



Transforming Patient Care with Point-of-Care **CRP** Testing



● CRP TESTING AT THE POINT OF CARE; SUPPORTING IMPLEMENTATION, a POCT manager's perspective

- Understand how point of care teams are helping clinical teams implement lab quality, traceable results at the point of care

● ENHANCING CLINICAL DECISION MAKING; A CLINICIAN'S PERSPECTIVE

- Understand how CRP POCT is:
 - helping with clinical decision-making
 - avoiding unnecessary antimicrobial prescribing and hospital admissions
 - benefitting the patients



DARREN BROWNE
*Point of Care Testing
Manager, Dartford &
Gravesend NHS Trust*



ANDY WADE
*Enhanced Clinical Practitioner
(ECP), Dorset Urgent Community
Response (UCR) Team*



ABOUT US - UNA HEALTH

We are a leading UK **provider of diagnostics** for the **point of care** and **laboratory**.

- Family-owned business
- Founded in 2009 with a single product - OPTI blood gas analyser. Point of care has always been at the heart of what we do!
- Now offering 100s of products across extensive range of partners
- Our team of 30 operate across the country with our head quarters based over two sites in Stoke on Trent, Staffordshire

Our Aim:

To reshape the patient journey and improve overall healthcare.





SOLUTIONS TAILORED FOR NEAR-PATIENT TESTING

WITH POCT STANDARDS & ISO IN MIND



We work with many partners with expertise in POCT, covering **urinalysis, cardiology, OAT monitoring, blood gas, diabetes, oncology and respiratory care**



Aidian

QuikRead Go

One portable device, multiple tests
CRP, HbA1c, FIT, Strep A

- Results in 2 to 6 mins at the point of care
- Used by virtual wards, hospital at home and UTCs in the community
- NICE MedTech innovation briefing in 2016
- Subscribed to EQA schemes



Point of Care testing from Finland



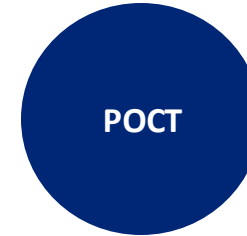
Finnish IVD company with more than 50 years of expertise.



We develop and manufacture reliable, fast, high-quality, and easy-to-use diagnostic tests especially for primary care.



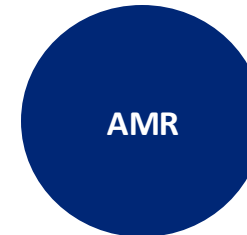
ISO13485:2016 certified and in compliance with FDA QSR requirements. IVDR compliant.



Market leader in several European countries



Placed worldwide



Fighting antimicrobial resistance globally





QuikRead go multianalyte system provides undeniable benefits

CRP, CRP+Hb, HbA1c, FIT,
Strep A



1. **Easy to use** – Minimal hands on steps
2. **Fast** – Quantitative CRP results in 2 minutes
3. **Reliable** – Results comparable to laboratory methods
4. **Portable** – Battery use ensures full portability
5. **Flexible** – CRP sample stability 2 hours
6. **Traceable results** – Excellent LIS/HIS connectivity options
7. **Carefree** – No need for regular maintenance or calibration



QuikRead go POCT CRP Testing at Darent Valley Hospital, Dartford, Kent



By Darren Browne

POCT Manager

November 2024

Introduction

- Started my Biomedical science career (Biochemistry) at Whipps Cross Hospital in 1996 and went on to also work at Basildon University and Southend University Hospitals. Strong back ground in Point-Of-Care-Testing (POCT).
- Became the 1st POCT manager for current Trust (Dartford & Gravesham NHS Trust) in May 2015. There were a lot of challenges but also of engagement from the staff so that today the POCT service is well established and in 2019 I was the winner of the **Trust Individual Improvement & Innovation award**.
- I am currently working on the Virtual ward project that includes the Children's Hospital-At-Home Team POCT CRP testing and result forwarding from the POCT middleware, AegisPOC to the EPR (Miya journey Board).



*Darren Browne MSc FIBMS CSci,
POCT Manager, Darent Valley Hospital,
Dartford, Kent*

The need for bringing CRP test results closer to the patient

Patient pathway before CRP POCT



(L to R) Harriet Broszek (RGN), Shelley Yong (RGN & Team leader) & Kelly Ponton (HCA)
Children's Hospital at Home Team,
Darent Valley Hospital.

The need for bringing CRP test results closer to the patient (cont)

