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ATENCIÓN DOMICILIARIA AVANZADA: OPORTUNIDADES Y DESAFÍOS PARA LAS PRUEBAS EN EL LUGAR DE ATENCIÓN.

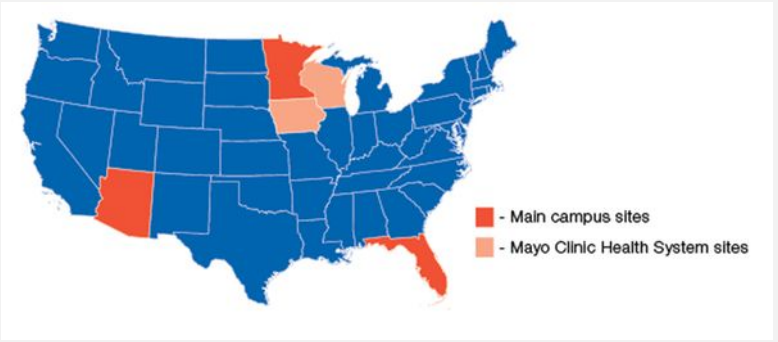
ADVANCED HOME CARE: OPPORTUNITIES AND CHALLENGES FOR POINT-OF-CARE TESTING.

RAVINDER SINGH, Mayo Clinic, USA

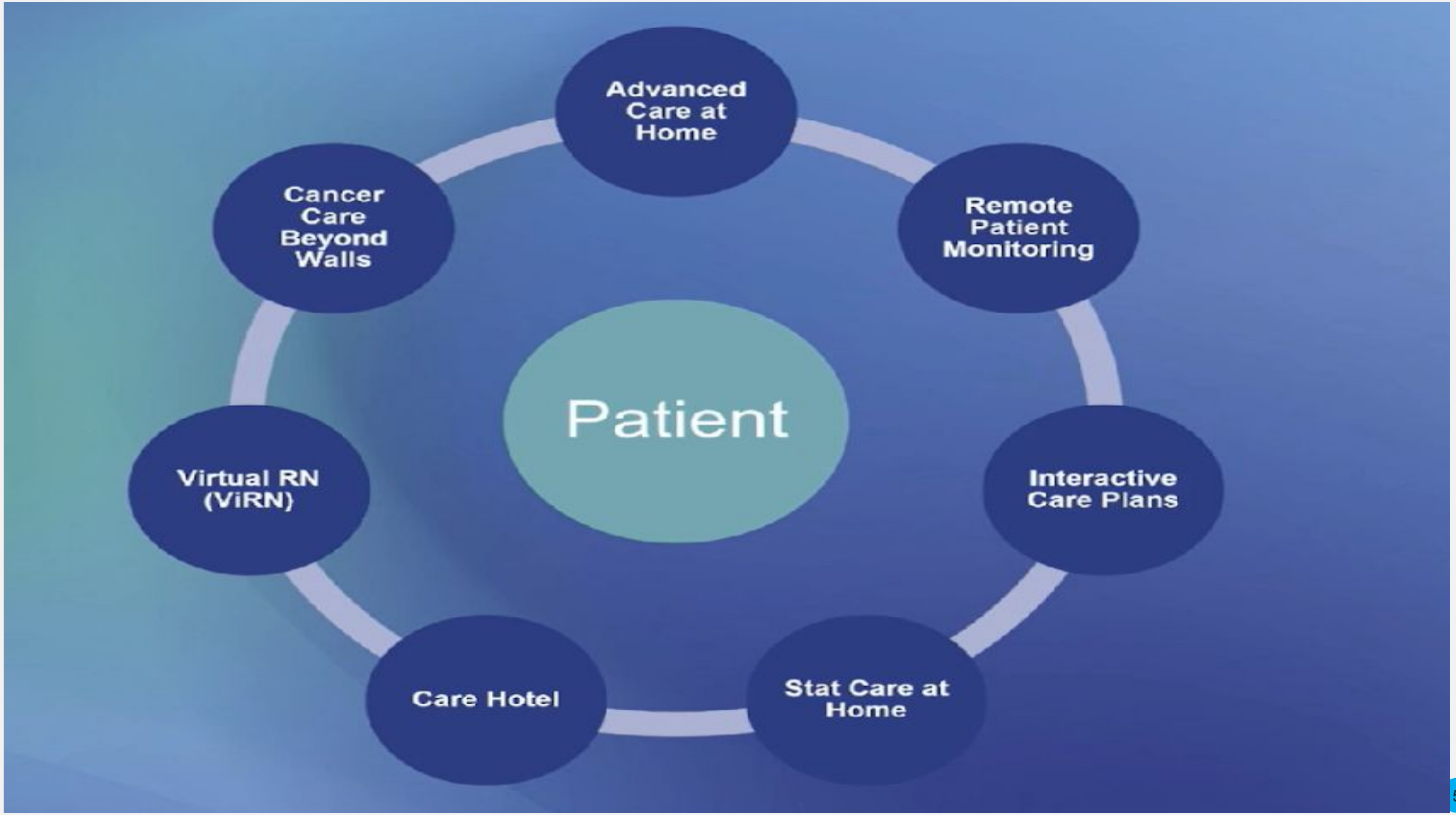
MAYO CLINIC PROVIDED COMPASSIONATE CARE FOR ABOUT 1.3 MILLION PATIENTS IN 2022

- Mayo Clinic cared for patients from every U.S. state and nearly 130 countries.
- Mayo Clinic cared for 6,700 international patients.
- Mayo Clinic had nearly 5 million outpatient visits and performed more than 141,000 surgeries.
- Mayo Clinic performed 1,858 solid organ transplants.
- Mayo Clinic conducted 515,665 telemedicine appointments.
- The number of patients served through Mayo Clinic remote care offerings, including Advanced Care at Home and Care Hotel, doubled in 2022 to more than 2,400.

MAYO CLINIC USA



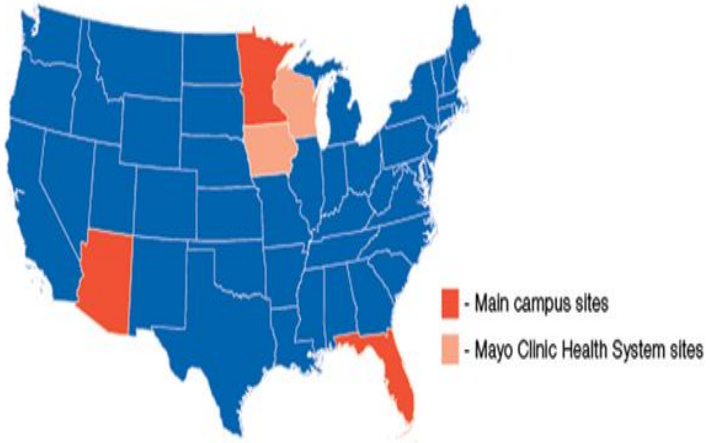
- Mayo Clinic Hospital, Jacksonville, Florida: The hospital has 304 beds, but is expanding to 428 beds by 2026. The expansion will include 13 floors and 1.4 million square feet of space.
- Mayo Clinic Hospital, Methodist Campus, Rochester, Minnesota: This campus has 794 beds and 37 operating rooms.
- Mayo Clinic Hospital, Saint Marys Campus, Rochester, Minnesota: This campus has 1,265 beds, 70 operating rooms, and 10 intensive care units.
- Mayo Clinic Hospital, Phoenix, Arizona: This hospital has 353 staffed beds
- The Mayo Clinic Hospital – Rochester is a 2,059-bed teaching hospital located in Rochester, Minnesota.
- Mayo Clinic Hospital – Rochester is ranked first on the 2019–20 U.S. News & World Report Best Hospitals Honor Roll.


Advanced Care at Home
Remote Patient Monitoring
Interactive Care Plans
Stat Care at Home
Care Hotel
Virtual RN (ViRN)
Cancer Care Beyond Walls
Patient

Implementation of a virtual and in-person hybrid hospital-at-home model in two geographically separate regions utilizing a single command center: a descriptive cohort study

Margaret R. Paulson[1], Eliza P. Shulman[2], Ajani N. Dunn[3], Jacey R. Fazio[3], Elizabeth B. Habermann[4], Gautam V. Matcha[5], Rozalina G. McCoy[4,6], Ricardo J. Pagan[5] and Michael J. Maniaci[5*]

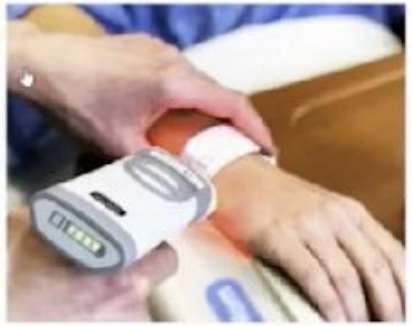
We describe the implementation of Advanced Care at Home (ACH), Mayo Clinic's hybrid virtual and in person hospital-at-home model that combines a **single virtual physician-staffed command center** with in-home advanced practice provider visits and a vendor-mediated in-person medical supply chain that can deliver care in two diverse settings, urban and rural.



We hypothesize that the ACH model of hospital-at-home can use a centralized, single command center to coordinate and deliver inpatient-level care to high-acuity patients in two separate US regions while maintaining the high-level of safety and quality outcomes seen in previous hospital-at home models.

Paulson *et al. BMC Health Services Research (2023) 23:139*

Advancing Technology



Paulson ***et al. BMC Health Services Research (2022) xxxx***

1) Command Center:
Staffed with physicians, registered nurses (RNs), and advanced practice providers (APPs: nurse practitioners and physician assistants), who work alongside non-clinical service coordinators, linked together by technology to provide around-the-clock care to patients enrolled in the program across all sites.

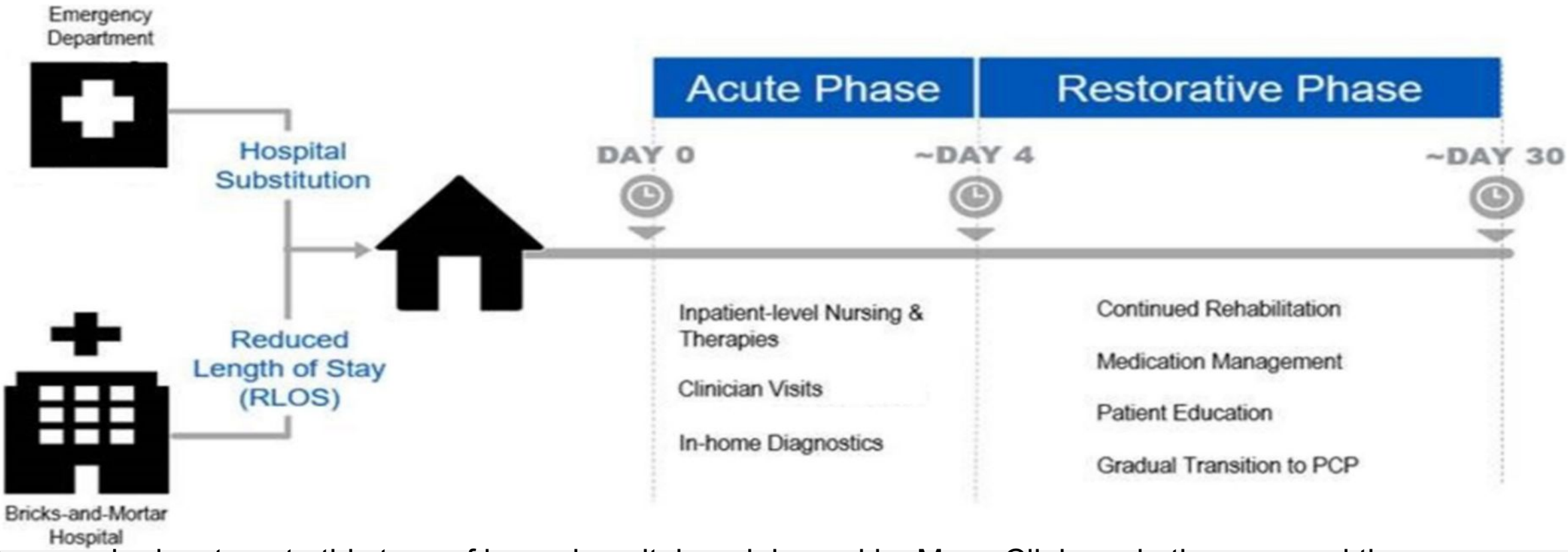
2) Technology in the Home:
Custom technology kits, including biometric devices for monitoring vital signs (Bluetooth-connected sphygmomanometer, thermometer, pulse oximeter, and a floor scale), a custom-configured tablet with video visit capability, a telephone to facilitate 2-way communication, a backup power supply, a backup cellular communication cradle-point, and an emergency response system bracelet to keep patients and their families connected to the care team.

3) Care Delivery Services:
The model includes a full suite of care services, including APPs, community paramedics, RNs, aides, rehabilitative services, infusion therapy, phlebotomists, and basic radiography technicians dispatched to the patients' homes to allow for the provision of scheduled and acutely activated urgent patient care needs.

