

Determining the CMV-status from buccal swab samples

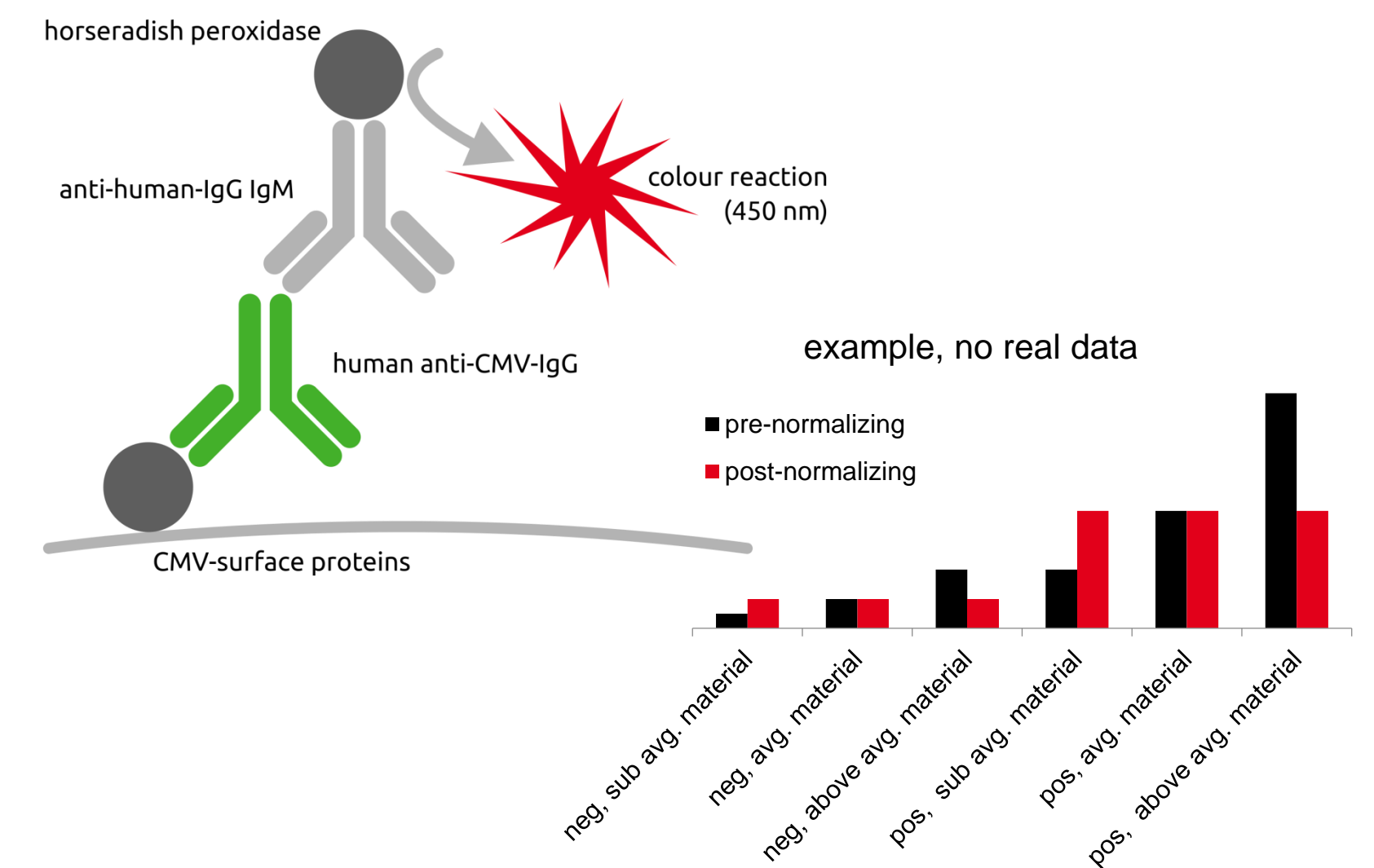
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Aim

CMV infection or reactivation after hematopoietic stem cell transplantation is associated with detrimental effects on overall survival. Therefore, CMV infection status matching is recommended if multiple, otherwise HLA-compatible, donors are available. This can be facilitated by testing for CMV status already at donor registration. Since many donor centres have shifted to buccal swabs for sample collection, we have developed an assay to determine CMV status from dried buccal swab samples.