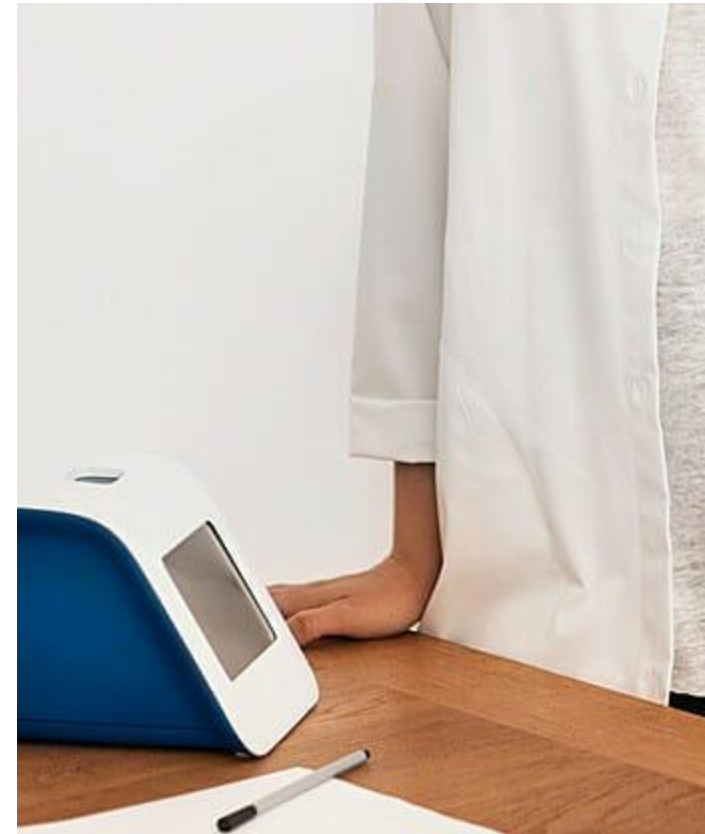


QuikRead go CRP testing

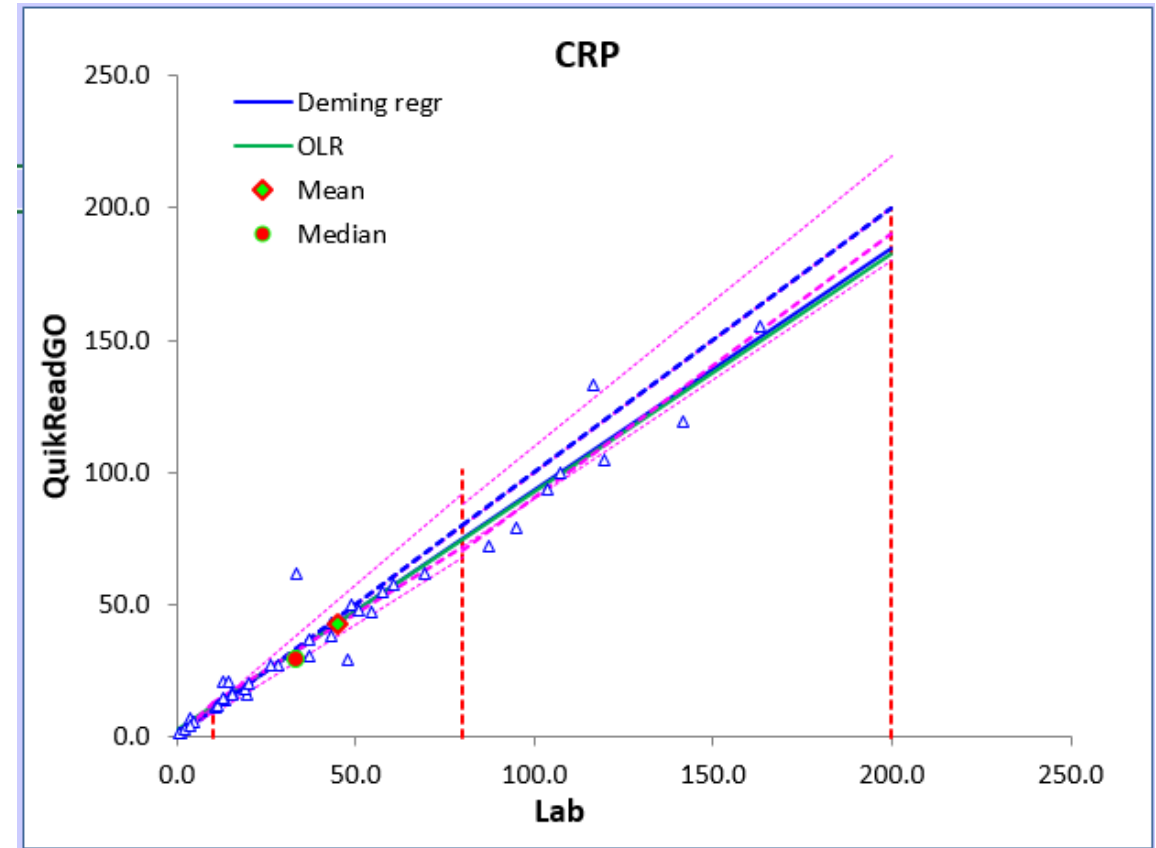
Why the QuikRead Go device chosen for our Children's Hospital-At-Home Team (Virtual Ward)?

Key decisions:

- Support from Una Health during a trial of the Quick Read Go device before purchasing two brand new QuickRead Go device and accessories (Funded via Virtual ward project)
- Verification checks passed
- Can test children under 2 years old
- Portable, sample volume (10 UL), easy-to-use, Robust, results in 2 minutes, storage of consumables & shelf life of kits (up to 12 months)
- Battery powered as well as mains powered device
- Bi-directional full connectivity (wired & wireless) to AegisPOC middleware



Bias assessment QuikRead go vs laboratory (Beckman-Coulter)- 39 patients



Partitioning of Lab results				Number:	Average bias:	Bias %	s(X)	s(Y)	t _{dep}	p-value	Signif.	Slope	Interc	Coeff det	Display
Low:	0.0	to	10.00	6	0.98	37.1			1.971	0.106	NS	1.29	0.19	0.762	Y
Mid:	10	to	80.00	25	-0.35	4.1			-0.219	0.828	NS	0.84	4.88	0.809	Y
High:	80	to	200.00	8	-9.50	-8.6			-2.303	0.055	NS	1.00	-9.63	0.822	Y

