OUR JOURNEY TO Blood Bank AUTOMATION

by Edith Hein, MLT II

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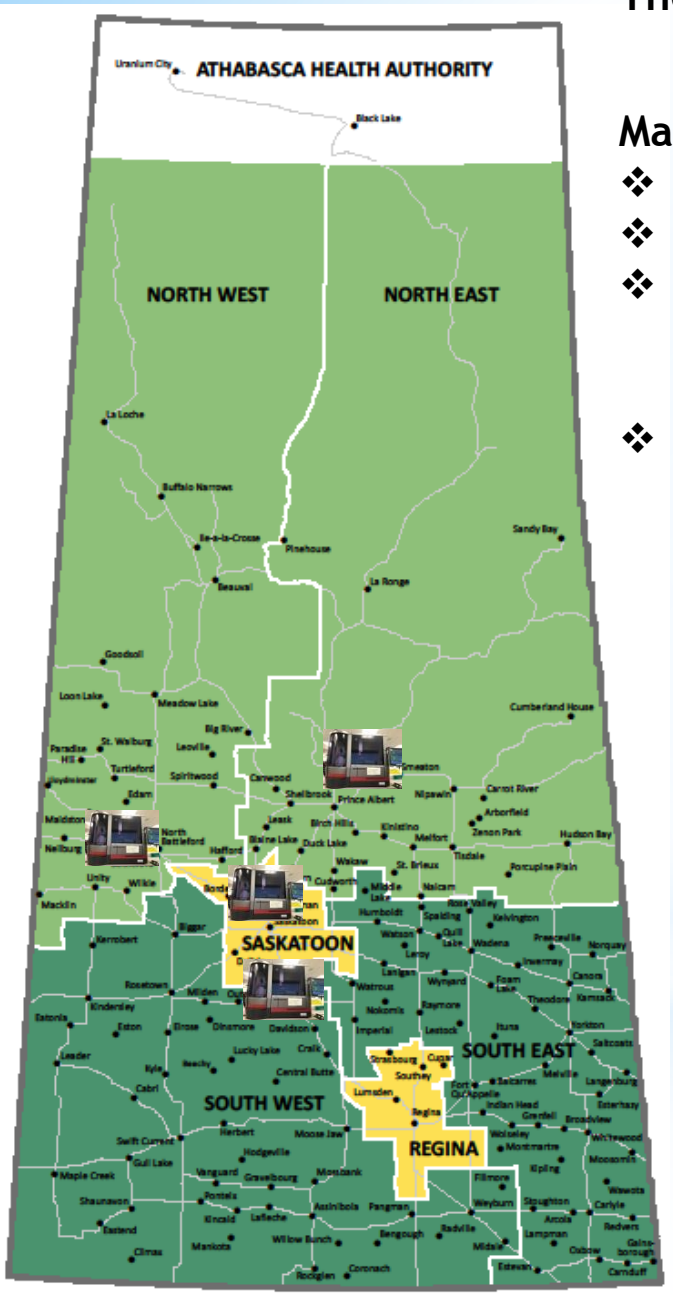


