2014).
Results for this batch: E. coli 5 %, S. aureus -17 %.

Volume, pH, sterility & productivity certified by:

September 5, 2019

Jimmy Kjellén
Quality Manager

Warranty
Warranties arising in connection with the use of the products where such liability results from the actor omission of LabRobot Products AB shall be limited to the free replacement of the product(s) in question. For sterility guaranty, please refer to our ***Sterility Test Procedures in Dilucup Production****.*

LabRobot Products AB – SWEDEN
www.labrobot.com

BPRN-043 / 2019-09-04

Quality Control of Dilushaker III



- Software OK? ☑
- LED panel OK? ☑
- Foot pedal OK? ☑
- Power supply OK? ☑
- Stability OK? ☑
- RPM OK? ☑
- Aesthetics OK? ☑

Issue certificate and release →



LabRobot

QUALITY CERTIFICATE

PRODUCT: DILUSHAKER III DIGITAL
PRODUCT NUMBER: 40DS42PRXT
SERIAL NUMBER: 190138
FIRMWARE VERSION: SKAK 42:15

Dilushaker III digital

Technical specifications
Motor: PAPST VD-3-43.10
Speed: 400 rpm ~ 600 rpm ±5%
Mains: AC 100-240 V 50/60 Hz
Dimensions: LxWxH 345x260x118 mm
Weight: 5,4 kg

This instrument was released by Quality Control after a full check of the following criteria. All criteria satisfied the requirements as defined in LabRobot Procedures.

- Foot Pedal Function
- Time
- Stability
- Appearance
- Power Supply
- Speed:

The instrument used to measure this criterion was calibrated and met the LabRobot standards of traceability. The measures are traceable to international standards, i.e. COFRAC or DKD.

Measurement results:

Speed	Value	Value Displayed
1	400	403 rpm
2	500	501 rpm
3	600	600 rpm

August 9, 2019

Jimmy Kjellén
Quality Manager

Warranty
Warranties arising in connection with the use of the products where such liability results from the actor omission of LabRobot Products AB shall be limited to the free replacement of the product(s) in question.

LabRobot Products AB – SWEDEN
www.labrobot.com

BPRN-047 / 2019-04-01

Quality Control of Dilucup™ ELEGANCE

PHYSICAL/CHEMICAL EVALUATION

PRE PRODUCTION

- pH control of product
- Weight and volume dispensed in cups

DURING PRODUCTION

- Weight and volume dispensed in cups
- Tearing test
- Peeling test
- Vacuum control
- Aroma test (MRD only)
- Print (label) inspection

POST PRODUCTION

- pH control of product
- Weight and volume dispensed in cups
- Vacuum control
- Peeling test

Quality Control of Dilucup™ ELEGANCE

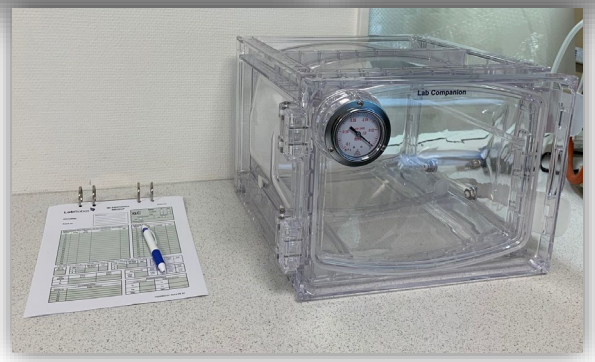
MICROBIOLOGICAL EVALUATION

Test	Why?	When?	QC limits
Contamination test	To determine initial and final microbiological load	Before and after sterilization	< 50 CFU/ml before sterilization < 1 CFU/ml after sterilization
***Bacillus pumilus* test**	To determine efficiency of sterilization	After sterilization	< 1 CFU/ml
Productivity test	To ensure that Dilucup solution doesn't affect growth of microorganisms (*E. coli* and *S aureus*)	After sterilization	< 30 % difference between sample t_0 min and t_{45} min