Methods

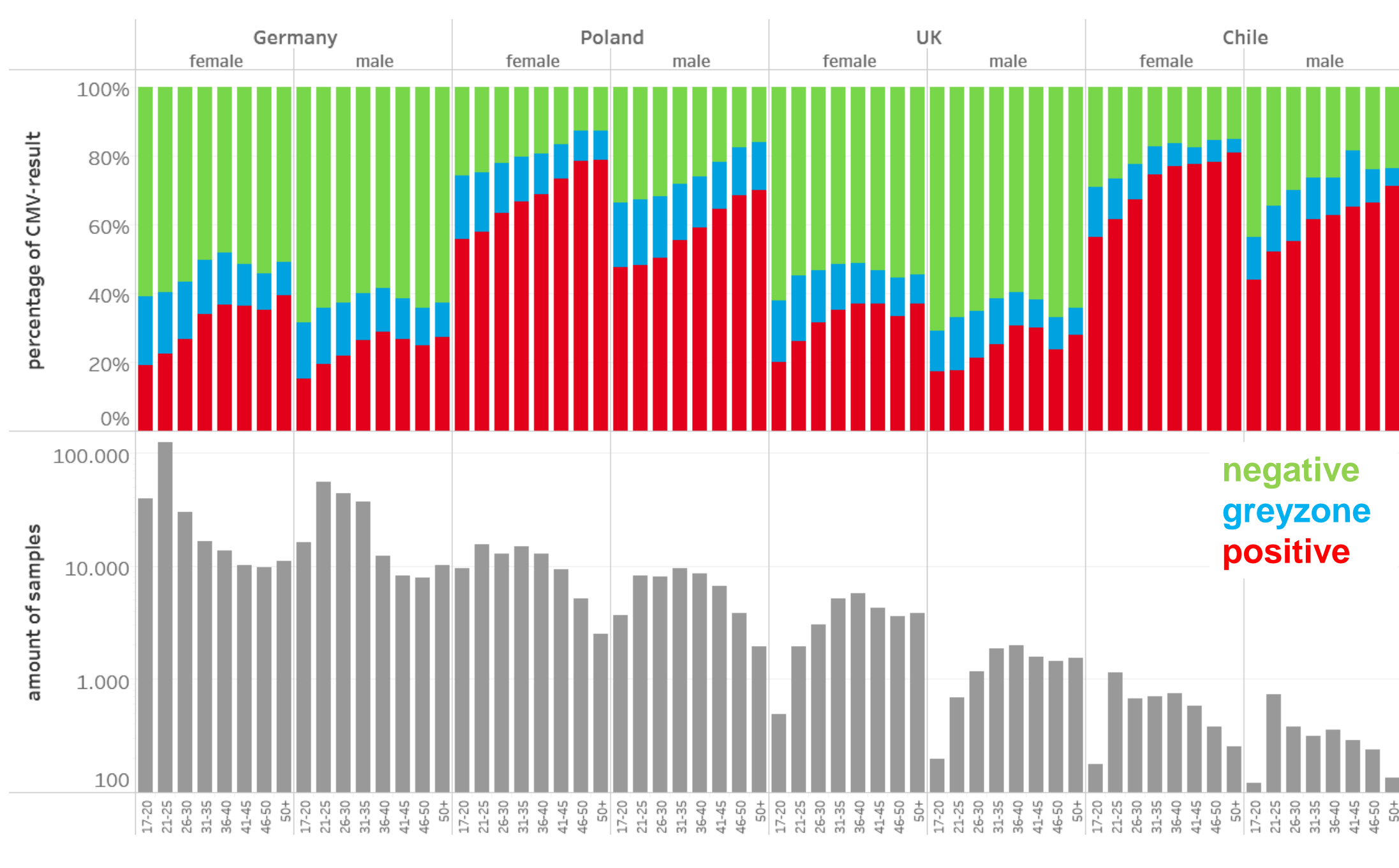


- ✓ IgG based ELISA
- ✓ Reference standards on each plate
- ✓ Secondary total protein assay to normalize samples
- ✓ Fully automated high throughput: 5000 samples per day per platform
- ✓ Automated result generation
- ✓ Plausibility checks per
 - panel (79 samples)
 - run (30-40 panels)
 - long term (weeks to month)