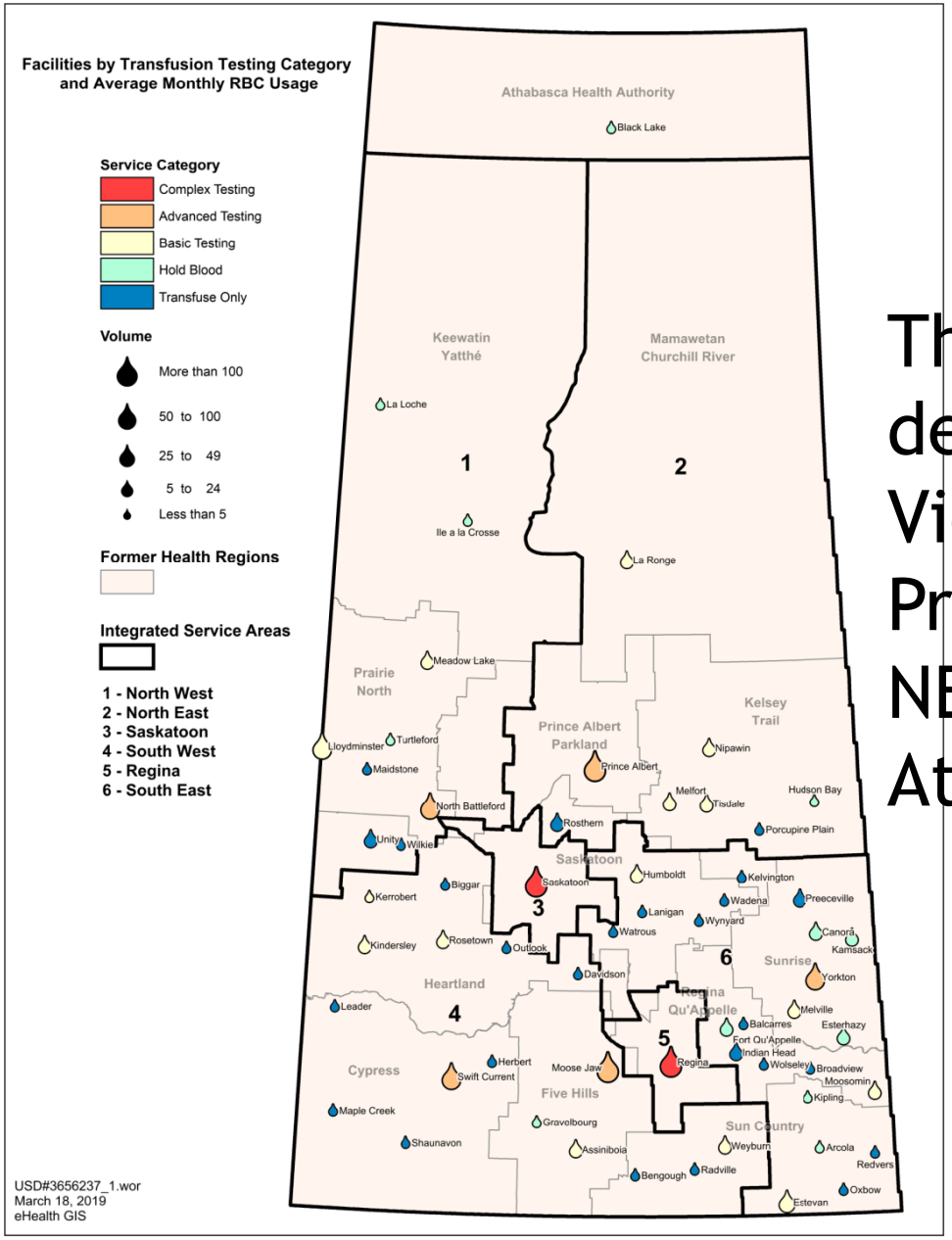
The Victoria Hospital is a 200 bed regional hospital located in Prince Albert Saskatchewan, 140 Km NE of Saskatoon.

Many factors led to the need for full automation.

- Chronic staff shortage
- Significant staff turnover
- Increase in workload due to the closure of diagnostic testing by CBS and designation as an advanced testing site.
- Increase in area covered by our Transfusion Medicine department due to the closure of Saskatchewan Transportation Company and the transitioning from the 12 health care regions to 6 zones.

Lab Administration was in the process of upgrading our Chemistry Analyzer in Shellbrook Hospital when Ortho Clinical proposed the Ortho Vision Analyzer for our laboratory. At the same time our complex testing site the Royal University Hospital in Saskatoon was upgrading from the ProVue to the Ortho Vision. The timing could not have been more perfect.

The Ortho Vision was delivered and installed March 2018. We had to wait a bit for IT to get us connected. The validation began in May 2018 and took approximately two weeks. We went live May 23, 2018.



The transfusion medicine department at the Victoria Hospital serves Prince Albert, the entire NE Saskatchewan and Athabasca.

The Validation Process

PQ Summary of Results				
Analyzer Type:	Vision and/or Vision Max			
Serial No:	50002726			
	Test	Interpretation		
Sample ID	ABD Forward / Reverse	ABO	RH	Evaluation (Pass/Fail)
C3140021	VISION PQ Result	O	POS	PASS
75140078	Expected Result	O	POS	
C3140022	VISION PQ Result	O	POS	PASS
75130207	Expected Result	O	POS	
C3140023	VISION PQ Result	O	POS	PASS
75130234	Expected Result	O	POS	
C3140024	VISION PQ Result	B	POS	PASS
75130301	Expected Result	B	POS	
C3140025	VISION PQ Result	A	POS	PASS
75130442	Expected Result	A	POS	
C3140026	VISION PQ Result	O	POS	PASS
75130858	Expected Result	O	POS	
C3140027	VISION PQ Result	O	POS	PASS
75130969	Expected Result	O	POS	
C3140028	VISION PQ Result	O	POS	PASS
75130978	Expected Result	O	POS	
C3140029	VISION PQ Result	O	POS	PASS
75120061	Expected Result	O	POS	
C3140030	VISION PQ Result	O	POS	PASS
75120070	Expected Result	O	POS	
C3140031	VISION PQ Result	A	POS	PASS
75120119	Expected Result	A	POS	
C3140032	VISION PQ Result	O	POS	PASS
75120457	Expected Result	O	POS	
C3150012	VISION PQ Result	A	POS	PASS