Table 2 Patient Diagnosis

	Florida $n=408$	Wisconsin $n=278$	Total $n=686$
INFECTION	218 (53.4%)	158 (56.8%)	376 (54.8%)
Pneumonia	96 (23.5%)	89 (32.0%)	185 (27.0%)
Septicemia / Bacteremia Complicated	60 (14.7%)	19 (6.8%)	79 (11.5%)
Skin / Soft Tissue infection	24 (5.9%)	19 (6.8%)	43 (6.3%)
UTI or pyelonephritis	14 (3.4%)	14 (5.0%)	28 (4.1%)
Infective Arthritis or Osteomyelitis	7 (1.7%)	10 (3.6%)	17 (2.5%)
Gastroenteritis / Intestinal Infection	11 (2.7%)	2 (0.7%)	13 (1.9%)
Peritonitis and intra-abdominal abscess	4 (1.0%)	4 (1.4%)	8 (1.2%)
Other infection	2 (0.5%)	1 (0.4%)	3 (0.5%)
CARDIOVASCULAR DISEASE	46 (11.3%)	45 (16.2%)	91 (13.3%)
Heart Failure	38 (9.3%)	41 (14.7%)	79 (11.5%)
Cardiac Dysrhythmia	3 (0.7%)	1 (0.4%)	4 (0.6%)
Circulatory disease	3 (0.7%)	1 (0.4%)	4 (0.6%)
Other Cardiac	2 (0.5%)	2 (0.7%)	4 (0.6%)
HEMOTOLOGIC AND ONCOLOGIC DISEASE	13 (3.2%)	4 (1.4%)	17 (2.5%)
Cancer / Neoplastic	5 (1.2%)	4 (1.4%)	9 (1.3%)
Venous Thromboembolism	5 (1.2%)	0 (0.0%)	5 (0.7%)
Anemia / Neutropenia	3 (0.7%)	0 (0.0%)	3 (0.4%)
AIRWAY DISEASE	23 (5.6%)	9 (3.2%)	32 (4.7%)
COPD	9 (2.2%)	4 (1.4%)	13 (1.9%)
Aspiration pneumonitis	5 (1.2%)	3 (1.1%)	8 (1.2%)
Respiratory failure	2 (0.5%)	1 (0.4%)	3 (0.4%)
Bronchitis or sinusitis	1 (0.2%)	1 (0.4%)	2 (0.3%)
Other Airway Disease	6 (1.5%)	0 (0.0%)	6 (0.9%)
SURGICAL DIAGNOSIS	27 (6.6%)	26 (9.4%)	53 (7.7%)
Complication after surgery	9 (2.2%)	15 (5.4%)	24 (3.5%)
Complication of a device, implant, or graft	6 (1.5%)	11 (4.0%)	17 (2.5%)
Complication of Transplanted Tissue	12 (2.9%)	0 (0.0%)	12 (1.8%)
GASTROINTESTINAL AND HEPATOBILIARY DISEASE	30 (7.4%)	6 (2.2%)	36 (5.2%)
Biliary tract disease	7 (1.7%)	3 (1.1%)	10 (1.5%)
Diverticulosis and diverticulitis	6 (1.5%)	0 (0.0%)	6 (0.9%)
Oral and esophageal	3 (0.7%)	1 (0.4%)	4 (0.6%)
Intestinal obstruction or ileus	2 (0.5%)	1 (0.4%)	3 (0.4%)
Inflammatory Bowel Disease	2 (0.5%)	0 (0.0%)	2 (0.3%)
Other gastrointestinal and hepatobiliary	10 (2.5%)	1 (0.4%)	11 (1.6%)
KIDNEY AND UROLOGIC DISEASE	30 (7.4%)	3 (1.1%)	33 (4.8%)
Acute renal failure	20 (4.9%)	1 (0.4%)	21 (3.1%)
Chronic kidney disease complication	5 (1.2%)	1 (0.4%)	6 (0.9%)
Fluid and electrolyte disorders	3 (0.7%)	1 (0.4%)	4 (0.6%)
Other Kidney and Urologic	2 (0.5%)	0 (0.0%)	2 (0.3%)
MUSCULOSKELETAL DISEASE	5 (1.2%)	11 (4.0%)	16 (2.3%)
Osteoarthritis	0 (0.0%)	6 (2.2%)	6 (0.9%)
Pressure ulcer of skin	1 (0.2%)	2 (0.7%)	3 (0.4%)
Other Musculoskeletal	4 (1.0%)	3 (1.1%)	7 (1.0%)
ENDOCRINE DISEASE	7 (1.7%)	9 (3.2%)	16 (2.3%)
Diabetes mellitus with complication	5 (1.2%)	8 (2.9%)	13 (1.9%)
Pituitary disorders	2 (0.5%)	1 (0.4%)	3 (0.4%)
OTHER / MISCELLANEOUS	9 (2.2%)	7 (2.5%)	16 (2.3%)

Paulson ***et al. BMC Health Services Research (2023) 23:139***



A second advantage to this type of home hospital model, used by Mayo Clinic and others around the country, is the ability to recruit **non-hospital owned resources** in the form of multiple community **medical vendors** and use them to physically deliver health care in the home.

This hub-and-spoke mechanism of the home hospital model used at Mayo Clinic promotes both safety and scalability.

The vendor-mediated in-person medical supply chain can be established separately from the central institution housing the command center, covering a much larger geographic area or even different cities, as seen in ACH.

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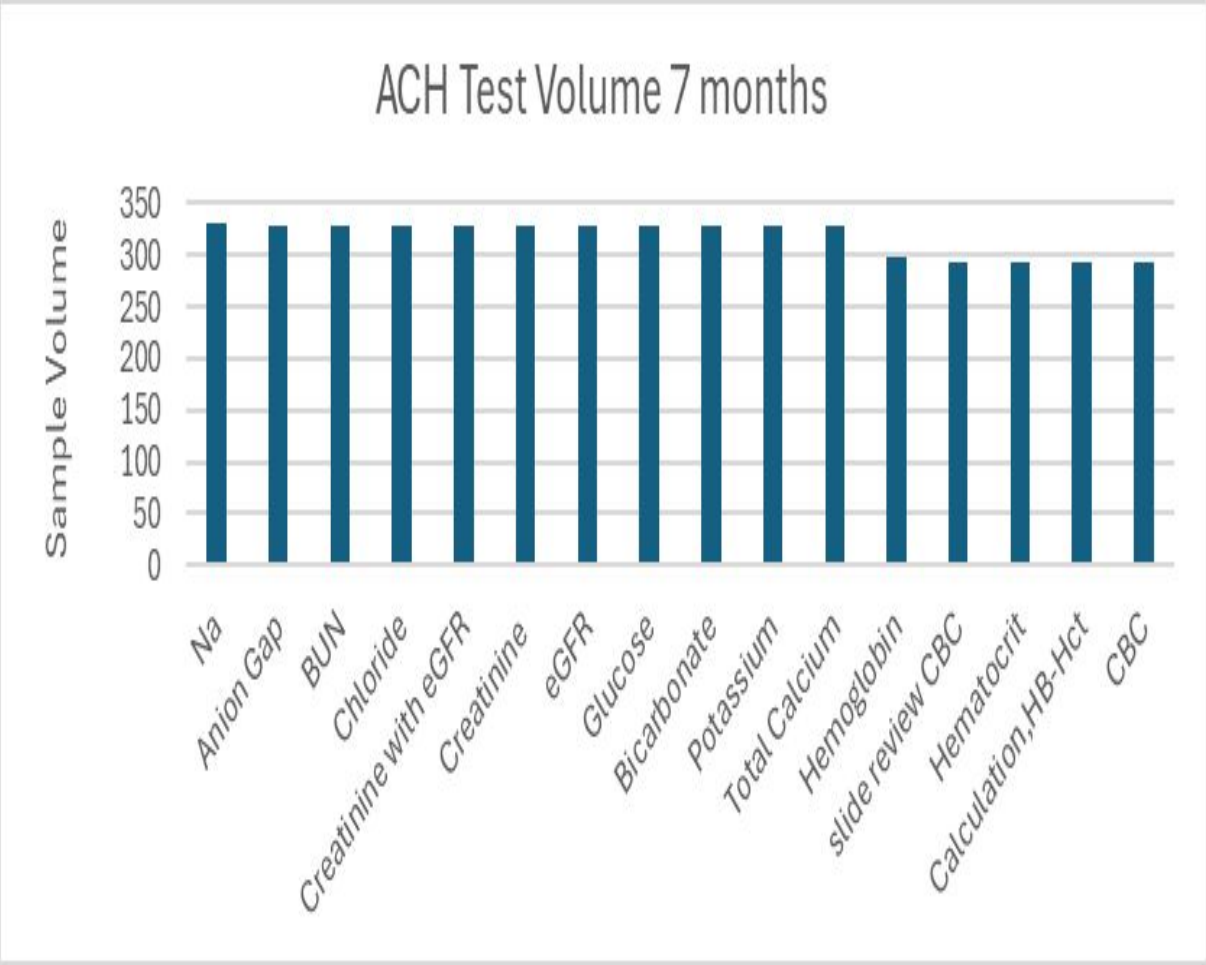
CENTRAL CLINICAL LAB VS VENDOR COLLECTION VS POCT

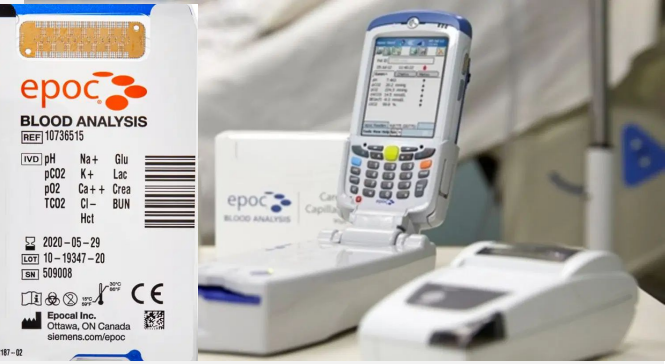


	Accountable	Average	Median
Time from Collected to Received by Lab	Vendor	1h 30m	1h 12m
Time from Received to Resulted	Lab	1h 34m	0h 32m
Time from Collected to Resulted	Vendor + Lab	3h 4m	1h 43m

	Volume	Percentage
Samples with Collected to Received <= 120	574	87.8%
Samples with Collected to Received > 120	80	12.2%
Total Samples	654	100.0%

MAYO FLORIDA POCT OPERATION

- **Nova (glucose meters) 395, 3000 RN's**
- **Hepcon 3 (ACT) (HDR) (HPT) 6 users-OR1 OR2 and Pump room**
- **Hemochron 14 (ACT) LR and HR -EP lab 1,2,3, OR 18, ana workroom, Cath 1,2,**
- **Istat 14 CG8(CMP) Creat OR1, OR2, ER, CT, MRI, Mangurian, EP**
- **HemoCue 14 GI, EP lab, OR1 and OR2, Ana workroom**
- **Clinitek 5 (Beaches, Gate, ST Aug, Family med, CIM) UA and HCG**
- Liat 3 (Flu A and Flu B and RSV) 12 operators
- **Tear lab. 1 (osmolality) 50 ophthalmology**
- Avox 1000E 3 (OHb) Cath 1, cath 2 75 operators
- **CoaguChek 7 (INR) coumadin clinic, 10 operators**



Evaluation of the Enterprise Point-of-Care (EPOC) System for Blood Gas and Electrolyte Analysis

James H. Nichols, PhD, DABCC, FACB, Aparna Rajadhyaksha, MD, and Mirian Rodriguez, MA, LA

The EPOC blood analysis system consists of individual test cards (front and back of card in lower half of figure) that can provide blood gas and electrolyte analysis in multiple configurations. This configuration uses a card reader (upper left) that detects signals from the biosensor on the test card and transmits the data wirelessly to a handheld
PDA that contains the EPOC software to calculate analyte concentration from the raw card signals. Other configurations
allow the card reader to wirelessly connect to PCs or other hardware running the EPOC software.

Product	epoc Test Card	G3+	CG4+	EG6+	EG7+	CG8+	G	Crea	E3+	EC4+	6+	CHEM8+	EC8+
pH	●	●	●	●	●	●							
pCO_2 (partial pressure of CO_2)	●	●	●	●	●	●							
pO_2 (partial pressure of O_2)	●	●	●	●	●	●							
Na (sodium)	●			●	●	●			●	●	●	●	●
K (potassium)	●			●	●	●			●	●	●	●	●
iCa (ionized calcium)	●				●	●						●	
Hct (hematocrit)	●			●	●	●			●	●	●	●	●
Glu (glucose)	●					●	●			●	●	●	●
Anion gap	●											●	●
TCO_2 (total CO_2)	●	●	●	●	●	●						●	
HCO_3 (bicarbonate)	●	●	●	●	●	●							
BE ecf (base excess in extracellular fluid)	●	●	●	●	●	●							
BE b (base excess in blood)	●												
sO_2 (saturated oxygen)	●	●	●	●	●	●							
Hb (hemoglobin)	●			●	●	●			●	●	●	●	●
Lactate	●		●										
Creatinine with estimated GFR	●							●				●	
BUN (blood urea nitrogen)	●										●	●	●
Cl (chloride)	●										●	●	●

(Point of Care 2008;7:7Y11)

TABLE 2. Total Precision of the EPOC System

	pH	P_{CO_2}	P_{O_2}	Na	K	iCa	Hct
Level 1							
Mean	6.992	86.2	74.9	113.4	2.15	2.18	23.8
SD (% CV)	0.0107 (0.15)	2.4 (2.8)	2.8 (3.8)	1.2 (1.0)	0.03 (1.5)	0.04 (1.7)	0.7 (2.9)
Level 2							
Mean	7.673	24.1	140.1	153.1	6.71	0.662	45.0
SD (% CV)	0.0108 (0.14)	0.7 (3.1)	2.8 (2.0)	1.6 (1.0)	0.07 (1.1)	0.01 (1.9)	0.8 (1.8)

Total precision was conducted at Epocal during the pilot manufacturing stage. Two levels of controls (Mission Diagnostics) were analyzed for each batch of test cards using up to 6 card readers. Over a 2-month period, 20 different test card lots were evaluated with 16 card readers. Hematocrit was performed using 2 levels of Hct control (Mission Diagnostics) at Baystate Health and was performed on 2 card readers using 6 different test card lots.