Precision study

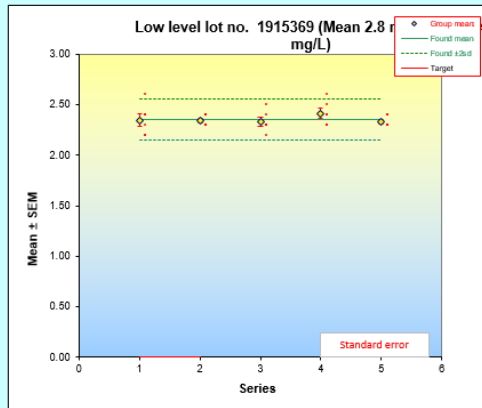
Tri- level Quality controls

Low & normal level controls



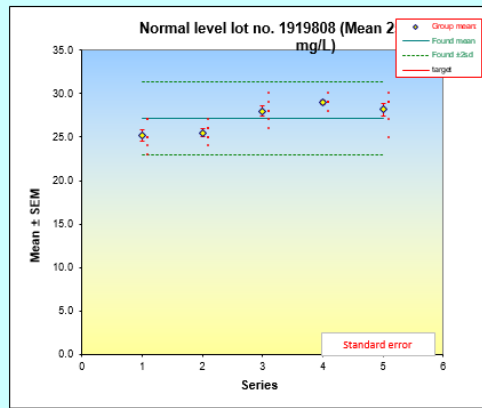
Replicate	1A	2A	3A	4A	5A	6A	7A	8A	9A	10A	1B	2B	3B	4B	5B	6B	7B	8B	9B	10B
1	2.4	2.4	2.2	2.5	2.3						25.0	26.0	28.0	29.0	27.0					
2	2.2	2.3	2.4	2.4	2.4						25.0	25.0	27.0	29.0	29.0					
3	2.2	2.4	2.3	2.3	2.3						27.0	27.0	28.0	28.0	29.0					
4	2.6	2.4	2.3	2.6	2.4						27.0	24.0	26.0	29.0	25.0					
5	2.3	2.3	2.3	2.4	2.3						24.0	25.0	30.0	29.0	29.0					
6	2.4	2.3	2.5	2.3	2.3						23.0	26.0	29.0	30.0	30.0					
7																				
8																				
9																				
10																				

Group mean:	2.35	2.35	2.33	2.42	2.33
SD:	0.15	0.05	0.10	0.12	0.05
%CV:	6.45	2.33	4.43	4.84	2.21
SEM	0.06	0.02	0.04	0.05	0.02
Number obs:	6	6	6	6	6



Display overall mean ± 2 SD (Y/N)?	Y
Display SEM (SE), SD (SD) or none (N)?	SE
Display target means (Y/N)?	N
Hide individual observations (Y/N)?	N

25.17	25.50	28.00	29.00	28.17
1.60	1.05	1.41	0.63	1.83
6.37	4.11	5.05	2.18	6.51
0.65	0.43	0.58	0.26	0.75
6	6	6	6	6



Display overall mean ± 2 SD (Y/N)?	Y
Display SEM (SE), SD (SD) or none (N)?	SE
Display target means (Y/N)?	N
Hide individual observations (Y/N)?	N

Number of observations:	30	30
Mean:	2.36	27.17
SEM:	0.02	0.37
Average of average of series:	2.36	27.17
Average of series' SD:	0.10	1.37
Within series variance:	0.01	1.89
Between series variance:	0.1	2.64
Intralaboratory variance:	0.01	4.53
Within series imprecision s(X):	0.10	1.37
Between series imprecision s(X):		1.63
Intralaboratory imprecision (SD):	0.10	2.13
Within series rel imprecision (%CV):	4.4	5.1
Between series rel. imprecision (%CV):		6.0
Intralaboratory imprecision (%CV):	4.4	7.8

Calc SEM:	0.1316	1.3
CV target (%CV):	4.7	5.3
Bias:	-0.44	2.17
CV test:	0.13	1.38
z-score:	-0.03	0.02
α %:	5	5
t-value (t):	2.045	2.045
High ver value:	3.1	27.8
Low ver value:	2.5	22.2
Conclusion:	Reject!	Accept

Default values of rejection rate is set to 5% .
Uncertainty may be entered as CV% or SD, however,
SD, if present, takes precedence over CV%

Claimed repeatability (SD):	4.70	5.30
Claimed repeatability (CV%):		
False rejection rate (α %):	5.0	5.0
Verification value:	5.99	6.76
Conclusion:	Accept	Accept
Claimed intra-lab (SD):		
Claimed intralab (%CV):		
False rejection rate (α %):	5.0	5.0
Verification value:		
Conclusion:		
Critical Grubbs value (15):	5	5
Upper outlier		
Lower outlier		

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Precision study

Tri- level Quality controls

High level level controls

Imprecision by analysis of variance components (ANOVA)

Operator: Darren Browne		Instrument: QuikRead GO		Operator: _____		Instrument: _____	
Date(s): 13.06.24 - 19.06.24		Comments: Serialnumber A23042179402 & A24042166078		Date(s): _____		Comments: _____	
Reagents: ORP		Calibrator: _____		Reagents: _____		Calibrator: _____	