GROUP	
A	40
B	36
AB	25
O	38
	139
RH	
POS	111
NEG	30

With becoming one Health Region and working towards standardization, the numbers to achieve for validation were directed by Dr. S. Harding a TM Physician from RUH in Saskatoon. These were the numbers that she suggested to achieve for the validation of their own Ortho Vision analyzer.

In Order to achieve the best confidence Level:

- ABO = total of 100(i.e. aim for 25 of each group)
- Rh = total of 100 (i.e. pos= 70, neg = 30)

The Implementation objective was to ensure accuracy of ABO and Rh determinations of the Vision using ID-MTS™Gel Cards and to correlate with the ABO/RH manual tube on the bench.

Patients samples and segments from the units were used to achieve the numbers. The correlations between the bench and the Vision agreed 100%.

The Validation Process

	Test	Column Graded Results (+ / 0)				
Sample ID	2 Cell Screen	Surgiscreen Cell 1	Surgiscreen Cell 2	Surgiscreen Cell 3	Interpretation	Evaluation (Pass/Fail)
C3140009	VISION PQ Result	NEG	NEG	NEG	NEG	PASS
73250392	Expected Result	NEG	NEG		NEG	
C3140010	VISION PQ Result	NEG	NEG	NEG	NEG	PASS
73250181	Expected Result	NEG	NEG		NEG	
C3140011	VISION PQ Result	NEG	NEG	NEG	NEG	PASS
73250358	Expected Result	NEG	NEG		NEG	
C3140012	VISION PQ Result	NEG	NEG	NEG	NEG	PASS
73250357	Expected Result	NEG	NEG		NEG	
C3140009+AS	VISION PQ Result	0	3+	0	POS	FAIL
Solid Phase	Expected Result	NEG	NEG		NEG	
C3140011+AS	VISION PQ Result	0	3+	0	POS	FAIL
Solid Phase	Expected Result	NEG	NEG		NEG	
C3140016+AS	VISION PQ Result	0	3+	0	POS	FAIL
Solid Phase	Expected Result	NEG	NEG		NEG	
C3140018+AS	VISION PQ Result	0	3+	0	POS	FAIL
Solid Phase	Expected Result	NEG	NEG		NEG	
C3140019+AS	VISION PQ Result	0	3+	0	POS	FAIL
C3140012+AS	VISION PQ Result	1+	0	0	POS	PASS
Solid Phase	Expected Result	0	1+		POS	
C3140013+AS	VISION PQ Result	3+	0	0	POS	PASS
Solid Phase	Expected Result	4+	2+		POS	
C3140017+AS	VISION PQ Result	0	3+	4+	POS	PASS

Best Confidence Level:

- Antibody screens = total of 100(i.e. neg =50, pos =50)

Negative Screens:	56
Positive Screens:	51

Correlations for the antibody screen were between the 3 cell screen on the Vision and the 2 cell screen solid phase (Capture Technology) on the bench.

Negative screens from previously tested patient samples using solid phase method were saved and repeated on the Ortho Vision.

Positive screens from previously tested patient samples using solid phase were saved and repeated on the Ortho Vision. To achieve the numbers, positive screens were also created using known antisera.

The Validation Process

Donor ID / Recipient ID	Crossmatch-IAT	Interpretation	Evaluation (Pass/Fail)
C053018701901/732	VISION PQ Result	COMP	PASS
50357/C3140003	Expected Result	COMP	
C053018701908/732	VISION PQ Result	COMP	PASS
50357/C3150003	Expected Result	COMP	
C3140014/AB UNIT	VISION PQ Result	INCMP	PASS
5881	Expected Result	INCMP	
C3140014/AB UNIT	VISION PQ Result	INCMP	PASS
1437	Expected Result	INCMP	
C3140014/AB UNIT	VISION PQ Result	INCMP	PASS
0743	Expected Result	INCMP	

Best Confidence Level:

Crossmatched neg=100
pos=100

Segments from units were used to achieve the numbers.