TABLE 3. Correlation Statistics Between the EPOC System and i-STAT

	pH	P_{CO_2}, mm Hg	P_{O_2}, mm Hg	Na, mmol/L	K, mmol/L	iCa, mmol/L	Hct, %
Regression	$0.03 + 1.00x$	$-0.9 + 1.04x$	$-1.7 + 1.05x$	$-0.04 + 1.02x$	$8.8 + 0.94x$	$0.1 + 0.91x$	$-1.1 + 1.07x$
i-STAT Mean	7.35	49.1	87.4	137.8	3.86	1.14	33.7
EPOC Mean	7.34	50.3	90.9	138.5	3.90	1.14	34.8
$S_{y.x}$ (% CV)	0.018 (2.5)	2.5 (4.9)	6.6 (7.3)	0.09 (2.4)	2.1 (1.5)	0.03 (2.5)	1.4 (3.9)
r	0.987	0.990	0.978	0.989	0.880	0.943	0.987
Range of results	6.95–7.56	18.5–122.3	22.9–232.1	126–147.5	2.5–6.6	0.79–1.62	18.5–77.0
n	142	143	142	142	142	143	142
i-STAT Precision of replicates, SD (% CV)	0.013 (0.17)	1.49 (3.0)	4.6 (5.3)	0.6 (0.4)	0.047 (1.22)	0.016 (1.4)	0.58 (1.7)
EPOC Precision of replicates, SD (% CV)	0.006 (0.08)	1.10 (2.2)	2.7 (3.0)	0.8 (0.6)	0.046 (1.18)	0.014 (1.2)	0.64 (1.8)

Units are noted for each analyte. Correlation equation calculated by least squares regression. N indicates number of results; r, regression coefficient; $S_{y,x}$, SE of the estimate.

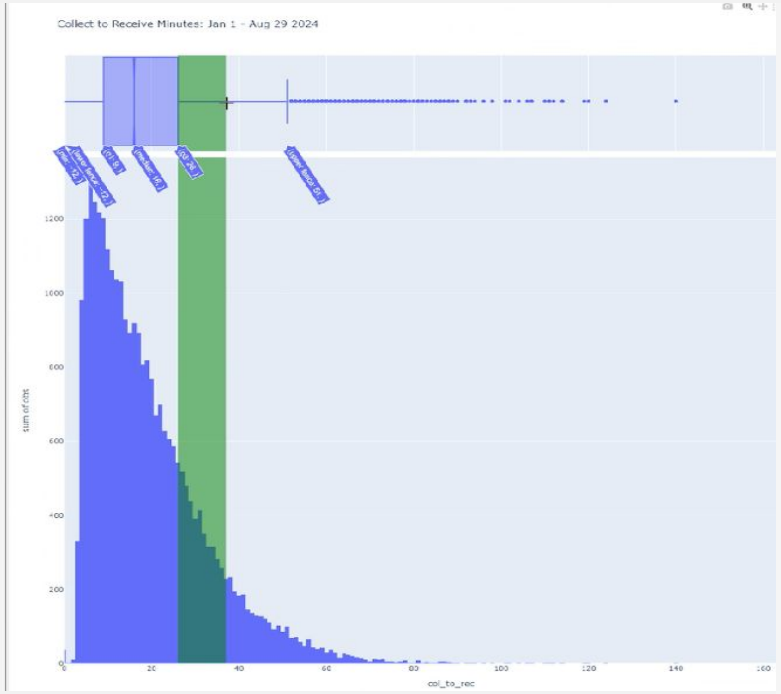
MAYO VALIDATION OF EPOC

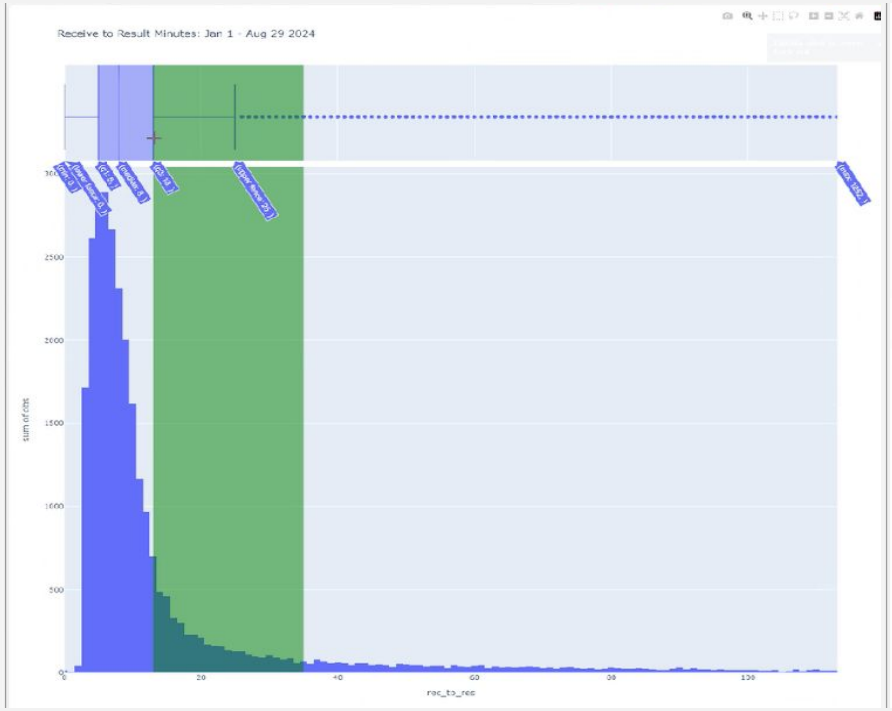
Accuracy (epoc)

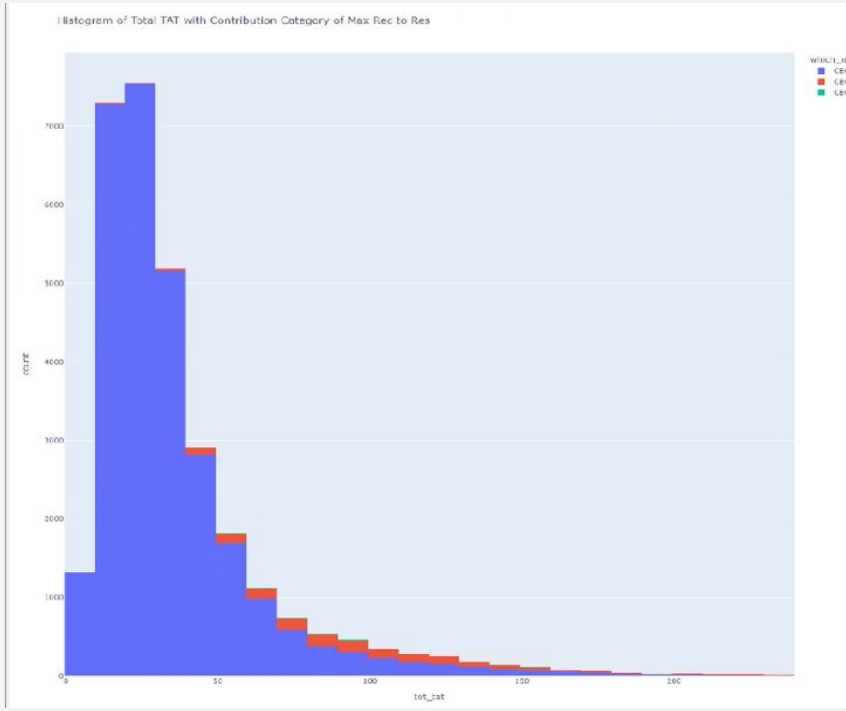
Parameter		Passing-Bablok fit Estimate	Passing-Bablok fit Bootstrap 95% CI		Minimum	Maximum	N	Correlation - r
pH	Intercept	-0.03264	-0.3222 to 0.2937	Reference (Radiometer)	7.187	7.603	53	0.992
	Slope	1.005	0.9612 to 1.045	epoc	7.187	7.626		
pCO2	Intercept	-1.009	-3.064 to 0.4804	Reference (Radiometer)	19	70	53	0.988
	Slope	1.052	1.018 to 1.099	epoc	19	78		
pO2	Intercept	-1.954	-2.581 to -0.9013	Reference (Radiometer)	21	348	52	0.999
	Slope	1.060	1.045 to 1.071	epoc	19	377		
Na	Intercept	0	-22.32 to 0	Reference (Radiometer)	115	160	53	0.980
	Slope	1.0000	1.0000 to 1.154	epoc	113	166		
K+	Intercept	0	-2.665E-15 to 0	Reference (Radiometer)	2.8	5.9	53	0.994
	Slope	1.0000	1.0000 to 1.000	epoc	2.9	5.9		
iCa	Intercept	0.4288	0.7161 to 0.01500	Reference (Radiometer)	3.1	10.9	52	0.995
	Slope	1.096	1.000 to 1.155	epoc	3.0	11.6		
Cl	Intercept	18.18	3.806 to 36.55	Reference (c501)	76	117	53	0.942
	Slope	0.8197	0.6410 to 0.9664	epoc	78	118		
TCO2	Intercept	2.335	0.7391 to 3.699	Reference (c501)	16	37	52	0.976
	Slope	1.070	1.012 to 1.136	epoc	18	38		
Hct	Intercept	-6.487	-15.86 to 8.542	Reference (Sysmex)	32.6	50.1	14	0.965
	Slope	1.184	0.8475 to 1.429	epoc	30.0	51.0		
Glu	Intercept	5.823	11.20 to 0	Reference (Radiometer)	74	371	52	0.996
	Slope	1.046	1.0000 to 1.091	epoc	66	398		
Lac	Intercept	-0.1850	-0.2919 to -0.1120	Reference (Radiometer)	0.6	7.1	44	0.992
	Slope	1.100	1.025 to 1.153	epoc	0.6	7.1		
BUN	Intercept	-0.7710	-1.959 to 0.4248	Reference (c501)	5.7	62.2	52	0.987
	Slope	1.035	0.9627 to 1.106	epoc	4.0	56.0		
Crea	Intercept	0.1544	-0.01087 to 0.2479	Reference (c501)	0.3	3.5	52	0.950
	Slope	0.8620	0.7297 to 1.059	epoc	0.4	3.2		

	Lvl	Mean	Repeatability SD	Repeatability CV	Reproducibility SD	Reproducibility CV	Allowable CV
pH	1	7.012	0.0103	0.1%	0.0113	0.2%	0.1%
	2	7.433	0.0027	0.0%	0.0037	0.1%	0.1%
	3	7.738	0.0076	0.1%	0.0076	0.1%	0.1%
pCO2	1	70	1.23	1.8%	1.52	2.2%	3.7%
	2	31	0.21	0.7%	0.28	0.9%	3.5%
	3	24	0.65	2.7%	0.70	2.9%	3.4%
pO2	1	60	4.79	8.0%	4.79	8.0%	6.4%
	2	99	3.74	3.8%	3.74	3.8%	4.9%
	3	188	4.70	2.5%	6.21	3.3%	3.4%
Na	1	113	0.5	0.5%	0.5	0.5%	0.7%
	2	140	0.5	0.3%	0.5	0.4%	0.5%
	3	167	0.5	0.3%	0.5	0.3%	0.6%
K+	1	2.1	0.00	0.0%	0.00	0.0%	1.9%
	2	3.9	0.03	0.7%	0.03	0.7%	1.5%
	3	5.9	0.03	0.5%	0.03	0.5%	1.0%
iCa	1	6.1	0.12	2.0%	0.15	2.5%	1.2%
	2	4.6	0.05	1.0%	0.05	1.0%	1.5%
	3	2.4	0.05	2.1%	0.06	2.3%	1.7%
Cl	1	78	1.4	1.8%	1.4	1.8%	0.5%
	2	98	0.8	0.8%	0.8	0.8%	0.6%
	3	115	1.1	1.0%	1.2	1.1%	0.7%
TCO2	1	19	0.20	1.0%	0.25	1.3%	1.2%