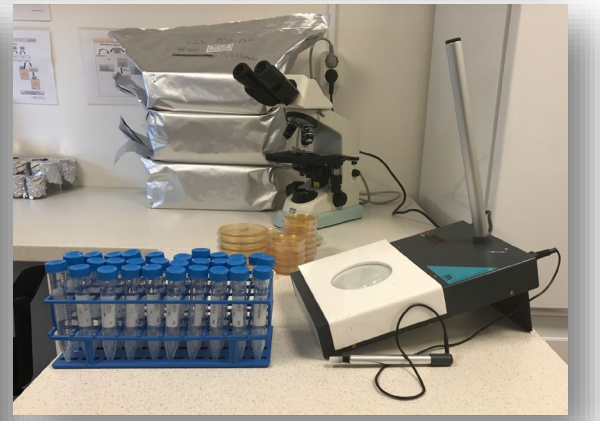
Interior of Quality Control Lab











Interior of Clean Room



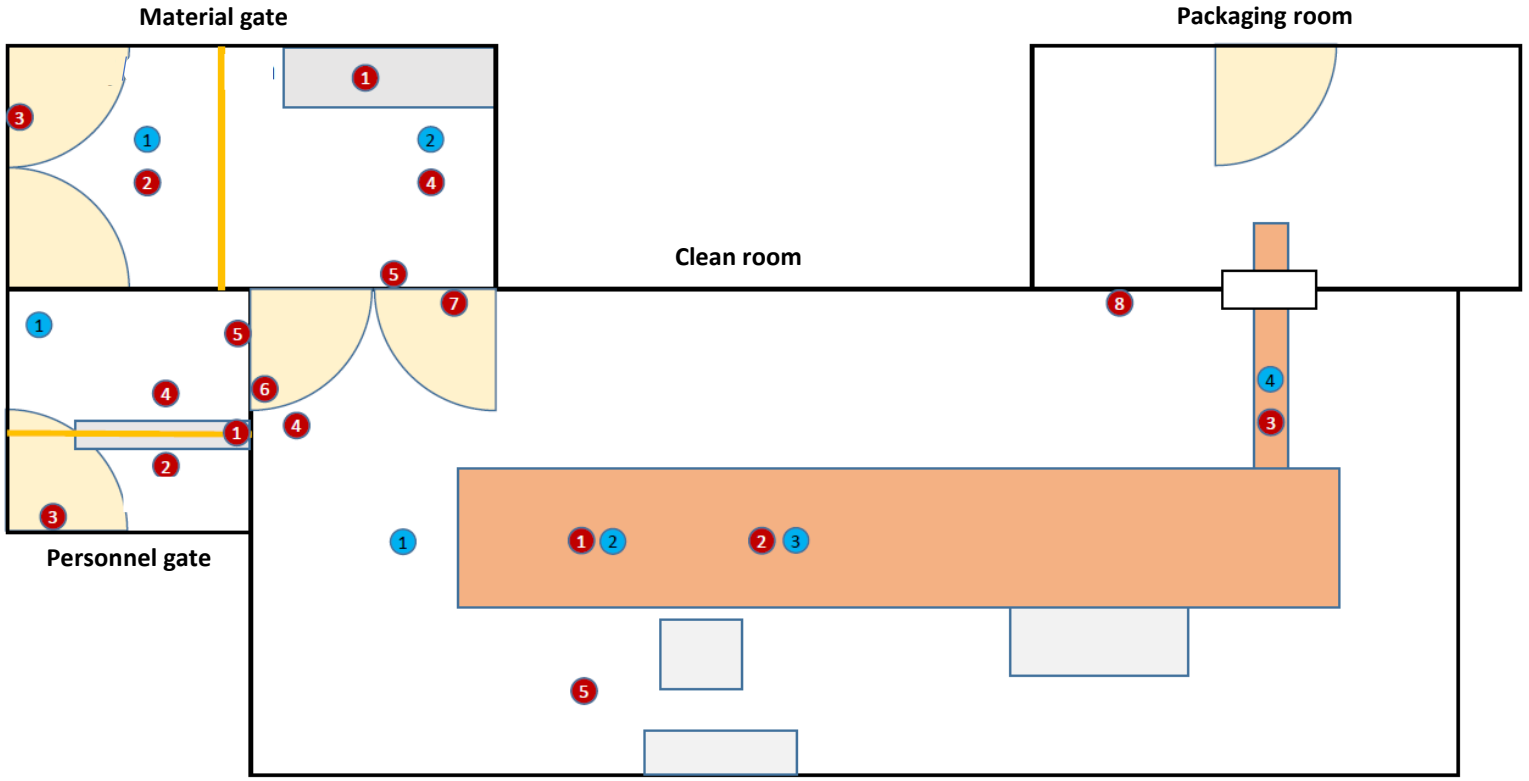





Quality Control Clean Room

Quality control points

Air samples Surfaces



Contact plates for surface sampling



Regular plates for air sampling



QC TEAM

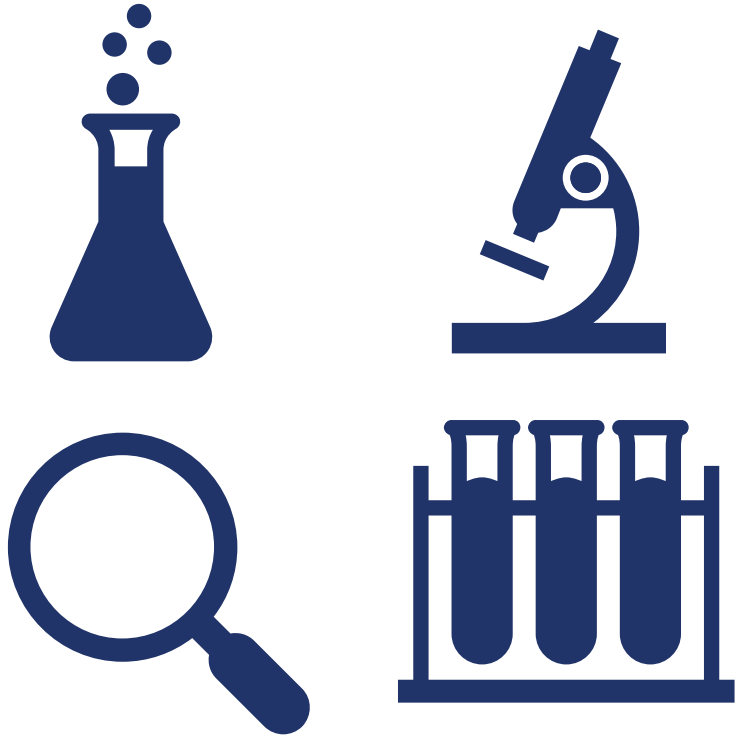


Karin Vilén
Laboratory Manager



Elisabet Núñez Gaitan
Laboratory Technician

- Preparation of products, handling of chemicals
- QC testing scheme for Dilucup
- Lab studies/Competition analysis