10 antibody identifications were performed on the Ortho Vision and Solid phase as part of the requirements for validation by Ortho Clinical.

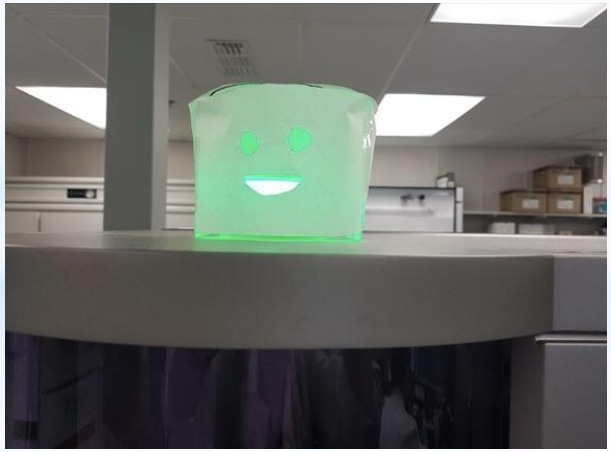
During the validation process, our LIS tech Dawn Callaghan, was creating testing labels, checking that our orders and profiles were working between Softbank and the Ortho Vision, collecting data and entering into the excel spread sheets.

Len Fligg from Ortho Clinical booked two weeks to assist us with our validation. In that time he helped us:

- ❖ Configure the Vision.
- ❖ Trained myself and our LIS Tech Dawn Callaghan as the two key operators.
- ❖ Performed the validation.
- ❖ Trained the trainer

Theo Srivastava came to help us set up a standing order for reagents around this same time.

Our platform's operation and performance protocol had satisfactorily qualified and we went live May 23/18.



GROWING PAINS

- The training was not only in learning how to operate the Ortho Vision but we were switching from Solid Phase to Gel. Most of our staff had never seen Gel before.

- The next issue was feeling comfortable reading a card that required a manual review, learning what to do when there is error code, and calling the hotline when not sure.

- We had a lot of rejected cards at the start due to splashes. My manager and I spoke to materials management about the handling of the cards. Although we were not sure if the problem occurred during shipment or after delivery to the lab, Ortho did replace our cards.

THINGS WE LEARNED

- Within the time of validation, we started looking at our back up method for antibody Ids which was tube method. As an advanced testing site, should we not have gel as our back up method for Antibody ID. So we pled our case to management, the cost of the Ortho Vision work station is approximately $5000. The cost of an antibody id panel (tube method) is around $200/month, which we may never use and throw out at the end of the month. Not to mention having to pay for a separate CAP survey. The workstation would pay for itself in a couple of years and we will save money by using the same reagents.

- Another lesson learned is to order cards in larger volumes with long dating in the Spring and Fall to avoid the periods of extreme heat and extreme cold.

- The antibody id panel is made up of very tiny bottles which they have not made evaporation caps for. Our staff had to learn to gently invert, remove caps, check for bubbles before placing on the analyzer, then returning to fridge as soon as testing was complete. Due to the small volumes, the bottles tend to evaporate quickly.

Solid Phase VS Ortho Vision

Solid Phase:

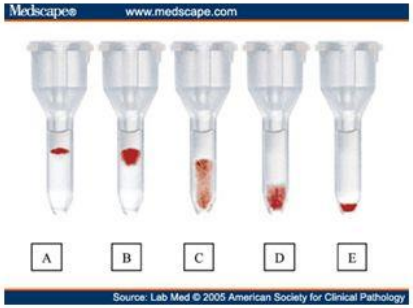
- No cold antibodies
- Maintenance on Solid Phase minimal
- Smaller foot print