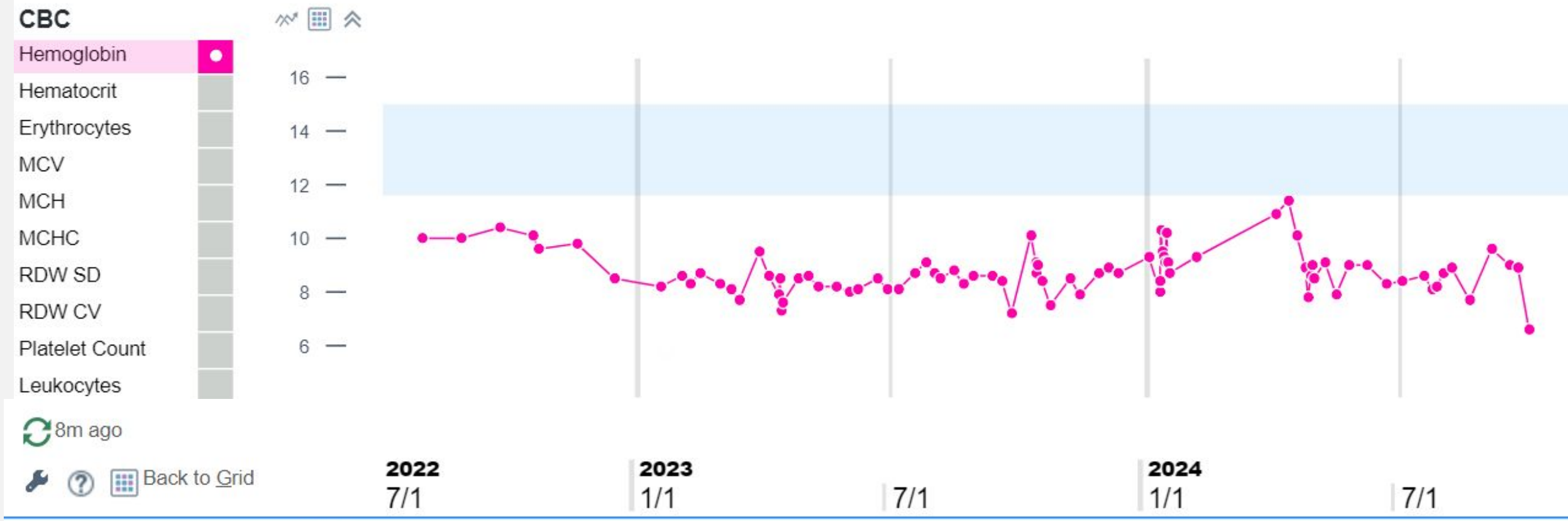
Oncology Doctors are not happy with TAT for CBC for Cancer Patients

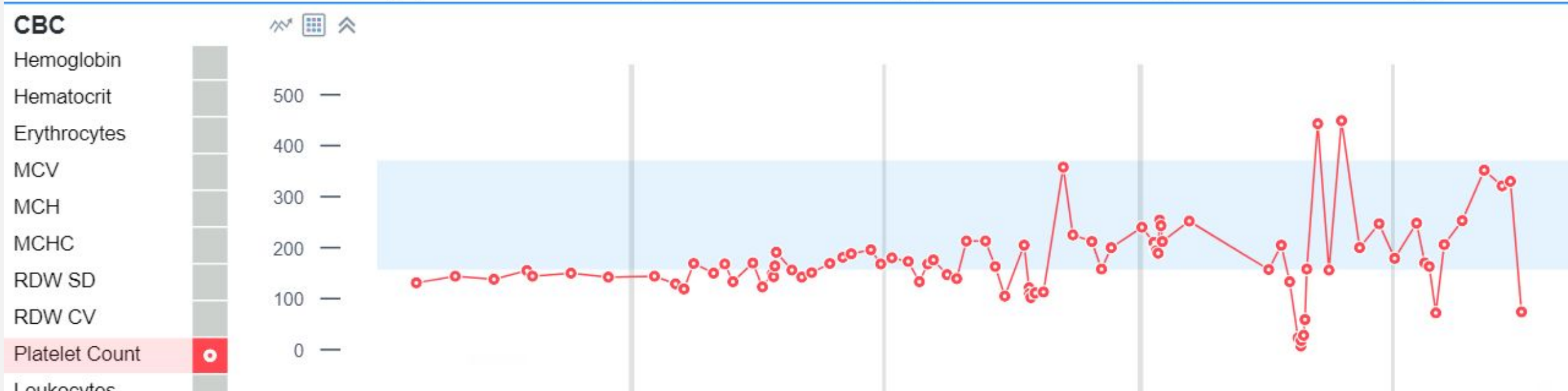




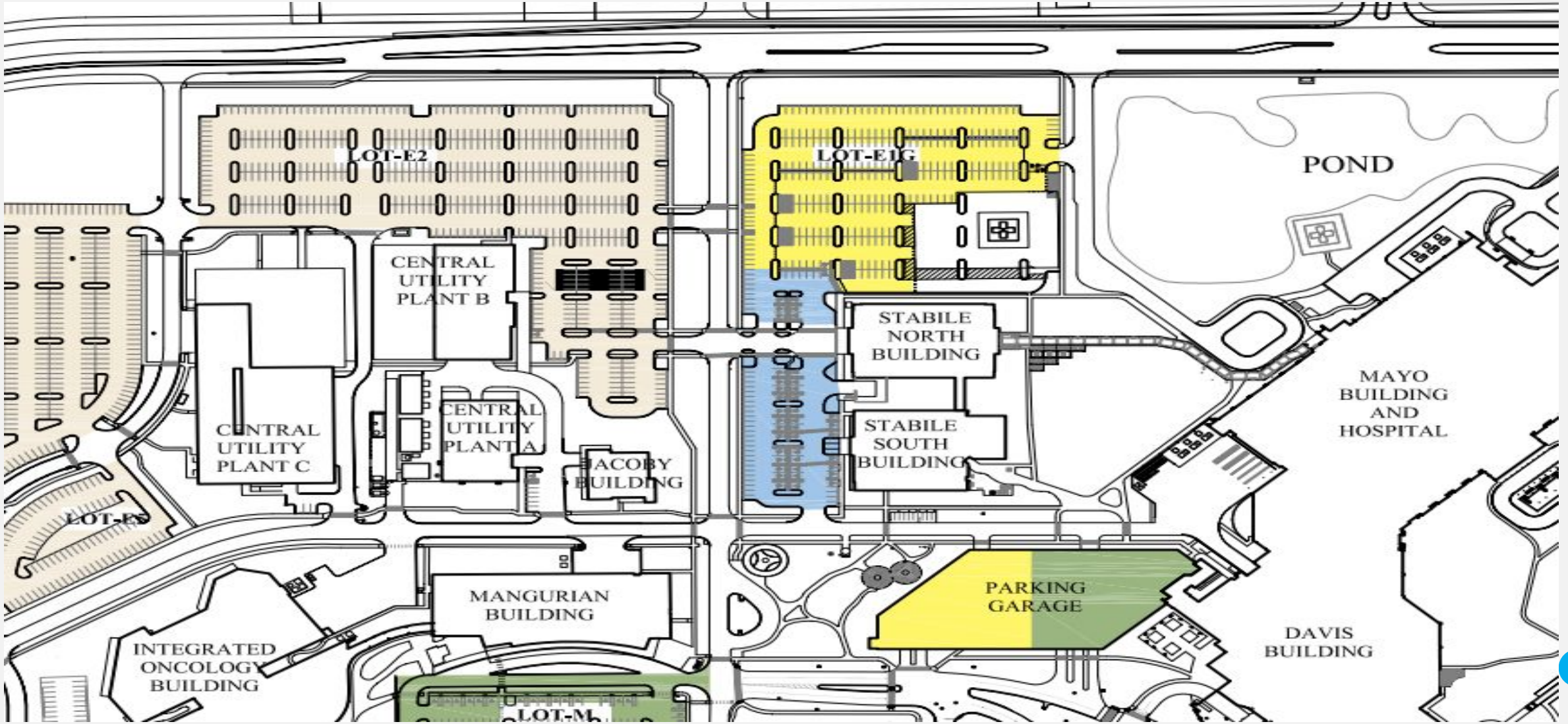


	Total Annual Cost of CBC Cartridge FY22 # Chemo treatments		
	Stabile Core	Hemoscreen*	Hospital Core
Cartridge Costor Exact Cost	$9.71	$10.00+ labor	$10.97
Annual Cost	$273,531	$281,700+labor	$309,025
	*originally told $11-14 per cartridge, but quote stated a pack was $500 for 50 cartridges *not accounting for exact cost of work by tech and others		


CBC
Hemoglobin
Hematocrit
Erythrocytes
MCV
MCH
MCHC
RDW SD
RDW CV
Platelet Count
Leukocytes
16
14
12
10
8
6
8m ago
Back to Grid
2022
7/1
2023
1/1
7/1
2024
1/1
7/1


CBC
Hemoglobin
Hematocrit
Erythrocytes
MCV
MCH
MCHC
RDW SD
RDW CV
Platelet Count
Leukocytes
500
400
300
200
100
0

Map of Mayo Jacksonville Florida



Chemotherapy Unit - 30537 - Key Drivers										
Description	FY 2019	FY 2020	FY 2021	FY 2022	FY 2023	FY 2024	2025	2026	2027	2028
No. Of Treatments	23,465	23,368	25,446	28,170	30,796	30,391	30,999	31,619	32,251	32,896
YoY % Δ		*-0.41%*	*8.89%*	*10.71%*	*9.32%*	*-1.32%*	*2.00%*	*2.00%*	*2.00%*	*2.00%*

CBCNA	JXC	MCF - Hem Clinic	CBC Chemo - No Alerts
CBCPA	JXC	MCF - Hem Clinic	CBC with Differential/Platelet Agg.
CBCJ	JXC	MCF - Hem Clinic	Complete Blood Count
CBCJD	JXC	MCF - Hem Clinic	Complete Blood Count with Differential

Mayo Test ID

CBCNA

Location

JXH: Jacksonville Hospital

Reporting Name

CBC Chemo - No Alerts

Published Name

Complete Blood Count, Chemotherapy, No Alerts, Blood

Testing Algorithm

Hemoglobin, platelet count, white blood cell count, and absolute neutrophil count will be reported. No other complete blood cell count parameters will be reported, and no differential will be performed. Critical values obtained will not be phoned to the healthcare provider.

Method Name

Direct Current/Photometric/Flow Cytometry

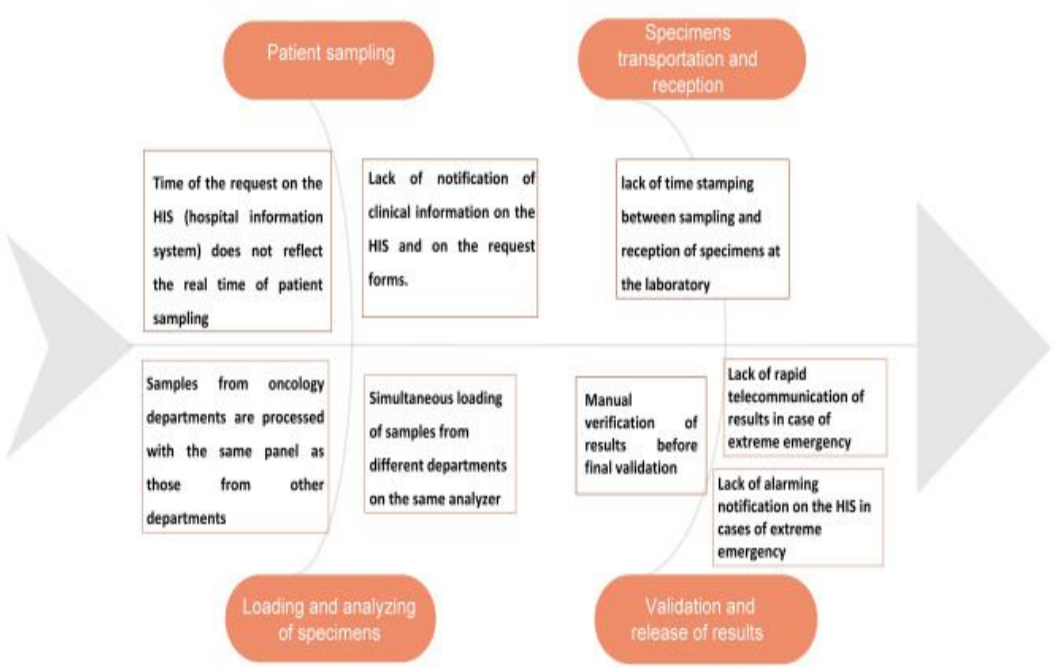
Turnaround Time of the Hematology Results of Cancer Patients During the COVID-19 Pandemic: An Opportunity to Initiate a Quality Improvement Process