- Product development
- Follow-up customer claims

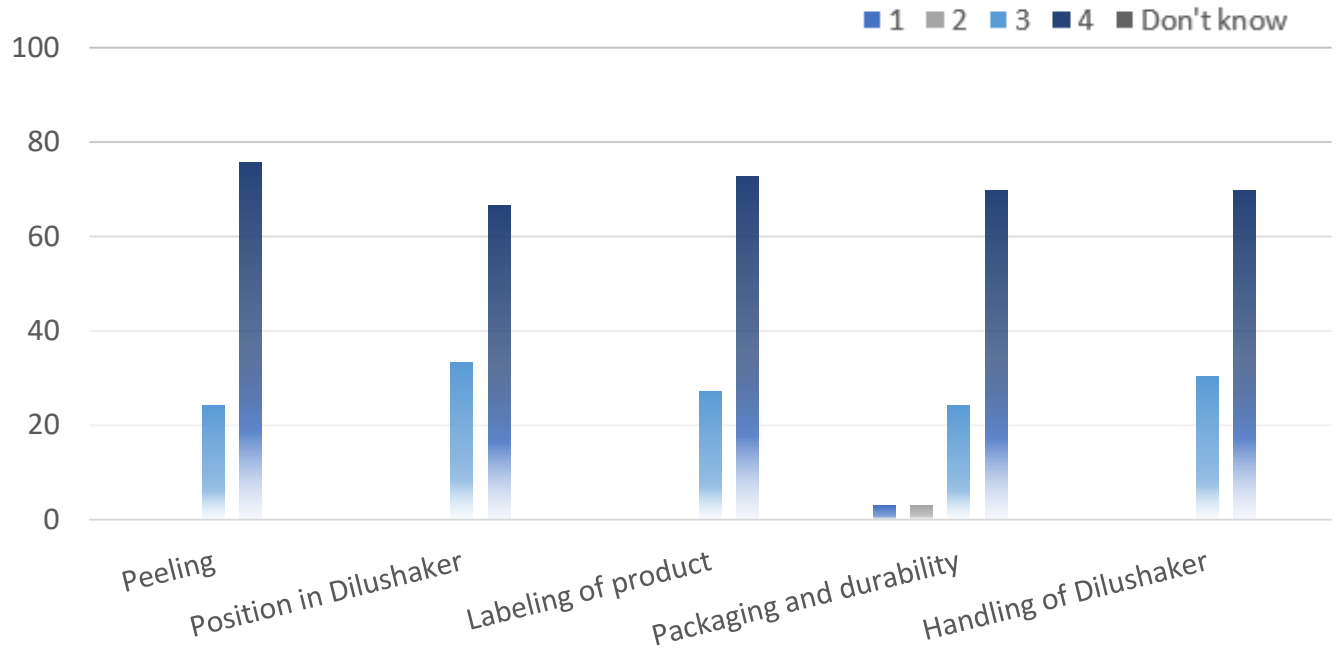


Customer Survey 2019

- Survey sent to 122 customers and distributors → 27 % answered
- Questions on customer views on:
  - LabRobot as supplier
  - Ease of use of the Dilucup system
  - Quality of the Dilucup system
  - Delivery quality
  - Products and services
  - Customer service
  - ISO 9001/14001
  - Dilucup Elegance
- Rating from 1 (lowest) to 4 (highest)
- GQI (Global Quality Index) at 3.84 compared to 3.70 2018.