Group (day, rep or instrument)

		High level lot no. 1917661 (Mean 73; range 58-88 mg/L)																			
		13.06	14.06	17.06	18.06	19.06															
		1A	2A	3A	4A	5A	6A	7A	8A	9A	10A	1B	2B	3B	4B	5B	6B	7B	8B	9B	10B
Replicate	1.	73.0	78.0	77.0	73.0	76.0															
	2.	78.0	68.0	81.0	72.0	74.0															
	3.	78.0	79.0	88.0	76.0	76.0															
	4.	86.0	77.0	81.0	78.0	74.0															
	5.	72.0	75.0	80.0	71.0	74.0															
	6.	77.0	85.0	79.0	74.0	74.0															
	7.																				
	8.																				
	9.																				
	10.																				

Group mean:	77.33	77.00	81.00	75.00	74.67
SD:	4.91	5.55	3.74	3.22	1.03
COV:	6.42	7.21	4.62	4.30	1.38
SEM:	2.03	2.27	1.53	1.32	0.42
Number:	6	6	6	6	6

High level lot no. 1917661 (Mean 73; mg/L)

High level lot no. 1917661 (Mean 73; mg/L)

Display overall mean ± 2 SD (Y/N)?	Y
Display SEM (SE), SD (SD) or none (N)?	SE
Display target means (Y/N)?	N
Hide individual observations (Y/N)?	N

Display overall mean ± 2 SD (Y/N)?	Y
Display SEM (SE), SD (SD) or none (N)?	SE
Display target means (Y/N)?	N
Hide individual observations (Y/N)?	N

The scale of the Y-axis is 'automatic' by default but can be adjusted individually via 'Format axis' and 'Scale'. It is usually sufficient to adjust the 'minimum level'.

Licensed to ACB 2018

High level lot no. 1917661	
Between group df:	4
Within group df:	25
Number of observations:	30
Mean:	77.00
SEM:	0.80
Average of average of series:	77.00
Average of series' SD:	4.02
Within series variance:	16.13
Between series variance:	3.63
Intralaboratory variance:	19.88
Within series imprecision (R):	4.02
Between series imprecision (R):	1.92
Intralaboratory imprecision (SD):	4.46
Within series rel. imprecision (COV):	5.2
Between series rel. imprecision (COV):	2.5
Intralaboratory imprecision (COV):	5.8

High level lot no. 1917661	
Target value:	73.0
σ target (SEM):	
σ target (COV):	
Bias:	
σ bias:	
σ error:	
σ ₂ :	5
σ ₅ :	5
t-value (k):	2.045
High tier value:	
Low tier value:	
Conclusion:	

Default values of rejection rate is set to 5%.
 Uncertainty may be entered as CV% or SD, however, SD, if present, takes precedence over CV%.

Claimed repeatability (SD):	
Calc SD:	6.24
Claimed repeatability (CV%):	8.1
False rejection rate (α %):	5.0 5.0
Verification value:	7.95
Conclusion:	Accept
Claimed intralab (SD):	
Claimed intralab (CV%):	
False rejection rate (α %):	5.0 5.0
Verification value:	
Conclusion:	
Critical Grubbs value (1/5):	5 5
Upper outlier:	
Lower outlier:	

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Can test CRP in children under 2 years old

- The CRP value is automatically corrected on the basis of the sample's haematocrit level. Haematocrit (Hct) results are not displayed but are used in the calculations.
- HCT range of QuikRead go easyCRP is 15-75%
- There are two CRP kits available (easy CRP and wCRP)
- We opted for the easy CRP test
- Measurement range 1-200 mg/L in whole blood samples
- Measurement range in serum/plasma samples 1-120 mg/L



4 Reagents

Content of the kit

Component name and origin	Symbol	QuikRead go® easy CRP Cat. no. 153287 50 tests
QuikRead go easy CRP Reagent Caps ORIG SHP	REAG CPS	2 x 25
Buffer	BUF	2 x 25 x 1 ml
QuikRead go Sample Collector 10µl (sample collector)	SAMPL COL EDTA	50
Instructions for use		

The reagents contain sodium azide as a preservative. Please see Section 5, "Warnings and precautions".

Storage

Kit component	Opened at 2...8°C	Opened at 18...25°C	Unopened at 2...25°C
Reagent Caps	6 months	6 months	Until the expiration date of the kit
Buffer	Foil pouch: 6 months Single prefilled cuvette: 2 hours	Foil pouch: 3 months	
Sample collector	Storage at 2...25°C until the expiry date of QuikRead go Sample Collector 10µl box		