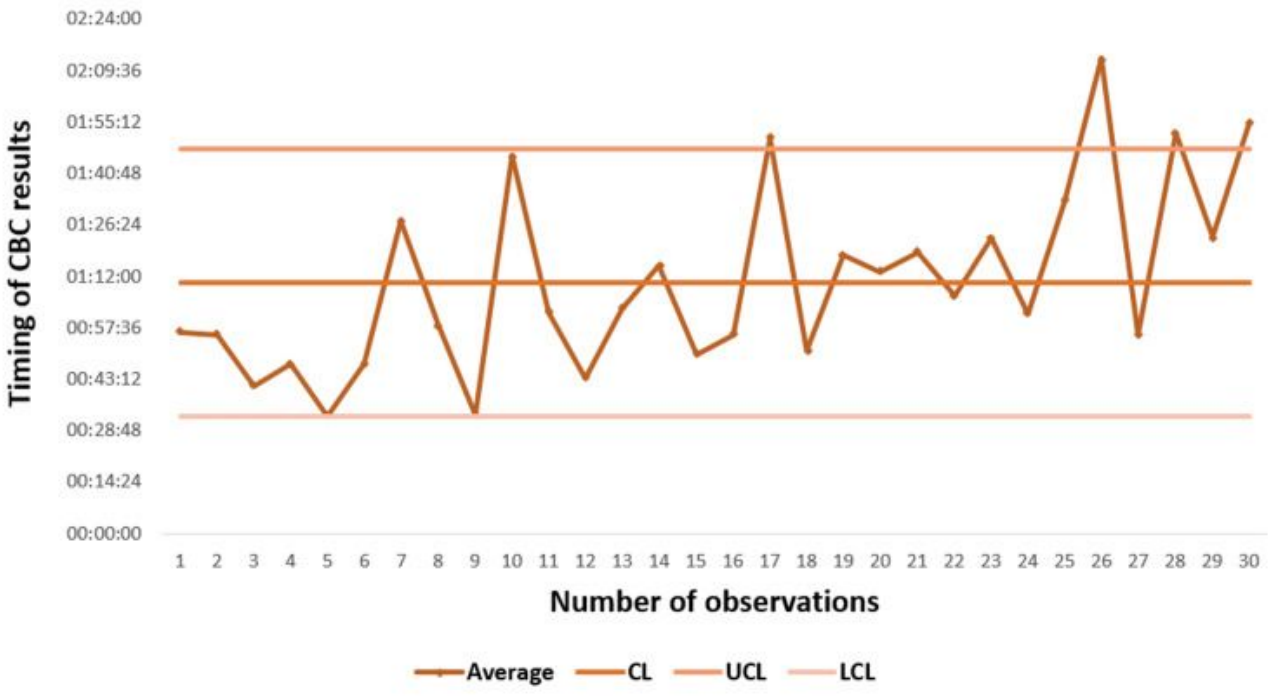
Asmae El Assil [1, 2], Souad Benkirane [1, 2], Yasmine El Kettani [3, 2], Ali Cherif Chefchaouni [3, 2], Hassane Mamad [1, 2], Younes Rahali [3, 2], Azlarab Masrar [1, 2]

1. Central Laboratory Hematology, Ibn Sina University Hospital Center, Rabat, MAR 2. Faculty of Medicine and Pharmacy, Mohammed V University, Rabat, MAR 3. National Institute of Oncology, Ibn Sina University Hospital Center, Rabat, MAR

Time (minutes)	Interval 1: registration acquisition on HIS, n=263		Interval 2: acquisition validation on HIS, n=263		Intra-lab TAT, n=263	
	n	%	n	%	n	%
<30	135	51.72	174	66.66	33	12.64
30-59	93	35.63	65	24.90	112	42.91
60-89	14	5.36	18	6.89	69	26.43
90-119	10	3.83	1	0.38	24	9.19
120-149	4	1.53	2	0.76	8	3.06
>150	5	1.91	1	0.38	15	5.74

TABLE 1: Contribution of all turnaround times of results in minutes from the analytical to the post-analytical phase



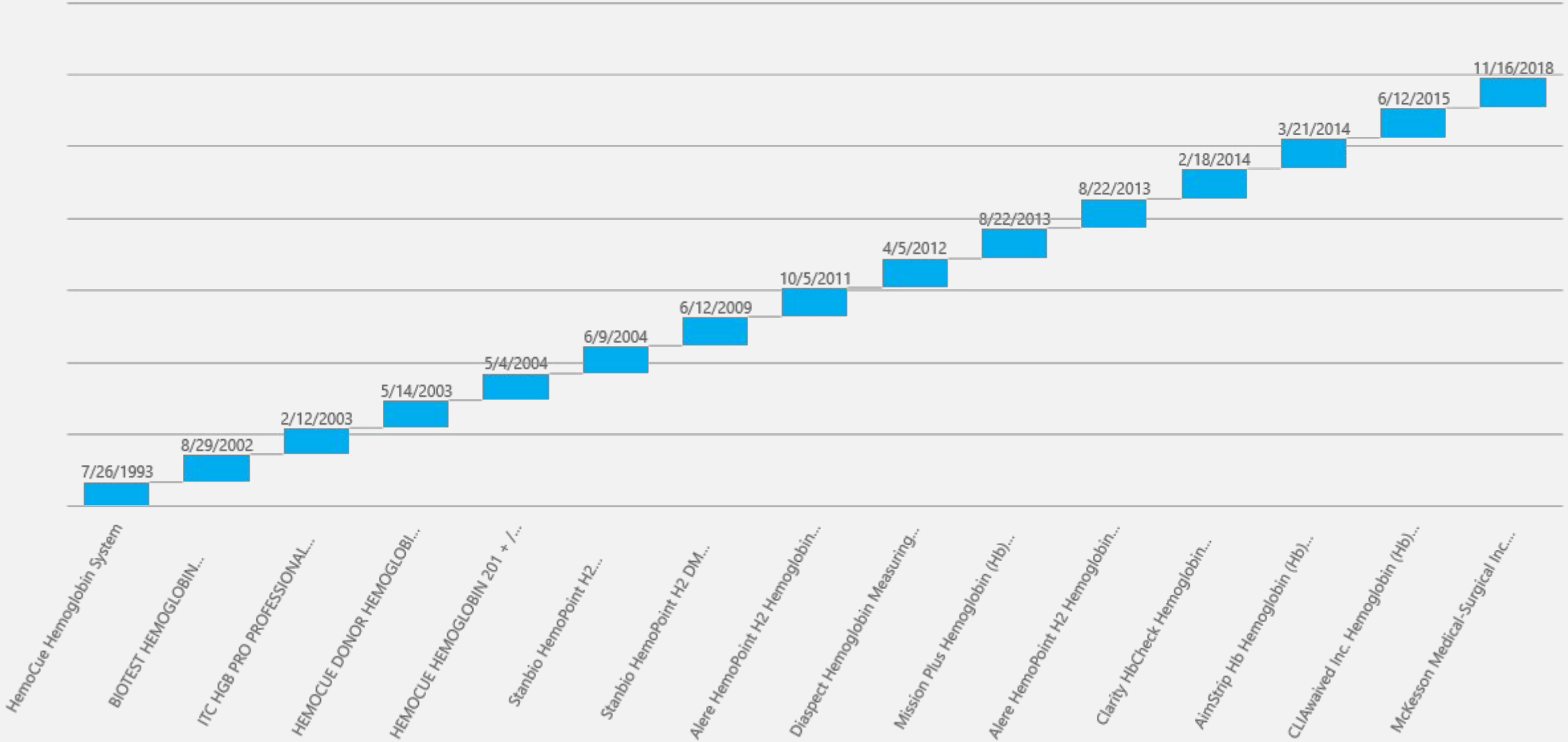


SMALL SCALE LAB CAPITAL REQUIREMENTS CBC AND CMPS
$148,440.50 – $188,440.5

	XN-1000 R	XN-1000 BR	XN-1000 PR	XN-1000 BPR	XN-1000-010
					
Model ID	XN-1000-100-R-01	XN-1000-100-BR-01	XN-1000-100-PR-01	XN-1000-100-BPR	XN-1000-010
Components					
XN-10 or XN-20	XN-10	XN-10	XN-10	XN-10	XN-20
Automated reflex/rerun	0	0	0	Included	Included
Reticulocyte License (R)	Included	Included	Included	Included	Included
Body Fluid License (B)	0	Included	0	Included	Included
Fluorescent Platelet (P)	0	0	Included	Included	Included
WPC Channel	0	0	0	0	Included
Floor-standing wagon option	← Available →				
Analyzer Dimensions	← 20.5"(W) X 26.6" (D) X 33.0" (H); 150LBS →			← 25.4" (W) X 29.7" (D) X 33.7" (H); 172 LBS →	

- **Sysmex XN-1000 Tower - $60K-100K depending on model and application**
- **Roche COBAS C311 - $60K (for CMPs)* or cost of storage of current 701s**
- **Olympus BX46 LED Cytology Microscope- $8,870.50**
- **Fridge/Freezer-$9712 & $ 9858**
- **Centrifuge- reallocate current ones**
- **Sysmex and Roche line managed by HTM and vendors- Must add to Master Agreement**

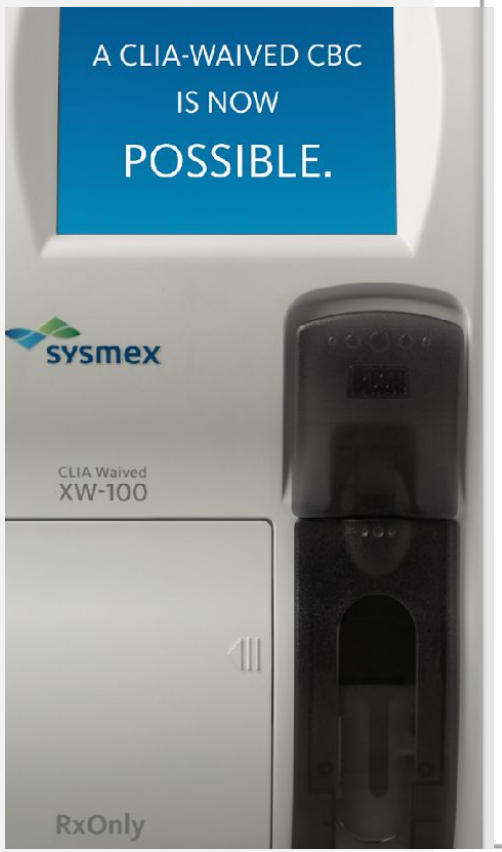
Waived Hemoglobin Tests cleared by the FDA

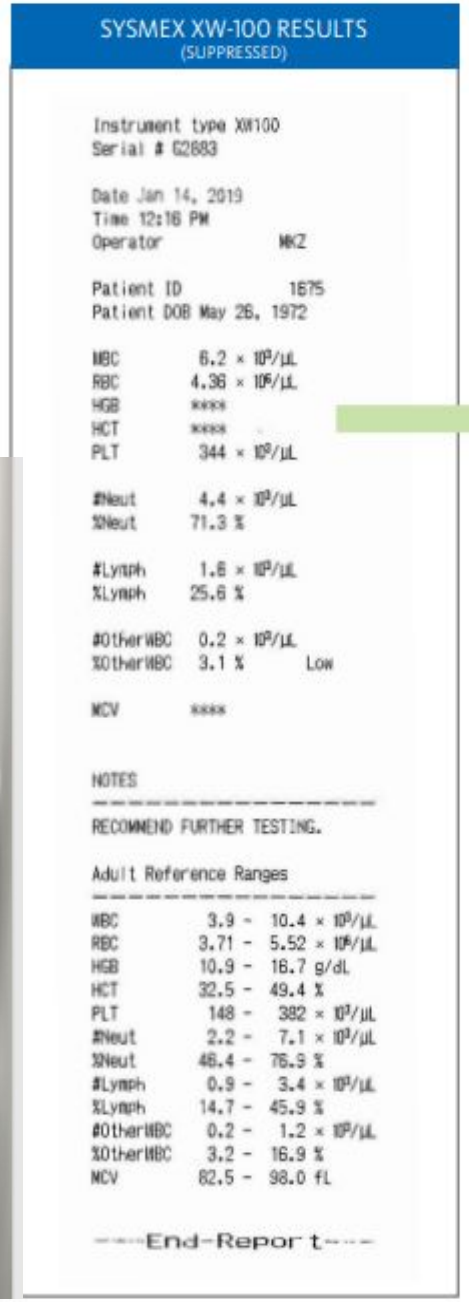


The Sysmex XW-100 offers a

3-part differential with 12 different parameters:

- Total #WBCs
- Total #RBCs
- Hemoglobin
- Hematocrit
- Total #platelets
- Total #neutrophils
- % of neutrophils
- Total #lymphocytes
- % of lymphocytes
- Total #other WBCs
- % of other WBCs
- MCV





SYSMEX XW-100 RESULTS
(SUPPRESSED)

Instrument type XW100
Serial # G2683

Date Jan 14, 2019
Time 12:16 PM
Operator MKZ

Patient ID 1675
Patient DOB May 26, 1972

WBC	6.2 × 10³/µL	
RBC	4.36 × 10⁶/µL	
HGB	****	
HCT	****	
PLT	344 × 10³/µL	
#Neut	4.4 × 10³/µL	
%Neut	71.3 %	
#Lymph	1.6 × 10³/µL	
%Lymph	25.6 %	
#OtherWBC	0.2 × 10³/µL	
%OtherWBC	3.1 %	Low
MCV	****	

NOTES

RECOMMEND FURTHER TESTING.