Customer Survey 2019

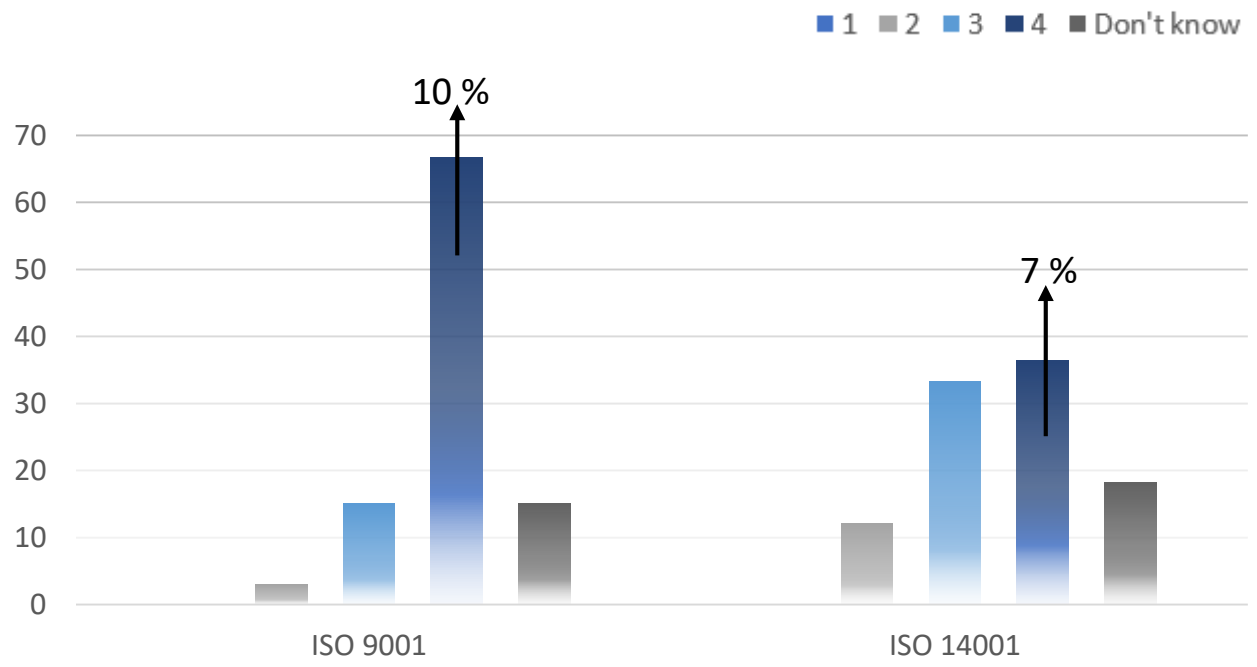
- Ease of use of the Dilucup system



	Average	
Question	**2019**	**2018**
Total	3.69	3.50
Peeling	3.76	3.26
Position in Dilushaker	3.67	3.56
Labeling of product	3.73	3.63
Packaging and durability	3.61	3.59
Handling of Dilushaker	3.70	3.48

- **Dilucup System generally percieved as easy to handle**
- **Experience of peeling has improved**

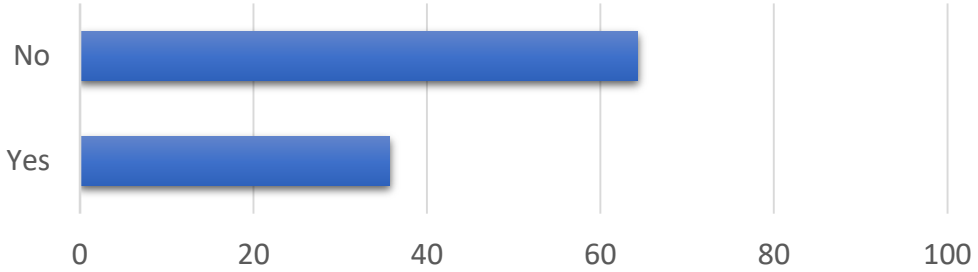
- Quality/Environmental assurance



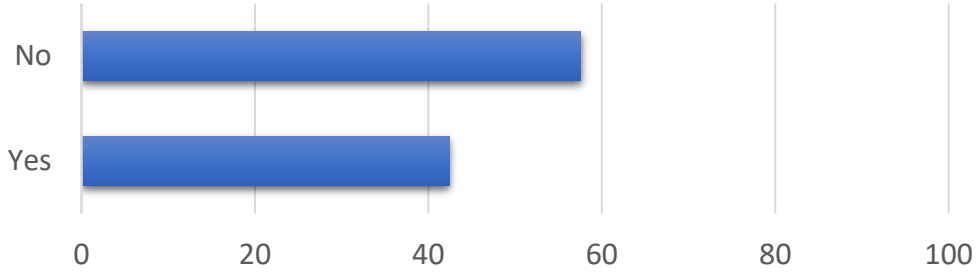
- **Customers view LabRobot certification to ISO 9001 as important**
- **ISO 14001 certification slightly less important to customers**

LabRobot on the web and in social media

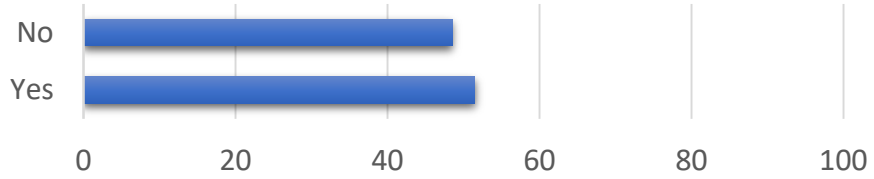
Since autumn 2018 LabRobot has a company page on LinkedIn, have you noted this?