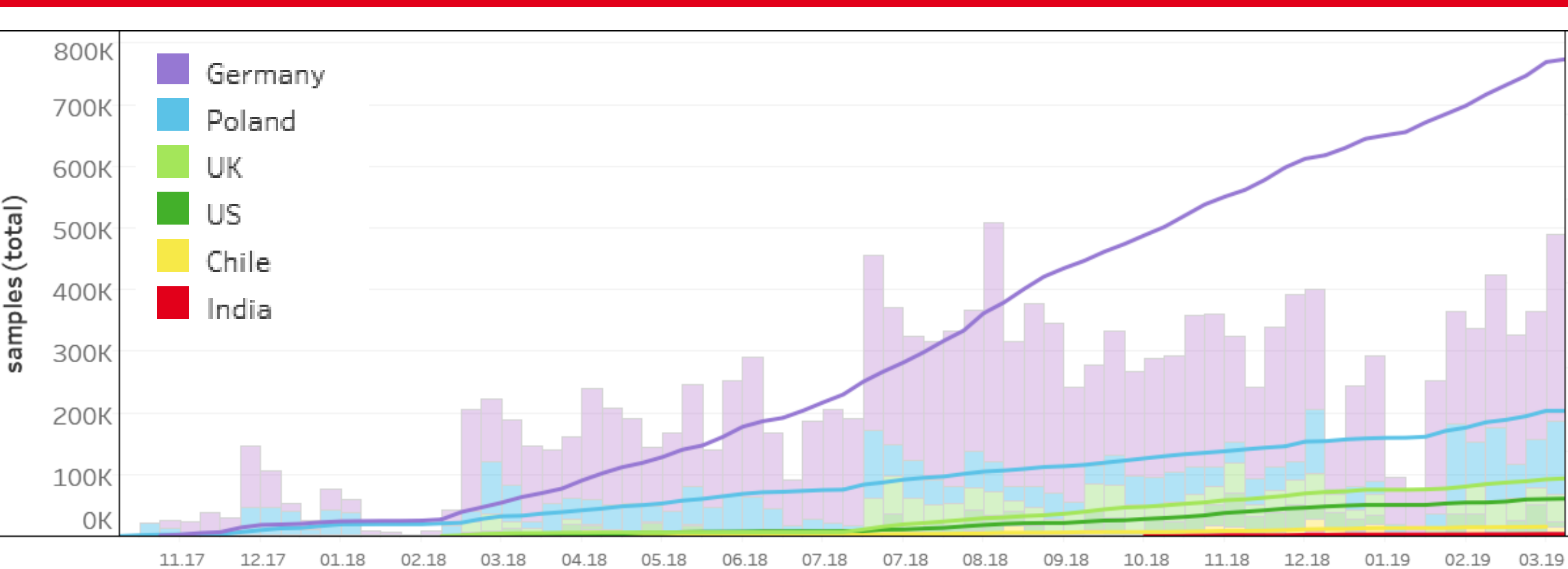
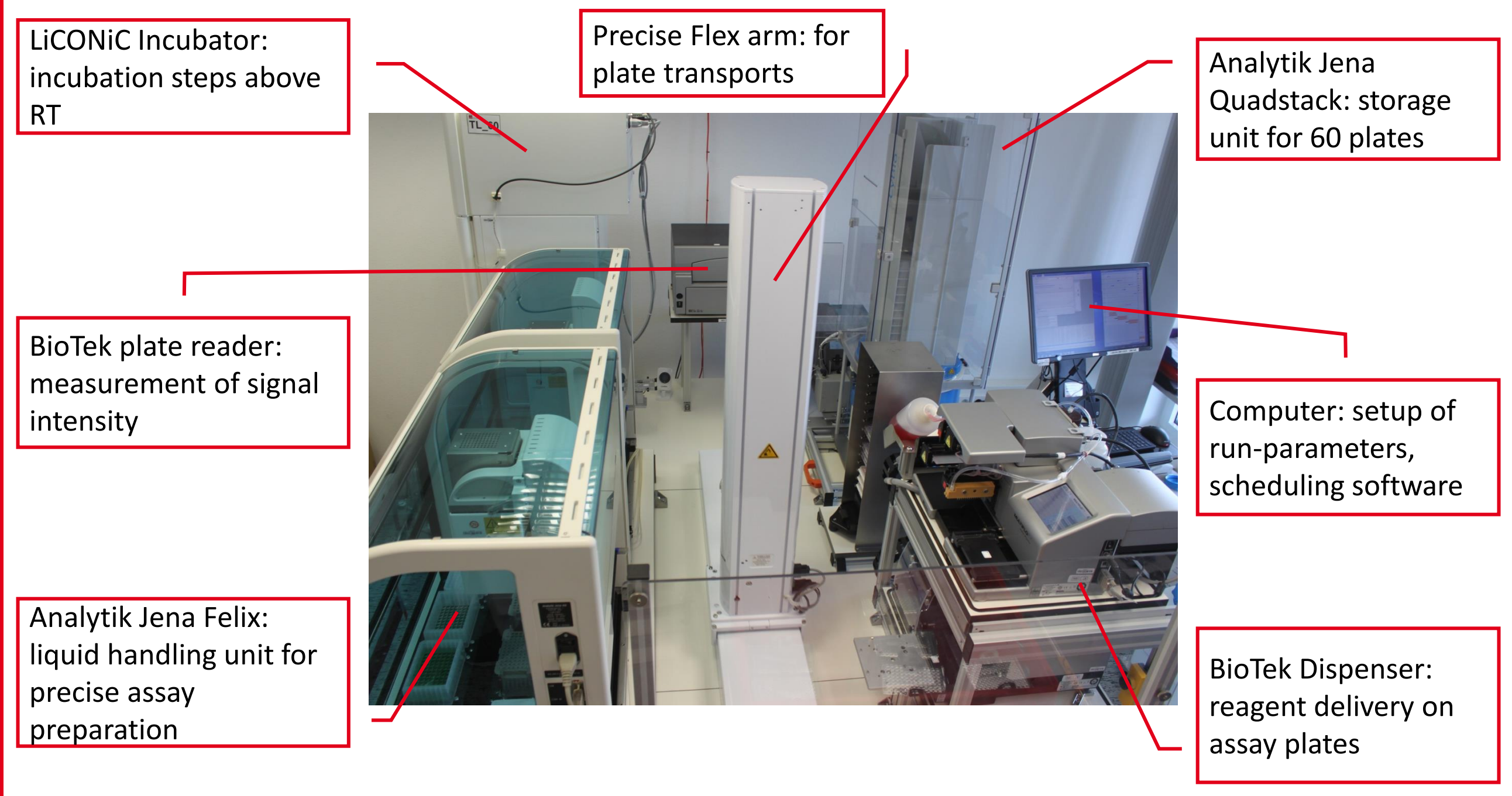
Validation Data