Adult Reference Ranges

WBC	3.9 - 10.4	× 10³/µL
RBC	3.71 - 5.52	× 10⁶/µL
HGB	10.9 - 16.7	g/dL
HCT	32.5 - 49.4	%
PLT	148 - 382	× 10³/µL
#Neut	2.2 - 7.1	× 10³/µL
%Neut	46.4 - 76.9	%
#Lymph	0.9 - 3.4	× 10³/µL
%Lymph	14.7 - 45.9	%
#OtherWBC	0.2 - 1.2	× 10³/µL
%OtherWBC	3.2 - 16.9	%
MCV	82.5 - 98.0	fL

----End-Report----

Rerun sample if device alerts to do so. If results are still suppressed, send sample out as per your standard protocol.

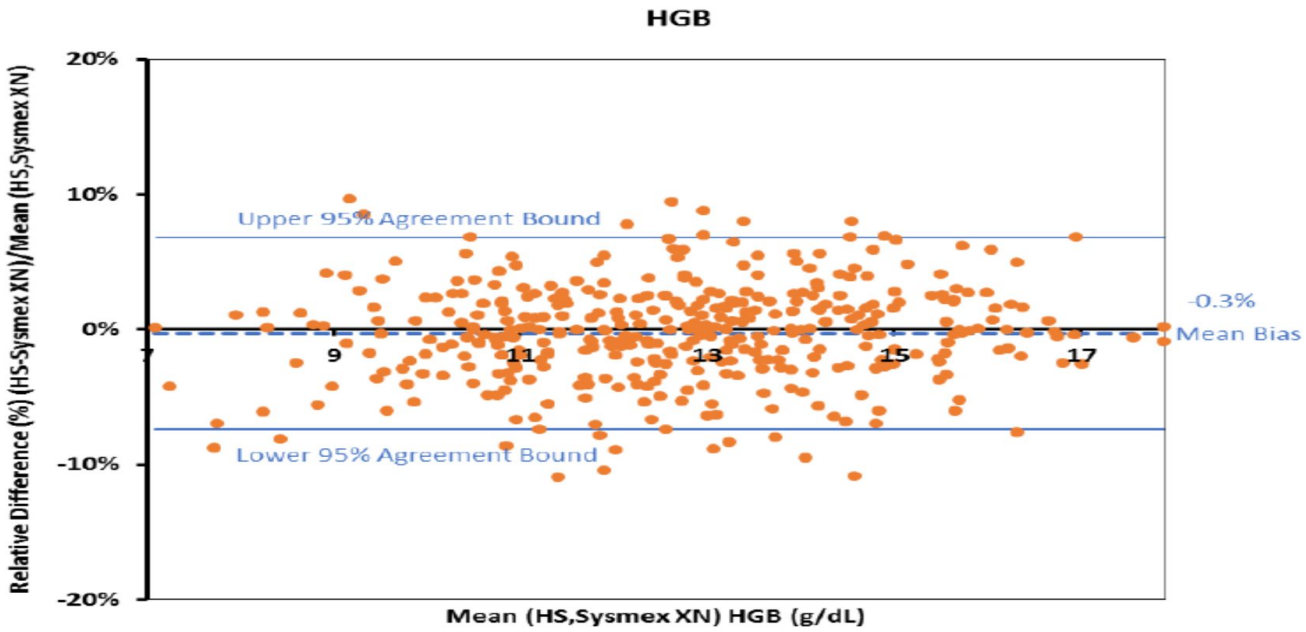
JALM | 532–542 | 6:2 | 2021

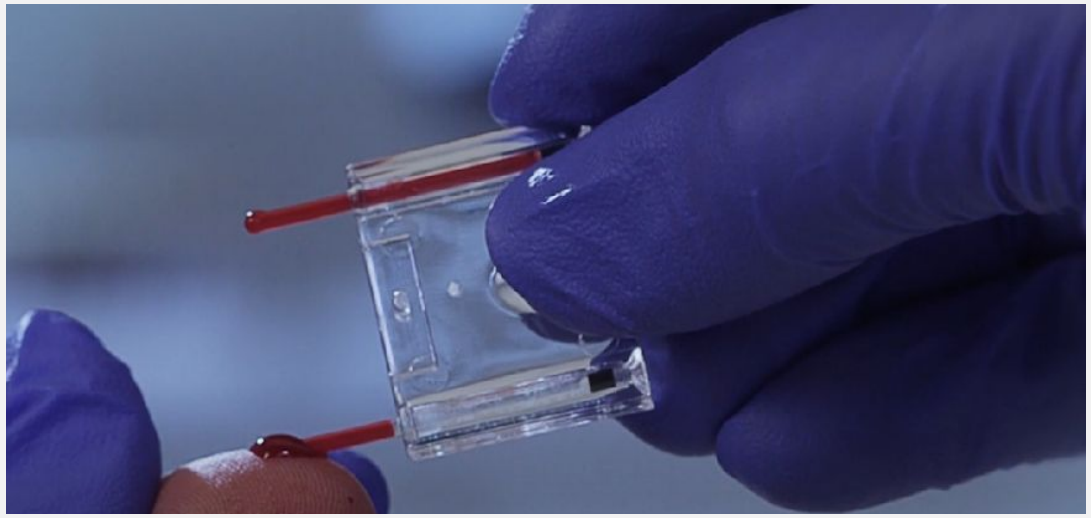
SPECIAL REPORT

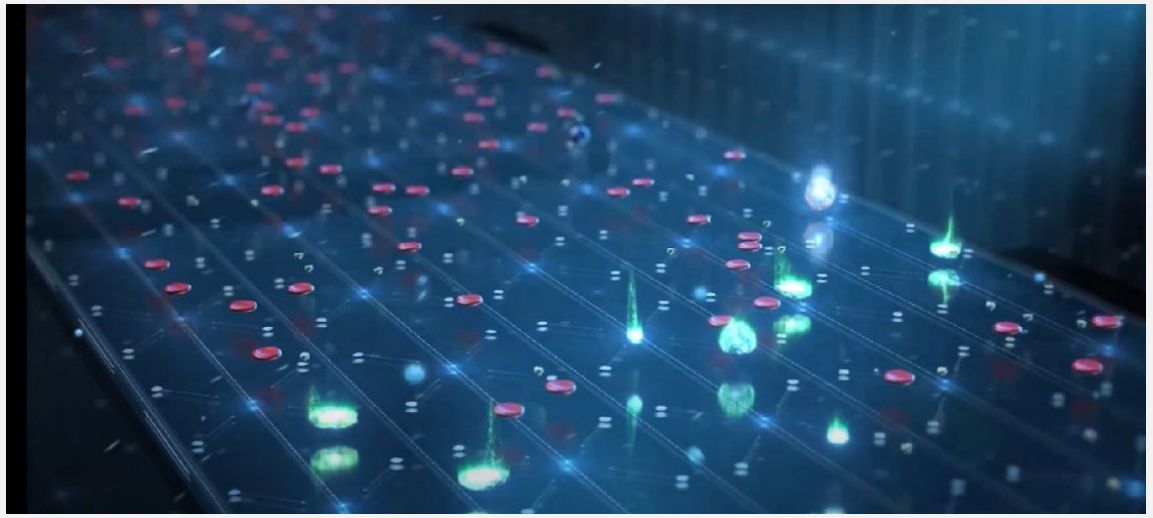
A Novel Approach to Hematology Testing at the Point of Care

Avishay Bransky, [a]Anders Larsson,[b] Elisabeth Aardal,[c,d] Yaara Ben-Yosef,[a,*] and Robert H. Christenson[e]

Summary: The HemoScreen analyzer demonstrates lab equivalent performance, tested at different clinical settings and sample characteristics, and might outperform standard techniques in the presence of certain interferences.
This new approach to hematology testing has great potential to improve quality of care in a variety of
settings.

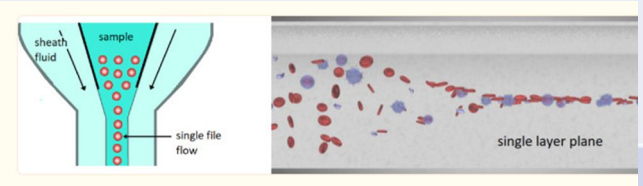
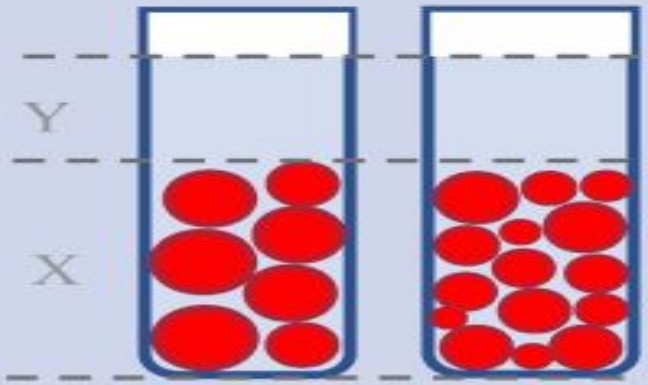
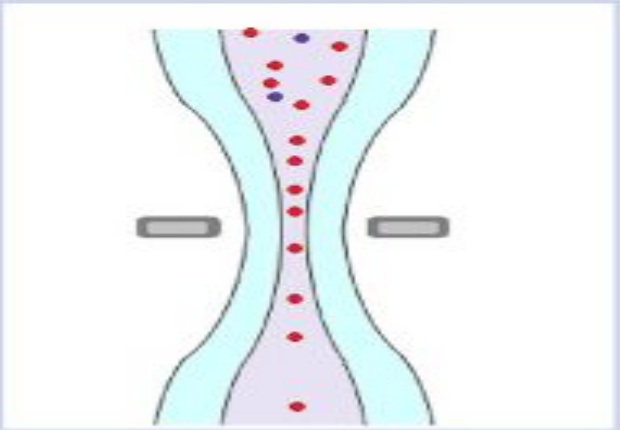
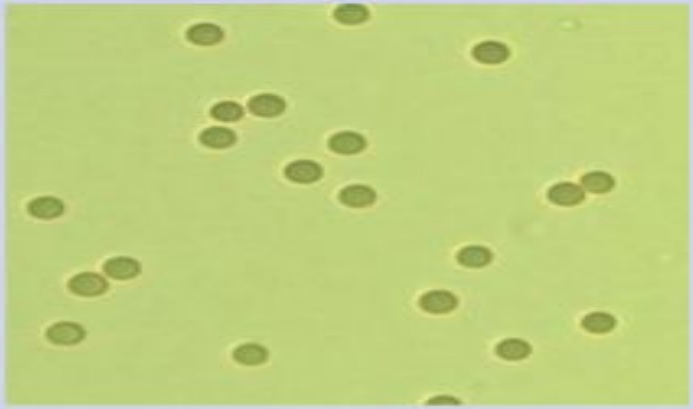






1. Microfluidic viscoelastic focusing 2. Lab-on-a-Cartridge 3. Machine vision and AI

HemoScreen cartridge accepts a disposable dispenser that acquires two minute blood samples

Reference method (Spun HCT)	Sysmex XN	HemoScreen
The sample is centrifuged and the ratio of packed cells' volume to whole blood volume is calculated	Direct Current, electric pulse: cell volume is measured based on electric impedance divided by estimated serum volume.	Cell volume is directly measurement from image. HCT is attained from MCV and RBC product
$HCT_{ref} = X/(X+Y)$ X,Y - lengths JALM | 532–542 | 6:2 | 2021	$MCV_{XN} = k\sum_{i=1}^{n}\frac{P}{n}$ P — pulse height n — number of cells k — empiric factor $HCT_{XN} = k\sum_{i=1}^{n}\frac{P}{v}$ v — est. volume	$MCV_{HS} = \sum_{i=1}^{n}\frac{V_i}{n}$ V — cell volume n — number of cells $HCT_{HS} = MCV_{HS} * RBC$ 
		
Result depends on cell volume distribution and not only on distribution mean.	Indirect measurement, depends on cell electric properties and other factors	Direct measurement of MCV from image. HCT is based on the actual volume of cells without empty spaces in between cells

PMC full text:

J Appl Lab Med. 2020 Dec 4 : jfaa186.

Published online 2020 Dec 4. doi: 10.1093/jalm/jfaa186

Table 1

Correlation coefficients for RBC, MCV, HCT, MCH, HGB, and PLT obtained from comparisons done for the HemoScreen vs Sysmex XN, Abbott CellDyn, and Siemens Advia at different clinical settings.