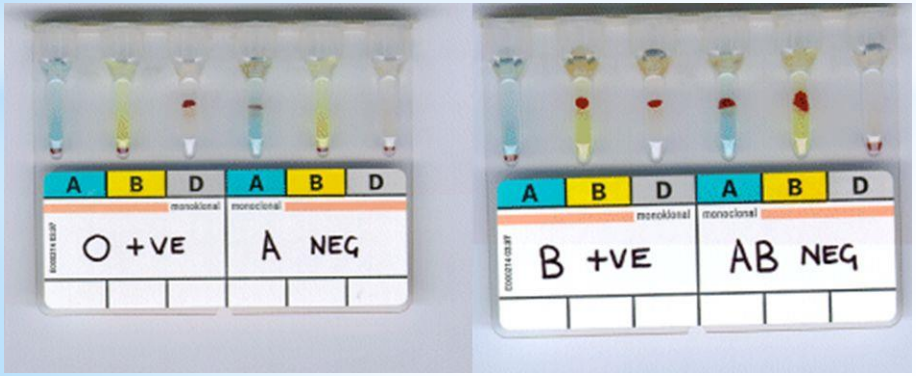
Ortho Vision:

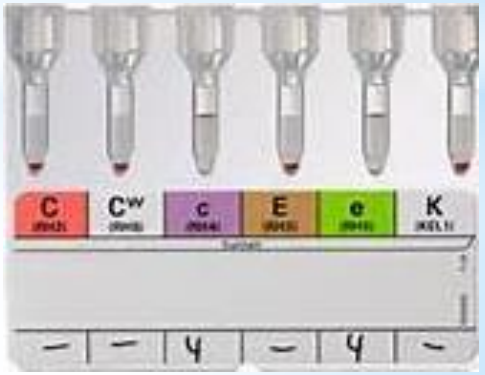
- Techs do not have to stay past their shift to finish an antibody screen. It can be released by another tech.
- The freedom to put samples on the analyzer and walk away. Most helpful on a night shift when there is only one MLT running the whole core lab.
- With manual procedures, there can be tech errors due to interruptions which is one reason by techs will not release another tech's work.
- The results are uploaded from the analyzer to Softbank where they are finalized by the tech. Less chance of an error in data entry from solid phase.
- Saves time with antibody id and even thought we do not have the middleware to connect to RUH, we can print off our report and send it with the samples for complex testing.
- Samples can be added anytime without extending the length of testing of samples already processing.

Testing Techniques - Gel

- Nonagglutinated cells pass freely through gel and pellet at bottom of microtube.
- Agglutinated cells are to large to enter the gel matrix and remain at top of column.
- A= positive and E=negative

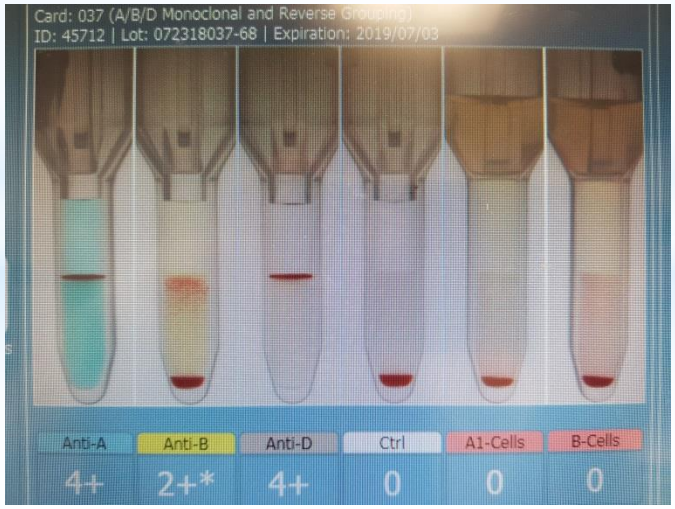






Mixed Field Reaction

Patient is a known AB Positive patient receiving Group A Positive packed red cells. Reverse group shows Group AB. Edit the forward group. In this case the MF is changed to 2+. Repeat ABO/RH with tube method if patient has no known history.



The Ortho Work Station:

- Management did purchase the Ortho Work Station. Liliane Sylvain from Ortho came for the day and did group training sessions.
- It was the perfect opportunity for staff to ask questions and she was able to help them with the things they were feeling uncomfortable with.
- I believe the training put everyone at ease and their whole attitude turned around 100%.