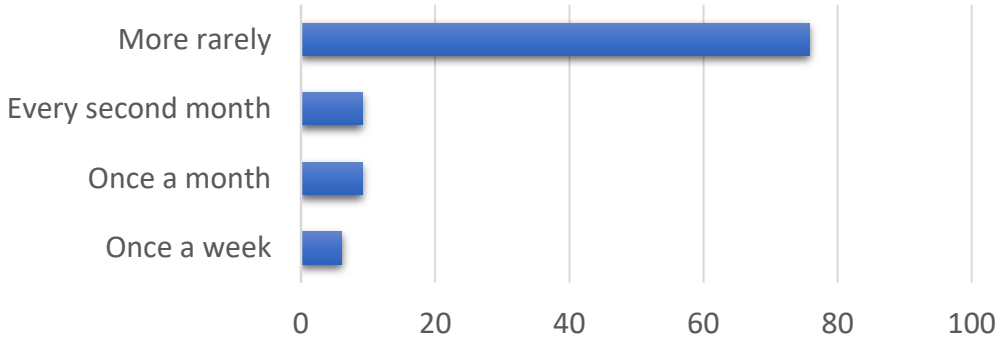
Would you appreciate more activity from LabRobot on social media?



LabRobot launched an updated website in the autumn of 2018, have you visited the website since that?



How often do you visit LabRobot's website?



DILUCOR CAR SYSTEM

- DiluCor CAR System for customer claims
- Easier to track customer claims

  → Faster handling time → DiluCor reference # for compensation
- Register at www.labrobot.com
- Customer claims Dilucup:
  - Product type MRD/NACL/BPW
  - Batch/Lot no.
  - Box number
  - QR code information
- Customer claims Dilushaker:
  - Serial no.

Improvements since 2017

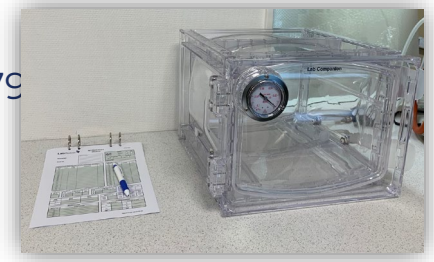
- New vision for LabRobot
- ISO 9001:2015 updated certification
- DiluCor CAR System for customer claims
- Extended expiration time 30 months (unopened bags) from bat 1617
- Extended expiration time 3 months (opened bags)
- QR Code on Dilucup since batch 1607
- New logotype on boxes from batch 1591
- New improved peeling (Magic!) since batch 1479
- New vacuum chamber and updated test
- Phileas 250 disinfection (H_2O_2) in cleanroom

LabRobot – A PART OF AddLife

Developing sustainable dilution systems for today and tomorrow

ISO 9001:2008 Transition ISO 9001:2015





DiluCor

Projects 2019-2020 and beyond

- Lower irradiation dosage
  - Higher product integrity
  - Potential to keep current price level
- Measuring of particles in clean room
- Quality Network within AddLife
- Recycled materials in plastic raw materials
- Enlarged storage area, packaging room and cold storage room

LabRobot

Volume Assurance of Dilucup Elegance

Quality control of volume:

- every cup
  - manually measured at the beginning and end of production
- every blister (3x7 or 6x7)
  - automatically weighed during production