Clinical setting	Comparative method	Sample size (*n*)	RBC (*r*)	MCV (*r*)	HCT (*r*)	MCH (*r*)	HGB (*r*)	PLT (*r*)
Primary Care, Gimo Primary Care Health Center, county of Uppsala, Sweden	Sysmex XN	160	0.969	0.927	0.950	0.927	0.963	0.983
Emergency Department, Norrköping and Linköping, Region Östergötland Sweden	CellDyn Sapphire	150	0.994	0.965	0.987	0.935	0.983	0.987
Operating Room, University of Uppsala, Uppsala, Sweden	Sysmex XN	145	0.986	0.935	0.960	0.934	0.971	0.983
ICU (cardiothoracic, neuro and general ICU), University of Uppsala, Uppsala, Sweden	Sysmex XN	104	0.993	0.938	0.981	0.944	0.980	0.994
Unilabs AB, Sweden	Advia 2120i	139	0.984	0.958	0.973	0.943	0.980	0.980

Open in a separate window

Received: 21 August 2022 | Revised: 21 August 2022 | Accepted: 24 August 2022
DOI: 10.1002/jha2.566

eJHaem

RESEARCH ARTICLE

HemoScreen hematology analyzer compared to Sysmex XN for complete blood count, white blood cell differential, and detection of leukocyte abnormalities

Anna-Maria Linko-Parvinen[1,2] | Kristiina Keränen[1] | Kaisa Kurvinen[1] | Anri Tienhaara[1]

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Email: anna.linko-parvinen@tyks.fi

Compared a point-of-care HemoScreen hematology analyzer to an automated Sysmex XN analyzer for complete blood count (CBC) and white blood cell (WBC) differential, and evaluated its capacity to detect leukocyte abnormalities.
A total of 100 K2-EDTA whole blood samples, median age 56 years (2 months to 92 years), were compared.
For CBC and WBC differential we compared 74 samples with no confirmed abnormal leukocytes.
For 26 samples both analyzers gave flagging regarding leukocytes and the accuracy of the flagging was compared. Abnormal leukocytes were confirmed with manual microscopy (200 cells).

eJHaem.2022;3:1126–1134. https://doi.org/10.1002/jha2.566

TABLE 1 HemoScreen analyser repeatability with two control samples (CBC PIX Hematology Controls)

	Control low			Control high		
Analyte	Goal	Mean	Within run/Total CV%	Goal	Mean	Within run/total CV%
WBC ($\times 10^9$/L)	3.0	2.9	5.8/5.8	8.1	7.9	5.2/5.2
RBC ($\times 10^{12}$/L)	2.8	2.8	1.9/2.0	4.7	4.7	1.4/1.4
HGB (g/L)	80	82	1.8/2.6	152	152	1.4/1.8
HCT (%)	20	20	2.0/2.1	38	37	1.3/1.3
PLT ($\times 10^9$/L)	75	73	3.6/3.6	273	270	2.0/2.0
MCV (fl)	71	70	0.41/0.41	79	79	0.28/0.28
MCH (pg)	28	30	1.2/1.2	32	32	0.65/0.65
MCHC (g/L)	400	420	1.5/1.5	410	410	0.81/0.81
RDW (%)	16	15	0.48/0.67	12	12	0.28/0.55
Neutrophils ($\times 10^9$/L)	1.5	1.4	7.7/7.7	4.1	3.9	5.0/5.0
Lymphocytes ($\times 10^9$/L)	1.1	1.2	4.4/4.4	3.1	3.2	7.3/7.3
Monocytes ($\times 10^9$/L)	0.2	0.2	15/15	0.50	0.52	8.7/8.7
Eosinophils ($\times 10^9$/L)	0.10	0.096	22/22	0.30	0.24	14/14
Basophils ($\times 10^9$/L)	0.1	0.012	9.9/9.9	0,1	0.035	5.7/5.7

Note: Protocol was $2 \times 2 \times 3$, with control analysis twice in every sample series twice a day for three consecutive days.
WBC, white blood cells; RBC, red blood cells; HGB, hemoglobin; HCT, hematocrit; PLT, platelets; MCV, mean corpuscular volume; MCH, mean corpuscular hemoglobin; MCHC, mean corpuscular hemoglobin concentration; RDW, red blood cell distribution width.

JALM | 1028|08:06|2023

ARTICLE

Analytical Performance Evaluation of Three Point-of-Care CBC Analyzers for Management of Clozapine Therapy in Ambulatory Psychiatry Clinics

Robert D. Maynard,[a] Tony Funk,[b] William Harrill,[b] Jenny Jin,[b] Dawn Smith,[b] Gina Smith,[b] and Nichole Korpi-Steiner [a,*]

Neutropenia — Potentially life-threatening agranulocytosis led to restrictions on clozapine's use in many countries, but neutrophil monitoring has allowed for safer use of the medication. The US Food and Drug Administration requires patients in the United States to have a minimum absolute neutrophil count (ANC) greater than or equal to 1.5 × 10^9/L to initiate clozapine.

Table 1. Imprecision of CBC with differential parameters.

		OLO			HemoScreen			pocH-100i		
Analyte	Units	QC assigned mean (SD)	Observed mean (SD)	CV	QC assigned mean (SD)	Observed mean (SD)	CV	QC assigned mean (SD)	Observed mean (SD)	CV
WBC	10^9/L	3.1 (0.3)	3.1 (0.2)	6.1%	3.0 (0.9)	3.0 (0.2)	6.2%	3.0 (0.4)	3.3 (0.1)	2.7%
		9.2 (0.7)	9.1 (0.3)	3.8%	8.1 (1.7)	8.2 (0.3)	3.6%	6.6 (0.7)	6.9 (0.1)	1.9%
		24.4 (1.7)	24.7 (0.6)	2.3%	19.5 (3.0)	19.9 (0.7)	3.5%	17.6 (1.8)	18.2 (0.3)	1.6%
RBC	10^{12}/L	2.9 (0.2)	2.85 (0.1)	1.6%	2.82 (0.30)	2.88 (0.1)	2.0%	2.81 (0.21)	2.76 (0.1)	1.8%
		4.9 (0.2)	4.89 (0.1)	1.3%	4.73 (0.60)	4.81 (0.1)	2.6%	4.54 (0.26)	4.47 (0.1)	1.3%
		6 (0.3)	6.02 (0.1)	1.0%	5.58 (0.60)	5.67 (0.1)	2.0%	5.75 (0.26)	5.63 (0.1)	1.0%
HGB	g/dl	7.7 (0.4)	7.7 (0.1)	1.0%	8.0 (0.9)	8.6 (0.2)	2.3%	7.0 (0.3)	7.1 (0.1)	1.3%
		13.6 (0.4)	13.7 (0.1)	1.0%	15.2 (1.8)	15.9 (0.4)	2.6%	13.3 (0.7)	13.3 (0.2)	1.1%
		17.3 (0.5)	17.2 (0.1)	0.6%	19.9 (2.7)	21.1 (0.5)	2.2%	17.3 (0.7)	17.9 (0.2)	1.1%
HCT	%	22.2 (2)	22.1 (0.3)	1.5%	20.0 (2.0)	20.3 (0.5)	2.3%	21.1 (1.6)	21.1 (0.4)	2.1%
		41.5 (2.5)	41.3 (0.8)	1.8%	37.6 (4.5)	37.7 (1.0)	2.6%	39.1 (2.7)	39.0 (0.6)	1.5%
		54.8 (3.3)	54.4 (1.1)	2.0%	49.4 (6.5)	49.9 (1.2)	2.4%	51.5 (3.9)	51.5 (0.7)	1.4%
MCV	fL	76.1 (2.3)	77.6 (1.4)	1.8%	71.0 (5.0)	70.7 (0.3)	0.4%	75.0 (12.7)	76.3 (1.0)	1.3%
		85 (2.6)	84.5 (1.6)	1.9%	79.4 (5.0)	78.4 (0.4)	0.5%	86.0 (10.6)	87.2 (0.9)	1.0%
		91.2 (2.7)	90.4 (1.9)	2.1%	88.5 (5.0)	87.9 (0.7)	0.8%	89.6 (11.3)	91.5 (0.9)	1.0%
MCH	pg	26.3 (0.8)	27.0 (0.2)	0.9%	28.4 (4.5)	30.0 (0.2)	0.7%	24.9 (3.4)	25.5 (0.4)	1.6%
		27.9 (0.8)	28.0 (0.2)	0.8%	32.1 (5.0)	33.1 (0.1)	0.3%	29.3 (3.1)	29.8 (0.5)	1.8%
		28.8 (0.9)	28.6 (0.2)	0.9%	35.7 (4.5)	37.3 (0.2)	0.5%	31.2 (2.7)	31.8 (0.4)	1.1%
MCHC[a]	g/dL	34.6 (1.4)	34.8 (0.5)	1.5%	40.0 (5.0)	42.4 (0.4)	0.8%	33.3 (4.1)	33.5 (0.6)	1.9%
		32.9 (1.3)	33.1 (0.5)	1.6%	40.5 (5.0)	42.2 (0.2)	0.5%	34.1 (3.8)	34.2 (0.7)	1.9%
		31.6 (1.3)	31.6 (0.6)	2.0%	40.3 (5.0)	42.4 (0.3)	0.8%	34.8 (3.9)	34.7 (0.4)	1.3%
PLT	10^9/L	83.2 (12)	82.0 (5.2)	6.4%	75 (21)	73.0 (2.0)	2.7%	57 (17)	54.2 (2.8)	5.1%
		200 (25)	192.2 (8.6)	4.5%	273 (45)	266.4 (5.1)	1.9%	220 (36)	204.2 (5.1)	2.5%
		490 (98)	488.6 (23.2)	4.7%	587 (80)	579.0 (9.1)	1.6%	524 (60)	474.9 (8.7)	1.8%
MPV	fL		NA[b]		9.1 (3.0)	9.3 (0.2)	2.1%	10.1 (1.6)	10.5 (0.2)	2.3%
					9.1 (2.0)	9.2 (0.1)	1.6%	9.9 (1.1)	10.1 (0.2)	1.8%
					9.2 (2.0)	9.6 (0.1)	1.4%	9.6 (0.9)	10.0 (0.1)	1.4%
ANC	10^9/L	1.4 (0.2)	1.4 (0.1)	7.6%	1.5 (0.3)	1.5 (0.1)	8.1%	2.2 (0.4)	2.2 (0.1)	2.3%

ARTICLE

Analytical Performance Evaluation of Three Point-of-Care CBC Analyzers for Management of Clozapine Therapy in Ambulatory Psychiatry Clinics

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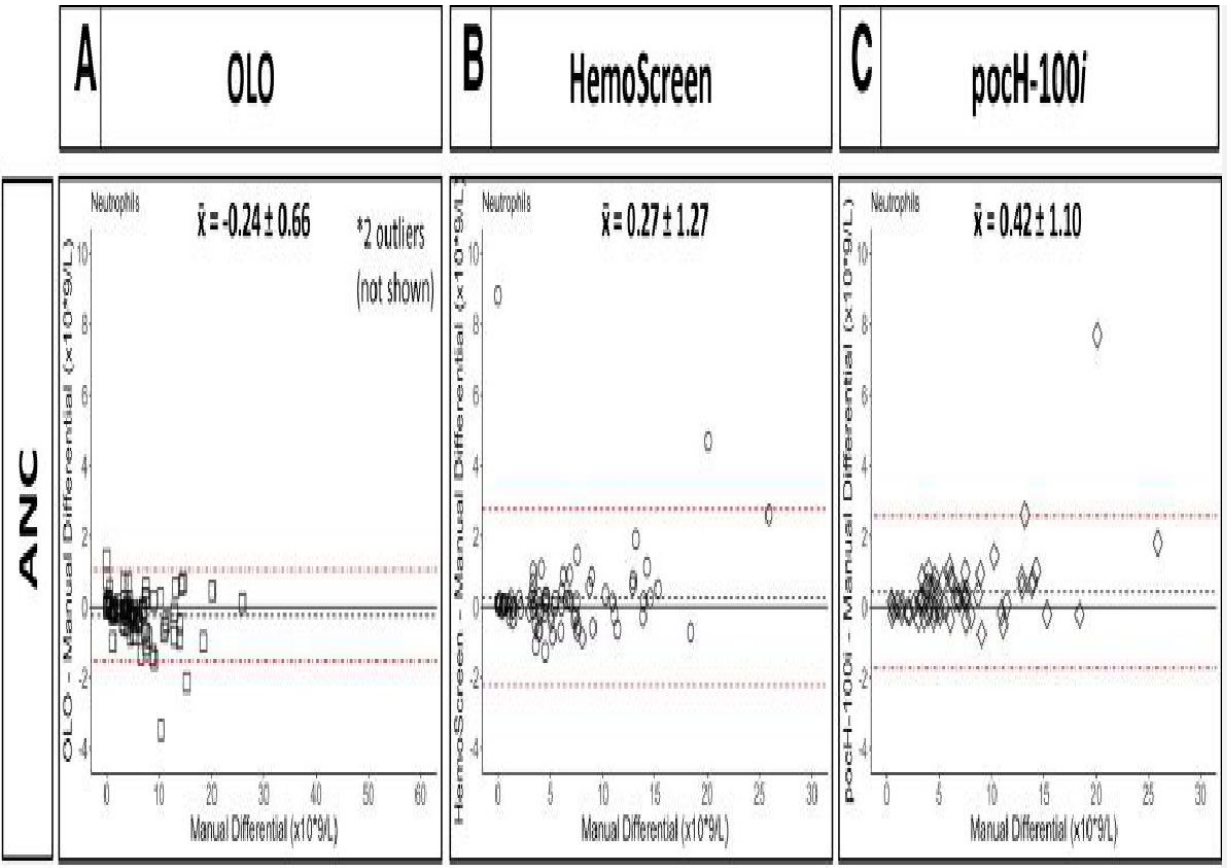

Results: For CBC parameters, a CV ≤ 6.4% was observed on the OLO, CV ≤ 6.2% for the HemoScreen, and CV ≤ 5.1% with the pocH-100i.
Each device accurately identified ANC with the greatest mean bias ±0.42 × 10^9/L using the pocH-100i vs manual differential.
For results near the medical decision points (ANC <1.5 × 10^9/L), clinical concordance of ANC results was 55.6% for the OLO, 89.5% for the HemoScreen, and 82.4% for the pocH-100i.
Conclusions: The HemoScreen device demonstrated the best clinical concordance in ANC values at medical decision thresholds for clozapine therapy management.