Reagent preparation and storage conditions

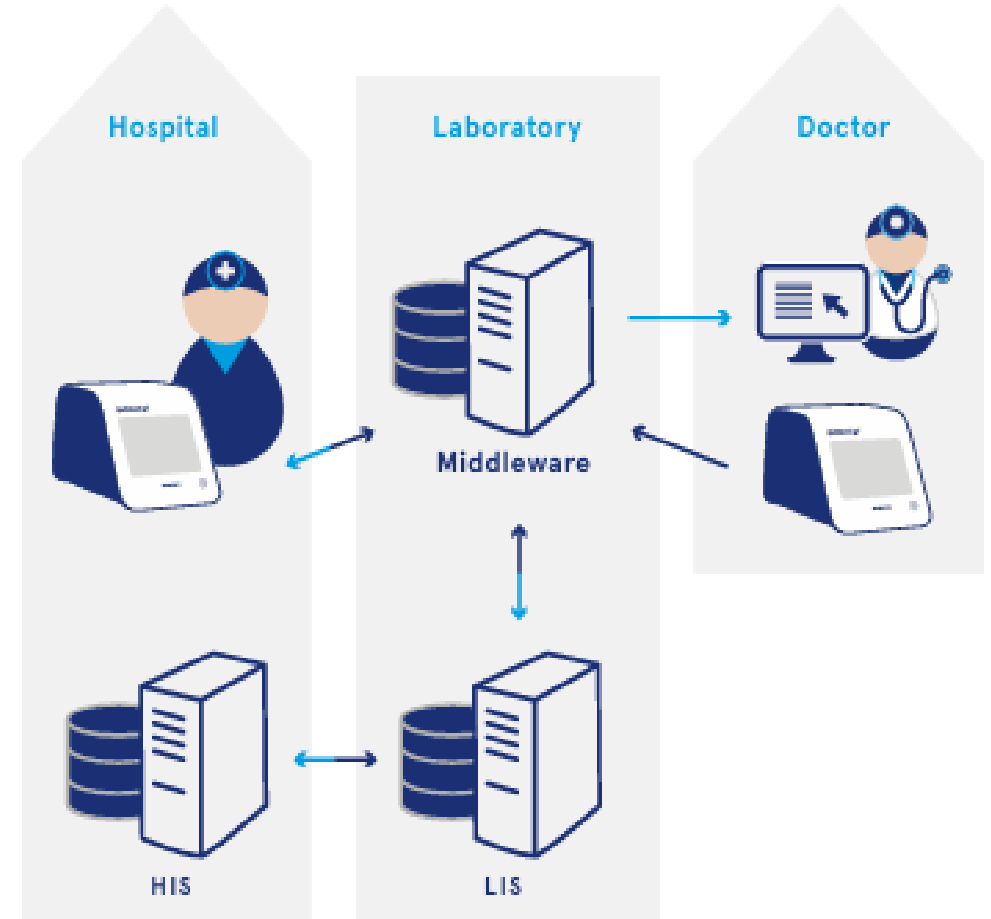
All reagents are ready to use. Keep the CRP Reagent Caps away from moisture. Close the aluminium tube immediately after taking out the required number of reagent caps.

Reagent storage

Connectivity

What we needed

- Positive patient ID recognition
- Bi-directional (POCT1-A connectivity)
- Only trained users can access the device via a barcoded operator ID
- Operator management done via AegisPOC middleware (excellent driver) but can also be done via the analyser
- Barcoded access after face-to-face training initially set-up for a 1 year period to keep barcode active for subsequent years the end – users need to perform a certain number of tests and pass E-learning quiz in order to keep barcoded operator ID access to QuikRead go device.
- The staff switch on the device to update patient list before going out in community setting to allow the latest patient lists to download to the device, even if the hospital number is not matched to a patient it can be matched when they return to DVH. Cartridge Lot numbers & QC are added to the device via AegisPOC.



Connectivity (cont)



Dartford and Gravesham
NHS Trust

- DVH is a PFI hospital so getting a Ethernet port installed in the CHAHT room can be a challenge (expensive & time consuming). To get round this issue the devices are connected wirelessly via wireless dongle attached to one of the USB ports at the back of the QuikRead go device.
- Results are uploaded to the AegisPOC within a minute of establishing a wireless connection at DVH.
- In the community setting they can use the supplied printer or analyser screen for results
- I am currently working with Abbott and Alcidion on moving the POCT CRP results from the AegisPOC middleware to our EPR (Miya Journey Board)

Key Benefits of implementing the QuikRead go device for the Children's Hospital-At-Home-Team (CHAHT)

- CRP result in two minutes. Treat appropriately (supports antimicrobial stewardship) in a timely manner unlike taking a sample in community setting bringing it back to the laboratory waiting for result before treating (2nd visit).
- Sample sent to the laboratory may be haemolysed so no result – how frustrating for the staff and child & parents !!!
- Sample size 10 uL – less invasive and distressing than venepuncture, especially in children.
- Portability (kits, QuikRead Go device) all contained in a special transport bag (supplied from Una Health)
- Training important e.g. under-filling/overfilling capillary can give false low/high CRP hence initial face-to-face training will resolve this issue
- Connectivity
- Relatively low cost of QuikRead go device and consumables

Support from Una Health

- Support from Una Health during a successful trial of the Quick Read Go device for POCT CRP testing before purchasing two brand new QuickRead Go device and accessories (Funded via Virtual ward project)
- Loan QuikRead Go device for POCT trial
- Support throughout verification for patient testing (Bias assessment) and precision checking using tri-level quality controls
- Company support for on-site training, communication (phone & email)
- CPD accredited e-Learning
- Mon-Fri 9-5pm ongoing technical support

Advice for anyone wanting to implement CRP POCT

- **Securing funding** – Business case or in our case we secured funding via Health Tech Accelerator fund. We were approached to make a bid by the ICB. Not only do you need to think about the capital purchase of the POCT equipment but also on-going cost of the consumables.
- **Engage** with your POCT Team as they will guide you on the POCT device application process and approval via POCT committee. Also POCT team involved on the technical side (Advice on the items to purchase e.g battery, scanners etc. Initial set-up of device, connectivity & , Proficiency testing, Batch-acceptance, on-going training, Operator management, trouble shooting etc.
- Ask to **trial** the device (Try before you buy) with the supplier.
- **Talk** to other sites who have implemented POCT CRP testing.
- **POCT connectivity** not just for capturing results & operator management but also audit trails (good governance).