ISO 6887-1 requirement: 9 mL	± 2 %
LabRobot requirement: 9 mL	± 1 %



Volume assurance of Dilucup Elegance during production





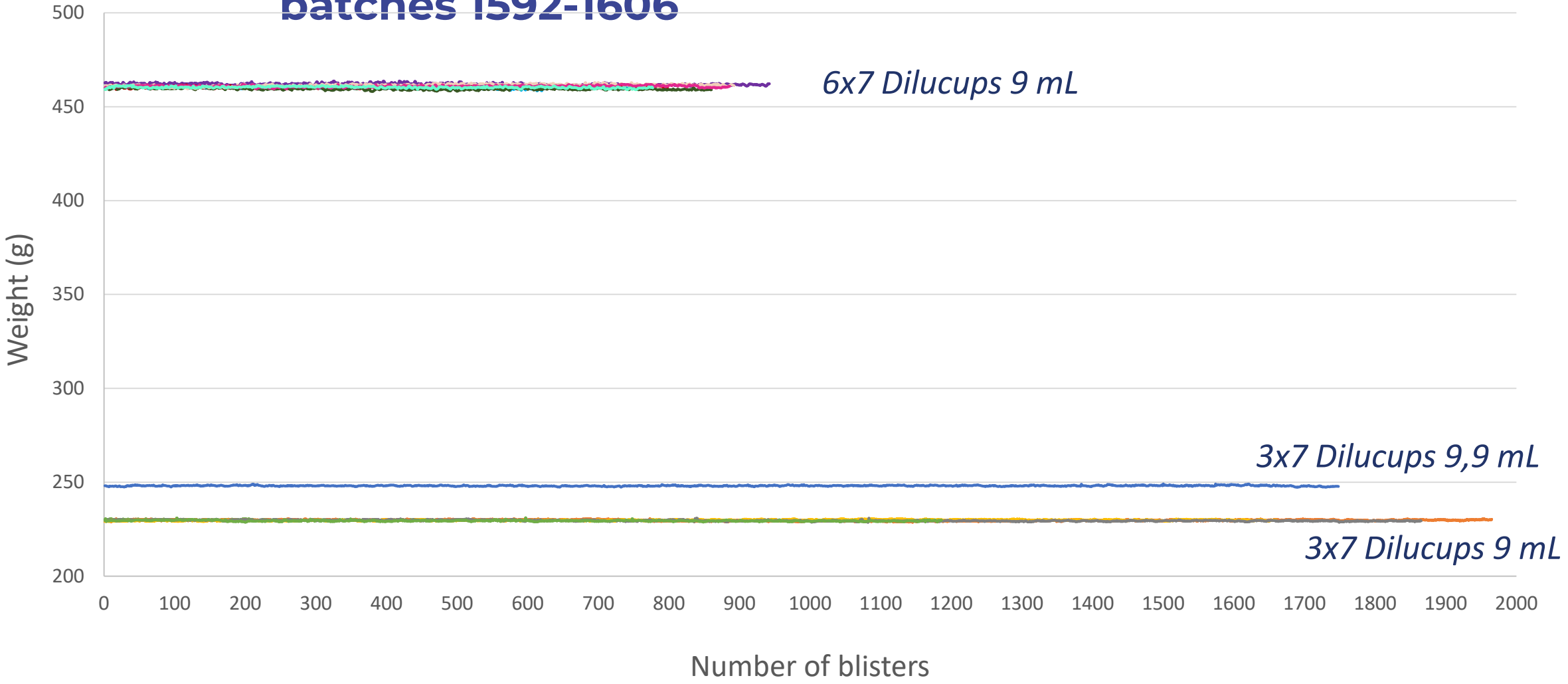


Every blister is automatically weighed during production

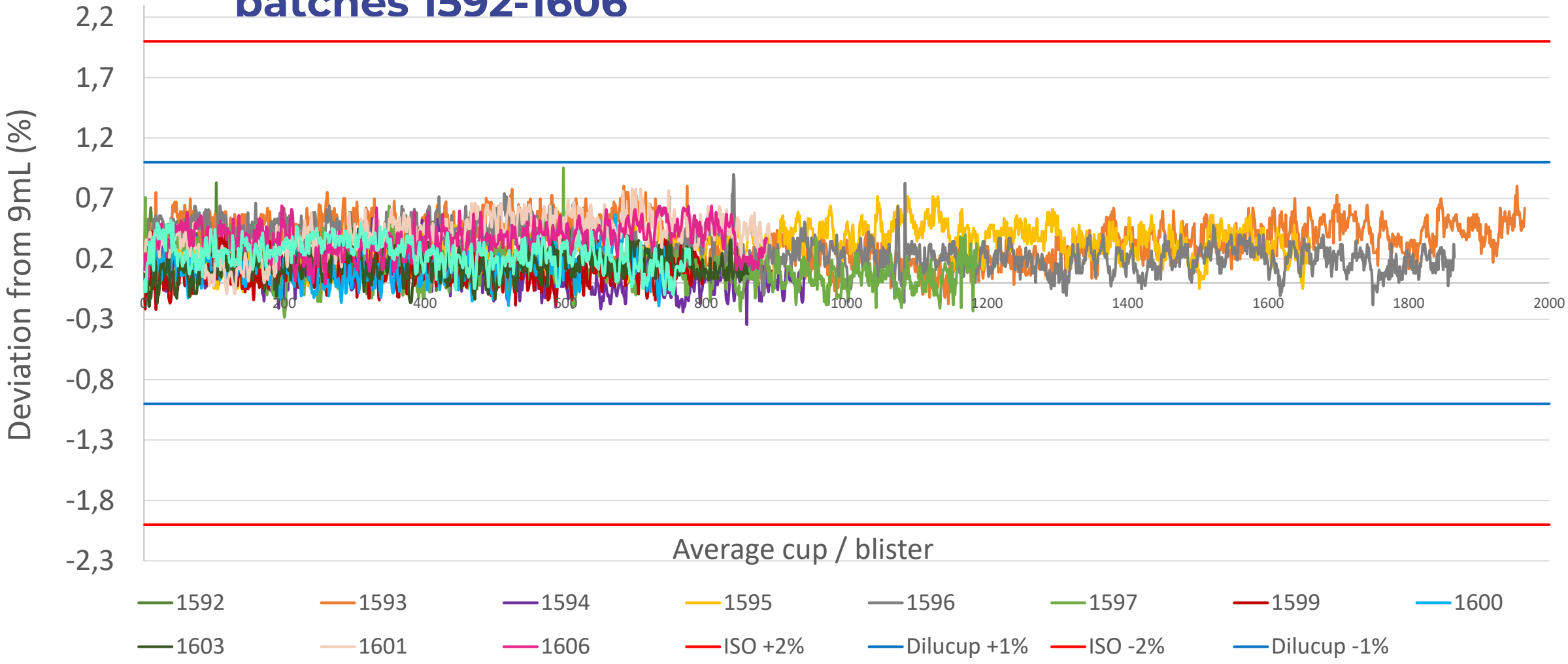
Every blister must have a weight within in-house requirement of ± 1 g (0.2-0.5 %)