FOOTPRINT


Antibody Panels


Ovechkin


Controls


Reagents
ORTHO VISION REAGENTS


Gel cards

WORKLOAD

Ortho Clinical Diagnostics

ORTHO PLUS SM

PARKLAND HEALTH DISTRICT-1389074

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ORTHO VISION® Performance Dashboard

VICTORIA HOSPITAL,PR ALBERT (5570886)

Month: Mar 2019

Analyzer Performance Results

Breakout of Tests Run | Average Turnaround Time | First Pass Yield

Testing Breakout

Test Group	Total Test	Mean TAT (in min.)
ABO Types	565	16
Antibody IDs	19	35
Antibody Screens	333	30
Other	28	29

Reagent Usage

Card Name	Usage Count
A/B/D Monoclonal and Reverse Grouping	367
A/B/D Monoclonal Grouping	118
Anti-IgG	247

RedCells	Total Usage (in ml)
0.8% Affirmagen	18
0.8% Resolve Panel A	0
0.8% Resolve Panel B	0
0.8% Surgiscreen	16

Diluent	Total Usage (in ml)
MTS Diluent 2	47
MTS Diluent 2 Plus	150

Planned Maintenance

Type	Completed Count	Avg. Time Spent	Bench marked time comparision (in min.)	
			Delta	Benchmark
Daily	31	16	1	15
Weekly	4	34	4	30
Monthly	1	4	-11	15

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ORTHO PLUS SM

PARKLAND HEALTH DISTRICT-1389074

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ORTHO VISION® Performance Dashboard

VICTORIA HOSPITAL,PR ALBERT (5570886)

Month: Apr 2019

Analyzer Performance Results

Breakout of Tests Run | Average Turnaround Time | First Pass Yield

Testing Breakout

Test Group	Total Test	Mean TAT (in min.)
ABO Types	475	16
Antibody IDs	32	38
Antibody Screens	296	30
Other	22	29

Reagent Usage

Card Name	Usage Count
A/B/D Monoclonal and Reverse Grouping	316
A/B/D Monoclonal Grouping	91
Anti-IgG	248

RedCells	Total Usage (in ml)
0.8% Affirmagen	15
0.8% Resolve Panel A	0
0.8% Resolve Panel B	0
0.8% Surgiscreen	14

Diluent	Total Usage (in ml)
MTS Diluent 2	42
MTS Diluent 2 Plus	124

Planned Maintenance

Type	Completed Count	Avg. Time Spent	Bench marked time comparision (in min.)	
			Delta	Benchmark
Daily	30	15	0	15
Weekly	4	25	-5	30
Monthly	1	29	14	15

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Ortho Clinical Diagnostics

ORTHO PLUS SM

PARKLAND HEALTH DISTRICT-1389074

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ORTHO VISION® Performance Dashboard

PARKLAND HEALTH DISTRICT-1389074 (1389074)

Month: Feb 2019

Analyzer Performance Results

Breakout of Tests Run | Average Turnaround Time | First Pass Yield

Testing Breakout

Test Group	Total Test	Mean TAT (in min.)
ABO Types	467	15
Antibody IDs	21	34
Antibody Screens	275	30
Other	32	30

Reagent Usage

Card Name	Usage Count
A/B/D Monoclonal and Reverse Grouping	310
A/B/D Monoclonal Grouping	92
Anti-IgG	216

RedCells	Total Usage (in ml)
0.8% Affirmagen	15
0.8% Resolve Panel A	1
0.8% Surgiscreen	14

Diluent	Total Usage (in ml)
MTS Diluent 2	54
MTS Diluent 2 Plus	125

Planned Maintenance

Type	Completed Count	Avg. Time Spent	Bench marked time comparision (in min.)	
			Delta	Benchmark
Daily	28	16	1	15
Weekly	4	26	-4	30
Monthly	1	39	24	15