CRP POCT – A clinician's perspective (Dorset UCR)

Andy Wade – UCR ECP



Agenda

- Our clinical service - UCR
- Patient pathway before implementing POC
- What patient care/clinical challenges were we facing?
- Where in our patient pathway are we using CRP testing?
- How does CRP help us make decisions on patient care?
- How we have implemented CRP testing
- Advice for anyone who wants to implement CRP POCT in their service



UCR

The urgent community response (UCR) team is a collective name for services that improve the quality and capacity of care for people through the delivery of urgent, crisis response care within two hours and/or reablement care within two days, which is national standard.

The service provides a person-centred approach to optimise the independence and confidence, enable recovery and prevent a decline in functional ability. It enable people to live independent lives for as long as possible in a place they call home and reduces the need for escalation of care to non-home settings.

It facilitates a timely return to their usual place of residence, following temporary escalations of care and supports collaborative working required to deliver necessities of the hospital discharge model. It is a community-based service, provide by a multi-disciplinary mix of allied health professionals.

What we offer?

- To provide a two-hour urgent (not emergency) response to patients who are entering and Health/ social crisis across the whole of Dorset (only UCR team to cover whole region).
- Provide enhanced levels of assessment to investigate, diagnose & treat patients in their own environment (including care homes) and prevent unnecessary hospital admissions.
- Provide therapy intervention and expertise, including assessment and provision of equipment and refer where needed to other community teams to provide on-going support.
- Direct working/collaboration with NHS 111/999 as well as other integrated community teams and Primary Care networks/ Frailty teams across Dorset, Secondary care e.g. SDEC, Elderly care, specialities where appropriate, SPOA, OOGP's/ NHS 111 GPs.

We have a multi-disciplinary team including ACPs, trainee ACPs (MSc pathway), specialist paramedics/nurses, senior physiotherapists/occupational therapists and assistant practitioners and student nurses.

What other skills do we have?

- Venepuncture/cannulation.
- SC/ IV fluids.
- PGDs- antibiotics, emergency protocol drugs (anaphylaxis, ACS, oxygen, Fluids, nebuliser driven medication, glucagon/ glucogel, general sales list medication to supply (paracetamol, ibuprofen, glycerol suppositories, senna) other analgesia.
- Wound care and closure by Glue, staple and suture.
- Urgent catheterisation- male, female and suprapubic (not routine change). Alongside bladder scanning.
- Verification of death.
- Full systems review - HAPE or equivalent.
- ECG interpretation.
- Non-medical prescribing (clinician dependant).

What equipment do we have?

- Raiser chair
- ECG machine
- Nebuliser (air driven)
- Bladder scanner
- Therapy equipment inc- Wheeled Zimmer Frames, Wheeled commodes, static commodes, trolleys, urine bottles, bed leavers etc. Can order from NRS for same day delivery
- PGDs (+ oxygen and Entonox)
- Venepuncture/ specimen collection equipment
- SC fluid equipment and IV fluid equipment.