parameter	determination	samples total	samples without result			samples with result					Specificity	Sensitivity	
			total	low protein content	grey-zone	total	correct	false positive	false negative				
parameter determination	absolute	713	147	71	76	566	557	197	360	3	6		
	%	100%	20.62%	9.96%	10.66%	100%	98.41%	35.37%	64.63%	0.53%	1.06%	99.2%	97.0%
Donor Drive I	absolute	496	123	66	57	373	369	152	217	4	0		
	%	100%	24.80%	13.31%	11.49%	100%	98.93%	41.19%	58.81%	1.07%	0.00%	98.2%	100.0%
Donor Drive II	absolute	886	163	105	58	723	713	174	539	8	2		
	%	100%	18.40%	11.85%	6.55%	100%	98.62%	24.40%	75.60%	1.11%	0.28%	98.5%	98.9%
Donor Drive III	absolute	402	71	38	33	331	327	105	222	2	2		
	%	100%	17.66%	9.45%	8.21%	100%	98.79%	32.11%	67.89%	0.60%	0.60%	99.1%	98.1%
Total w/o parameter group	absolute	1784	357	209	148	1427	1409	431	978	14	4		
	%	100%	20.01%	11.72%	8.30%	100%	98.74%	30.59%	69.41%	0.98%	0.28%	98.6%	99.1%

Population Data



Robot Platform



Summary

The new assay provides the CMV status from dried buccal swab samples with excellent specificity and sensitivity of 99%. The current setup of two fully integrated robotic platforms provides a maximal throughput of 50,000 samples per week. More than 1 million CMV results have been generated since January 2018 for buccal swab samples from five countries, thereby more than doubling the number of DKMS donors with CMV status.