CBC parameters as biomarkers of Sepsis

Pros

- Rapid turn-around time;
- Easy to perform;
- Available in all laboratories;
- Low cost;
- Easily available to Clinicians

Cons

- They are not specific for sepsis;
- Do not provide information on the etiology of sepsis;
- Their values can be influenced by several clinial conditions.

https://doi.org/10.1038/s41591-024-03034-2

Point-of-care testing for sepsis in remote Australia and for First Nations peoples

setting, it is within these remote primary care facilities that tools for the early detection and treatment of sepsis have the greatest potential to provide benefit.

The Australian Government has funded a team of investigators, via the Medical Research Future Fund's (MRFF) Primary Health Care Research initiative, to collaboratively test whether using a FBC point-of-care testing device (HemoScreen, PixCell Medical Technologies) can build on the substantial point-of-care testing expertise within remote NT primary care centers and its workforce, with the aim to improve sepsis detection in a cost-effective and culturally appropriate way. The team will embed the WCC and platelet count biomarkers into existing primary care sepsis pathways. In addition to sepsis, the FBC test, or subsets thereof, form key components

Brooke Spaeth[1,2] ✉, Sean Taylor[3,4], Mark Shephard[1,2], Richard L. Reed[2], Rodney Omond[3], Jonathan Karnon[2], Billie Bonevski[2], Chris Rissel[5], Shahid Ullah[2], Tina Noutsos[4,5,6], Jacqueline H. Stephens[2], James A. Smith[5], Annabelle Wilson[2], Brett Abbenbroek[7], Emma de Courcy-Ireland[1,2] & Simon Finfer[7,8]

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AJCP / Original Article

Implementation of Point-of-Care Testing in an Ambulatory Practice of an Academic Medical Center

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From the Departments of [1]Medicine and [2]Pathology, Massachusetts General Hospital, Boston, and [3]Harvard Medical School, Boston, MA.

Key Words: Point-of-care testing; Practice efficiency; Cost-effectiveness; Primary care; Hemoglobin A_{1c}; Lipid panel; Comprehensive metabolic panel

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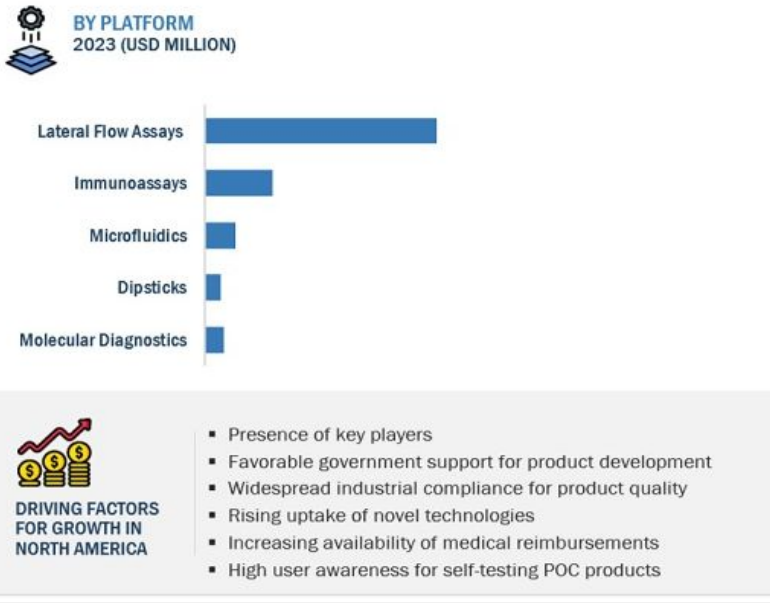
Results: Following implementation of POCT, there was a 21% decrease in tests ordered per patient (P < .0001); a decrease in follow-up phone calls and letters by 89% and 85%, respectively (P < .0001 and P < .0001); and a 61% decrease in patient revisits (P = .0002). Estimated testing revenues exceeded expenses by $6.62 per patient, and potential cost savings from improved efficiency were $24.64
per patient.
Conclusions: POCT can significantly improve clinical operations with cost reductions through improved practice efficiency.

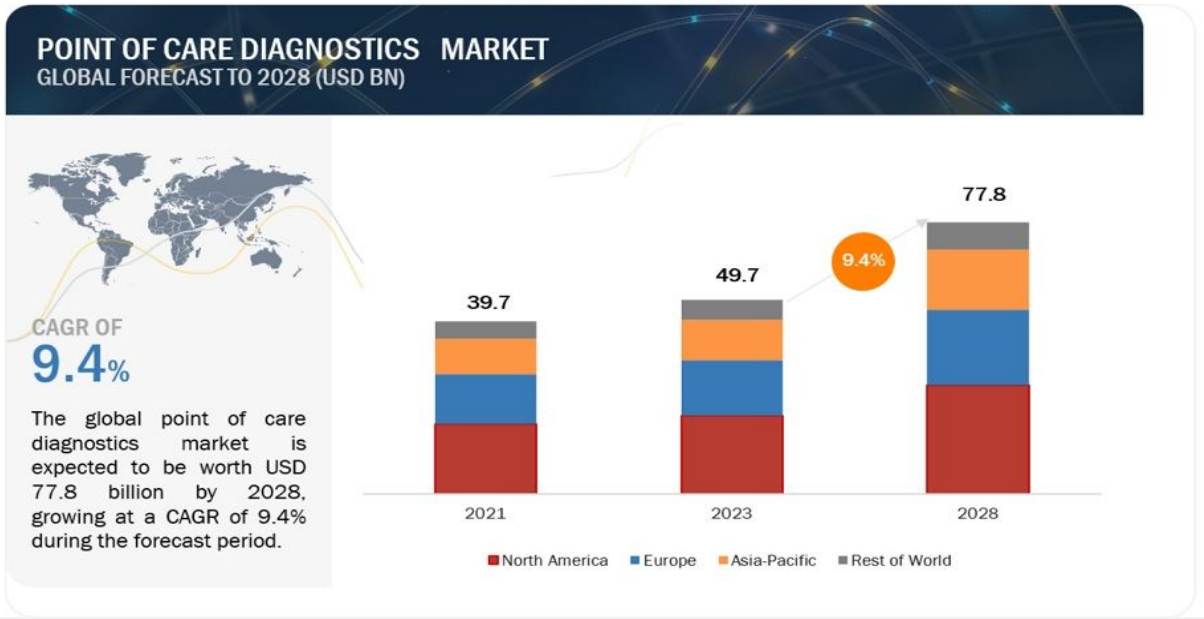
Table 2
Practice Metrics for Control Patients and Those Who Received Point-of-Care Testing

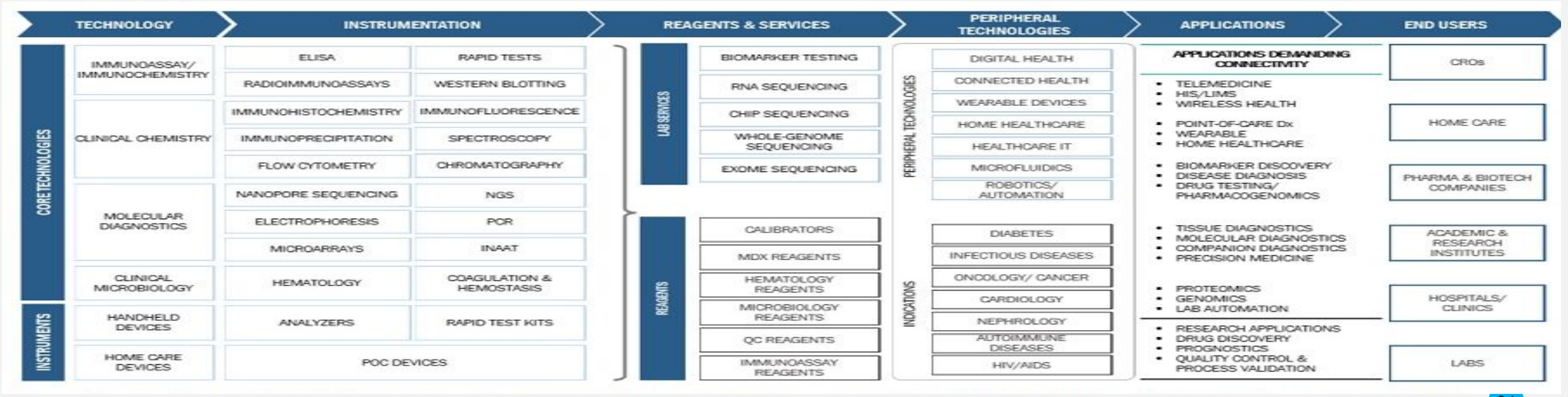
Metric and Visit Type	Mean (95% CI) Control	POCT	% Red
Tests/patient			
New patient	2.45 (2.32-2.61)	2.35 (2.13-2.57)	4
Annual	2.59 (2.38-2.84)	1.88 (1.62-2.14)	27
Follow-up	1.95 (1.69-2.21)	1.32 (1.13-1.47)	32
Total	2.34 (2.22-2.47)	1.85 (1.71-1.99)	21
Calls/patient			
New patient	0.11 (0.02-0.18)	0	100
Annual	0.19 (0-0.38)	0	100
Follow-up	0.49 (0.26-0.72)	0.08 (0-0.13)	85
Total	0.23 (0.13-0.32)	0.03 (0-0.05)	89
Letters/patient			
New patient	0.86 (0.74-0.98)	0.19 (0.07-0.28)	79
Annual	0.81 (0.66-0.97)	0.1 (0-0.17)	88
Follow-up	0.62 (0.46-0.77)	0.08 (0-0.13)	88
Total	0.78 (0.7-0.86)	0.12 (0.07-0.17)	85
Additional visits/patient (due to abnormal laboratory results)			
New patient	0.42 (0.26-0.58)	0.24 (0.11-0.35)	43
Annual	0.31 (0.16-0.47)	0.12 (0.02-0.21)	62
Follow-up	0.41 (0.21-0.59)	0.09 (0.02-0.17)	77
Total	0.39 (0.28-0.5)	0.15 (0.09-0.21)	61

Table 3
Cost/Revenue Analysis for Point-of-Care Testing in a Primary Care Setting

Item	$US per Patient
Cost of testing[a] (reagents, consumables, labor)	25.25
Cost of instrumentation[b]	0.00
Cost of site set up and oversight[c]	See below
Revenue from visit[d]	31.87
Net per-patient margin	6.62
Estimated savings from improved practice efficiency[e]	24.64
Total financial impact	31.26







https://www.marketsandmarkets.com/Market-Reports/point-of-care-diagnostic-market-106829185.html

Revenue	Profit	Employees	Businesses	Wages
$85.1bn	$XX.Xbn	354k	26,519	$XX.Xbn

Diagnostic & Medical Laboratories in the US industry analysis

Services provided by diagnostic and medical laboratories play a crucial role in patients' medical evaluations and treatment, with the data collected by laboratories benefiting the broader healthcare market, giving healthcare practitioners insights into the onset, severity and causes of patients' ailments and illnesses. The aging population and the preventive medicine movement are pivotal factors propelling the increased need for laboratory services. For instance, the increasing number of elderly patients undergoing preventive screening tests has increased demand, particularly to address irregular screening results. 2020 witnessed a surge in demand for testing services due to COVID-19, necessitating increased government funding for laboratories. This resulted in a 2020 spike in revenue, contributing to strong performance over the past five years, with industry revenue growing at a CAGR of 5.3% to reach $85.8 billion, experiencing a 2.5% increase in 2023 alone.

TRENDS AND INSIGHTS :

- **Advances in medical technologies have posed a competitive threat to laboratories.** Point-of-care testing has allowed hospitals to perform their own tests, avoiding medical laboratories.
- **The clinical pathology service market has expanded.** This results from its crucial role in interpreting patients' clinical data and diagnosing and classifying their conditions.
- **Diagnostic and medical laboratories are often found near healthcare facilities.** This is mainly so these hospitals and doctors' offices can easily refer their patients for lab work.
- **Price competition in medical laboratories is intense.** This drives consolidation as larger laboratories can better take advantage of low costs due to economies of scale and meet competitive market prices.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Dr. Brad Karon, Mayo Clinic;
I am not familiar with Hemoscreen. The devices generally fall into two buckets.
Those like OLO that use digital imaging to take a picture of cells and perform count and differential, and those like Sysmex poC-Hi that are conventional cell counters made smaller and simpler for use at POC.
I am not convinced that technologies using digital imaging will achieve required specificity and precision at defined cut-offs as noted by 55% concordance in the clozapine paper.
Keep in mind these patients may have low neutrophil counts but normal cell populations. Throw in abnormal cell populations like you will see in oncology patients and I suspect performance will be even worse.
The miniature conventional cell counters like poc-Hi might be reasonable to try. poc-Hi in particular is waived but approved only for otherwise healthy outpatients, use on label is contraindicated in anyone with cancer diagnosis.
So you would be using off-label but as long as it flags for abnormal cell populations like other cell counters do so you can reflex to other lab method should be OK.
We use a poc-Hi in our high consequence infectious disease lab and seems to correlate well with other Sysmex devices so might want to look at that.