Patient pathway before crp poct

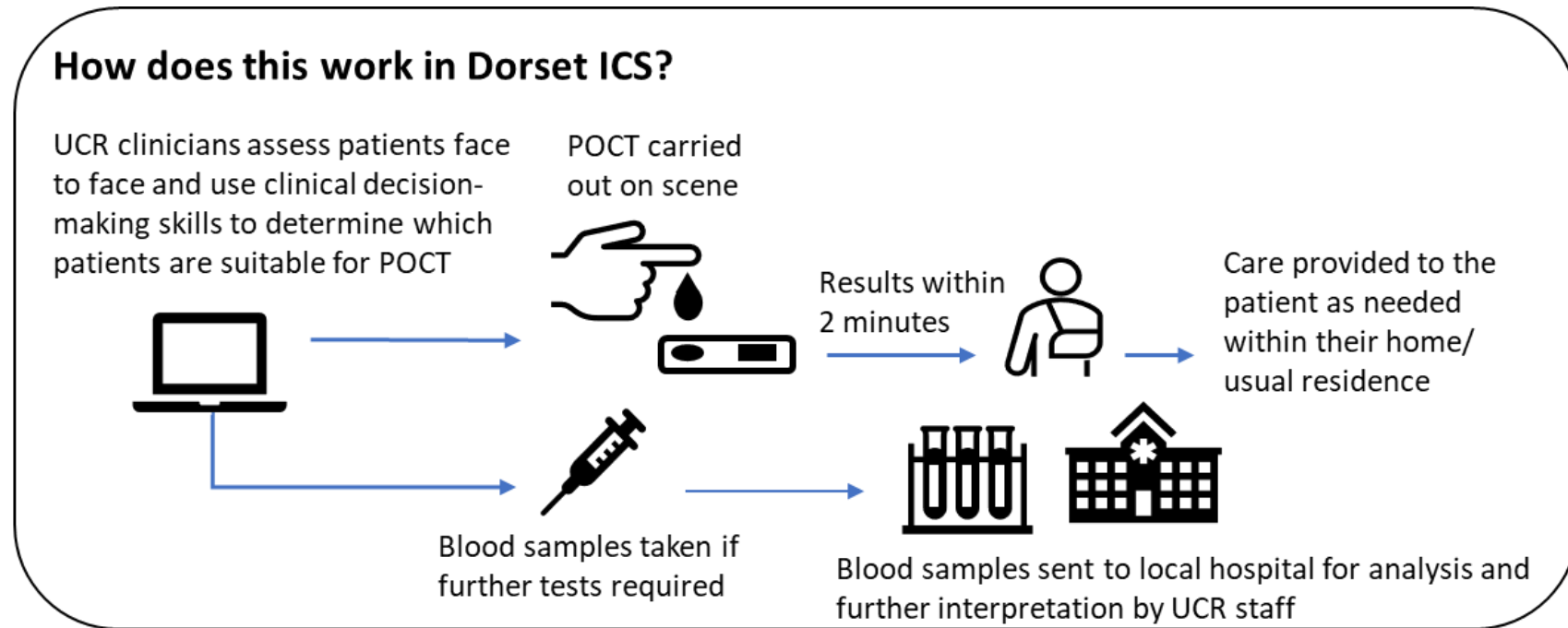


Figure 1. POCT pathway and blood sampling pathway

Patient care/challenges

- Time consuming, lowering resilience and resource for further UCR visits due to travel time to local acute hospitals
- Having to rely on pathology lab's running the tests as urgent and uploading the results to the patient's electronic record
- More invasive for the patient to have a venous sample taken than peripheral POCT
- Many of our patients are elderly and are difficult to obtain a venous blood sample from for various reasons e.g. dehydration

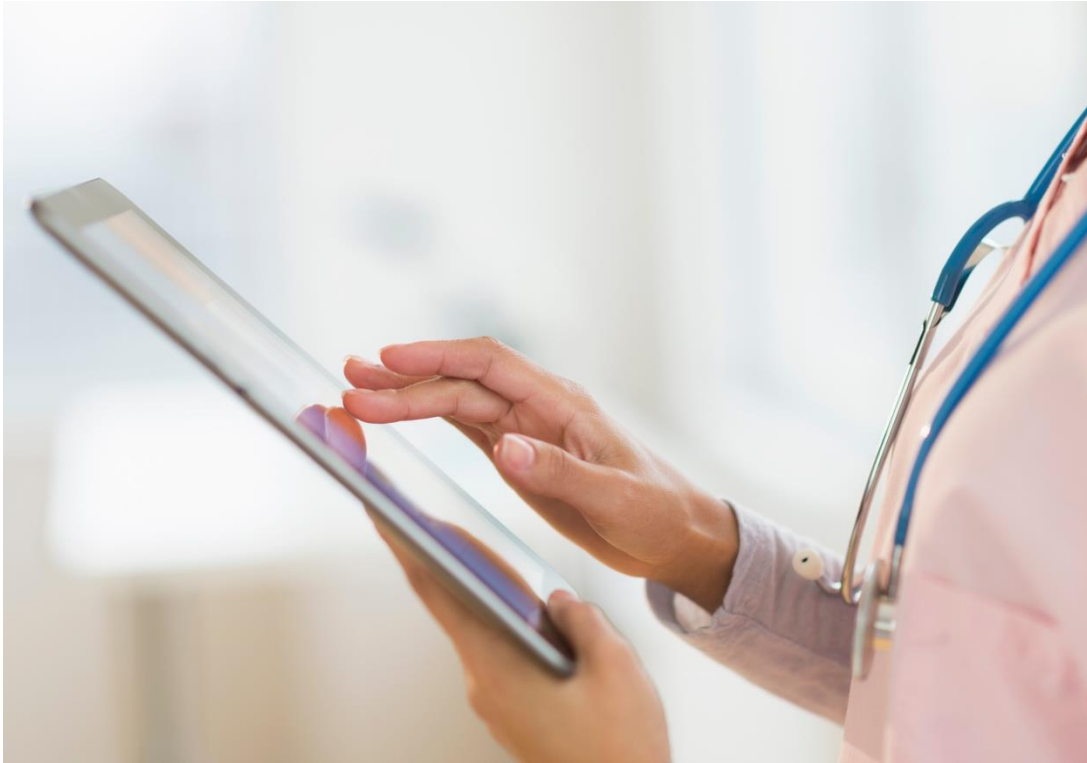


Where are we using POCT in the patient journey

- CRP POCT is utilised at the point of face-to-face visit – it is decided by the visiting clinician if it is clinically indicated to make a difference to the patient's management plan
- Recently, the QuikRead go POCT devices have now been implemented in the Dorset Virtual Ward roll out and can be utilised in the ongoing monitoring of the patient e.g. those started on oral antibiotics to ensure their CRP is improving



HOW DOES THIS HELP US MAKE DECISIONS



- CRP measurement aids in the diagnosis, evaluation, and monitoring of infection, tissue injury, inflammatory disorders, and associated diseases.
- CRP is an acute-phase plasma protein present in healthy individuals at low concentrations. Bacterial infections and inflammatory conditions stimulate the production of CRP in the liver. From the initial stimulus, CRP levels become detectable in 4-6 hours and peak in 36-48 hours.
- Near-instant results support patient flow, meaning faster treatment implementation and a better patient pathway, outcome and experience.