If not, it will be automatically discarded.

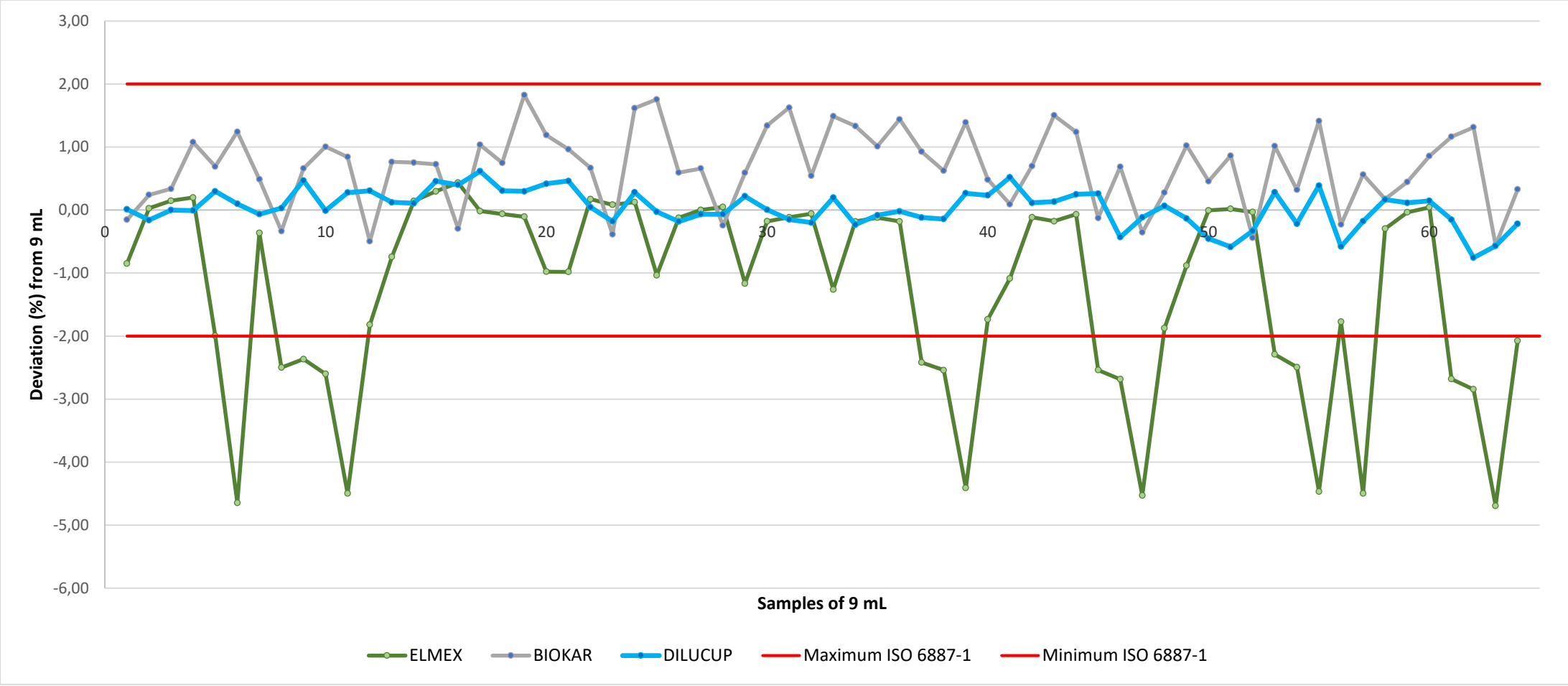
Weight analysis of all blisters produced in batches 1592-1606