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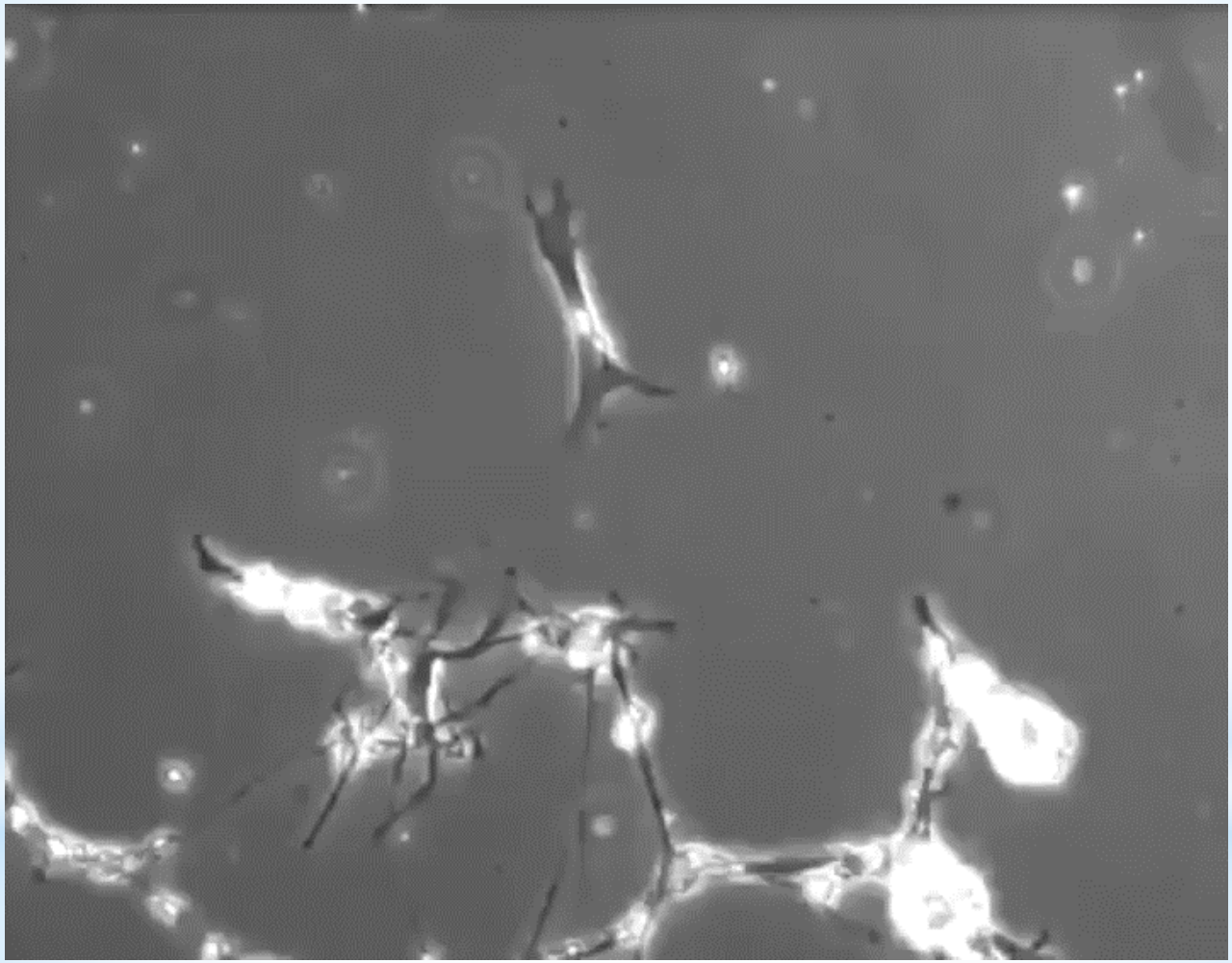
First six months after “go-live”

Victoria Hospital									
Data Collection Period		June, 2018	July	Aug	Sept	Oct	Nov	Total	% query
Type and Screen									
ABO/ Rh		338	302	340	366	362	350	2058	
? ABO/ Rh		17	9	5	4	1	3	39	1.90%
Ab Screen		337	287	315	346	334	330	1949	
? Screen		11	7	3	3	0	5	29	1.50%
Donor confirmation		224	174	256	188	217	203	1262	
?		0	0	0	0	0	0	0	0
XM		28	38	29	29	17	27	168	
?XM		0	1	2	0	0	0	3	1.80%
Ab Identification		25	19	17	16	16	22	115	

QUESTIONS



This is an image of neurons making connections with other neurons. This is how our thoughts look.

THANK YOUs

Thank you to Ortho for giving me this opportunity and for taking care of us. The hotline has always been helpful 24/7.

Thank you to everyone for taking the time to listen. If anyone requires help with their SOPs, they can contact me via edith.hein@saskhealthauthority.ca

Acknowledgements

Dawn Callaghan (LIS) and Jill Allen (she performed all the solid phase correlation testing)

Theo Srivastava - helping us out with the rush orders and checking in on us.

Eric Ching for following up with a Lunch and Learn and for being a general source of knowledge

Thank you to the Royal University Hospital for helping us with our validations and just being a constant source of reference. They told us we were going to love the Ortho Vision and we do!