NICE GUIDANCE (BASED ON LRTI)



Immediate antibiotic treatment should be offered if the CRP level is more than 100 mg/litre and a delayed prescription should be considered at levels between 20 and 100 mg/litre. It is not recommended for CRP levels less than 20 mg/litre.



NICE's quality standard on infection prevention and control states that in order to help prevent the development of antibiotic resistance in bacteria, it is important to prescribe antibiotics according to the principles of antimicrobial stewardship. These include prescribing antibiotics only when needed (and not for self-limiting mild infections such as colds and most coughs, sinusitis, earache and sore throats) and reviewing the continued need for them.

Point-of-Care Testing (POCT) and blood sample pathways for UCR – Dorset ICS

The Strategy Unit

What was the problem?

- Patients requiring urgent blood tests had to have blood samples taken from a vein, and then the samples were conveyed to the most local acute trust for testing. A UCR clinician had to interpret the results remotely and liaise with the patient to make a shared treatment plan which is often difficult over the phone with our cohort of patients.
- Antibiotics were sometimes unnecessarily prescribed which results in increased risk of antibiotic resistance.

How does POCT work in Dorset ICS?

- POCT devices including **blood sugar, ketone and C-reactive protein (CRP)** were purchased and utilised by the UCR service

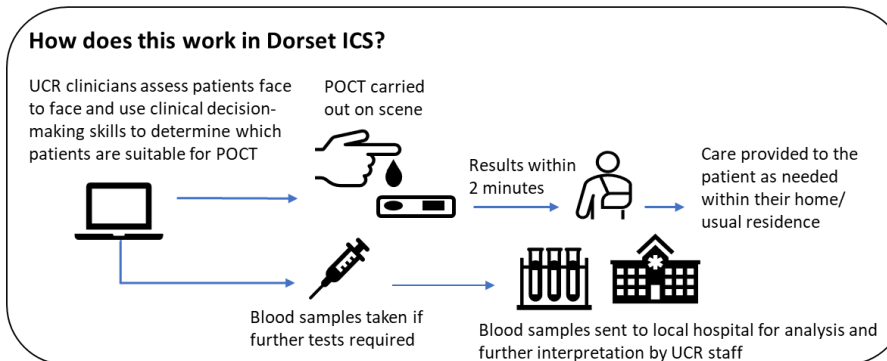


Figure 1. POCT pathway and blood sampling pathway

What's working well?

- POCT devices are **easy to use**, require **minimal training** and need only a **fingertip capillary blood sample** which is **less invasive**
- **Efficient supported clinical decisions can be made** as results are obtained within 2 minutes

"Being able to provide patients with point of care testing as well as antibiotics, obviously relieves the pressure on all of those services [A&E, ambulance service, GPs] because we are providing that antibiotic treatment there and then and blood tests if needed"

What's improved?

Dorset staff have reported:

- **Reduced time waiting** for results for patients and staff
- **Fewer trips to hospital** for blood analysis – improved service capacity
- **Improved antibiotic stewardship** as POCT results aid decision making for prescribing

What's next?

Dorset ICS are planning:

Access to ICE system and thermal labelling printers to further streamline blood sample processes and improve governance.

Local contact details
Nathalie Law – Clinical Lead
UCR
(nathalie.ironson@nhs.net)



How we implemented CRP POCT

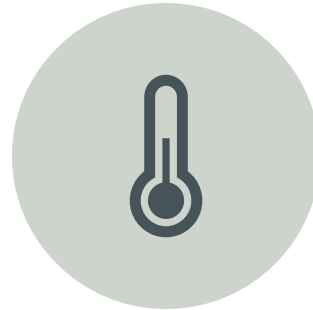
- This was implemented as a service improvement project and was discussed at Medical Device lead level as well as reviewing several different devices to find the most suitable one for UCR e.g transportability, size, test assay.
- A business case was put forward, including the costings of purchasing and running the machines over a 12-month period within the UCR team
- A SOP was written and signed off by Governance Leads – this had to include temperature control records, QC testing results etc.
- Since the roll out within UCR, the Trust have now purchased additional QuickRead Go devices across different services including out of hours and virtual ward



Advice for anyone wanting to use POCT in their clinical service



Know what you want to measure (test assay) and why this will benefit the patient



Know the ideal dimensions of the device you wish to implement e.g. for us a big factor was it being transportable and being able to withstand hot and cold temperatures, for some services this won't be a concern e.g. in an inpatient setting



Be able to demonstrate how this will be financially viable past the outlay costs



Ensure staff engagement – training, QC tests, maintenance of the machines will be everybody's responsibility

Thank you

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Resources:

[QuikRead go easy CRP: Fast and easy to use CRP test for point of care \(aidian.eu\)](http://aidian.eu)

[QuikRead go[®] easy CRP: a perfect fit for the Hospital-at-Home model - Una Health](#)

[QuikRead go for C-reactive protein testing in primary care \(nice.org.uk\)](http://nice.org.uk)

[Medical_Devices_Point_of_Care_Devices_Protocol_IN-419.pdf \(dhc.nhs.uk\)](http://dhc.nhs.uk)

**THANK YOU
FOR LISTENING**



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