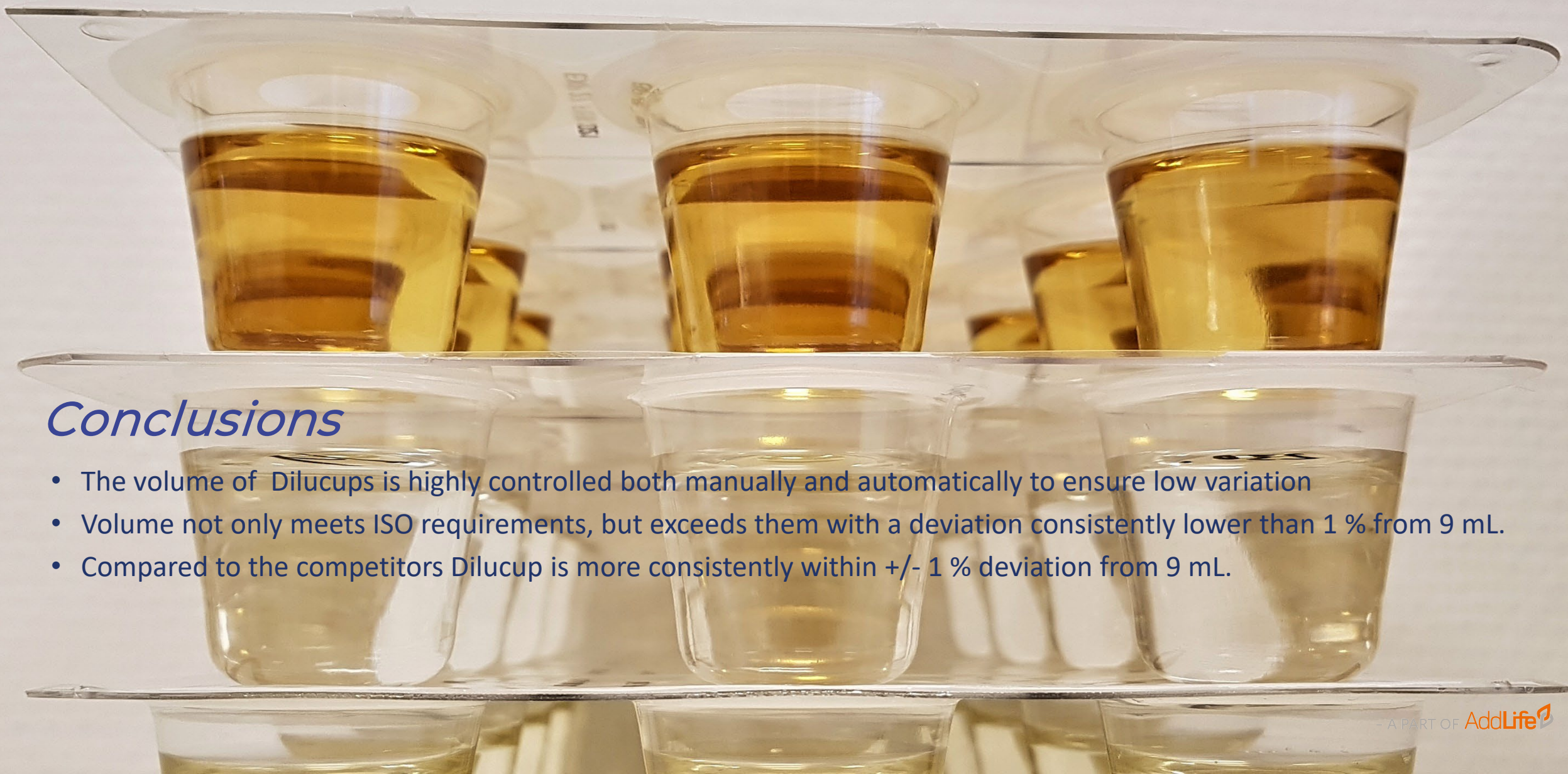


Average deviation (%) from 9 mL/cup per blister in batches 1592-1606



Deviation (%) from 9 mL of Dilucup vs competitors





Conclusions

- The volume of Dilucups is highly controlled both manually and automatically to ensure low variation
- Volume not only meets ISO requirements, but exceeds them with a deviation consistently lower than 1 % from 9 mL.
- Compared to the competitors Dilucup is more consistently within +/- 1 % deviation from 9 mL.

Time saving with Dilucup

		Tube 9 mL	Dilucup	Tube 9 mL	Dilucup	Tube 9 mL	Dilucup
	Replicate	Shaked 2 s		Shaked 5 s		Shaked 10 s	
Operator 1	1	35	22	55	23	60	32
	2	40	19	42	23	55	33
	3	43	18	45	23	61	33
	4	38	17	46	22	58	33
	5	40	17	44	23	60	32
	6	33	17	43	22	59	32
Operator 2	1	39	18	48	26	60	34
	2	37	19	45	26	56	34
	3	37	22	45	25	55	34
	4	34	18	47	23	56	33
	5	32	18	46	24	58	34
	6	33	19	48	23	56	33
2 dilutions + 1 mL Petrifilm		**37**	**19**	**46**	**24**	**59**	**33**
1 dilution + 1 mL Petrifilm		18	9	23	12	30	16

Table shows time in seconds needed for doing 2 dilutions followed by transferring 1 mL to a Petrifilm.

Conclusions:

Dilucup gives 50 % time saving compared to a conventional method, apart from improving comfort for the operator.

Thank you for your attention!